Observation

MEDICINE

The Healthcare System's Tincture of Time

Louis G. Graff

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Sample Condition Specific Guidelines/Order Sets

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Preface

My first exposure to emergency department (ED) observation units began in the early 1970's as a medical student at the Harvard Medical School hospitals. At that time they seemed to have little importance other than a site to 'park' patients while they were awaiting a 'real' bed in the hospital. The observation concept did not exist; the concept of a third pathway as an alternative to the two traditional ED disposition options of discharge versus acute care hospitalization. Traditionally the physician had 2 to 3 hours with the patient in the ED and then had to make the disposition discharge the patient home or admit them to the acute care hospital.

This perspective changed during the last 3 decades. Emergency medicine developed as a specialty in the 1980's, the possibility of providing short term extended service (4 to 24 hours) in an ED observation unit became a reality with this development. The observation bed increased the emergency physician's ability to evaluate and stabilize acutely ill patients who would otherwise need hospitalization. Political changes in the healthcare system supported the observation, third pathway concept. Prospective payment for inpatient services began in 1983 along with hospital admission criteria. The ability with observation to 80% of the time successfully avoid hospitalization became more valued in health care. During the 1990's observation services became more structured and defined. Whether in ED observation units or observation beds within the hospital wards, many hospitals 'did the right thing' and provided high quality services with observation at ½ the cost and charges of traditional hospital admission. Presently in the first decade of the new millennium we are seeing the use of observation is becoming mandated. The federal audits (PEPPER) in the 1990's benchmarked the rates of 1 day hospital admissions and identified those not using observation. This culminated in 2009 with the federal RAC program (Recovery Audit Contractors) which pays private contractors a bounty and denies the hospital and physician any payment for every case the RAC's identified that could have been treated as an outpatient with observation rather than hospitalized.

This textbook was developed by a group of physicians who have been active in the development of observation medicine as a discrete area of medicine. It is the latest in a series of initiatives by many in organized medicine codifying the concepts and standards used by physicians providing these services. These include efforts by the American College of Emergency Physicians on the management of observation units, the creation of two sets of CPT codes for physician reimbursement for observation services, and the formation of an observation medicine section of membership. They include the formation of an observation medicine committee by the Society for Academic Emergency Medicine in 1989 that led to an annotated bibliography, curriculum, and sponsorship of a formal debate on the value of observation services. This present textbook is the latest of a series of projects by the ACEP observation section focused on stimulating the development of this important area of clinical medicine.

We have included in this textbook information that is useful and necessary for the clinician providing observation services. The first section reviews the history, principles of practice, implementation of observation units, and the resources needed to manage an observation program. The second section reviews specific patient conditions that can be evaluated and treated in observation beds. The last section reviews how Observation services are provided around the world. The adoption of the concept on an international basis reflects the wide spread acceptance that the third pathway approach has now achieved.

Louis G. Graff, MD, FACEP
Editor

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History of Observation Medicine
Louis Graff, MD, FACEP

Observation

The art of clinical inspection and observation began 2300 years ago in Greece with Hippocrates. He used observation of the sick and injured to understand human pathophysiology. He used human reason to understand the disease process:

> "A great part, I believe, of the Art
> is to be able to observe."[1]

This was a great step forward from the superstitious beliefs of the times that evil gods and demons caused maladies and misfortunes. Hippocrates would go over the symptoms repeatedly until the clinical picture would declare itself:

> "Leave nothing to chance, overlook nothing: combine contradictory observations and allow enough time." [1]

A period of observation may have been used to formulate a prognosis. A period of observation may have been used to devise a plan for treatment. The physician's task was to understand and overcome the forces of nature that were causing the disease process. His advice for the physician has become the credo for physicians for all time:

> "Life is short, and the art long;
> the crisis fleeting;
> experience perilous, and decision difficult.
> The physician must not only be prepared to do
> what is right by himself, but also to make the
> patient, the attendants, and externals cooperate."[2]

The systematic and organized use of "tincture of time" was one of the physician's first tools. With the development of emergency medicine it has become a primary tool of the physician in his struggle to overcome disease and human misery.

Treatments for Acute Disease

Many physicians left their practices to organize emergency medicine in the 1960's. They recognized much could be done for the acutely sick and injured with the existent medical knowledge. Yet much was not being done because of lack of immediate availability of medical personnel and resources, lack of organization, and failure to emergently apply that existent medical knowledge.

The knowledge and techniques to manage major trauma existed by the 1960's, but needed the organized approach of emergency medicine. Effective treatment for injures from work and war had been developed over many centuries prior to the twentieth.[3] In 1553 Duke of Guise first implemented an agreement (Red Cross agreement) that the wounded would be helped and not massacred. By 1864 an international conference of Red Cross societies created the Geneva Convention; this universalized the philosophy to help, not harm the wounded. In 1792, Larrey introduced ambulances to the battle field as an organized method to transport injured patients quickly to medical personnel. Ambulance service for non military personnel was begun in 1869 by Bellevue hospital in New York City. In the 1850's Florence Nightingale showed that professional nursing could improve the care of injured soldiers. Long in 1842 and Morton in 1846 developed anesthesia with ether, making possible surgery without pain. Lister developed aseptic surgical technique in 1867, decreasing the risk of surgery related infection. X-rays, the means of diagnosing fractures and other injuries, were discovered by Roentgen in 1895. Intravenous hydration with plastic disposable needles, intravenous tubing, and sterile fluid containers were perfected by 1945.

Similarly, effective emergency treatment for heart disease had been developed by the 1960's, but needed the organized approach of emergency medicine.[3] In 1628 Harvey described the circulation of blood and cardiovascular physiology. In 1768, Heberden described the clinical syndrome of angina pectoris. In 1815 Laennec developed the stethoscope to diagnosis heart disease by listening to heart sounds. In 1902 Einthoven recorded the electrical impulses of the heart with the first electrocardiogram machine. These developments allowed many pathologic conditions of the heart to be diagnosed by the clinician. In 1956 Zoll showed that closed chest compression could successfully treat ventricular fibrillation. When Kouwenhoven showed in 1960 that closed chest compression could successfully resuscitate the victim of cardiac arrest, all the components existed for successful emergent treatment of heart disease.

Failure of the Health Care System

Many acute illnesses were not being adequately diagnosed and treated by the 1960's. Trauma remained a major killer of Americans. A report in 1966 by the National Academy of Sciences found greater than 25,000 people per year were disabled or injured due to the lack of an organized approach to trauma.[4] There were no standards for ambulance personnel and many mistakes were made by untrained personnel. There was a lack of adequately equipped ambulances, with more than 50% of ambulances being nothing more than mortician's hearses. There was lack of adequate communications. There was lack of hospital categorization or systems (emergency departments). Heart disease was not being approached in an organized fashion. It was a major killer in the 1960's, with 1.5 million Americans per year suffering a myocardial infarction and 300,000 dying of sudden death. Yet, 20-30% of deaths were preventable by instituting CPR in the first 5 minutes, defibrillation in the first 10-15 minutes, and prompt transfer to the hospital.[5,6]

When the patient arrived in a timely fashion, hospitals were ill prepared for their arrival. Emergency departments were staffed either by unsupervised, ill trained house staff or by private attendings who were on call from their offices.

Emergence of Emergency Medicine

Emergency medicine was born in the 1960's to answer the lack of an organized approach to acute disease. It began in 1960 with four physicians who left their practices in Alexandria, Virginia to dedicate themselves full time to emergency medicine. By 1990 there were 24,000 physicians practicing in emergency medicine. The American College of Emergency Physicians was founded in 1968, and by 1989 there were over 17,000 members. Emergency medicine became medicine's 23rd specialty, when the American Board of Emergency Medicine was established in 1976, and officially recognized by the American Board of Medical Specialties in 1979. It was officially recognized in 1979. By 1990 there were

over 7,000 physicians board certified in emergency medicine.

Well organized EDs evolved as the specialty developed. Ill equipped "emergency rooms" in inaccessible areas of the hospital became relics of the past. Emergency departments became the gateways to the hospital. They were readily available for emergent therapy of serious conditions, evaluation of critical diagnostic syndromes, and help for humans in need. The number of ED visits grew from 42 million in 1960 to 90 million in 1990 as the value of well organized EDs became recognized.

Emergency medical systems (EMS) developed in communities throughout the US to promptly bring a patient with an emergent illness or injury to the hospital.[7] In 1966 the National Highway Safety Act authorized creation of the Department of Transportation, with the goal of providing funds to states to improve their highway safety programs. Ambulances, communications, and training for prehospital medical services were funded. The EMS Systems Act of 1973 provided further impetus for the development of emergency medicine by providing funding to communities for development of a "systems" approach to all emergencies. Physicians with training and expertise in emergencies were required to man the EDs. As improvement in emergency medical care and EMS was made a national goal, emergency medicine grew to fulfill its mission.

Beginning of Observation Services

Development of EDs with full time emergency physicians created the opportunity for ED observation services. Many EDs were designed in the 1960's and 1970's with observation beds: Peter Bent Brigham Hospital in Boston, New Britain General Hospital in Connecticut, Kansas City General Hospital in Kansas, UCLA-Harbor Hospital in Los Angles, University of North Carolina Memorial Hospital in North Carolina, Cook County Hospital in Chicago. Emergency departments were staffed with physicians 24 hours a day, 7 days a week. Thus physicians were available not just during morning rounds as for inpatient services with private physicians, but at all times and thus always able to respond rapidly to changes in a patient's condition, and discharge or admit the patient. The goal was to provide short term observation services similar to the hospital short term admission, but with a difference. Patients admitted to the hospital for short term stay were automatically kept in the hospital for days until discharge was arranged. In contrast, patients admitted to the ED observation unit for short term stay of hours and with a plan for discharge after this evaluation and management unless admission was arranged. Observation services were readily available and accessible, whether for diagnostic evaluation of an acute diagnostic syndrome, short term therapy of an emergent condition, or to meeting pressing human needs.

Observation Medicine Research

The value of these services was demonstrated with research beginning in the 1960's. In 1965 Boose offered one of the first reviews of the use of ED observation beds and their value in patient care.[8] Taubenhaus in 1972 reported on the use of ED observation beds at Beekman Downtown hospital in New York City, where 5% of ED patients were observed.[9] He reviewed the types of conditions observed, and enumerated the advantages of ED observation units. Two percent of ED patients were observed at Kansas General Hospital according to Landers in 1975.[10] He reviewed the types of services offered, and found that 80% of observed patients were not admitted to the acute care hospital after observation. In 1976 Diamond published UCLA Harbor General Hospital's experience with ED observation beds, finding 77% that of patients could be discharged home without hospital admission.[11] Bozien at University of North Carolina Memorial Hospital found that 5% of their ED patients were observed, with 78% discharged home after observation.[12]

During the 1980's research shifted to specific conditions that benefit from observation. Rosenthal at Kansas City General Hospital showed that 54% of patients with a first seizure could be managed in an ED observation unit without hospital admission.[13] Graff at New Britain General Hospital found that

observation could help diagnosis in patients with abdominal pain and an intermediate probability of appendicitis to distinguish those patients with appendicitis from those without.[14] Willet randomized patients with asthma to an ED observation unit versus a hospital ward bed. He showed lower costs ($1133 vs $1987) and shorter length of stay (1.63 vs 2.95 days) for patients in the observation unit.[15] Ammons at Denver General Hospital found that patients with thoracic trauma without apparent injury could be safely managed in an ED observation unit.[16] 80% were sent home without hospitalization. Lee at the Brigham and Women's Hospital used a computer protocol to estimate probability of myocardial infarction in patients with chest pain.[17] He showed in the mid 1980's that patients with initial low probability of myocardial infarction could be safely observed in an ED observation unit with cardiac biomarker testing every 12 hours. This meant that a protocol for testing over 24 hours could be used to evaluate patients with chest pain rather than daily testing in the hospital over a number of days. One third of patients with chest pain could avoid hospital admission using this strategy. Then in 1989 Gibler at the University of Cincinnati led the Emergency Medicine Cardiac Research Group to examine the performance of cardiac biomarker testing every hour. They found that sensitivity was very high within 3 to 4 hours of the patient's arrival in the ED. This enabled ED observation units to safely shorten the time for testing to every 2 or 3 or 4 hours and safely discharge selected patients home within 10 to 16 hours.[18] Since then there have been 4 random clinical trials confirming the safety and cost effectiveness of this rapid outpatient approach.[19-22] Henneman in 1989 at UCLA Harbor General Hospital showed that patients with blunt abdominal trauma and negative peritoneal lavage could be safely managed in an ED observation unit.[23] 83% were sent home without hospital admission.

By the 1990's there was a robust literature on the safety and effectiveness of outpatient observation services as an alternative to acute care hospital admission and this has continued into the next millennium. Heart failure, which is one of the most common conditions requiring acute care hospitalization, has been shown to be safely and effectively managed in observation units.[24] The opportunity has been illuminated to improve quality of patient care in the evaluation of abdominal pain patients (the most common presenting complaint of patients in the ED) and address important issues in the accurate diagnosis of acute appendicitis (the most common acute surgical emergency).[25] There are now 4 random clinical trials (RCT) on chest pain patients (19-22), 1 RCT on asthma patients.[26] 1 RCT on atrial fibrillation patients,[27] 1 RCT on syncope patients,[28] and 1 RCT on TIA patients.[29] All these RCT's have validated what prior, less sophisticated research trials have shown in the past. That is, for selected patients observation provides equivalent or superior clinical patient care compared with traditional acute care hospital inpatient services and it does that at one half the cost.

Cost Effective Health Care

Health care cost containment initiatives, which began in the 1980's, became powerful incentives for the use of ED observation units. In October 1983 prospective payment was implemented as the method of reimbursement for services for Medicare patients. Instead of hospitals being reimbursed at cost for all services, hospitals received one lump sum reimbursement based on the patient's DRG code. Hospitals could profit under this system if they had low costs for patient care, few complications of patient care, and early patient discharges. Inefficient hospitals that provided inefficient patient care, with long lengths of stay suffered losses. Objective admission criteria were implemented to prevent hospitals from profiting from admission of patients who were not sick.

As health care payors cut reimbursement for many services, hospitals could remain financially viable by use of lower cost sites for patient care. Costs for patient care in ED observation units are lower than for patient care in the hospital.[30] This became an incentive for use of "outpatient" observation services.

Exemption from acute care hospital admission criteria was another reason hospitals for use of ED observation beds. Many acutely ill patients do not have objective admission criteria.[31] Use of observation

units enabled the hospital and physician to continue to offer services to these patients. If the physician admitted these patients to the acute care hospital he faced sanctions for "defrauding the government," including the loss of his right to practice medicine. If the physician sent the patient home, he risked the patient suffering a bad outcome, with a malpractice suit and criticism of the quality of his patient care. Use of an outpatient observation bed to refine the admission decision process was the logical answer to the problem.

Observation Medicine Organizes

Many ED observation units were organized by the end of the 1980's. ED observation units became an integral component of emergency medicine; nearly one third of American acute care hospitals ED's having observation units by 1989.[32] ACEP's practice management committee published a policy statement on ED observation units in January 1988[33] and guidelines for management of ED observation units in December 1988.[34] The first course on provision of observation services was given by Leslie Zun in September 1988 at the ACEP *Scientific Assembly*.

The Society for Academic Emergency Medicine (SAEM) recognized the importance of ED observation services in October 1989. Under the leadership of Jerris Hedges an Observation Medicine Committee was formed. The committee created an annotated bibliography of observation medicine[35] and a curriculum relevant to ED observation units.[36] A research group was founded to encourage multicenter research trials by academic centers with ED observation units. The committee sponsored a debate at the society's annual meeting in 1991 on the value of ED Observation Units.[37]

During the same time period ACEP organized a Section on Short Term Observation Services. The solicitation for the formation of the section began in April 1989 by Lou Graff shortly after ACEP's Board of Directors approved a policy on sections of membership. There was enough support for ED observation units that by March 1990, the Section was approved as ACEP's fifth section of membership.

In the next twenty years ACEP's Observation section was an active organization with an annual meeting at ACEP's *Scientific Assembly*, new leadership elected each year with representation from all regions of the country, and numerous projects supporting observation services. The first edition of the Observation Medicine textbook was published in 1993 and contains many of the principles useful to physicians who provide observation services. ACEP published in 1997 the second Observation Medicine textbook focused on implementation and management strategies for Observation Units. In 2001 Mike Ross and Lou Graff edited a special edition of Emergency Medicine Clinics of North America on Observation Medicine. In 2009 the two observation medicine textbooks were merged into a 2nd edition textbook on ACEP's web site. The section continues to sponsor educational programs on observation medicine including a national program in 2008 and 2010 organized by Mike Ross in Atlanta, Georgia at Emory Medical School.

Recognizing the needs to further organize for providing observation services to patients with chest pain, Lou Graff founder of ACEP's Observation Services section of membership and Ray Bahr founder of Early Heart Attack Committee founded the Society of Chest Pain Center had been meeting. Their goal was to join emergency medicine and cardiology to collaborate on the mission of improving the quality of care provided to patients with chest pain. The first formal collaboration as the 1st National Congress of Chest Pain Centers (CPC) was in 1993 in Savannah, Georgia. The next meeting was the 2nd National Congress CPC in 1995 in Phoenix, Arizona. At the 3rd National Congress CPC in 1998 in Detroit, Michigan they founded the Society of Chest Pain Centers. Since the Society has sponsored conferences to support quality in the care of chest pain patients: 4th National Congress C PC - 2000 Baltimore, Md; 5th National Congress CPC - 2002 New Haven, Ct; 6th National Congress CPC - 2003 San Francisco, Calif; 7th National Congress CPC – 2004 Chicago, Illinois; 8th National Congress CPC – 2005 Orlando, Florida;

9th National Congress CPC – 2006 Boston, Mass; 10th National Congress CPC – 2007 Nashville, Tenn; 11th National Congress CPC – 2008 Orlando, Fla; 12th National Congress CPC – 2009 Memphis, Tenn; 13th National Congress CPC – 2010 Las Vegas, Nevada.

By the end of the millennium emergency observation medicine had been recognized by organized medicine for its value of equivalence in quality and lower in cost compared to in-hospital admission. In 1990 the Joint Commission on the Accreditation of Health Organizations removed its restrictions on the use of ED Observation beds by removing the 8 hour time limit and holding them to the same standard of care as hospital observation beds.[38] Because of concerns about the value of observation services in 2000 the Centers of Medicare and Medicaid (CMS) services of the federal government stopped separately reimbursing for observation services when they changed from cost reimbursement to prospective payment for outpatient services (APC's – ambulatory payment categories). Lou Graff, Mike Ross, and Ray Bahr organized efforts to meet with CMS on the value of observation services. This included support by the Society of Chest Pain Centers, American College of Cardiology, American Heart Association, American College of Emergency Medicine, and American College Nuclear Cardiology. This was successful and an APC (#0339) was created for facility reimbursement for observation services in 2002 although limited to services for patients with chest pain, heart failure, or asthma. Fortunately, in 2007 Mike Ross was successful in advocating to CMS through its APC committee to enlarge the scope of reimbursement to observation for all patients with a condition appropriate for observation with new APC's created for this service (#8002 & #8003). These new APC's combined the facility reimbursement for observation with the reimbursement for the ED or the clinic visit of the patient. This represented a landmark for observation services with nearly all payors by this point in time recognizing the value of observation services, reimbursing the service, encouraging the use of the service, and even mandating the use of the service [CMS takes back payment on low probability of disease patients who were admitted rather than observed by use of RAC's (recovery audit contractors)].

Observation medicine originated nearly three decades ago to meet many pressing health care needs: improved diagnostic evaluation of many critical diagnostic syndromes, improved short term therapy of many emergent conditions, and lower health care costs. It has become an integral component of emergency medicine. It marks another benchmark in Emergency Medicine's commitment to provide the highest quality care to all who are sick and suffering.

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2

Principles of Observation Medicine
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The emergency physician is often faced with a dilemma solved only by observation. Some patients are too severely ill for outpatient therapy, but don't clearly need hospitalization. Other patients need more intensive services than available in the outpatient setting; but not necessarily hospitalization. Some patients are at risk of a dangerous disease, but not at high enough risk that admission is mandatory. Other patients the clinician identifies very pressing human needs, but not a medical problem that would justify acute care hospital admission. Observation ("Tincture of Time") is the traditional tool the physician uses to resolve these dilemmas.

Observation services have traditionally been provided in the hospital ward. There was little need to differentiate these services from other inpatient services in the past. They were classified, reimbursed, and managed similarly to other inpatient services unless labeled "short stay admissions" with abbreviated admission forms. Emergency care and walk in care are outpatient services provided over 1 to 5 hours. Patients who require further services are admitted to the acute care hospital for overnight admission even if only they require a few hours more service. Observation services offer an alternative to extend the window for outpatient services to 24 to 48 hours.

In the last two decades a number of developments in the health care system have necessitated differentiation of these services from other inpatient services. The first was the requirement that patients meet admission criteria to be hospitalized. This became policy when prospective payment was implemented in October 1983. Under prospective payment, services rendered to admitted patients were reimbursed by large prospective payments based on the patient's diagnosis related group (DRG). An average reimbursement was provided for each type of disease condition (DRG). Hospitals which could manage patients at low costs profited. Hospital admission criteria were devised to prevent patients from being admitted who had little need for hospital services. Unfortunately, under these admission criteria many patients who were seriously ill were deemed to not need acute care hospital services.[1]

The "23 hour bed" concept was a practical solution, ie, a patient who is in the hospital for less than 24 hours hasn't been admitted.[2] This concept was acceptable to Medicare, since they did not have to pay the large lump sum "prospective payment." This was acceptable to both the physician and the hospital. They could still provide care to short term admission patients, which comprise up to one fourth of hospital admissions (Table 1), and they could avoid severe penalties from Medicare for "inappropriate admissions." The cause of the development of the 23 hour bed concept was reimbursement, but the result was to further differentiate observation services from other services offered in the acute care hospital.

The second development in the health care system was the evolution of emergency medicine as a specialty. Physicians were present in EDs 24 hours per day and available to supervise continuing care. Since the 1970's ED attached observation units have been used as a second site for observation services in the acute care hospital.[3-4] They have gained wide usage and acceptance in the present climate of cost containment and restriction on hospital admissions.[5-6] They are clearly not inpatient services as they are provided in the outpatient area. For those without space for an ED observation unit, the emergency physician identifies patients appropriate for observation. Then the patient is placed in an inpatient observation bed and provided observation services by inpatient attending.

By 2009 the payors created a third major change in the health care system; they mandated the use of observation services. The Centers for Medicare and Medicaid Services (CMS) is the largest payor. For 5 years it created quarterly reports (PEPPER reports) for each hospital in the United States on utilization. These reports showed each hospital its performance with comparison to benchmarks. The rate of one day admissions was a primary metric with those hospitals not using observation having high rates. By 2009 CMS outsourced utilization issues to RAC's (Recovery Audit Contractors). These private companies were given the CMS PEPPER reports on each hospital with a bounty of 10% to 13% for any money they could recover. The largest opportunity for 'recovery' of the RAC's and for CMS from the hospitals is 1 day admissions that could have been observed.

Thus over time many factors have been delineated which differentiate observation services from inpatient services (Table 2).

1) Focused Patient Care Goals

Focused patient care goals is one of the factors most clearly differentiating observation services from other type of patient care. Patients appropriate for observation have been identified by a physician as having a focused medical need. 50% of patients in observation units are observed for diagnostic evaluation of critical diagnostic syndromes (eg, chest pain, abdominal pain). Another 10-30% of patients are observed for short term, intensive therapy of serious emergency conditions (eg, asthma, heart failure, dehydration). Patients with psychosocial ills (eg, substance abuse, mental illness) comprise 5-20% of patients observed in observation units. Completing the list of patients requiring observation services are those 5-20% having outpatient procedures (therapeutic or diagnostic).

Diagnostic Evaluation

ED attached observation units[1,3-4,7-14] accept a wide spectrum of patients for diagnostic evaluation (Table 3). These patients all have at least one diagnostic possibility that cannot be safely evaluated as an outpatient. They have three characteristics that make them appropriate for evaluation in the ED observation unit. First is a balance between the probability of the disease and the dangerousness of the disease under consideration. For different critical diagnostic syndromes the probability of disease in patients being observed by physicians varies from .3% to 25% (Table 4). The dangerousness of the diseases under consideration varies from .01% to 50% mortality (death in the first week) (Table 5). Comparing the probability of disease with the dangerousness of the disease shows an inverse relationship for observation patients. A patient being evaluated for a disease which is very dangerous (eg, chest pain, question myocardial ischemia) is appropriate for observation only at low probability of disease. Such a patient would be admitted to the hospital if there is a moderate to high probability of the disease. A patient

being evaluated for a disease which is less dangerous (eg, abdominal pain, possible cholecystitis) is appropriate for observation at moderate probability of diagnosis. Such a patient would be admitted to the hospital for diagnostic evaluation only at very high probability of disease and discharged for outpatient treatment at low probability of disease. A patient being evaluated for a disease which has very little danger (eg, abdominal pain, possible kidney stone) is appropriate for observation only at high probability of diagnosis. At lower probability of disease the patient would be discharged home for outpatient evaluation.

Second, the condition is one which the physician can not readily diagnose with testing. For some diseases a readily available definitive test does not exist, eg, patients with abdominal pain who may have appendicitis. Abdominal pain is the most common chief complaint and most cannot be evaluated with abdominal CT scan imaging because of cost and radiation exposure issues. For other clinical conditions a definitive test exists but is not readily available. This can be because it takes a prolonged time period to do the test, for example, CPK has a high sensitivity in diagnosing myocardial infarction in patients with chest pain only if the test is done serially over 12-24 hours.[15] Or it can be because it takes time to schedule the test, for example, ultrasound for diagnosis of cholelithiasis is usually available only during the day.

Third, the condition is one for which the physician's diagnostic performance is inadequate, indicating methods are needed to aid the physician diagnostic performance beyond the routine diagnostic evaluation. Clinical studies of diagnostic outcome (Table 6) or of emergency physician malpractice risks (Table 7) identify those conditions for which physicians have inadequate performance. Observation focuses on patients with intermediate probability of disease to improve diagnostic accuracy. For example, 7.5% of patients with appendicitis have an intermediate probability of appendicitis on presentation.[16] If the physician makes an immediate decision in these patients regarding whether or not to perform appendectomy, he will have to accept a high false positive[17,18] or high false negative rate.[19] Yet in this intermediate probability group during observation the mean probability of appendicitis increases from 50% to 65% in the appendicitis patient and decreases from 35% to 22% in the patient without appendicitis.[16] Thus changes signs, symptoms and tests over time aid the physician to more accurately identify the patients needing emergency surgery. Chest pain rule out ACS[20-33] and abdominal pain rule out appendicitis[19, 34-38] are some of the most common conditions evaluated in observation units.

Short Term Therapy

The second most common reason to admit patients to an observation unit is for short term therapy of emergent conditions (Table 8). These are conditions for which there is a high probability of therapeutic success (within 24 hours) (Table 9). These are conditions requiring a limited amount of services, consistent with the amount of services available for a patient in an observation bed. Patients with low probability of therapeutic success within 24 hours and/or high intensity of service needs are more appropriately treated as admitted patients in the hospital. Acute asthma[39-43], heart failure[44-53], infection[54,55], dehydration, and diabetes with poor control of blood sugar are examples of conditions appropriate for observation services with high probability of success within 24 hours of treatment.

Facilitate Outpatient Procedures

Another common reason for admission to an observation unit is to facilitate outpatient procedures. Some procedures are performed for therapeutic reasons, such as transfusions for patients with chronic anemia, parenteral antibiotics for patients with serious infections, or

cardioversions for patients with stable arrhythmias. Other procedures are performed for diagnostic reasons, such as angiograms, myelograms, bronchoscopy, thoracentesis, GU procedure, GI procedure, and biopsies (lung, abdominal organs, or other tissues). Use of a short period of observation can expedite the performance of these procedures on an outpatient basis.

Management of Psychosocial Needs

The short term management of patients with psychological or social problems is often the responsibility of EDs. Many people are brought to the ED with social and psychological problems. Our society has identified the ED as their portal of access for help. When social problems are too extensive to be adequately addressed on the initial physician-patient interaction, then the physician must arrange further services for the patient. Admission criteria prevent these patients from being admitted to the hospital. Standards for admission of patients with psychiatric problems have toughened as most psychiatric services have been deinstitutionalized. In the United States the number of psychiatric hospital beds have decreased from 722,000 in 1960 to less than 170,000 in 1990. A period of observation often enables the physician to develop a complex outpatient approach to meet these patients' psychosocial problems (Table 10).

2) Limited Duration and Intensity of Services

Observation services are low intensity services provided to patients for a limited duration of time. When provided in EDs attached observation units the period of patient care is limited to less than 24 hours. The intensity of service is equal to that offered on the hospital ward. The duration and intensity of service is limited because of the limited resources available in the observation unit for patient care. When provided in 23 hour bed units the duration of service is by definition less than 24 hours. The intensity of service is the same as that for other patients on the hospital ward.

Differences in duration and intensity of service differentiate observation patient care from other types of services provided in the acute care hospital. Walk-in services have a shorter duration (less than one hour) but similar low intensity. They are provided in the outpatient setting. When not triaged out of the ED they comprise from 15% to 40% of the patient visits. Critical care services have a high intensity of service, often with a nurse to patient ratio of one to one and physician to patient ratio of one to one. They are initially provided in the ED. They comprise a small portion of ED visits (2% to 4%). Emergent services are of moderate intensity but short duration (a few hours). They comprise the bulk of ED visits (from 54% to 83%). Inpatient services are of a large range of intensities for patients requiring patient care for an extended period of time (over 24 hours). Walk-in and emergent service require relatively little physician service per patient (Table 11). Small changes in the number of patients have only a small effect on the overall amount of services demanded from the treatment area.

Outpatient services are for patients with limited intensity of service needs. Observation services are similar to other outpatient services in the limited intensity of service needs per patient per unit time. This is important in outpatient treatment areas which manage large numbers of patients with a limited number of staff. Patients with high intensity of service needs place a large demand on the limited resources and are more difficult to manage for a limited number of staff.

Inpatient services have greater service needs and require a large amount of physician or nursing service per patient. Patients admitted to the hospital ward require services for a prolonged time period. Patients requiring critical care services require a large amount of service

per patient in a short time period (Table 11).[56] Small changes in the number of these patients have large effects on the overall amount of services demanded. The policy for outpatient treatment areas, such as the ED, is to transfer patients requiring inpatient ward or critical care out of the department as soon as possible to the appropriate inpatient treatment area. This helps minimize the adverse effects that sudden large patient care demands place on the limited resources of each department.

3) Hospital Sites of Service

Two sites have the personnel and equipment necessary to provide observation services: the ED and the hospital ward.[57] One fourth of acute care hospitals presently use ED attached observation beds as the site for observation.[5-6] This service comprises 2% to 5% of their ED visits (Table 1). Nursing personnel are designated for the observation area, and emergency physicians provide direct supervision.[5-6] Three fourths of acute care hospitals use the hospital ward as the site for observation service.[5-6] This service comprises 8% to 25% of their acute care hospital admissions (Table 1). The patients may be treated in beds in a distinct unit, or in beds scattered throughout the hospital.[2] Hospital ward staff and equipment are used to provide services. Each patient has an attending physician, although direct supervision of patient care may be by nurse managers.

There are differences in the types of patients treated at the two sites. Higher intensity services such as diagnostic evaluations or short term therapy are most frequently observed in the ED attached observation unit beds. This is consistent with the usefulness to these patients of the immediate availability of an emergency physician. Lower intensity services such as observation associated with procedures (eg, transfusions, cardiac catheterization, endoscopy, myelography) are more frequently provided on the hospital ward. This is consistent with the lack of need for constant physician supervision for these services. When both sites are available in one hospital for observation services, most patients are treated in ED observation beds (70-90%).[7]

One advantage of the ED observation unit over the "23 hour bed" as the site for observation is the removal of the patient from the inpatient setting. Before the development of the observation concept, patients needing services beyond a few hours in the ED were admitted to the hospital. The designation of the ward bed as a 23 hour bed did not change the physician's admission threshold or pattern of practice. The patient needing emergency evaluation or therapy beyond a few hours was still "admitted" by the admitting physician to an inpatient setting. The paperwork lists the patient as a "23 hour bed" patient but the same staff and principles of ward medicine (once per day rounds, etc.) were followed. Admission of a patient to the "23 hour bed" required no more than paperwork. In contrast, the development of ED sites of observation raised the physician's threshold at which he hospitalizes patients. Patients were managed in the outpatient setting with staff using very oriented toward solving the patient's problem in a few hours and discharging the patient. Emergency personnel including physicians were constantly present and frequently rounding on the patients with the goal of discharge of 70% to 80% of patients home in 8 to 12 hours. In comparison to the "23 hour bed" patient, admission of the ED observation patient to the hospital requires more than a change in paperwork. The admitting physician needs to come into the hospital and see the patient and the patient has to be physically moved into the hospital into an acute care bed.

Sites outside the hospital may be appropriate for some types of observation that have traditionally been treated in the hospital. Patients with alcohol and substance abuse problems have been managed in "sobriety centers" that are not attached to the acute care hospital.[143] Many

psychiatric problems have been managed in crisis centers not associated with acute care hospitals.[144] Services that do not require direct supervision by physicians or ready availability of acute care hospital equipment and personnel are appropriate for sites outside the hospital.

4) Acute Care Staffing

Adequate nurse and physician staffing is necessary to provide observation services. Additional nursing personnel are needed at staffing levels similar to that in the hospital ward (1:8 nurse to patient ratio).[43] Additional physician personnel are needed depending upon the site used for observation. In the 23 hour bed observation unit, additional physician staff is not needed. The admitting physician makes daily rounds as he does on all his admissions to the hospital wards. Emergency physicians are usually not involved in the care of these patients. In the ED attached observation unit emergency physicians are readily available and do rounds at least every eight hours. Thus additional emergency physician staffing is needed compared with EDs who do not provide observation services.

A system is needed to calculate the amount of additional staffing needed in EDs providing observation services. Nursing staff full time equivalents (FTE's) needs can be calculated by one of numerous staffing formulae.[58-67] Many of these are based on the amount of services provided per patient. Physician staff FTE's needs cannot be estimated from traditional staffing guidelines,[68-72] because these do not consider the requirements for specialized services such as observation. A formula is needed which calculate physician staffing needs based on the amount of physician services provided; one such formula is the LIVES formula.[56] The staffing needs should be recalculated periodically, as the amount and mix of services may change.

5) Continuing Care in the Outpatient Setting

Traditionally observation services have been provided in the hospital wards according to principles of care evolving from an inpatient model. In the ED observation unit, the inpatient care principles need to be followed even though the services are now classified as outpatient, and are provided in outpatient settings.

Continuing Care versus Episodic Care

Observation patient care differs from other outpatient services in the need to follow inpatient principles of continuing care. The history and physical are more extensive than in other types of outpatient services. All organ systems are surveyed. The testing is more extensive and may occur over an extended period of time. The orders are in depth, with plans made for care of all the patient's needs over a time period lasting up to 24 hours. Orders include diet, daily medications, reason for observation, working diagnosis or differential diagnosis, treatment plan, disposition plan, the physician responsible for the period of observation, and the physician responsible for the patient's disposition. Documentation with multiple notes is needed to track changes in the patient's condition. Arrangements need to be made to provide amenities to the observation patient on a timed schedule. Formal protocols, procedures, and guidelines are needed, because of the multiple personnel and the complexity of the organization necessary to provide the services.

This contrasts with most other outpatient services (eg, office visits, ED visits, clinic visits) which follow outpatient principles of episodic patient care. The interaction is limited to the episode that brought the patient to the physician. The history, physical, and testing are focused upon the patient's presenting complaints. Orders for testing and medicating are limited to

the immediate problem. Chart documentation is often limited to a one time note by one physician. There are no physician rounds. The patient is expected to seek amenities (food, baths, grooming, etc.) on their own after their outpatient visit. Most of the service is provided by one physician with little ancillary help. Extensive protocols, procedures, and guidelines are not needed.

Observation Bed vs. Holding Bed

Services for patients in holding beds is a different type of service than for patients in observation beds, and places different demands on the ED.[56-73] Both types of care may be provided in the ED, either in a distinct unit or in scattered beds. Both are provided according to continuing care principles of inpatient care. Yet services for observation patients are limited in scope. The patients have defined problems which can be managed over a short period of time with a low level of services, eg, diagnostic evaluation of abdominal pain, or short term therapy of asthma. In contrast, holding bed care is for patients awaiting admission to the hospital. They may require very high level of services for a prolonged period of time, eg, patients may be awaiting admission to intensive care units, and require one to one nurse to patient staffing. Observation services are reimbursed by cost, so the more services are provided, the more funds are generated for the ED to hire staff to render those services. Inpatient services (holding bed patients) are reimbursed by prospective payment, so the ED does not get financial credit for having provided those services. The hospital gets the same reimbursement whether the patient is in the ED one hour or three days. This can lead to added workload for the ED staff without additional staff to provide the service.

When the ED becomes filled with many admitted patients waiting for hospital beds, the ED's function becomes compromised. The ED loses its ability to handle either new emergency patients or patients already requiring ongoing observation services.

6) Intensive Managerial Review

Observation patient care requires more oversight than routine inpatient services. Strong managerial review and control are necessary to ensure a high standard of care. Protocols, procedures, and guidelines are advisable to define the complex service needs of patients receiving observation care.[73] Departmental statistics and quality assurance monitors relating to observation services need to be analyzed to identify patient care problems. Statistics need to be kept on utilization (# patients, types of patients, % admitted, timeliness of care) to ensure proper use of limited resources. Statistics need to be kept on quality assurance (admitted patients, mortality in unit, adverse patient complaints, incident reports, complaints, AMA) to ensure services meet the highest standards. Policies are developed to address problems as they are identified. With a very structured process observation beds can offer the optimal patient care for defined clinical conditions.

7) Economical Service

The primary impetus for the delineation of observation services has been the financial savings available to the health care payor. This has been shown to be significant in the past.[9,12,22,44,76,77] Patients who otherwise would have to be admitted to the acute care hospital can often be sent home after a short period of treatment in the observation unit. In addition, treatment times for equivalent conditions are shorter in ED observation units than in the traditional inpatient setting.[77] Additional savings are the lower costs of ED observation units services when

compared with services in traditional inpatient settings.[43] Charges are also lower in ED attached observation units since charges are per hour or shift rather than per day and are often set at lower rates.[10]

These savings have increased under prospective payment. Outpatient services are reimbursed at cost, but inpatient services are reimbursed under prospective payment at one lump sum for all patients in the same DRG. Since the observation patient services are at the lower end of the range in length of stay and costs for each DRG category, savings by use of observation beds have increased under prospective payment ($1187/patient less in one study[43]).

The American health care system is in a crisis. At a time of unsurpassed medical progress, there are near unlimited patient expectations conflicting with limited health care resources. Patient services are being limited to patients who can "prove" they are truly "sick" and need acute care hospitalization. The clinician is asked in circumstances, where the need for hospitalization is not obvious, to have diagnostic decision making accuracy beyond what is presently possible in a single patient physician interaction. Observation services are a rational solution by which physician can provide high quality patient care in the present cost efficient environment.

Table 1: Utilization of Observation Services

Parameter Measured	ref	7	8	4	9	10	3	11	12	13	14	14
ED Vol (1,000/study)		42	10	43	11	75	10	19	10		17	32
ED Vol (1,000/year)		44	41	52	120	75	25	56	25		35	65
Observed (1,000/study)		4.1	.5	1	.2	.5	.5	.6	.5	8	.4	1
Observed (1,000/year)		2	2	1	2	1	1	2	1	1	1	2
% ED Patients Observed		3	5	2	2	2	5	3	5		2	3
Hosp Adm (1,000/year)		15						5			5	13
Obs Unit as % All Adm		8						25			12	14
% Obs Pts Discharged		77		58	77	80	56	77	78	83	91	82
No. Beds Observation Unit		6	10	7	8	8	10	6	7	8	12	10

Table 2: Principles of Observation Medicine

1	Focused Patient Care Goals
	a) Diagnostic Work-up of Critical Diagnostic Syndrome
	b) Short Term Therapy
	c) Facilitate Outpatient Procedures
	d) Meet Psycho-social Needs
2	Limited Duration and Intensity of Service
3	Hospital Site of Service
4	Acute Care Staffing
5	Continuing Care in the Outpatient Setting
	a) Continuing Care versus Episodic Care
	b) Observation Bed versus Holding Bed
6	Economical Service
7	Intensive Managerial Review

Table 3: Observation Services - % for Diagnostic Evaluation

	ref	7	8	4	9	10	3	11	12	13	14	14
Abd Pain, Flank	3.1							4	2			
Abd Pain, Other	13.7		4	6	23	10	11	8			10	10
Trauma	9.2	38	21	14	34	38	5	11	10		87	31
Head Injury	2.4	23	8	7			2	7			62	15
Trauma	5.9	15	13	7	20	38	2	4	10		25	16
Back Pain	.9				14		1					
Cardiac	10.8			9	7		14	8				14
Chest Pain	8.4		1		7			6				7
Palpitation	1.1											
Syncope	1.3					10	2					7
Neurologic	5.1		8	18			4	7	7	18		
Dizziness	1.4							2				
CVA/TIA	.7				10			1	3			
Seizure	1.5		8	5				2	3			
Headache	.9							2				
Confusion	.6				3			1				
Weak	1.0							1				
Gi/Gu Bleed	.7											
Vaginal Bleed	.3						1	12	1			1
Fever	1.4		2				1	5	4			
Overdose	3.3	41	16	24				3	5	5		
Total	48.6	79	52	52	57	68	51	39	37		97	56

Table 4: Probability of Disease by Triage Decisions

	Home	Observe	Admit	Ref
Abd Pain				
Appendicitis	0.5	17	31-57	15-18
Ectopic Pregancy	0.2-4		85	19-21
Flank Pain		25		22,12
Chest Pain				
MI	1-3	3-8	8-32	22-26
Major PE		21		27-30
UGI Bleeding				
Need Surgery		4	28	31
Headache				
Subarachnoid	0.1			32
Fever, No Source				
Sepsis	10			32
Seizure (First Time)				
Brain Lesion		25-37		34-36
Syncope				
Cardiac	6	11	26-27	37-40
Trauma				
Head Injury	0.01	0.3-3.3	22	12,41-42
Abd Blunt		1-4	28-96	43-45
Chest Blunt		13-20	70	46-48
Chest Penetrate		1.2-13	15-65	49-51

Table 5: Dangerousness of Disease

Condition	Mortality immediate	one yr	Ref
Abd Pain			
Appendix	0.01-3.6		53-54
Ectopic Pregnancy	0.1		21
Chest Pain			
MI	35	50-55	55-57
Unstable Angina	5-10	50-55	58
Headache			
Sub Hem	25-35	57	32,59-60
Fever (No Source)			
Sepsis	0.7		33
Seizure (First)			
Br Lesion	0.1		61-62
Syncope			
all	0.4-0.8	5-15	37-38
cardiac	2.5	30	37
unknown		6	37
TIA			
CVA	0.4-0.8	5-10	63-64
Trauma			
Head Injury (severe)	50		65
Head Injury (mild)	0.2		41-42
Abdominal Blunt	17-46		43-44,66-68

Table 6: Physician Diagnostic Performance

	Sens[*]	Spec*[*]	PPV[***]	Accuracy	Ref
Abd Pain					
Appendix	70-84	80-99	80-90	83-95	69-73
Ectopic Pregnancy	64-82			50-75	74-76
Chest Pain					
MI	94-95	60	23-31	64	26,77
Major PE	16-38		38-68		78-84
Confusion					
Meningitis	50-64				85-86
CVA	65-70				85-86
GI Bleeding					
Needs Surgery	74	71		31	
Headache					
Subarach	36-91				32,60
Fever					
Sepsis	67-81				33,87
Seizure (New)					
Br Lesion	76				34
Syncope					
Cardiac	61		26-27		37, 40,87
Trauma					
Head	82				89
Abd Blunt	86-96		79-99	90-99	45,90-91
Chest Blunt	92				52

[*] Sensitivity
[**] Specificity
[***] Positive Predictive Value

Table 7: Physician Diagnostic Performance – Malpractice Awards

	% of cases	% $ paid	Ref
Abd Pain			
Appendix	4.8-10.5	4.8-5	92-93
Ectopic Pregnancy	2-2.5	2.1-8.2	92-93
Chest Pain			
MI	3.5-10.2	19.7-31.8	92-93
Confusion			
Meningitis	2.3	9.4-15.4	92-93
Trauma			
Head	2.3-3	2.9	92-93
Abdomen	1.2	2	92-93

Table 8: Observation Services - % Short Term Therapy

ref	7	8	4	9	10	3	11	12	13	14	14
Allergy	.1		.6				1				
Respiratory	5.1		3	5	12	10	9	10	18		
Asthma	3.6		2	3			7	9			
SOB, Other	1.5		1	2			2	1			
Pneumothorax	.04										
CHF	.9		1	7			5	2			
Pneumonia	.8		2					2			
Hyper/hypoglycemia	.6		1.7				2				
Dehydration	3.7		3	6			2	6	13		
Hypertension	.3		1								
Urine Retention	.3					4				1	8
Hematologic	.1		4	4	5	2	14	17	8		
Epistaxis	.06		2					5			
Sickle Cell	.04		2				1	3			
Hemophilia	0						3	4			
Total	11.9	0	16	22	17	16	23	32	39	1	8

Table 9: Success of Short Term Therapy (%)

	Length of Therapy			
	<4 hr	<12 hr	<24hr	Ref
Respiratory				
Asthma	67-76	89	92	109-13
Chronic CHF			>50	11, 114-124
Pneumonia			>80	125
Dehydration			61-98	11, 126
Hypertensive Urgencies			93-100	127-128
Kidney Stone			75	10
Pyelonephritis			84-98	129-130
Hematologic				
Transfuse (2 units)			100	
Sickle Cell		75-80	93	11, 131
Hemophilia			81	11
Pneumothorax				
spontaneous		30-65		132-134
traumatic, simple		75-94		135-138

Table 10: Observation Services - % Psycho-Social Needs

Needs		7	8	4	9	3	11	12	13	14	14
Psych	7.9	3	.8	4	10	5	4				
Psychosis	4.0										
Self Lac[*]	.8										
Depressed	2.1										
Adjust Reaction[**]	1.0										
Etoh/Drug	11.1		16	20		1	7				
Social		.7	2	3		2				8	9
Total	19.3	5	20	20	10	5	7	7	5	8	9

[*] Self Laceration
[**] Adjustment Reaction

Table 11: Amount of Physician Service Provided in Different Types of Services[161]

Type of Service	Intensity (Hr/Pt/MD)	Length (Hours)	Service (Hours)
Critical Care	.3-1	1-4	.32
Walk in Care	< .1	1-2	.16
Nondifferentiated	.3	1-2	.37
Observation Care	< .1	5-24	.75

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6

Hospital Based Observation Unit Design
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Summary: Observation units (OUs) may be categorized into four groups based on the level of training of the providers and nurses and how the unit's patients are clustered within the hospital. Although there are benefits and liabilities to all four OU types, the more successful units result from highly trained providers and nurses with clustered patients in a specific location within the hospital (Type IV OU).

Hospital Observation Units

The choice of hospital observation unit is largely dependent upon the available resources, space, training, and budget of the hospital. Usually, trained personnel managing a distinctly located unit results in better operational efficiencies.[1,2] Observation Units are categorized into four types (Table 1). Each OU type has its own strengths and weaknesses (Table 2) and presents its own managerial challenge if the hospital is to operate the unit successfully and in full compliance.

Two major variables are used to differentiate hospital OUs: The concentration of observation patients and the quality of training of the observation care providers (faculty, nursing, and ancillary staff). OUs with specific identifiable hospital locations (Types II and IV) can improve long term hospital costs by reducing redundant equipment costs, administrative workload, and personnel variation.[1,3] However, there is no specific requirement that requires an OU to be located in a specific location.[4] Similarly, there is no specific policy mandating that OUs have specialized health care providers trained in observation medicine although systems with trained OU personnel have reported better economic and non-economic outcomes than OUs without specific provider training.[1,4-7] Presently, federal billing guidelines outline specific documentation requirements for observation services, but have not mandated any specialty training in observation medicine as a prerequisite for establishing an OU. As a result, there may be much variability in the quality of training from the hospital's physicians, nurses, and staff.[8,9] Units staffed by physicians, nurses and staff who as part of their practice, participate in observation services and have at least some knowledge of the processes of observation medicine (eg risk stratification, care pathways, and billing requirements) would be considered 'generally informed' and occupy the type I and II units. (Table 1) Specifically trained physicians and nurses utilizing goal directed care pathways, are specifically trained in observation processes, and who participate in the OUs quality assurance oversight, utilization review and feedback are considered 'well informed.'[1,2,8] These groups of providers are found in Type III and IV units. While these descriptive classifications are useful, hospitals may modify a particular observation unit type to better meet its patient care goal and needs and particular institutional goals. Advantages and disadvantages of the four units are considered below.

Type 1: Scatter-bed Observation Unit (location diffuse/care team generally informed)

In this model, any bed in the hospital may be designated as observation. Patients are placed in the unit from the emergency department (ED) or directly by an outpatient office practice. The responsible provider generates all orders and oversees the patient's care during the visit. Observation care orders may be generated at time of placement into the unit, eliminating the requirement for standard protocols, but introducing potentially

wide variability in management. The nursing staff in conjunction with the physician develops and implements a specific care plan for each patient's visit.[8] The Type I unit provides considerable provider flexibility to allow patients to be placed under observation services. This system is attractive to hospitals employing many smaller physician groups where gaining consensus for standard practice protocols would prove extremely challenging. Hospitals with little resources to provide specific space or training but are seeking to expand their observation census may also choose this type of unit design.

While these units are inexpensive to implement, they also suffer from process inconsistencies that can be difficult to monitor and correct. Variability and inconsistency of care with the similarly managed patient (such as low risk chest pain) leads to delays in care, lack of standardization with resultant inefficiency, higher rates of denials for ineligible services, and communication errors between the providers and the unit. The effective administrative response is to have utilization management fully empowered and integrated into the patient care team from first encounter until the patient leaves the facility. However, due to the type I unit's lack of process consistency, relatively untrained physicians and staff, and wide variation in practice, this unit generally provides less effective care than the more organized units.[2,7]

Type II: Open Observation Unit – (location specified/care team generally informed)

Type II units are located in specific areas within the hospital. Each patient is attended to by his/her own primary care physician, hospitalist or specialist. The location may be immediately adjacent to the ED, or throughout the hospital, but the location is formally designated as an OU. These units achieve some level of efficiency in their clustering of observation patients. Operational efficiencies are achieved through specially trained nursing and ancillary care personnel that become familiar with the management of clustered patients with similar care needs. The type II unit's anchored location results a number of operational efficiencies, including opportunities to train specific nursing and ancillary staff in OU processes, purchase and maintain specific equipment beneficial to OUs (eg cardiac monitoring equipment, utilization review software), and establishing processes unique to OUs such as providing elapsed patient times, care pathways, and utilization review.

However, specific patient care may vary by provider. Without rigorous standards, protocols and utilization control, there exists a tendency for the untrained provider to vary from the care protocols, resulting in loss of efficiency and delay. As with the type I unit, operational and communication efficiencies may occur when specialized providers that are not required to follow strict care pathways or are allowed to modify the observation care at point of admission. However, the type II OU's location may overcome some of these inefficiencies by providing unit specific policies designed to improve outcomes. One example is a unit mandate requiring that all patient care plans must have a reasonable (~80%) chance of discharge by 24 hours. Enforcement of the unit's policies occurs through the offices of nursing, the OU's medical director, and case management. The type II unit requires more administrative oversight than the type I or III unit. It is often deployed in larger hospitals with a diffuse hospital staff with large observation system requirements.

Type III: Virtual Observation Unit (location diffuse/ care team well informed)

The type III unit is generally operated by an ED physician or hospitalist. Unlike the type I or II units, these practitioners are very knowledgeable of observation care, have developed or participated in the observation care pathways, and maintain a rigorous quality control process.[1,2] Any bed in the facility can be designated for use as observation. Type III OUs are generally located within or adjacent to EDs. The ED may initiate the observation protocols within the ED, creating a 'virtual OU' that characterizes the type III unit. Hospitals choose Type III units when effective observation protocols and trained personnel are available but the hospital lacks the immediate resources to provide a specific location. Clustering patients in or adjacent to the ED, or effectively concentrating the observation patients, is another characteristic of the type III unit.

Disadvantages to the type III unit are exhibited through the limited resource issues. ED physicians concomitantly managing observation patients while staffing the ED may result in delays in disposition, decision making delays, and inefficiency. Since the ED is presumed to have the sicker, more undifferentiated patients, the OU patient and not the active ED patient is most likely the recipient of these multitasking delays. Well trained nurse driven care protocols may automate the type III unit and reduce multitasking burden resulting from this 'virtual' (type III) unit. Hospitals systems operating with significant ED overcrowding, patients waiting for presumed short inpatient stays, or systems with high rates of inpatient admission denials, might consider the type III unit until sufficient resources are available to aggregate patients into the type IV model.

Type IV: Closed Observation Unit – (location specified / care team specified)

Type IV OUs utilize designated hospital OUs generally located near or adjacent to the ED. The OU is staffed by specially trained nurses and ancillary staff. All OU patients are placed in a care specific protocol and are managed through a select provider group (hospitalist or emergency physician). Well trained practitioners are obligated to follow the designated care sets with little practice variation permitted. The type IV 'closed' designation is defined by strict adherence to prewritten care pathways, qualifying admission policies that distinguish specific OU patients while discouraging transfers of inappropriate observation patients, designated well trained practitioners, nursing and ancillary staff, and sufficient administrative oversight to insure optimal quality control. Type IV units initially require extensive oversight through quality control, case management, medical, and nursing directorships. However, once the unit's policies are defined and reinforced, fewer resources may be required.

The combination of a specifically located unit with well trained staff typically results in the most efficient OUs. Outcomes such as mean length of stay, percent discharged by 23 hours, and admissions rates are usually better optimized through a type IV unit.[3,6] However, this unit is the most costly to implement, both because of the space and personnel requirements. Startup costs are substantially higher than the scattered (type I) or virtual (type III) units. However annual operating costs are often similar because localized OUs (types II and IV) may share resources (eg, ECG machines) and personnel within the unit where the scattered or virtual units (type I and III) must allocate redundant equipment and personnel throughout the hospital.

OUs and the General Manufacturing Process
Observation units operate most efficiently when emulating the processes of a manufacturing plant. Using process controls and policies similar to a mass production facility, the goals of the OU leadership are to reduce variation in patient throughput by standardizing care pathways, train staff to perform similar tasks, organize equipment and resources so they are not underutilized (resulting in resource waste) or overutilized (resulting in delays in care), and streamline processes.[1,3,7-9] Constant systems review and continuous policing of operational policies should accompany the processes to insure maximum operating efficiency.[1,2,4,7] For example, efficient OUs track the mean aggregate times for each protocol, but also track key times within each protocol (such as time from discharge order to release from unit). Care pathways that routinely exceed the unit's defined acceptable mean time (often 23 hours) should be reviewed for correctable delays or notable inefficiencies. These manufacturing principles of streamlined process, defined responsibilities and well trained personnel, written policies and operational guidelines, quality control, and continued resource utilization are supported in the policy resource education paper from the Observation Medicine Section of the American College of Emergency Physicians.[2,5]

Estimating OU Size and Personnel
Established observation practices report an estimated 4-10% of annual ED visits as a reasonable target volume for a new OU. An efficient OU will have a turnover rate of 300 to 330 patients per bed per year. Because nursing care generally represents the highest proportion of an OU's operational budget, units are commonly designed around nurse staffing. OU nurse to patient ratios are generally 4:1 to 6:1 with one study reporting an average of 4.2:1 nurse to patients. Using these estimates, a hospital with an average acuity case mix

and a 30,000 patient ED volume might expect to have 1200-3000 eligible observation patients. With a 300 pt/bed turnover annually, the hospital may chose to build a 10 bed unit with 5:1 nursing, or an 8 or 12 bed unit with 4:1 nursing.

Table 1: Types of Observation Units

		CONCENTRATION OF PATIENTS	
		DIFFUSE AREA	**SPECIFIC AREA**
PROVIDERS *(STRATIFIED BY TRAINING LEVEL)*	**GENERALLY INFORMED**	Type I Scattered *(Diffuse Area/Generally Informed)*	Type II Open *(Specific Area/Generally Informed)*
	WELL INFORMED *(TRAINED ON PROTOCOLS)*	Type III Virtual *(Diffuse Area/Well Informed)*	Type IV Closed *(Specific Area/Well Informed)*

Table 2: Advantages and Disadvantages of Observation Units

Type	Advantages	Disadvantages
Type I: Scattered Unit	'any provider – anywhere' may increase number of enrolled observation patients - Inexpensive - Relatively easy to implement - No additional staff required - Uses existing hospital beds	- No system change - Unregulated or no protocols introduces practice management variation - Little or no care standardization - Lack of nursing focus, input - Requires intense case management - No team approach, little feedback - Redundant equipment resources required
Type II: Open 'Defined' Observation Unit	'any provider – specific location' - Focused attention on patient movement through the system - Specific location allows for targeted nursing and unit training - Trained 'compliant' unit may overcome provider inexperience though close communication and tight unit protocol compliance - Reduces redundant resources	- Unknowledgeable or uncooperative providers may disrupt unit and reduce efficiency - Lack of protocol standardization may result in wide variation in practice management - Lack of unit oversight may lead to loss in efficiency - Requires rigorous case management and tight controls - Requires appropriate space
Type III: Virtual Observation Unit	'trained provider – any location' - Specified 'compliant' providers improve efficiencies by standardizing work-ups - Standardized protocols may adjust for lack of untrained or uncoordinated unit - Appropriate resource allocation	- Unclustered patients reduce efficiency, requires redundant resources - Nursing untrained or unfamiliar with protocols may disable system or reduce efficiency - May require transfer of care to another provider if bed located away from ED - Requires moderate case management
Type IV: Closed Observation Unit	'trained provider – specific location' - Focused attention on patient movement through the system - Trained staff delivering standardized care pathways - Clustered patients provide enhanced efficiencies - Seamless system may be designed from ED to unit	- Expensive to implement - Requires additional staff (physicians, nursing, support staff) - Requires appropriate space and additional resource allocation

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7

Reimbursement Challenges

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Clearly the provision of observation services has great merit with respect to the quality and efficiency of care. In order however, to develop and perpetuate an effective observation service, a number of reimbursement challenges must be addressed and payor opportunities seized. Physician compensation for observation services is principally defined within ten Evaluation and Management E/M Services while hospital reimbursement is and will continue to be an evolutionary, and occasionally, a dynamic issue. In this chapter, we will identify the salient reimbursement issues regarding the Centers for Medicare & Medicaid Services (CMS) documentation guidelines and Current Procedural Terminology (CPT) coding. In addition, data entry issues and payor contracting options will be identified, along with current evolving concepts in physician compensation. The chapter content will be organized as follows:

Documentation Requirements
      History, Physical Exam, Medical Decision Making

Evaluation and Management Codes
      Observation Codes (Transcend Initial Calendar Date)
            Initial Observation Service   99218-99220
            Discharge from Observation   99217
      Subsequent Observation Care   99224-99226
      Observation Codes (Within Same Calendar Date)
            Observation & Discharge   99234-99236
      Emergency Service Codes   99281-99285

Procedural Service Codes

Modifier Utilization

Payor Contract Options
      Indemnity Payments (Physician versus Facility component)
      Global Capitation
      Hybrid Options
      Ambulatory Payment Classifications

Physician Compensation Issues

Documentation Requirements

With the implementation of the 1995 CMS, documentation guidelines as amended in 1997, it is important that physicians providing observation services be cognizant of these rules. Indeed, the CMS documentation guideline descriptors utilize common phrases that may seem generic but rather, have very specific and technical interpretations. These components include the *history, physical exam* and *medical decision making activities* within the observation services. Except for the lowest level code in each category, observation services require a "comprehensive history" and "comprehensive physical exam." It is therefore important that physicians understand the specific components of them. A comprehensive history requires an extended History of Present Illness (HPI) that addresses four or more of the characteristics listed in Table 1.

Table 1
History of Present Illness

- Location
- Quality
- Severity
- Duration

- Timing
- Context
- Modifying factors
- Associated signs and symptoms

One may also meet the requirements for an extended HPI if the examiner addresses the status of three or more chronic or ongoing medical problems. A comprehensive history also requires addressing at least one attribute within the past medical, social or family history and 10 or more components of the review of systems. Remember that the observation codes have a higher history requirement in the area of past medical, family and social history (PFSH) than the ED E/M codes. For observation services, you must record findings from all three of these components rather than the two of three required for ED services.

The recognized categories for the review of systems appear in Table 2.

Table 2
Body Systems

- Constitutional
- Eyes
- Ears, Nose
- Mouth, Throat
- Resp
- GI

- GU
- MS
- Integ/Skin
- CV
- Psych

- Endocrine
- Hema/Lymph
- Allergic/
- Immunologic
- Neuro

The second component required in upper level observation services is a comprehensive physical exam. In order to be compliant with the 1997 documentation guideline multi system physical exam, examiners must document two bulleted elements within each organ systems or body areas. As an example this may include documentation of auscultation and palpation of the abdomen. A comprehensive exam requires recognition of at least nine organ systems or body areas identifying eighteen or more physical findings such as those listed in Table 3.

Table 3		

Physical exam record*:*

- Multiple area exam
- Affected body site with other related areas
- Pelvic/rectal
- Constitutional (eg, vital signs general appearance)
- Eyes
- Ears, nose, mouth & throat
- Cardiovascular

- Respiratory
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Skin
- Neurologic
- Psychiatric
- Hematologic/lymphatic/ immunologic

The third component of required documentation, medical decision making, will determine which of the three observation codes is appropriate for an individual patient. Medical decision making involves the "range of management options," "amount and complexity of data reviewed" and management risk "considerations." The three principal codes used to describe observation services in CPT nomenclature 99218, 99219 and 99220 are differentiated primarily by the degree of medical decision making. The documentation of medical decision making is distinguished by the "amount and/or complexity of data to be reviewed," the "number of diagnostic or management options" and the "risk of complications and/or morbidity or mortality." The three levels of observation services are therefore differentiated by medical decision making of Straightforward, Low, Moderate and High Complexity. Table 4 identifies the components for the categories of medical decision making involved in the provision of observation services.

Table 4

Type of Decision Making	Number of diagnoses or management options	Amount and/or complexity of data to be reviewed	Risk of complications and/or morbidity or mortality
Straightforward	Minimal	Minimal	Minimal
Low Complexity	Limited	Limited	Low
Moderate Complexity	Moderate	Moderate	Moderate
High Complexity	Extensive	High	High

Generally the level of medical decision making is determined by the conceptual median of its components. In other words, two of the three MDM categories must meet or exceed the overall level assigned. As an example, an extensive number of diagnostic or management options and extensive review of data with morbidity would be most consistent with medical decision making of high complexity. Similarly, multiple diagnostic management options and limited data review with low risk would be most

typically associated with low complexity medical decision making. More detailed information regarding prevailing CMS reimbursement documentation guidelines can be obtained from the specific Medicare Administrative Contractors or the American Medical Association (AMA).

Evaluation and Management Codes

Approximately 93% of observation services physician revenue is generated by the utilization of the Evaluation and Management codes within Common Procedural Terminology (CPT). This family of codes includes the Observation Services codes and Emergency Department Visit codes. Patient care describing observation service is best characterized by utilizing the family of Initial Observation Care codes -- 99218, 99219 and 99220 or the Observation and Discharge from Observation Service code 99234, 99235 and 99236. New in 2011 is a family of Subsequent Observation Care codes 99224-99226, which describe the middle day of observation services for those rare occasions when the service period transcends three calendar days. Of note that could be well under 48 hours of actually care for a observation encounter that begins late on day one, covers all of day two and is discharged early in the morning on day three. These codes may not be used in conjunction with the Emergency Medicine codes on the same calendar date, except when services are provided by a physician with a different specialty or different legal entity that reports using a different payer identifier. Examples of this phenomenon may include initial stabilization of the patient by the emergency medicine group with referral to a hospitalist providing the observation services. In that instance, the Emergency Department codes, the 9928X series, and the Observation Service codes, the 9921X series, would be entirely appropriate when reported by the different providers rendering each service.

For complete observation services, including admission and discharge, provided within the same calendar date, three codes are available to describe this type of service.

They include the 99234, 99235 and 99236 services and are used to report all observation services including discharge activities that occur on the same calendar date. For observation services transcending the initial calendar date, the discharge services may best be identified by the 99217 *Observation Care Discharge* code. This code is to be utilized by the physician to report all services provided to a patient on discharge from observation services if the discharge is on other than the initial date of observation status. Examples of this circumstance would include an individual with reactive airway disease admitted at 8:00 p.m. to observation services and ultimately discharged at 6:00 a.m.the next day to home care.

Recent Relative Value Units (RVUs) for Emergency Department and Observation codes are reflected in Table 5.

Table 5 2011 Observation Total RVUs							
Emergency Department Codes		**Initial Observation Service Codes**		**Subsequent Observation**		**Obs. Admission and Discharge Codes**	
CPT code	RVUs	CPT code	RVUs	CPT code	RVUs	CPT Code	RVUs
99283	1.80	99218	1.89	99224	0.82	99234	3.87
99284	3.40	99219	3.16	99225	1.45	99235	5.07
99285	4.98	99220	4.42	99226	2.17	99236	6.30
		99217	2.04				

The above table demonstrates that relative physician work values assigned to the *Evaluation and*

*Management s*ervice codes most typically provided in an observation unit. As indicated, the 99220 *Observation Service with Comprehensive History and Exam* and high medical decision making has a value of 0.56 RVUs less than its emergency department counterpoint. In those instances in which the observation services transcend a calendar date, the combination of 99220 and 99217 would be most appropriately be reported. Of note, the RVUs for family of observation services are currently under CMS review and may change significantly in the 2012 Medicare Physician Fee Schedule.

Procedural Service Codes

In many instances, the patient's care within observation service requires additional services not included in the typical Evaluation and Management Service codes. This may include the placement of central venous access, laceration repairs and endoscopic procedures. In those instances, the evaluation and management code should be used with the -25 modifier. This modifier is used to describe significant, separately identifiable evaluation of management services by the same physician on the same day of the procedure or other services.

Modifier Codes Utilization

In 1996, Medicare policydetermined that interpretive services could be provided in addition to evaluation and management services, when those services are provided contemporaneously with patient care in hospital based settings. In order to render an electrocardiographic or radiographic interpretation, a separate, signed and identifiable report must be documented. In addition, the -26 modifier should also be used to designate the professional service component on the radiographic interpretations. Examples of this may include chest x-ray interpretation, 77010-26 for *Radiographic Examination Chest with a Single Frontal View*.

Facility Payment Issues

The facility component of indemnity payments has been based on a multitude of methodologies due the absence of an analogous CPT coding methodology or stringent CMS documentation guideline equivalents applicable to facility charge capture. These methodologies however, are essentially focused on time based or stratified service methodologies. Time based methodologies are those that are generally limited to nursing services and are an estimate of the cost of providing the services as a unit of time. Typically, these are calculated upon historical hospital charge and cost structure or by prevailing market precedence. Time based hospital charge capture methodologies should be clearly identified on a clinical record and the UB-92 claim form. Time based methodologies, as an example, may feature an initial hospital facility admission charge and one hour incremental charge units.

An alternative methodology utilized in indemnity payment environments to capture hospital revenue is stratified facility charges. Stratified methodologies are more analogous to CPT theory and indeed in some instances, hospital authorized "levels of service" can be coupled to the known CPT counterparts. The number of hospital "levels of service" have not been codified or, as of this writing, required by the payment community. A hospital therefore, could have two to five "levels of care" based on the intensity of services provided. Indeed, many programs have elected to utilize three levels of service that correspond approximately to the physician CPT counterparts. The current monetary value assigned to these levels of service varies widely throughout the country, but are significantly more than of the physician component counterpart. In most programs, either time based or stratified methodologies do not include ancillary services such as laboratory, X-ray or respiratory services. These charges however, could be included for programs that have a stable physician group and an adequate database on which to extrapolate anticipated future costs.

The facility reimbursement component is an area of interest to all physicians as changes in

payment policy can restrict resources for the provision of observation services. The types of reimbursement methodologies can include facility bundled payments such as the Medicare Ambulatory Payment Groups (APC's), to indemnity payments for "cost plus" services to global capitated services in which the hospital's component is included in a much larger package of services. In addition, it is possible in the years ahead that episodes of care (EOC) or accountable care organizations (ACO) payment models may evolve that include the physician component in a single payment to the hospital.

While it is difficult to speculate at this juncture all permutations of facility reimbursement model, it is important physicians maintain an active dialogue with hospital leadership to ascertain local challenges as they unfold. Clearly, methodologies that threaten adequate access to resources pose a threat to the provision of contemporary observation services.

Physician Compensation Issues

Physician compensation will be a dynamic arena in the years ahead. With increasing intensity of services, along with required operational metric and quality marker compliances, may create difficulties for traditional fee for service payment methodologies for all physicians in observation settings.

Contemporary compensation theory would suggest an evolution in methodology to include considerations for production, "bed to greet" and similar operational metrics, quality marker compliance and customer satisfaction. The most recent theory, suggesting a production based compensation methodology using RVUs and constituting approximately 50% of the physician compensation, appears to be gaining support within progressive physician groups. As an example, a net dollar payment per physician RVU work unit can be agreed upon and constitute approximately 50% of physician income.

In addition, progressive physician compensation packages may include allocations based on quality markers such CMS Core Measure, PQRI methodologies, internal metric goal compliance and utilization review compensation consideration. Up to 50% of physician compensation may be allocated based upon deviation or convergence from either intergroup or intra-group parameters. Utilization review may include ancillary services such as lab and x-ray but increasingly are including considerations of sub-specialty consultation expenses. Typically, 1-2 standard deviations are thresholds of consequence in determining these levels.

In specific instances, compensating physicians based on "group citizenship" has received recent interest. Group citizenship can be defined in a number of ways and should be applied to specific activities that are uniquely of interest to the program. Examples of group citizenship consideration could include assistance in the development of observation service clinical pathways and/or compliance with recognized operational protocols. Clearly, this consideration is the most subjective of the components currently being considered in progressive observation service physician compensation programs. It is one that may prove to be an important one however, in managed care environments. The impact of such a consideration on the total compensation is felt to be by many however, to appropriately be in the 2-4% range of total compensation.

In concept, a compensation methodology incorporating physician productivity, local operational metrics, quality markers resource utilization, customer satisfaction and group citizenship is one with a great deal of theoretical merit, but one with which few have had practical experience. Clearly, these concepts will evolve and mature in the years ahead. One type of operational incorporation of these concepts can be achieved by utilizing RVU theory with parameter specific conversion factors. As an example, a physician could be compensated based on their total RVS work units multiplied by a program specific conversion factor. An internal conversion factor can be calculated most simplistically by taking total collected revenue minus overhead, divided by the total RVS units worked per physician. This base conversion factor could

then be modified by parameter specific conversion factor modifiers that may range from 90% to 110% of the base conversation factor for each of the identified areas desired by the physician group. An operational equation of these concepts would appear as below in Table 6. Clearly innovative physician compensation methodologies have application in the provision of observation services for progressive physician groups in the years ahead.

Table 6
Physician Compensation: $\$_t = RVU_o \times (CF_I \times [CF_{metric} \times CF_{quality\ marker} \times CF_{group\ citizenship}])$ where $CF_I = \dfrac{\underline{\text{Total collected dollars - total service overhead allocation}}}{RVU_t}$

A number of significant challenges and compelling opportunities exist in the provision of observation services. None are any more compelling than those revolving around service reimbursement and physician compensation issues. Without adequate reimbursement resources, hospital space and nursing and physician components will be inadequate. Without the development of creative physician compensation methodologies that recognize the resource expense in providing observation service 24 hours a day, seven days a week while capitalizing on the system efficiencies, it will not be possible to retain adequate physician expertise in the arena. Clearly, dynamic periods in healthcare payment reform will require adaptive and creative responses. Physicians focused on providing quality care and promoting patient advocacy however, will continue to be those best suited to address challenges and capitalize on opportunities as they develop.

RESOURCES

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8

Management - Staffing

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Outline

General introduction to observation-unit specific considerations regarding staffing.

Contrast acute care emergency department (ED) versus observation unit staffing

Specific roles:
- Leadership (nursing and physician)
    - Training, oversight, resources (protocols, policy manual)
    - Provider satisfaction
- Attending physicians
    - Billing differences
    - EM versus non-EM (mention location, staff availability)
- Midlevel practitioners
- Resident physicians
- Nursing
    - Dedicated versus floating staff
- Ancillaries and consultants
    - Medical assistants and unit secretaries
    - Specialists, social workers, physical therapists
- Special considerations
    - Overcrowding and flexibility

Observation units are typically staffed with a mix of physicians, midlevel practitioners, nurses, ancillary and consultant staff. The optimal combination of these individuals will likely vary by institution, depending upon patient needs and available resources. In addition to hospital-specific factors that may influence staffing, billing requirements may also play a role, especially for physician staffing. Observation units also may play a role in ED crowding and serve as a resource to allow for more flexibility in the department.

EDs that offer observation services are providing services beyond that provided in a traditional ED, where patients always move onto another destination after an initial evaluation (ie, discharge, transfer or admit). To ensure high quality patient care for this added service there must be adequate dedicated personnel and oversight. Past standards for ED staffing have been based on average EDs. These standards do not take into consideration additional specialized services, such as observation, offered in some EDs today.

Observation Leadership Structure

An observation unit should have both physician and nursing leadership in place. This structure establishes accountability, training, oversight and feedback. A transparent leadership structure encourages free communication and encourages staff to elevate concerns to the appropriate party. Another key role these positions play is in training staff to maximize the potential of the observation unit. This training includes insights into the appropriateness of specific patients for observation care.[1-3] Clinicians need to understand the patient characteristics that would enable or impede a patient from successful observation management. Diagnostic and treatment protocols are another tool that should be developed by unit leadership to ensure less variability by provider. These tools are discussed in more detail elsewhere in this text.

Regular feedback on important metrics such as observation unit use, length of stay, conversion rate to inpatient admission and others should be provided from leadership to the physicians admitting to the unit. Finally, a policy manual that provides transparency as to the goals and resources for the observation unit should be developed by leadership, updated regularly and made easily accessible to all staff.[4]

Leadership can also measure and address staff satisfaction with observation patient management. Since observation medicine has continued to spread to more institutions over the past several decades, many clinicians are being introduced to working in this setting. Many of them were unaware of even the concept of observation care as they underwent clinical training. The clinical interaction in an observation unit differs from those in an acute care ED in many significant ways, as patients have already been seen by a colleague, testing is underway or completed and the timeframe for decision making shifts from minutes to hours. As a result, leadership needs to emphasize the importance of the work done by clinicians in an observation unit and support them with the tools and feedback to optimize the care of their patients.

Observation Unit Attending Physician Coverage

Payer requirements and quality standards generally dictate that an attending physician personally perform both an observation admission and discharge assessment.[5] As a result, the involvement of the attending physician is a constant element of observation care. However, during the course of the observation period, the attending physician need only be available, not physically present, for the care of observation patients. This allows for cross coverage of other areas in the hospital, including the acute care ED. The typical attending emergency physician can oversee observation patients in addition to staffing new patients in the acute care ED. The distribution of patients assigned to any single physician must recognize the demands of both volume and complexity, taking provider capacity into account, not just at the averages, but also at peak times as well.[6] An uninterrupted minimum of an hour is usually needed to round on a typical 10-bed observation unit when taking over for another physician, and once patients are reassessed and plans are confirmed, the physician can step away to see new patients, but is always available to return if needed. Table 1 outlines key factors that influence physician productivity.

Table 1: Factors Affecting the Efficiency of Emergency Physicians[7-9]

Decrease Efficiency

Amount of time patients wait until they see the physician
Time waiting for the attending physician to come in and admit the patient
Inadequate intake staff
Lower levels of staffing while staff at meals
Inadequate number of patient treatment areas
Daily census - inpatient

Peak volumes of patients
Hourly number of patients
Number of critical care patients
Number of admitted patients awaiting a bed (boarded patients)
Teaching responsibilities

Observation services need to be carefully monitored to ensure sufficient staffing is in place to provide the needed services. The total service requirements per patient are greater than for other typical ED patients due to the much longer length of stay seen with in observation units. Time studies should be performed in different observation units to define the mean amount of service per patient. For example, if this is near our norm 0.75 hours of physician time is required for each observed patient, then the amount of staffing is 0.75 hour per patient times the number of patients treated per year. In a department that observes 6% of the 44,000 annual visits, that represents 2,640 observation visits per year. We then estimate the total physician staffing needs at 1,980 hours per year (0.75 hour per patient x 2,640 patients per year). Assuming one physician works 1,725 hours per year, the department requires 1.1 FTE (full time equivalent) of physician staffing for observation services.

Traditional staffing formulae are based on the number of patients seen per year and the average amount of service provided per observation patient. The recommendations for staffing have been expressed in three ways: thousands of patients per physician per year, the number of patients per physician per hour, or minutes per patient per physician. (Table 2) The American Academy of Emergency Medicine has recommended the standard of a maximum 2.5 patients per hour for acute ED patients.[10] At this time, there are no clear published benchmarks or consensus recommendations for the number of observation patients that should be managed per hour by a single physician.

Table 2: Physician Service Time (Different mean Staffing Needs)

Service time (hr/pt)	Pt/MD/Hour	Pt/MD/Year
.89	1.13	2,000
.59	1.69	3,000
.44	2.26	4,000
.37	2.7	5,000
.29	3.5	6,000
.26	3.9	7,000
.22	4.5	8,000
.18	5.6	10,000

Assume work 1771 hr/yr (37.5 hr/wk, 46 wk/yr)

One other important staffing consideration is related to the professional fees billed for observation services. Physicians from the same specialty and same practice cannot bill for both the acute care ED visit and the initial observation admission on the same date.[11] In cases where the observation stay crosses midnight and the patient is discharged on day 2, an observation discharge code (CPT 99217) can be billed in addition to the services billed on day 1.[11] However, some groups have navigated this requirement by establishing a new physician group that only staffs the observation unit at any given time, allowing for both acute care ED billing codes (CPT 99281-99285) and initial observation billing codes (CPT 99218-99220 and 99234-99236) to be billed on the same date.[11] This concept is discussed in more detail elsewhere in this text.

One way to avoid the billing obstacles outlines above is to staff the observation unit with non-emergency physicians. For example, an observation unit staffed by hospitalists with internal medicine training would allow for maximal billing on the initial date of service, since these physicians are from a different specialty than the emergency physicians staffing the ED. However, this model may introduce inefficiencies and potential for errors. When the emergency physician continues to staff a patient in

observation whom he or she initially encountered in the ED, no additional physician passoff is necessary, at least until that physician's shift terminates and patients are transition to the oncoming provider. Adding passoffs can introduce communication errors, which can lead to patient harm.[12] Additionally, some other efficiencies may be gained by keeping the span of control of the observation unit within the ED. Recent National Hospital Ambulatory Care Survey shows that only about 2/3 of large volume hospitals (defined as over 50,000 annual visits to the ED) with an observation unit have it operated by emergency physicians.[13] Some studies have suggested that length of stay is significantly lower for emergency-department based observation units versus observation units elsewhere in the hospital managed by non-emergency physicians.[14] It is unclear what creates this efficiency gap, but factors such as more strict enforcement of length of stay maximums, patient selection, adherence to protocolized care pathways and perhaps even faster turnaround time for diagnostic studies ordered from the ED all may play a role.

Physician staffing can also follow an open or a closed model. In a closed model, typically only the emergency physicians caring for a patient who is a candidate for observation unit management can admit to this unit. This policy allows for the tightest control over patient selection for observation care, as a relatively homogeneous group who uses observation frequently is in direct control of which patients are observed. This group can be given regular feedback about their unique patient selection history, such as their own rate of observation patients who require further inpatient admission. These physicians are typically accountable to ED leadership. They have an intimate understanding of the spectrum of patients seen in the ED and are best positioned to identify those who cannot be discharged home but also do not require a typical inpatient admission. Alternatively, the open model allows for more flexibility, as non-emergency physicians, such as primary care providers, can have access to directly admitting their patients to the observation unit. These physicians often continue to staff these patients while in observation, either personally or via their group. Many of the advantages of a closed model are lost in such an arrangement, but local resources and relationships may dictate that an open model best suits a particular unit.

Finally, another aspect of the observation unit that may influence physician staffing is the physical location of the unit. Many times, an observation unit is established when there is a need for one and existing space suddenly becomes available. This space is not always within or immediately adjacent to the ED. As a result, institutions must determine the staffing model that is logistically possible in order to allow the responsible physicians to be available to the observation patients. For example, if an observation unit is created on the opposite side of a large hospital that would create significant transit times for the physician to travel back and forth from the observation unit to the ED, it may not be practical to expect that physician to be responsible for both locations at the same time. However, a brief elevator ride may not impose any significant obstacle to adequate coverage. Finally, not all institutions have adequate emergency physician coverage to allow for observation unit staffing. As more emergency physicians enter the workforce in the coming years this coverage gap should diminish, but it still persists today in many hospitals.

Observation Unit Midlevel Practitioner Staffing

Many observation units are staffed by mid-level providers, such as nurse practitioners or physician assistants. These professionals have special training to function autonomously in many clinical settings. By sitting in the physical space of the observation unit, a nurse practitioner or physician assistant can rapidly assess patients, respond to nursing questions or suggestions and ensure results are followed up and testing is completed.

Even with the use of a mid-level provider, a supervising physician should be ultimately responsible and available for each patient in observation. Critical decisions, such as the overall observation management plan and endpoints for successful discharge, are usually made by the supervising physician and subsequently managed by the mid-level provider. If a patient decompensates or if test results are concerning, the supervising physician is re-engaged to intervene. However, much of hands-on work needed to care for observation patients can be safely handled by an experienced midlevel practitioner.

Observation Unit Resident Physician Staffing

In hospitals with resident physicians, they may play a role in observation unit staffing. As observation units become more common, familiarity with observation admission and management has become a useful skill for the emergency physician in training. The resident physician does not replace the attending physician; however, they may function in a similar role as the midlevel practitioner discussed above. In this way, departments may not need to rely on 24/7 midlevel coverage if supplementation with resident physicians is feasible. This model may provide two benefits: valuable experience for the trainee and lower costs for the hospital due to reduced midlevel coverage.

One caution with trainee staffing is that the lack of experience in the observation setting may result in longer patient length of stay. Opportunities to complete plans of care may be missed due to missing diagnostic test ordering deadlines, suboptimal communication or other inefficiencies. However, the attending physician's role is to support the trainee and keep the patient's stay on track. This relationship helps to ensure that a safe and efficient unit can be run with the involvement of resident physicians.

Observation Unit Nurse Staffing

Observation units are typically staffed by registered nurses (RNs), who have the clinical skills and experience to care for this patient population. One important aspect of observation care that is helpful to remember is that for many patients the medical decision making may be straightforward, but the nursing care required may be complex. Accordingly, patients that will likely require more nursing care than what can be adequately provided in the observation unit should be managed elsewhere. The degree of nursing intensity in the observation unit is usually less or similar to those provided on an inpatient hospital ward. Approximately one nurse is needed per shift for every 5 to 6 patients in an observation unit, whereas one nurse is usually staffed for every 4 patients on an inpatient floor.[15,16] Thus far, national guidelines for nursing ratios have not specifically addressed the observation setting. Usually an observation unit will have a fixed number of beds, which will determine the number of nurses needed based on the staffing ratio above. For example, a typical 10-bed observation unit will be staffed by two RNs.

A more exact method of calculating staffing needs is to use multifactorial formulae which categorized patients into 4 or 5 levels of care. They are based on factors that correlate with the intensity of service or the amount of time needed to provide different patient care services (eg, vital signs, bath, discharge of the patient, I's and O's, specimen collection).[17] The observation patient requires many services beyond the basic needs of ED patients. No matter which nursing staffing formula is used, the amount of services provided need to be tracked to identify changes in the number or length of services offered. When service demands change significantly, the staffing should be adjusted.

Another important consideration for nursing staffing is the use of float pool nurses versus dedicated observation or emergency nurses. Because the nurses influence the timeliness of patient care so strongly, whenever possible, float nurses should be avoided in the observation unit.[4] Lack of familiarity with the unique needs of the observation patient population, standard protocols and the setting of the observation unit all lead to less efficient care. Since increased efficiency is one of the major benefits of observation unit use, any force that diminishes this capability seriously threatens the value proposition of the unit itself.

Observation Unit Ancillary and Consultant Staffing

Ancillary staff (ie, medical assistants, unit secretaries, etc.) can be delegated many of the tasks which will otherwise have to be done by nurses. This can lower nursing staffing requirements, lower staffing costs (ancillary staff salaries lower than nursing salaries), and improve nursing job satisfaction by removing the more menial tasks. An average observation unit will be staffed by one medical assistant and

one unit secretary. Coverage may vary overnight, when patients tend to be less active.

Consultants also play a critical role in an active observation unit. Common physician consultants include cardiologists, neurologists and general surgeons, among others. Not surprisingly, the need for consultants tends to mirror the most frequent types of complaints managed in observation.[18] Strong relationships between observation unit leadership and liaisons from these services are a key component to effective observation care. Consultations need to occur in a timely manner and recommendations for further diagnostics and treatments must take the timeframe and resources specific to the observation unit into consideration.

Non-physician consultants are another pivotal component of observation care. These typically include social workers, case managers and physical therapists, among others. The work that these staff do is often the rate limiting step to a satisfactory disposition from the observation unit, so maximizing their access to observation patients is very important. These staff typically have more limited availability overnights and on weekends and holidays, so clinical staff should consider these limitations when determining the plan of care for their observation patients.

Overcrowding and Gridlock Situations

Many EDs around the US are experiencing crowding.[19] Their hospital is full and admitted patients are held in the ED for days while awaiting an inpatient bed. In these circumstances, the ED can be gridlocked and unable to provided routine emergency services, let alone observation services. The ACEP task force on crowding identified a number of strategies to deal with this problem.[20] Each department should have a protocol for these circumstances (ie, a gridlock or surge protocol). Care should be taken to avoid filling the observation unit with inpatients awaiting admission elsewhere.[4] These patients have different needs than the observation population and typically have an undefined endpoint. The observation unit is not designed or staffed to care for them and their presence will limit the potential to care for actual observation patients.

Increased Flexibility

EDs are open ended and accept patients as they present themselves. At any one time there will be staffing and beds available to provide services to a limited number of patients. Observation patients add to the department's total service needs and as a result, staffing must be increased overall to meet these needs. This can aid the department's flexibility as the pool of resources increases for the department. The observation patient's needs are spread out over a long time period, so the service needs per hour are actually small when contrasted to undifferentiated acute emergency patients. Accordingly, observation patients place limited demands on the department. As a result, peaks in number of patients presenting to the ED can be better met in those departments with observation units, as they have more resources from which to draw upon.

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10

Patient Quality (Continuous Quality Improvement), Safety, and Experience for the Observation Unit

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BACKGROUND

Patient Quality, Safety and Experience

The goal of any Continuous Quality Improvement (CQI) is to continually work on improving the process or system in order to positively impact patient care and improve patient outcomes instead of blaming individuals.[1,2] The purpose of patient safety programs is to create an environment that fosters a culture of patient safety with improved identification of problems rather than hiding problems by blaming individuals.[2] The focus of an "experience" program is to render optimal care while simultaneously providing the best experience not only for the patient and family but also for the healthcare workers.[3] These efforts focus on patient/family centered care to empower health care consumers and their families to work with healthcare workers in patient-centered care initiatives.

Team Work Process Approach

Approaches of high reliability organizations[5,6] (eg, aviation flight team, lean initiatives, six sigma,[7,8] benchmarking for best practices[9,10]) approach can be used in the OU. A team approach that has a mechanism(s) in place for allowing input from all OU personnel is desirable. It supports collaboration with other hospital departments: radiology, laboratory, stress testing and others, and medical/surgical services from cardiology to neurology or gastroenterology and the surgical specialties. Meeting with representatives from the OU staff (physicians, nurses, clerical, technicians, housekeeping, others) on a regular basis fosters performance improvement with systematic review of issues or concerns. Including in meetings representatives from other departments promotes efficiency and improving processes. Other departments (eg, radiology, cardiology) may be invited to such meetings to solicit suggestions on streamlining care. Depending on the specific patient population, consideration may focus on scheduling stress tests or esophagogastroduodenoscopy (EGDs) and colonoscopies or how to shorten laboratory turn around times for cardiac enzymes or special radiology tests (CT scans, MRIs, etc.) for OU patients.

OU MEDICAL DOCUMENTATION

Physician or midlevel provider (physician assistant or nurse practitioner) documentation must be detailed. It should include patient information regarding the patient's admission and discharge, the treatment and/or diagnostics done in the OU.[9] There should be an OU admission history and physical examination by the physician or midlevel provider, as well as a progress and/or discharge note detailing diagnostic procedures done, treatment rendered, and a discharge plan. The discharge plan should include, when appropriate, new medications, outpatient procedures if any, and of course, follow-up care.

Nursing/respiratory therapy procedures (including intravenous fluids, medications administered, aerosol treatments, etc.) can/should also be noted or available in the OU records for clinical/patient care information and for itemized reimbursement by the hospital, if allowable. Other nursing assessments with

vital signs, pain assessment, neurologic or vascular checks, in addition to an admission assessment and discharge plan is important information that should be in the medical record.

OPERATIONS OF THE OBSERVATION UNIT
Policies and Procedures

Policies and procedures for the operations of the OU are mandatory for the functioning of an OU. (Table 1) Policies and procedures must be consistent with hospital and departmental polices, and either have a clinical practice (Tables 2,3) focus or an operational focus. (Table 4) Clinical practice protocols/policies are "diagnosis specific" (Table 2) or "condition specific" (Table 3) and deal with patient care. The framework for clinical protocols include: admission criteria, exclusion criteria, interventions (both diagnostic and treatment), discharge/inpatient admission criteria and a specific timeframe. For example, with the diagnosis of dehydration, the admission criteria in the CDU protocol would be: inability to take oral fluids, and/or persistent nausea/vomiting. Exclusion criteria would be shock or unstable blood pressure, significant electrolyte abnormalities (Na <125 or Na >150), organ dysfunction, other significant life threatening diseases, patients needing surgical intervention, or an intensive care unit. CDU interventions could include: monitoring vital signs, intravenous fluids, intravenous antibiotics, if indicated, antiemetics, pain medications, and antipyretics if febrile. Hospital inpatient admission criteria would be the development of unstable vital signs or shock, dehydration not responding or not improving with therapy within the given timeframe (generally, 24 hours) and/or continued inability to take oral medications. Criteria for discharge from the OU are: resolution or improvement in the dehydration, stable vital signs, and ability to take oral medications. (Table 2)

Common diagnoses treated in the OU include asthma, dehydration, pyelonephritis, sickle cell disease, syncope, transient ischemic attack (but not acute stroke), hyperglycemia (but not diabetic ketoacidosis), and overdose/infection.

"Condition specific" protocols (where the exact diagnosis or etiology of the symptoms is unknown) are also very similar to "diagnosis specific" protocols. The most common condition specific protocol is probably chest pain where the etiology of the chest pain has not yet been determined and acute coronary syndrome is being ruled out. Admission criteria would be chest pain, negative initial enzymes, and normal ECG or unchanged ECG from previous ECG. Exclusion criteria would be unstable signs, positive cardiac enzymes, ongoing chest pain (suggesting unstable angina), need for intravenous medication drips (such as heparin drip or nitroglycerin drip) which indicate ongoing chest pain as with unstable angina, or new acute ECG changes. CDU diagnostic interventions could include serial ECGs, serial enzymes, rhythm strip/vital sign monitoring, and a stress test. Treatment interventions might include an aspirin daily, and beginning antihypertensive medications in a patient with hypertension. Discharge criteria would be negative serial enzymes/ECGs or negative stress test. Hospital admission criteria would be positive enzymes, development of new ECG changes, or a positive stress test. The timeframe, of course, is specific, usually 24 hours. (Table 3)

Administrative protocols/policies are also important and should not be overlooked and generally begin with a policy or policies defining the purpose of the CDU. (Table 4) Mandatory protocols include: the scope of the OU (what can be done in the unit from monitoring vital signs/cardiac rhythm, intravenous fluids, medications, aerosols, etc.), and the administrative structure (how the OU functions on a daily basis and who is responsible or has overall authority for the unit; both for physicians and nursing personnel).

OBSERVATION UNIT DATABASE

A database for the Observation Unit (OU) or Clinical Decision Unit (CDU) is necessary for many reasons, not just for patient safety and quality or CQI. An OU database is essential for patient information/medical records, communication among providers, for meeting regulations (Joint Commission of Healthcare Organizations), government (federal, state, local mandates/requirements), contractual agreements, for payor information/insurers/health maintenance organizations as well as for education/training, research, and for improving patient satisfaction and experience.

Components of an Observation Unit Database

The critical components of the OU database are the same whether it is a computerized database, a written document, or a combination of both. In addition to the mandatory patient identifiers, methods or components for tracking times and dates, eg, the specific time of admission and discharge from the OU so a length of stay (LOS) in the OU can be determined are mandatory. This LOS does not include the time spent in the ED but begins when the patient arrives in the OU bed. Clinical information, such as chief complaint or admitting diagnosis, final diagnosis, disposition (discharge from OU or inpatient admission), is part of the essential data elements. Diagnostic procedures done, for example, ECGs, stress testing, EGD (esophagogastroduodenoscopy) can be tracked. Laboratory tests (such as, cardiac enzymes), or radiology diagnostic studies (from a chest roentgenogram or CT scan to an MRI) may be useful information to monitor. Data elements regarding the physician and/or mid-level provider (nurse practitioner or physician assistant) may be useful for yielding provider information.

Specialized Databases

Depending on the hospital/departmental needs or interests, more specialized data information sets in addition to the "core" or essential information can be designed and added to the primary database. If the OU is a chest pain CDU, then data on the number of stress tests done and/or the type (exercise, pharmacologic, etc) and the results whether positive or negative may be valuable for planning staffing, resources, ancillary services, and as a research tool.

Metrics for an Observation Unit

The goal of any CQI is to continually work on improving the process or system in order to positively impact patient care and improve patient outcomes instead of blaming individuals. The purpose of patient safety programs is to create an environment that fosters a culture of patient safety. The focus of an "experience" program is to render optimal care while simultaneously providing the best experience not only for the patient/family but also for the healthcare workers. With this in mind, metrics should not be used in a punitive or negative fashion but instead to foster progress. Such CQI programs are also necessary for the initial set up and the maintenance or daily functioning of the OU.

Volumetrics/Volume Data

One cornerstone of any data system or performance improvement model is volumetrics or volume data. Volume data for an OU are similar to that for any emergency department (ED). Such parameters include: OU admissions, final disposition (whether inpatient hospital admission or discharge from OU), length of stay (LOS) focusing on outliers such as length of stay greater than the set timeframe (eg, LOS >24 hours) or LOS less than a given time (eg, LOS <4, 6, or 8 hours).[1] An extremely short LOS (especially <4 hours) suggests the patient may not have needed admission to an OU and takes up valuable nursing time/resources in terms of an admission assessment (usually similar to an impatient admission) and discharge planning. Again, this may share characteristics similar to discharge planning for hospital inpatients and should involve discharge teaching. However, there may be instances where a short LOS is appropriate. An example would be a chest pain patient seen in the ED who is chest pain free on admission to the OU but then while being monitored in the OU develops chest pain and when an ECG and enzymes are done during an episode of chest pain, they are now positive so he/she is admitted for a cardiac catheterization. When there is a significantly prolonged LOS (much greater than 24 hours), the implication is that the individual probably should have been admitted directly to the inpatient floor and not to an OU.

Common ED/hospital metrics involve codes/resuscitations, deaths, patient falls, left against medical advise (LAMA) or left before treatment completed (LBTC), and patient complaints.[11] Such indicators are also useful for the CDU and sentinel event indicators, for example, deaths or codes,[12] should be evaluated on a case-by-case basis to determine if both patient care and disposition were appropriate. If trends are identified, then perhaps a clinical policy may need to be developed or modified.

Since the OU is designed for "low risk" patients needing nonintensive nursing care and nonintensive physician care, other indicators/monitors have been recommended for an OU. Some experts recommend these additional CDU monitors: any intensive care unit admission from the OU, any patient going to the operating room from the OU, any patient going to cardiac catheterization from the OU, patients receiving thrombolytics in the OU, and patients ruling in for acute myocardial infarction. (Table 5) Studies document about a 6.9% rule in for myocardial infarction in an OU[13], so a significantly higher percent may indicate inappropriate patients (such as patients with acute ongoing or crescendo angina or unstable angina) being admitted to an OU. This is considered a rate-based indicator when a given occurrence exceeds a set number that is anticipated. As an example, for an acute MI in the OU, based on a national study (with 6.9% rule in)[13], perhaps a rule in rate >10% or >15% may be set for a given OU. If this percent is exceeded, then the CQI program needs to reevaluate the OU chest pain admissions and may need to revise the OU admission criteria and/or make new recommendations. Alternatively, it may be that the patient population is extremely high risk and other actions to better risk stratify patients may be helpful.

Benchmarks

OU benchmarks can be externally (eg, national standards or other hospitals) or internally derived (such as other hospital departments) and can be used to set goals for the OU, thereby, improving patient quality, safety, and/or experience. In the ED, a benchmark might be to decrease the number of patients left before being seen (LBBS) from a given average (either nationally or the prior year) based on a percent of patients seen. An OU benchmark might be to decrease the number of technically poor ECGs, or blood samples needing to be redrawn, or patients in the OU greater than 24 hours. Benchmarks may also be "non-technical' as in increasing patient or employee satisfaction scores in the OU.

Summary

There are several key components needed for the success of an OU. There is an organizational framework and methodology for setting up and maintaining an OU using a CQI approach that can be adapted for any size, location, or type of OU.

TABLES

Table 1:   **Components of a Patient Quality/Safety/Experience Program for the Observation Unit**

Table 2:   **Clinical Protocols: Diagnosis Specific Protocol Dehydration**

Table 3:   **Clinical Protocols: Condition Specific Protocol Chest Pain**

Table 4:   **Administrative Protocol**

Table 5:   **Metrics for the Observation Unit**

Table 1: Components of a Patient Quality/Safety/Experience Program for the Observation Unit

- Policy and Procedure Manual:
    - Clinical Protocols: "Diagnosis Specific," "Condition Specific"
    - Administrative Protocols
- Documentation
- Database
- Benchmarks
- Metrics
- Standardized Order Sets
- Clinical Pathways (Care Maps)

Table 2: Clinical Decision Unit Diagnostic Specific Protocol: Dehydration

The Cleveland Clinic Emergency Services Institute Clinical Decision Unit: Dehydration Protocol

Admission Criteria:

1.   Hypovolemia treatable and expected to resolve in 24 hours (see Table for magnitude of deficit).
2.   Mild to moderate changes in electrolytes
3.   Milt to moderate changes in amylase, LFT's or renal function tests
4.   Stable vital signs (may have mild orthostatic changes) or mild hypotension

Exclusion Criteria:

1.   Severe dehydration
2.   Severe electrolyte changes (125 < Na > 150 mEq)
3.   Severe changes renal function, liver function, or other organ dysfunction
4.   Hypotension of moderate to severe degree
5.   Associated with causes not amenable to 24 hours treatment, or in need of surgery, or an ICU: Examples include but are not limited to:
        Surgical: Obstruction, pyloric stenosis, appendicitis, Intussusception, Meckel's
        Infections: Botulism, toxic shock
        Other: Bowel ischemia, DT's, heat stroke, burns, diabetes insidious, post obstructive diureses, DKA
6.   Cardiac dysrhythmia (significant)

CDU Interventions:

1.   Serial exams and vital signs
2.   Antiemetic
3.   Parenteral fluids to be given up to 24 hours infusion

Disposition Criteria

HOME
1.   Resolution of symptoms
2.   Stable vital signs
3.   Normal electrolytes (if followed)
4.   Taking PO fluids

HOSPITAL
1.   Rule in of exclusion causes
2.   Inability to correct symptoms
3.   Inability to take PO fluids

Table 3: Clinical Protocol: Condition Specific Protocol: Chest Pain Protocol

The Cleveland Clinic Emergency Services Institute Clinical Decision Unit Chest Pain Protocol

The CDU is intended to serve as an area for extended assessment of low risk patients. Patients meeting the following criteria may be considered for admissions.

1. **Admission Criteria**
   A. Patients without a prior history of CAD/Angina and
      1) Pain that is atypical of myocardial ischemia in duration or character
      2) Pain that is typical of myocardial ischemia if:
         a) The pain has resolved and
         b) There has been a consistent pattern established which has not changed in the recent past or
         c) The pain was new and was of brief (less than 20 minutes) duration

   B. Patients with a prior history of CAD/Angina and
      1) Pain that is atypical of their prior pattern of myocardial ischemia
      2) Pain that is typical of their myocardial ischemia and
         a) Was of brief (less than 20 minutes) duration and
         b) Has completely resolved and
         c) Did not occur in a pattern that was different from their typical angina

   C. Patients with a history of repeated visits for chest pain if
      1) The pain is of a similar pattern to their prior visits or,
      2) The pain is atypical for myocardial ischemia

   D. Patient meeting other criteria by agreement between the cardiologist and the emergency physician.

   E. Patients admitted to the CDU must have a chest radiograph with the preceding 24 hours prior to admission.

   F. An initial set of cardiac markers must be obtained within 4 hours prior to admission which do not demonstrate myocardial necrosis.

II. **Exclusion Criteria**
   A. The following EKG criteria preclude a CDU admission;
      1) New myocardial ischemia
      2) New LBBB blocks
      3) New 2nd degree or higher blocks

   B. Patients may not be admitted to the CDI if they have chest pain that is typical of myocardial ischemia that is ongoing and requires parenteral medication or if they have ventricular arrhythmias requiring initiation of antiarrhythmic therapy

   C. Cardiology consultation is recommended for patients with revascularization within the past three months.

   D. Patients should not be admitted to the CDU if they have persistent
      1) Systolic BP >200 mmHg;

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    2)   Diastolic BP >110 mmHg;
    3)   Systolic BP <90 mmHg;
    4)   Tachycardia >140.

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E.   No cardiac monitor available

F.   Unstable angina

III.   **CDU Interventions**

A.   Nursing will conduct an intake assessment and provide ongoing monitoring. The Emergency Physician will be notified if there is a significant change in the patient's condition.

B.   Cardiac monitoring will be initiated and maintained on patients admitted for a cardiac ischemia evaluation.

C.   Pulse oximetry may be used on either a continuous or discontinuous basis as ordered by the physician.

D.   Serial cardiac markers and EKG's will be performed. The specific cardiac markers which are to be obtained and the timing of those laboratory evaluations will be at the discretion of the admitting physician.

E.   Supplemental oxygen may be administered. Consideration should be given to maintaining oxygen saturation above 95%.

F.   Aspirin administration may be considered if no contraindications

G.   Oral or transcutaneous anti-anginal agents may be initiated, continued, or supplemented while the patient is in the CDU. Patients who are currently on anti-anginal medications may have those medications continued or have their treatment regimen intensified.

H.   Cardiology consultation may be obtained in the CDU as determined by protocol or by the treating physician.

IV.   **Disposition**

Home

A.   Patients who are at low risk for cardiac ischemia may be discharged to home without further treatment so long as their electrocardiograms and cardiac markers do not demonstrate myocardial infarction.

B.   The following disposition options may be considered for the patient who has had myocardial infarction ruled out in the CDI but yet, may have coronary artery disease.

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    1)   The patient may be discharged to home with a prescription for anti-anginal agents and follow-up with cardiology or the patient's primary care physician as appropriate.

    2)   Stress testing may be arranged prior to discharge from the CDU. The results of the stress test may then be used to guide the disposition decision.

    3)   Cardiology consultation may be obtained in the CDU. The patients further work up and disposition may be considered in light of the cardiologist opinion.

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V.   **Hospital**
        A.   Patients who manifest cardiac ischemia while in the CDU should be transferred to the appropriate inpatient unit, after consultation with cardiology. Parenteral anti-rhythmic therapy, parenteral analgesic therapy, or parenteral anti-anginal therapy may be initiated in the CDU while waiting transfer to an inpatient unit.

        B.   Significant EKG changes
                1)   1 mm or more ST segment elevation in two or more contiguous leads. Posterior MI's may just show ST depression in the anterior precardial leads, but are frequently associated with inferior ST elevation.
                2)   New onset LBBB. If the block cannot be determined to be of new onset, the severity of symptoms should be used as the indicator for thrombolytic treatment.
                3)   In presence of RBBB, ST segment changes are evaluated as in a B1

        C.   Significant evaluation of cardiac markers.

        D.   Persistent unstable vital signs.

VI.   **Timeframe**
        A.   24 hour observation

Table 4: Administrative Protocol: Admission to Unit

The Cleveland Clinic Emergency Services Institute Clinical Decision Unit: Admission to Unit

POLICY:

Patients can be placed in the CDU for a variety of conditions. Patients placed in the unit should have a reasonable expectation of discharge to home within 24 hours. Patients with clear indications for inpatient hospital admission are not to be placed in the CDU except for circumstances described in this manual.

The ED attending physician will write admission orders and an admission note. The ED history and physical exam can be accepted as the CDU admission history and physical. Documentation will include the admission diagnosis, the reason for admission, a treatment plan, clinical care tract (if available and appropriate), and the expected length of stay (LOS). Exclusions to admission are covered under specific conditions outlines in this manual. Unless otherwise noted, unstable vital signs refers to patients with evidence of shock or other hemodynamic compromise. A CDU progress note, and/or discharge note describing the diagnostic evaluation and or treatment in the CDU will be done by the ED attending physician.

PROCEDURES:
Only stable patients meeting admission criteria will be admitted to the CDU. Appropriate admission diagnoses include (but are not limited to):
1. Atrial Fibrillation
2. Undifferentiated Abdominal Pain
3. Asthma with Stable Vital Signs
4. Musculoskeletal Back Pain
5. Chest Pain with Low Probability of Myocardial Infarction
6. Clinical Stable Closed Head Injury
7. Exacerbations of COPD
8. Dehydration
9. Deep Vein Thrombosis
10. Drug Overdose
11. Headache
12. Hyperglycemia
13. Hypoglycemia
14. Hypertension
15. Inhalation Injury
16. Pyelonephritis
17. Renal Colic
18. Seizures
19. Sickle Cell Disease
20. Syncope

Table 5: Metrics for the Observation Unit

Volumetrics: Volume Data
- Admissions to OU (from ED) (Number or Percent)
- Disposition from OU
  - Inpatient admissions from OU
  - Discharge from OU
- Length of Stay
  - Greater than (>) 24 hours
  - Less than (<) 8 hours

Sentinel Events
- Deaths
- Codes/Resuscitations (Intubations, BLS performed, use of ACLS drugs and algorithms)

Specific Observation Unit Metrics/Monitors

  Cardiac
  - OU patients going to cardiac catheterization
  - OU patients receiving thrombolytics
  - OU patients who rule in for myocardial infarction
- Surgical
  - OU patients going to operating room

Intensive Care Unit Admissions: whether surgical, cardiac, medical, pediatric, respiratory, neurologic, etc

Common ED/hospital metrics
- Patient complaints
- Patient falls
- Returns to ED within 72 hours after discharge from OU (for same complaint or diagnosis)

Rate Based Indicators
- Overall admission (about 20-25%) nationally, (benchmarks could be >30-35% or <10%)
- Rule in for myocardial infarction (about 6.9% nationally) (benchmarks could be >10-15%)

Process indicators (monitors the steps/interrelated actions while providing patient care services)
- Example: steps involved in cardiac enzyme result: (order written, order transcribed or noted, labels/requisitions printed, phlebotomist or OU technician draws blood, blood labeled, blood to lab, lab registers blood sample, blood spun or centrifuged into serum, sample to appropriate sub-laboratory, (eg, chemistry, hematology, serology), test run, test reported, results to physician.

Patient Outcome Indicators (how the patient responds to a given intervention)
- Example: Effect of a drug:
  Positive outcome: improved peak flow in an asthmatic, decreased pain in patient with pain
  Negative outcome: side effect such as increased heart rate with a medication.

Benchmarks: comparison with national or other hospital or departments

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Risk Management
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INTRODUCTION
Observation units will and have become a valuable tool for health care systems to manage risk. With such units, physicians can improve quality, and meet both patient and provider expectations. It is important to note that in most emergency departments (EDs), the principle complaints of patients have not changed over the years. "I waited too long," and "they never told me anything," are still common refrains heard around ED waiting rooms. Complaints are from frustration with unmet expectations. Such frustration leads to anger which, in America today, leads to lawsuits. Risk management must deal with causes of unmet expectations if it is to mitigate the problems of the current medical/legal quagmire. It is only from this broader approach that better patient care and patient expectations will be realized.

Insurance companies have become the final arbiters of medical care, and they never take risk; they spread risk. Insurance rates will not go down until the actual risk goes down. This will only be accomplished through planned changes in the behavior of individuals, and more importantly through changes in the system. If the ED systems for evaluating patients leads to frustration, ie, long delays, poor service, etc., complaints and lawsuits can be expected. If the ED systems for evaluating patients leads to bad outcomes, ie, failure to diagnose serious disease, lawsuits are not just expected, but a certainty. The traditional ED system for evaluating patients fails to diagnose a considerable number of patients with acute myocardial infarctions and releases them home with false reassurance. Other serious conditions are similarly not reliably identified in the traditional ED, ie, 20-40% of patients with appendicitis, a considerable number of patients with ectopic pregnancies, etc. Observation units are a tool to address many of these risk problems in emergency medicine. More than that, they actually provide better care for less cost, which is a laudable goal of the health care system. The American College of Emergency Physicians has devoted an entire monograph to risk issues with regard to our specialty and the reader is referred to *Emergency Medicine Risk Management: A Comprehensive Review* for a more in depth discussion. [1]

What is risk management?
The actual definition of risk management has varied over the years; but the traditional role of risk management has been protection of the institution, the health care workers, and the asset base on which they function. Risk management has carried a negative connotation not only for the patients, but for the doctors. People from risk management departments have been viewed as meddling, nonphysicians, or at least nonpracticing physicians, who have come to preach as opposed to improve. Risk management has been viewed as an office in the hospital bureaucracy rather than a way to practice. It may be that the term "risk management" has outlived its usefulness. This has lead to considerable confusion and a general lack of respect within the medical community.

Who has the real risk?

The newer modes of risk management recognize that the only real risk is to the patient. The people who can truly be harmed by inadequate care are the people receiving that care. The only way to manage risk is to change the system and the care that is given. A quality assurance program which does not run hand and glove with a risk management program is doomed to failure. The function of risk management is to make certain that every patient feels they have been handled in a correct and humane manner. It is not just to manage claims and complaints, but to have a continuous feedback loop into the care that is given so the problems do not occur again. The true effect of risk management should be to help modify the system so that they no longer have anything to do. Perception is the only reality and the perception of care, as well as the care itself, is critical to the intrinsic operations of any ED.

The Quality of Risk Management Data

A tremendous problem of carrying on discussions of risk management and quality assurance is that the information collected over the years has been spurious at best. Most risk management departments define their losses as failure to treat or failure to diagnose, which rarely gets at the basic problems involved in risk management. When considering an evaluation of appendicitis, for example, the recorded claim is always failure to diagnose. When in fact, with the vast majority of such claims the patient did not have the criteria on which the decision to operate could be made. The real problem was in the follow-up care, time interval for being seen again, and the way in which the patient was instructed. It is not that a diagnosis was not made, but that a definitive diagnosis at that moment in time could not be made and that further evaluation on a time structured basis was needed. This is a question of the quality of the discharge program and the quality of system integration rather than a simple failure to diagnose.

This type of overly broad and nonspecific data collection is essentially useless when it comes to changing the system for the better. Humans only respond to specifics. A physician and a system must know exactly what behavior requires changing if they are to change in a predictable manner. Risk management data in the future will need to be much more carefully scrutinized and collected so that we actually understand the system, decision, or specific action which requires change. Most human beings, if handled correctly, can understand that medicine is complex. Instant decisions are often impossible, but correctly constructed systems which get the patient into health care, as opposed to into the hospital, will be required in the future if risk is to be mitigated.

System Thinking

Just as Deming totally changed the manufacturing world with his views of quality assurance, the current medical system which has grown up since WWII needs such an overhaul. [2] In the United States, since the end of WWII, there has been maximal money and minimal intelligence put into asking serious outcome questions with regard to health care. The concept of "what do we want from a health care system?" and "what should be the services provided by that system?" have never been seriously asked in a structured format. If medicine is to be more than a glorified magic show with the patient entertained by periods of incarceration in less than sterile buildings with toys and gadgets, definitive outlines of where we need to go must be drawn. To this end, fundamental questions about the function of hospitals versus outpatient care will need to addressed. System thinking is defining what outcomes will drive the health care system of the future. This form of thinking must be done as a partnership with those receiving the service. The focus must not be on identifying good and bad physicians, but on identifying good and bad systems for providing medical service.

Ultimately, physicians alone will not determine health care. A combination of scientific input by physicians and the wants and desires of the broader society will determine what services will be given and in what settings. As resources become more limited and the population continues to age at a rate which has never before been contemplated, the need to define what actual role and outcome medicine can play is paramount. Risk increases when the expectations of the general society are not mirrored in its institutions. If the expectation of the general society is that everyone with abdominal pain is admitted to the hospital,

whether it has anything to do with their improved health or not, failure to admit places extra risk on health care providers. That is why serious discussion needs to be undertaken. Drive through-deliveries, drive-through mastectomies, termination of life-support systems, and the like are not as much scientific questions as they are sociologic questions. Risk management is the interface between where technical and scientific problems have not yet become inculcated into societal thinking.

Improved Communications

No discussion in a textbook of generation would be complete without genuflecting to the intellectual god of communications. What people think is greatly a function of what they are told. If it is the norm that patients die at home, as it is in many countries, there is no problem with a death at home. In the United States where death is accompanied by sirens, ventilators, and transplants, communications with families becomes critical. The decision to employ expensive inpatient, high-tech medicine to a defined end-point will more and more require the input of patients, their families, and some true medical knowledge as to the likelihood that such interventions would restore meaningful life. It is often difficult to say in one brief moment in the ED to what degree family and patients understand the seriousness of their disease and the likelihood of a return to reasonable function. An often overlooked function of observation units is not just for physicians to monitor the course of a disease so as to be better able to predict interventional outcomes, but for families to become educated on the various options and what might to be done with regard to their loved ones. The real communication of medical facts as applied to the emotions of an ill loved one is a milieu devoutly to be wished. Restructuring the ED by adding a third disposition pathway, observation, to the traditional dispositions of hospital admission or discharge, empowers the ED staff to have hours, rather than minutes to spend communicating with patients and their families.

Improved Cost-Effectiveness

The EDs of the United States are increasingly becoming the arbiters of the application of science to human problems. At any hour, day or night, EDs are available throughout this country to process human misery and enter people into the health care system. This need is not decreasing. Whether the primary interests are social, such as the poor and uninsured, or a mixture of medically and financially important issues, such as in managed care, a tempest in medical care exists in EDs. The sorting out function has never been more important and has never required more skilled practitioners. It also requires wisdom. It is only in knowing what to do and to whom, that we are able to balance the three imperatives of access, quality, and cost. There is an ill-defined sense that there exists some linear relationship between the amount of money spent on health care and the health of society. Yet, some countries spend less than 1/3 that of the United States (on a gross national product basis) on health care actually produce better overall health outcomes. A third disposition pathway (transfer to observation) prevents the ED staff from hasty decisions on hospital admission and allows hours, rather than minutes before decisions must be made on committing a patient to extensive, costly evaluation in a hospitalized setting.

Legal Issues

When providers and consumers cannot agree on problems in risk management, resolution does not occur in the medical world, but in the realm of jurisprudence. The questions of duty, breach, harm done, and the proximate cause. The relationship between these elements is the exclusive arena of the law. Medical malpractice has been present in English Common Law since at least 1290 AD. Since the case of Hill versus Chynault in 1377, we have specific case law on which to base future legal decisions. The concepts of health and specific medical abilities in diagnosis and treatments have varied tremendously since the first medical/legal cases. The concepts of physician as assuming the role of healer have not changed in the last millennium. In legal terms, the physician is the retained agent and servant of the patient. The degree to which we understand our servant role is a measure of our maturity in medicine. By the same token, a physician and the medical community are health advisors to the individual. It is the interaction between the patient's rights and the physician's duty where risk management is most

challenged. Into the future, as resources diminish, the skilled physician is the one who can help the patient truly choose amongst options which will provide meaningful life with the most judicious use of resources. Creating a system for selected patients to receive prolonged interaction with ED staff enables emergency medicine to better meet both its moral and legal obligations.

High Risk Situations

Emergency departments must come to grips with the fact that high risk situations do exist. The role of observation units should be in simultaneously increasing the quality of care, reducing the overall cost of care, and providing the least disruption to patients' lives. The options of either ED discharge or an in-hospital admission must be supplemented by a third choice of observation. The third pathway is often the most intelligent pathway with certain types of conditions such chest pain, abdomen pain, headache, asthma, change in mental status.

Chest pain cases still constitute approximately 30% of all monies lost in emergency medicine malpractice cases.[3] A physician who believes he knows the exact cause of chest pain of every patient after the initial history and physical is often referred to by another name. That name is Defendant Physician. Chest pain is a constellation of diseases in which the initial history and physical may reveal nothing, while the patient actually has incredibly severe disease. Only through proper observation, retesting, and the application of certain test modalities will the question of chest pain be resolved. It is the ideal example of that intermediate condition in which decisions can be made without admission to the hospital, but often require more than initial history and physical.

Abdominal pain still constitutes a large percentage of money lost in emergency medicine malpractice.[4] The progression of disease may not be clear. Abdominal pain can be sensitive, but highly nonspecific. In those cases, in which close observation is required, the observation unit may be ideal. Certainly many patients with abdominal pain can go home and return in specifically stated times for reevaluation. The observation unit is ideal for those patients who have difficulty in logistics, transportation, understanding their disease, or for those patients the physician has high level of concern about the presence of serious disease.

Resolution of head pain with therapy is no indication that severe disease does not exist.[5] The performance of studies such as lumbar punctures, CT scans, and therapies with multiple drugs may require a more prolonged ED evaluation. In such cases, observation and treatment may be essential in arriving at a diagnosis without missing potentially life-threatening disease.

The vast majority of diabetics who enter mild to moderate ketoacidosis can be managed with aggressive fluids, insulin, electrolytes therapy and can be reversed without resorting to inpatient care. Such patients often understand the nature of their disease and how they got into trouble and actually admitting such patients, because it is an artificial situation, may prolong the time to stabilize and enter them back into the usual outpatient world.

Asthmatics, as a group, constitute the largest number of return visits to EDs.[6] This is frequently because they are not using their medications adequately, they are going back into contact with irritants, or they have not been properly stabilized before discharge. Observation/treatment units provide for such therapy and allow systematically administered steroids and other medications to stabilize the condition of the patient prior to discharge.

The quintessential ED patient is the alcoholic with mild alteration of mental status who may or may not have hit his head. Such patients are often minimally confused and yet hospitals simply do not have the resources to admit all such patients. Observation units are where frequent repeat examinations can be performed, and where community resources and family support can be organized to facilitate the proper management of such patients. In-patient therapy offers little to such patients who will then again return to the streets. The coordination function with regard to such community and family services, which can be carried out in a rapid treatment and decision unit, are often overlooked. The availability of resources for patients with altered mental status and psychiatric disease is often tremendously constricted in non-regular work hours. It is frequently the function of the ED to not only stabilize the medical

situation, but the social situation as well. This may be best accomplished through a rapid treatment and decision unit.

Conclusion

Risk management, in its older format of protecting the institution at all costs, is rapidly dying. Risk management in the future will look at the causes of risk and provide feedback and input into the system to control such risks by improving the care. The institution, the physician, and the patient will all be at less risk if systems are broadly understood by the people they serve. Some consensus as to what services will be offered and where those services are best provided is needed in this society. A total rethinking is necessary as to the role of the in-hospital setting. The new role of risk management in providing feedback to improving the system, as well as communications with patients and their families, will be critical as we are more and more challenged to properly utilize resources.

Risk Management Approach

Risk Management Goals
Improve Service
Improve Outcome

Strategy to Decrease Risk
Patient Handled Correct & Humane
Patient Feels Handled Correct & Humane

Risk Management Data
On System Function
On Decisions
On Actions

Observation to Redesign System
Improve Communications
Improve Cost Effectiveness

Observe High Risk Patients
Chest Pain Patients
Abdomen Pain Patients
Headache Patients
Asthma Patients
Altered Mental Status Patients

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Pediatric Observation Medicine
Sharon E. Mace, MD, FACEP, FAAP

BACKGROUND

Pediatric patients account for approximately 27% of all emergency department (ED) visits. The overall number of ED visits in 2005 was 115 million so pediatric visits are about 31.5 million on an annual basis.[1,2]

Although the majority of children and infants seen in the ED have a minor illness/injury or a benign condition, significant life-threatening illnesses/injuries frequently present with subtle physical examination findings and a nonspecific chief complaint. Thus, the difficult and almost impossible task of distinguishing a routine or minor disorder/injury, especially at the beginning of the illness, from a serious disease is obvious. [3]

Compounding the difficulties encountered in the evaluation and management of pediatric patients in the ED is the fact that infants and children have a greater susceptibility to infections, a limited physiologic reserve, and age/developmental considerations.[3,4] In addition, children with Special Health Care Needs (SHCN) and the existence of various high-risk pediatric patients place an additional layer of complexity. In recent years not only has the volume of ED patients increased but also the complexity and high acuity of patients has increased.[5] Among the many types of high-risk complex pediatric patients are Neonatal Intensive Care Unit (NICU) survivors, Pediatric Intensive Care Unit (PICU), survivors, transplant patients of all types (kidney, liver, pancreas, lung, heart), technology dependent patients, and the SHCN patients.[4]

Malpractice awards attest to the fact that missed or delayed diagnoses, in pediatric patients, unfortunately does occur. Common pediatric diagnoses; such as gastroenteritis and appendicitis are frequently cited in malpractice cases. In fact, the most commonly mentioned diagnosis in malpractice cases is gastroenteritis, while missed appendicitis accounts for 15% of all malpractice dollars paid. Considering cost per claim, meningitis ranks number one with missed meningitis responsible for 17% of all malpractice dollars paid.[4]

Patient Selection: Inclusion and Exclusion Criteria

Patients are appropriate for observation when they have a clinical condition requiring evaluation and management beyond what can be provided in the emergency department. An abdominal pain patient with the possibility of appendicitis is an example of a patient with a diagnostic condition that could benefit from a period of observation after their emergency department evaluation. An asthma patient who has not sufficiently cleared after the emergency department treatment is an example of a treatment condition that could benefit from a period of observation after their emergency department treatment. To ensure only patients are placed in pediatric observation units who are likely to benefit from observation services, pediatric observation units have inclusion and exclusion criteria. Examples of conditions that are typically found to benefit from pediatric observation unit care are listed as 'inclusion criteria' in Table 1. Examples

of exclusion criteria are listed in Table 2 that may indicate a patient is too sick and unlikely to benefit from a pediatric observation unit.

Interventions

Pediatric patients can be evaluated and managed in a pediatric observation unit for up to 24 hours when judged by the clinician to be appropriate. Pediatric patients can undergo diagnostic testing, if warranted, for up to 24 hours. They can receive monitoring and therapy for respiratory illnesses including: repeat vital signs/pulse oximetry, supplemental oxygen, steroid therapy, and nebulizer treatments, if indicated. They can receive hydration, replacement of electrolytes with correction of electrolyte abnormalities, and treatment of pain. Serial examinations can be done as well as repeat vital signs, neurologic checks, and pulse oximetry. Management and diagnostic evaluation in an ED Clinical Decision Unit (CDU) can occur for up to 24 hours.

Outcomes

Various authors have reported on the use of an observation unit (OU) to treat children and infants and have noted that there are many advantages of an OU evaluation and treatment of pediatric patients.[3,6-8] Many reports have documented the value of an OU in the treatment of asthma, pediatric respiratory illnesses other than asthma (such as bronchiolitis, croup, pneumonia), gastrointestinal illnesses (gastrointestinal illnesses, gastroenteritis, abdominal pain), dehydration, neurologic illnesses/injuries, accidental ingestions/overdoses, and various other conditions.[3,6,9-20]

Patient outcomes for pediatric asthmatics managed in an OU are equivalent or better compared to those treated as inpatients, with the OU being more cost-effective. Relapse rates at one month for pediatric asthmatics treated in a holding unit or as an inpatient were compared. For holding unit patients 11.4% (4/35) returned to the ED and none were readmitted. For inpatients hospitalized < 1 day, 31.1% (5/16) returned to the ED and 12/5% (2/16) were readmitted. For inpatients hospitalized > 1 day, 13.5% (7/52) returned to the ED and 7.7% (4/52) were readmitted.[11]

A retrospective chart review that used a random sampling of charts looked at return visits to the ED within 72 hours for pediatric asthmatics before and after opening a pediatric OU. Returns to the ED were 12.5% (44/352) with 39% (17/44) hospitalized pre-OU versus 24.3% (85/350) returns to the ED with 28% (24/85) hospitalized post OU.[12] Two other studies looked at outcomes for pediatric asthmatics treated in a holding unit. Of 154 pediatric asthmatics treated in a holding unit, 1.5% returned to the ED and none were hospitalized.[13] In the second study, 7% (5/71) if the pediatric asthmatics treated in the holding unit returned within 1 week to the ED with four (5.6% = 4/71) hospitalized.[14]

Furthermore, the OU was cost effective with the inpatient average charge greater than 5 times the holding unit average charge in one study.[14] In another report, the charge for the holding unit was $339 versus $526 for patients hospitalized ≤ 1 day.[11]

Other pediatric respiratory illnesses have been successfully treated in an OU. An Australian study reported discharge home from OU rates of 80% (for 2 years during 1991-2 pre-mandatory corticosteroid use) versus 97% (post mandatory corticosteroid use in 1993-5).[15]

A study of pediatric OU patients with gastrointestinal illnesses, found 81.5% of patients were discharged home.[16]

Pediatric patients with neurologic illnesses (e.g. seizures, head trauma) have been successfully treated in an OU with rates of discharge home in the 90% range.[16] A review of OUs has suggested that pediatric patients with an accidental ingestion/overdose can be observed in an OU, thereby avoiding a "costly hospital admission".[17] Pediatric patients with other diagnoses ranging from infections (cellulitis, pneumonia, urinary tract infection) to dehydration or fever have been managed in an OU according to numerous reports.[3,6,7,9,10]

According to a Canadian study, it is estimated that up to 39% of pediatric patients and 25% of adult patients could receive care in an OU instead of in an inpatient hospital ward (excluding psychiatric, surgical, and obstetric patients).[18] A report from the United States noted that 70% of all pediatric asthmatic patients could be treated in an alternative setting (specifically an OU) instead of as an

inpatient.[19] An editorial from the United States had similar estimates and suggested that 2/3 to ¾ of pediatric asthmatics could be treated in an OU instead of as pediatric inpatients.[20]

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Table 1: Pediatric Patient Inclusion Criteria*

Respiratory illness
        Asthma
        Pneumonia
        Bronchiolitis, croup
Infectious diseases
        Cellulitis, lymphangitis
        Fever (r/o bacteremia**) (r/o sepsis**)
        Viral meningitis (not bacterial meningitis)
        Pyelonephritis, urinary tract infection
Gastrointestinal disorders
        Abdominal pain
        Vomiting, diarrhea
Neurology
        Minor head injury
        Seizures (not status epilepticus)
Toxicology
        Ingestions, overdoses
Hematologic
        Hemophilia
        Sickle cell
        Anemia (not major gastrointestinal bleeding)
Status post-ED procedures (not a recovery room)
        Oversedated, s/p minor procedures
Chronic illnesses
        Diabetes mellitus (DM); hyperglycemia not diabetic ketoacidosis (DKA)
Others
        Dehydration
        Pain management (eg, kidney stone)

Table 2: Pediatric Patient Exclusion Criteria*

Respiratory failure or severe respiratory distress
Shock
Airway obstruction: retropharyngeal abscess, etc.
Significant arrhythmias (hemodynamically unstable)
Coma
Toxic patients
Sepsis (known vs. rule out)
Bacteremia (known vs. rule out)
Neutropenic fever
Epiglottitis
Bacterial meningitis
Severe electrolyte abnormalities (eg, Na>120, K>6,0, K<2.5)
Sickle cell disease – complicated
Newborn
Age criteria (other than newborn) (eg, > 1 month, 2 months, 6 months, 1 year) **
Markedly abnormal VS – need age- specific criteria

*Adapted from: Mace SE, Pediatric Observation Medicine. *Emerg Med Clin North Am.* 2001; 19(1): 239-254.
**May be excluded; is dependent on age limits or age considerations for a given Clinical Decision Unit. Some units will exclude neonates (age < 30 days), while others will exclude young infants or given age, eg, < 2years of age

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Chest Pain

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IF a patient has chest pain with low probability of acute myocardial infarction or ischemia and negative initial testing (EKG, Cardiac biomarker).

THEN the patient should be evaluated with a period of observation with electrocardiographic monitoring, serial EKG testing (at least 2)*, serial cardiac biomarker testing, and unstable angina testing, (eg, stress test, or cardiac nuclear imaging).

BECAUSE physician diagnostic performance and quality of care improves with observation (decreasing ten-fold the error rate for 'missed myocardial infarction', reducing mortality by 50%, improving patient satisfaction) and improves cost effectiveness (reducing costs one half to one third) (Level A recommendation, Class I Strength of Evidence).

BACKGROUND

In the ED, chest pain is common, accounting for 5% to 6% of visits to EDs. It is the symptom commonly associated with fatal cardiovascular diseases. This is the leading cause of mortality in the United States accounting for 42% of all deaths. According to latest statistics released by the American Heart Association, approximately 1.25 million patients suffer an Acute Myocardial Infarction (AMI) each year and AMI deaths total 218,229. Nearly 80% of patients with AMI present to the ED. Unfortunately between 2 and 8 percent of patients with AMI are inadvertently discharged home.[1,2] This is because roughly one out of 20 patients with AMI are not at all "typical" in their presentation. It has been shown that patients with AMI who are discharged home experience twice the death rate (25%) of those admitted. Failure to diagnose and treat AMI has consistently accounted for the greatest total dollar loss for malpractice claims against emergency physicians. To address these issues, many emergency departments are using observation units for extended evaluation of chest pain patients (sometimes called a chest pain unit).[3]

The 2 to 3 hour ED evaluation and treatment is not adequate for correct disposition of many patients. The majority of patients with acute MI do not have a positive test upon evaluation in the emergency department. Since physicians cannot rely upon initial test results alone, they must either do an extended evaluation in the hospital ("rule out MI" evaluation) when there is a suspicion of acute MI, or send the low risk patient home.

Physicians make hospital admission decisions based on the "risk" of the potential disease and the "probability" that the patient has this condition. With a condition like chest pain, patients are admitted to the hospital that are considered at risk of having an acute MI (high to moderate probability of disease) and the rest are released home. With the 'traditional' ED chest pain patient disposition pattern (ie, admit or discharge), 50% to 70% are admitted to the hospital for extended evaluation. Since only 10% of ED chest pain patients have an acute MI and 10% unstable angina[1] 50% to 80% of admitted patients will be found to no have a serious disease. By hindsight their hospitalization was unnecessary.[1] Patients are released

home who clinically appear unlikely to have an acute MI (low probability of acute MI). This results in 3-5% of patients with acute MI being inadvertently being released home.

There is an inverse relationship between the proportion of chest pain patients who receive a complete evaluation (admitted) and the rate at which AMI is missed. Various factors affect the physician's threshold for hospital admission decision and thus the MI miss rate: experience of the physician (more experienced physicians admit more patients and miss less disease), risk attitudes of the physician (physicians with low risk personalities admit more patients and miss less disease), hospital monitored bed capacity (physicians admit more patients when the hospital has high capacity for monitored beds and thus miss less disease), clinical presentation (physicians are more likely to admit patients with typical presentations than atypical presentations and thus fail to diagnose many acute MI patients who present atypically). For high performance acute MI patients with atypical presentations are identified during extended evaluations with repeated blood tests, ECG monitoring, and physician reevaluation.

IF: Patient Selection

Patients are appropriate for observation who have a history of chest pain or chest pain equivalent symptoms and low probability of myocardial infarction or ischemia. Patients with high or moderate probability of acute coronary ischemia should be admitted to the hospital. They should have normal or unchanged EKG, normal cardiac biomarkers, and stable vital signs.

Patients need to be risk stratified during the emergency department evaluation to determine which patients have low probability of acute coronary ischemia and thus are appropriate for observation. Many emergency departments use the physician's clinical judgment for this risk stratification. Others use the Lee and Goldman or the Posner and Selker algorithms which use the clinical findings (nature of the chest pain, patient age, presence of radiation of the pain) and EKG findings (normal versus t wave changes verse ST segment changes). This risk stratification can include computer assisted decision making. With proper risk stratification approximately 2% of observation patients during observation are found to have acute myocardial infarction and 10% are found to have acute myocardial ischemia.

THEN: Observation Unit Management/Intervention

The chest pain patient should be observed in a facility with electrocardiographic monitoring. There needs to be supplemental oxygen, periodic measuring of vital signs, serial EKG testing, serial cardiac biomarker testing, and unstable angina testing (in the unit or scheduled for within 2 days of release from the observation unit) such as stress testing, cardiac nuclear imaging, cardiac CT scan imaging.[4]

BECAUSE: Outcomes of observation unit interventions

The observation approach uses focused, accelerate protocols to provide services over 12 to 16 hours that traditionally were provided on an inpatient basis over 2 to 3 days. ED's with observation units lower the physician's threshold for use of extended evaluation and thus perform 'rule out MI' evaluations on a larger proportion of ED patients (61% vs 45% p<.05).[5]

Use of observation improves physician diagnostic performance and nearly eliminates missed MI errors. While the majority of patients with acute MI do not have a positive test upon the initial evaluation in the emergency department, nearly all patients can be identified with testing in the time frame of observation services (6 to 23 hours). With the identification of acute MI patients with atypical presentations, there is a ten fold decrease in the error rate for "missed myocardial infarction" (the rate at which heart attacks are inappropriately sent home) from 5% to < 0.5%. With the use of observation, the 22% death rate is avoided of those acute MI patients inadvertently released home. With the use of observation, the high complication rate (arrhythmias, heart failure, etc.) in many of those acute MI patients inadvertently released home are avoided as well. Such improvement in quality of patient care has become a national focus since the Institute of Medicine's report on errors.[6] In addition, observation

services lead to an overall improvement in patient satisfaction. Observation units have consistently been shown to provide better satisfaction and quality of life when compared with in hospital setting.

Observation improves utilization as well as quality of patient care. Chest pain patients are evaluated and managed at least as effectively as hospitalization but at approximately half the cost as shown in multiple clinical trials[7,8] including 4 randomized clinical trials.[9] With observation, a portion of patients who would have been admitted are 'ruled out' for acute MI and avoid unnecessary hospital admission (improved utilization). Most ED chest pain patients need extended evaluation with observation or hospital admission to identify those acute MI patients who present with atypical signs and symptoms of their disease. Increasing the percent of ED chest pain patients admitted to the hospital for an extended evaluation, rather being released home from the ED, increases the overall costs ($2764/patient vs $403/patient average cost). Observation has intermediate costs compared to inpatient and ED services. There are overall cost savings since there are greater cost savings from avoided admissions (observed rather than admitted to the hospital) than added costs from added extended evaluations (observed rather than released after the initial ED evaluation). With observation a portion of chest pain patients with atypical clinical findings are 'ruled out for acute MI' rather than released home after the ED evaluation or admitted to the hospital. Thus, more acute MI patients with atypical presentations are identified (improved quality of care) without as many unnecessary hospital admissions (improved utilization of resources). Observation units have been found to be a dominant strategy for high quality, efficient care in the modern hospital.[11]

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Observation and Chest Pain		
Inclusion Criteria		* low probability of acute myocardial infarction or ischemia (eg, atypical chest pain as evidenced by factors such as pain reproduced by palpation, not relieved by nitroglycerine, not related to exercise, no history of coronary artery disease, age < 45 year old males, age < 55 year old female)
Exclusion Criteria		* Positive cardiac biomarkers (eg, CKMB, Troponin I) * Positive acute EKG findings * Positive cardiac imaging (if performed) * pO2 < 60 or pCO2 > 50 (if performed) * K < 3 or HCO3 < 20 * heart failure (as evidenced by clinical findings such as rales, S3 gallop, jugular vein distention, or by CXR or cardiac biomarker such as bnp) * Significant aortic valve stenosis

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Heart Failure
W. Frank Peacock IV, MD, FACEP

Heart Failure: Summary (Level A recommendation, Class II strength of evidence)
IF a patient has a high likelihood of heart failure (HF) with pulmonary and/or systemic congestion, chest x-ray findings compatible with the diagnosis of HF, and without abnormal mental status, anasarca, HR < 50, HR > 130 bpm, systolic BP < 90, systolic BP > 175 mmHg, O_2 saturation < 90%, evidence of acute cardiac ischemia by ECG or cardiac markers, anemia (Hgb < 8, Hct, < 24), new onset murmurs, cyanosis, respiratory failure (pH < 7.35, pO2 < 50, pCO2 > 45, respiratory rate > 35, fever, comorbid illness such as pneumonia, thyrotoxicosis, sepsis;
THEN they are candidates for management and diagnostic evaluation in an ED OU with serial examinations and vital signs, supplemental oxygen, electrocardiographic monitoring, medications (eg, diuretics, vasodilators);
BECAUSE aggressive OU management improves physician decision making and efficacy of therapy with improved quality of life, decreased ED revisit rates, decreased hospital admission rates, decreased costs.

BACKGROUND

Heart failure (HF) is common. In the US alone, there are nearly 5 million HF patients, with 500,000 additional cases added annually.[1] The mortality rate of HF exceeds most cancers, with nearly 300,000 patients dying from HF, or its complications, each year.[1] It accounts for more mortality, hospitalizations (900,000 yearly), and re-hospitalizations, than any other single disease in the over-65 age group.[1] Finally, from a fiscal point-of-view, HF is the single greatest expense to the Centers for Medicare and Medicaid Services (CMS). As reported at the 1999 Heart Failure Society of America Annual Meeting, 1999 US inpatient costs were estimated at 23.1 billion dollars, and outpatient costs at 14.7 billion. With the aging of America, these projections are expected to increase.

Because of non-specific and insensitive findings by history, physical, ECG, and x-ray, HF is a difficult diagnosis.[2-14] In the ED, the diagnostic error rate is reported to be 12%. Half of the misdiagnoses were undetected HF, and the remainder were confounding conditions (eg, COPD) mislabeled as HF.[15]

IF: Patient selection

Patients are appropriate for observation who have a high likelihood of HF with pulmonary and/or systemic congestion, and chest x-ray findings compatible with the diagnosis of HF. They should be without abnormal mental status, HR < 50, HR > 130 bpm, systolic BP < 90, systolic BP > 175 mmHg, O_2 saturation < 90%, evidence of acute cardiac ischemia by ECG or cardiac markers, anemia (Hgb < 8, Hct, < 24), new onset murmurs, cyanosis, respiratory failure (pH < 7.35, pO2 < 50, pCO2 > 45, respiratory rate > 35, fever, or a significant complicating comorbid illness such as pneumonia, thyrotoxicosis, or sepsis. If any of these complicating factors are present, hospital admission is suggested.

THEN: Observation unit management / intervention

During the period of observation, the heart failure patients are evaluated and managed as "observation" for 6 to 24 hours. They are evaluated with serial examinations and vital signs. They are treated with supplemental oxygen, electrocardiographic monitoring, and medications (eg, diuretics, inotropic agents, vasodilators).

BECAUSE: Outcomes of observation unit interventions

Observation improves physician decision making by the tincture of time – ie, repeated physical examination and evaluation. Since most ED visits for heart failure are due to exacerbations of chronic heart failure with preventable and reversible events (dietary indiscretion, failure to take medications, etc.), a longer period of evaluation enables the physician time to clarify which heart failure patients require hospitalization due to alternative underlying pathology (eg, ischemia).

As a response to cardiac stress, synthesis of B-type natriuretic peptide (BNP) (15-23) occurs. Concentrations of BNP, and its inactive pro-hormone synthetic byproduct (NT-proBNP), can be measured. Knowledge of either level improves physician decision making. In HF, an elevated ED NP level predicts future adverse cardiac events,[24] and coupled with clinical impression,[25-27] may help select OU HF candidates. For HF, these assays have a negative predictive value consistently exceeding 95% and can be used to exclude the presence of decompensated HF. The positive predictive value of an elevated NP for the diagnosis of HF is 70-95%.[15,22-23,27]

An echocardiogram can also be used to determine the amount of myocardial dysfunction in HF. Left ventricular function measurement is indicated in those without an established diagnosis of systolic dysfunction, unless determined in the prior year.[1,28-31] While usually unnecessary in the ED, if left ventricular function is not known, it can be measured in the OU to assist in determining treatment strategies, Knowledge of systolic function is required by most quality improvement, regulatory, and certifying agencies.

Efficacy of Therapy

In HF, relief of congestion is often the rate-limiting step, commonly requiring more than the 3 to 4 hours available during the ED visit. This explains why > 80% of ED HF patients are admitted to the hospital. The OU offers an opportunity for a longer term of therapy, and may be used to ultimately obviate the necessity of inpatient admission.[32]

Diuresis becomes more effective with extension of the treatment period up to 24 hours. Thus in the OU, initial HF therapy is commonly directed at the relief of congestion with IV diuretics. It is recommended to administer the patient's normal oral dose of furosemide (or its equivalent) as an IV bolus, to a maximum of 180mg. If not currently on a diuretic, 40 mg is usually adequate.[32-35] Urine output and serum electrolytes are monitored and to evaluate therapeutic efficacy and to screen for treatment induced hypokalemia. If target urine outputs are not met during initial management, the diuretic dose can be doubled and re-administered. Adequate output should exceed 500 cc's within 2 hours and 1000 cc after 4 hours (unless the creatinine is >2.5 mg/dL, then 2-hour and 4 hour urine output goals are halved). Failure to meet these output goals suggest the need for inpatient hospitalization.[32-35]

Vasodilators (nesiritide, nitroglycerin, nitroprusside) provide symptomatic improvement in HF patients with elevated blood pressure (>100 mmHg) and are usually begun in the ED on presentation. Acute hypertensive HF patients may derive marked clinical benefit with aggressive blood pressure control, irrespective of which of the above vasodilators are selected. The nitrodilators, never specifically studied in the OU, may require intensive hemodynamic monitoring and select for a cohort for whom OU admission is precluded. Nesiritide provides similar hemodynamic[36-37] and clinical benefits,[38-42] and has been specifically evaluated with only ECG and cuff BP monitoring in the OU, where it decreased 30 day hospital re-admissions.[43] Its use is controversial due to a meta-analyses showing trends (p>0.05) of increased mortality.[44]

ACEI represent a class of medication with long term mortality reduction benefit of such magnitude that all HF patients deserve a therapeutic trial.[1,28-29,45-47] Angiotensin receptor blockers (ARB's) are only used if significant intolerance or ACEI contraindication exists.[1,28]

Initiating beta blockers in the OU is generally difficult, despite strong evidence of HF mortality reduction.[48-52] To initiate a beta-blocker, the HF patient must be hemodynamically stable, and without decompensation, thus excluding starting a beta blocker in most HF OU patients. However, since patients already on a beta blocker may suffer an acute decompensation if it is abruptly stopped, the recommended therapy for decompensated HF patients presenting already on a β-blocker is to continue it at one dosing level lower than the maintenance dose. If inotropes are required, the β-blocker may be withheld,[1,28] however patients at this stage of their disease are not OU candidates.

The aldosterone antagonist spironolactone also has been shown to decrease the relative risk of mortality in end stage HF.[37] Patients should receive 12.5 to 25 mg qd, as well as routine medications.[1,28] It is not recommend if creatinine >2.5 mg/dL or K+ >5.0 meq/L. It should be continued in OU patients.

Although not a first line agent, digoxin is recommended for rate control in atrial fibrillation (a frequent accompaniment of HF) and when there are recalcitrant symptoms despite maximal therapy with other mortality reducing agents.[1,28-29] In patients already on digoxin, levels should be measured and their usual daily dose maintained.[1,28-29]

With these interventions, approximately 75% of observation unit patients will be successfully treated during observation and discharged home.[32-35] This is predicated on the relief of dyspnea, improvement of congestion, and discharge to an adequate outpatient environment. If these goals cannot be met, inpatient hospitalization, or placement in an assisted living facility, should be considered. For the 25% of HF patients who require inpatient hospitalization after a 24 hour OU admission, there is still benefit to the period of observation since their total hospital time is still less than that of HF patients directly admitted to the hospital.[34]

Discharge planning is crucial in HF. Close consultation with the physician who will ultimately manage the outpatient course is necessary to provide optimum outcomes. HF is a chronic condition with significant recidivism. Non-compliance is estimated to cause 50% of HF re-hospitalizations.[53] For the discharged patient a team approach is needed with patient education and consultations with social work, dietetics, cardiologists, and advance practice nurses. With this approach a significant improvement can be expected in HF outcomes: decreased revisit rates, lower inpatient length of stay, and reduced hospitalization costs.[25,32-35,54-57]

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Observation and Heart Failure		
Inclusion Criteria		* high likelihood of Heart Failure * pulmonary and/or systemic congestion * chest x-ray findings compatible with the diagnosis of HF
Exclusion Criteria		* Syncope * Anasarca * Abnormal mental status * HR < 50, HR > 130 * Systolic BP < 90, or > 175 mmHg * O_2 saturation < 90% * Acute cardiac ischemia by ECG or cardiac markers * Anemia (Hgb < 8, Hct, < 24) * BNP < 100pg/mL, NtproBNP < 300 pg/mL * New onset murmurs * Respiratory failure (pH < 7.35, pO2 < 50, pCO2 > 45, respiratory rate > 35) * Fever * Severe comorbid illness (eg, pneumonia, sepsis, DKA) * Unsafe home environment for discharge home after observation

16

Syncope

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Recommendation

Syncope: SUMMARY
IF Adult patients with syncope of undetermined cause do not have a history of CHF, HCT <30, abnormal ECG, subjective dyspnea, systolic BP < 90mmHg, or conditions requiring hospital admission, such as acute CVA, confirmed ACS, or major trauma,
THEN these patients can be managed initially in an ED-based observation unit for a minimum of 6hrs, up to 24hrs on telemetry, with Q1hr VS, and timely targeted cardiac/electrophysiology studies when appropriate.
BECAUSE diagnostic yield is improved, with a decrease in hospital admissions and overall length of stay and no demonstrated increase in recurrent syncope or all-cause mortality.

Background

Syncope is a common presenting complaint in emergency medicine, accounting for 1-1.5% of annual ED visits and up to 6% of hospital admissions yearly.[1] Defined as a transient loss of consciousness and postural tone that spontaneously and completely resolves without intervention, syncopal episodes raise concern for possible life-threatening cardiac or neurologic conditions, frequently prompting inpatient admissions at a cost of approximately 2 billion dollars annually, with a mean of $5400 per admission for patients with a discharge diagnosis of syncope.[2,3] These inpatient syncope evaluations are frequently low-yield, with a nondiagnosis rate of 30-50%, and serious cardiac or neurologic etiologies are only found in 18.4%.[4]

In light of these statistics, several groups have attempted to identify sensitive clinical decision rules to help the emergency physician determine whether a patient should be admitted or can be safely discharged home. Two of the most well-known and well-validated include the San Francisco Syncope Rule (SFSR) and the Osservatorio Epidemiologico sulla Sincope nel Lazio (OESIL) score. The SFSR (see Table 1) was developed by Quinn et al. in 2004 with a reported sensitivity of 96% in ruling-out serious outcomes (death, myocardial infarction, arrhythmia, pulmonary embolism, stroke, subarachnoid hemorrhage, significant hemorrhage, or any condition causing a return ED visit and hospitalization for a related event) at 7 days after discharge, with a decrease of hospitalizations by 10%.[5] Further prospective validation by Quinn and colleagues demonstrated 98% sensitivity and a potential to decrease admission rates by 24%,[6]

although some external validation efforts have demonstrated lesser sensitivities ranging from 77-100% (depending on how strictly they adhered to the original study design).[7,8] The OESIL score (see Table 2) was developed by Colivicchi and colleauges in Italy; their validation study demonstrated significant predictive value of OESIL risk score for 12-month all-cause mortality (p<0.001).[9]

Several studies have attempted to compare the two; in the UK-based ROSE pilot study, Reed et al. found prospectively that the SFSR had a sensitivity of 100% in predicting adverse outcomes but still resulted in too many admissions for the sensitivity yield, while use of the OESIL can risk-stratify but does not seem to have an appropriate risk cut-off that appropriately balances sensitivity and specificity.[10] Dipaola et al. found that the OESIL risk score had better sensitivity but higher admission rate than the SFSR (88% v. 81% and 43% v. 40% respectively). Notably the admission rate for simple clinical judgment in this study was much less, 34%, but also was significantly less sensitive (77%, p<0.05). The authors concluded that both low-risk scores were partially lacking in predictive ability, but still better than clinical judgment alone.[11] More recently, Serrano et al performed a review and meta-analysis of the various studies evaluating the prognostic ability of SFSR and OESIL. They theorized that the inconsistencies between study results was likely due to inconsistencies in rule application and study design, and demonstrated that the overall sensitivities and specificities of both (86% and 49% for SFSR, 95% and 31% for OESIL) limit their ability to be used as definitive clinical decision rules in determining disposition from the ED.[12]

These studies have all compared the usability of clinical decision rules in the dichotomy of discharge versus admission to the hospital, and the variety of results demonstrates a lack of consensus on what predictors provide the most appropriate balance of risk-management and cost-efficiency. In light of these issues, it seems apparent that the ability to identify intermediate-risk patients and monitor them in a short-term clinical decision unit has become increasingly more relevant, and the role of observation medicine is clearly implicated.

Table 1.

Table 2.

Criteria of the San Francisco Syncope Rule:
• **C** - History of congestive heart failure
• **H** - Hematocrit < 30%
• **E** - Abnormal ECG
• **S** - Shortness of breath
• **S** - Triage systolic blood pressure < 90

The OESIL score:
• Age > 65 years
• History of CV disease
• Syncope without prodromes
• Abnormal ECG
1 point awarded for each; score ≥ 2 indicates increased risk of cardiac death

IF: Patient Selection

Patients appropriate for observation include those with syncope of unclear etiology after initial ED assessment and none of the following: history of CHF, hematocrit < 30, abnormal ECG, complaints of dyspnea, or systolic blood pressure <90mmHg, acute CVA, or major trauma. Patients who clearly do not have syncope (ie, vertigo, seizure, AMS, cardiac or respiratory failure) should not be submitted for syncopal evaluation in an observation setting.

THEN: Observation Unit Management/Intervention

Intermediate-risk syncope patients can be appropriately monitored in a observation unit based setting, on continuous monitoring and q1hr vital sign checks, with appropriately targeted cardiac studies such as carotid sinus massage, tilt-table testing, and echocardiography when indicated.

BECAUSE: Observation Unit Outcome

Many studies have demonstrated that inpatient hospitalization for patients presenting with syncope have low diagnostic yield despite substantial cost, while newer studies regarding the use of "syncope units" are showing that with targeted diagnostic approaches, definitive diagnoses are increasing with a decrease in the use of inappropriate and usually non-diagnostic tests, as well as a decrease in number of inpatient admissions and overall length of stay.

In a study published by Brignole et al in 2003, six hospitals equipped with cardiologist-managed syncope units were compared to six comparable hospitals without syncope units, and their results demonstrated an increase in diagnosis of neurally-mediated syncope by 56%, with significantly *fewer* basic lab tests, brain-imaging studies, and echocardiograms.[13] In another study based in Sweden, Fedorowski and colleagues demonstrated that specialized syncope units using standardized syncope evaluation guidelines resulted in more appropriately-targeted testing and subsequent diagnosis than did those either discharged from the ED with referrals for testing or those admitted to the hospital for evaluation.[14] Indeed, a common theme amongst the many studies pertaining to syncope work-up is that many of the tests are expensive and non-diagnostic. Several studies have found that serial cardiac enzymes, head CTs, carotid US, and EEGs rarely identify causative factors contributing to syncope.[15,16] Multiple studies demonstrate an improvement in diagnostic yield with the relatively inexpensive tilt-table testing,[17,18, 19] but this test is infrequently utilized relative to the number of admissions and ED visits for syncope. This may be in part due to some concern regarding false-positives when pharmacologic adjuncts are used. Unfortunately, passive tilt-table testing (testing without added pharmacologic administration) can have a fairly high false-negative rate.[20,21] This uncertainty corroborates the rationale of using tilt-table testing in the patients who are the most appropriate, and of utilizing directed electrophysiologic studies as needed after appropriate observation and evaluation in the syncope unit.

Initial syncope units in the literature were managed by hospital cardiology departments, but Shen and colleagues realized the implications for emergency medicine and its approach to syncope. In the Syncope Evaluation in the Emergency Department Study (SEEDS), they created a syncope unit with a multidisciplinary approach that included timely echocardiography and tilt-table testing, when indicated, for evaluation of "intermediate-risk" patients with syncope but no known cause after initial evaluation (history, physical exam, VS, EKG). Patients were risk-stratified to low, intermediate, and high-risk groups based on presentation, age, past medical history, and EKG findings, with low-risk patients being discharged and high-risk patients admitted to an inpatient setting. Intermediate-risk patients were randomized to either the syncope unit or to standard care generally received in the ED. Patients in the syncope unit were kept on continuous monitoring for 6hrs, receiving an echocardiogram or tilt-table testing if a pertinent cardiac diagnosis was suspected; if not received in the unit the testing was provided within 72hrs of discharge. Versus the patients in the standard care arm, a presumptive diagnosis was established in 57% more syncope-unit patients (p<0.001) with 55% less hospital admissions (p<0.001) and no significant change in survival or recurrent syncope at 2 years post-study.[19]

Extrapolating the SEEDS data to current estimated annual costs of syncope admissions, the use of such syncope units could result in a decrease in cost of 1.1 million dollars annually. It does not seem unreasonable then that intermediate-risk syncope patients *should* be managed in an observation unit setting similarly to the way chest-pain patients are increasingly managed, with tilt-table testing or other directed studies taking the place of the inpatient stress test after a circumscribed amount of monitoring and observation. Furthermore, in instances where the patient develops a serious cardiac or neurologic event during the observation period, it is arguable that ED physicians and nursing staff remain better able to care for these critical patients than the standard internal medicine healthcare workers.

The fact remains that the current cost: benefit ratio for inpatient syncope admissions is substandard, and an increasing amount of syncope-unit studies in the United States and internationally are demonstrating increases in diagnostic yield with simultaneous decreases in length of stay, unnecessary tests, and overall costs, with no increase in mortality. The multidisciplinary approach and inter-specialty collaboration demonstrated between cardiology and emergency medicine by the SEEDS trial is an appropriate model for use in observation units worldwide.

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17

Abdominal Pain
Louis Graff MD, FACEP

Level A recommendation, Class II strength of evidence
IF an ED patient has abdominal pain or symptoms suggestive of a possible serious acute abdominal condition (eg, appendicitis, cholelithiasis/cystitis, diverticulitis) and has non diagnostic initial testing with no clear evidence of serious disease
THEN the patient may be further evaluated in an observation unit with serial physical examinations, serial blood testing (eg, CBC, liver tests), and specialized testing (eg, ultrasound, CT scan)
BECAUSE physician diagnostic performance improves (decreased missed diagnoses, decreased resultant complications, decreased the false positive appendectomy rate from 25% to 5%), and cost of patient care decreases with the use of observation.

BACKGROUND

Abdominal pain is the most common diagnostic syndrome of patients presenting to emergency departments accounting for up to 8% of visits.[1] Many patients have serious dangerous diseases such as acute appendicitis (comprises 4% of patients with abdominal pain in the emergency department,[2,3] the most common surgical emergency), acute cholecystitis, ectopic pregnancy. Many patients present with classic signs and symptoms of their disease, however many present with non-specific symptoms.[4] Because physicians can not accurately tell which abdomen pain patients have serious acute disease, many patients are found to have no disease at operation (up to one fourth of appendectomy patients are found on operation to have no disease.)[5] In addition, many patients are inadvertently not diagnosed at their initial evaluation (up to a fourth of appendicitis patients are not diagnosed at their initial evaluation.)[6] Many of these patients suffer adverse outcomes from delayed diagnosis (eg, the perforation rate doubles in appendicitis patients,[7] the complication rate increases > 4 fold from 1.5% to 6.7% in cholecystitis patients.)[8] Failure to diagnose and treat acute appendicitis and other acute surgical abdominal conditions is the third greatest total dollar loss for malpractice claims against emergency physicians.[9]

IF: Patient selection

Patients are selected for an observation unit diagnostic protocol based on initial ED history, physical, and test results. The physician's risk stratification of patients is crucial in this decision on level of care: discharge home from the emergency department, refer to outpatient observation care, or admit to the acute care hospital. Patients are appropriate for an abdominal pain observation protocol who are found to be at low to intermediate probability of serious disease at the initial emergency department evaluation (initial history, physical examination, U/A, and blood tests). Patients with clear evidence of a serious dangerous condition should be admitted to the hospital rather than observed: hypotension, temperature >40 C (103 F), surgical abdomen (eg, rebound, rigidity, free air), immunocompromised, bowel obstruction, pregnancy related condition.

The clinician's risk stratification is aided by clinical tools such as the appendicitis score (or Alvarado score.)[10-11] It is a 10 point scoring system based on clinical findings (symptoms, signs, and lab results) with the patient with more clinical findings of acute appendicitis more likely to have acute appendicitis and at higher risk.[8]

Appendicitis Score:
Alvarado A. Ann Emerg Med 1986:15;557-564

Migration of Pain	+1
Anorexia	+1
Nausea and Vomiting	+1
Tender RLQ	+2
Rebound Tenderness	+1
Elevated Temperature	+1
Leukocytosis	+2
Shift to the Left	+1

Those patients chosen for observation will take advantage of the tincture of time, ie, patients with acute appendicitis or other serious disease often worsen during a period of short term observation while those patients without acute appendicitis or other serious disease will improve (see figure).[12]

Appendicitis Score Before & After Observation:
(Graff LG, Radford MJ, Werne CW. Ann Emerg Med 1991:20;503-507)
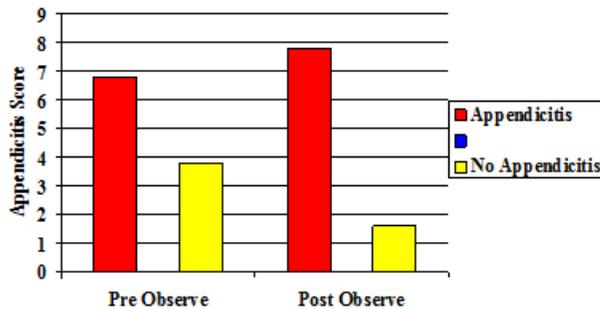
Prior to the development and wide spread usage of CT scan imaging of the abdomen, observation with repeated physical exam and testing was one of the only tools available for the clinician evaluating patients with acute abdomen. In the last two decades more patients with acute abdominal pain have CT scan imaging of the abdomen in the first 3 to 5 hours of evaluation in the emergency department to clarify their diagnosis. This reduces the portion of patients who have a need for observation to further clarify their diagnosis. Yet there is a significant amount of radiation exposure from CT scan imaging[13] and significant cost. Risk stratification with observation can be a useful tool aiding the clinician in improving their decision making and reducing to the patient their radiation exposure and cost.

THEN: Observation unit management/intervention

During observation the physician differentiates the patient with a serious acute pathologic process (eg, acute appendicitis) from the patient with self limiting disease. The emergency department evaluation is extended for up to 24 hours. The patient is kept NPO (nothing by mouth) and given intravenous fluid hydration. The physician examines the patient serially while the nurse periodically measures the patient's vital signs. Blood tests are repeated and the patient is scheduled for diagnostic imaging (as appropriate). Surgery and other specialties are consulted as indicated.

BECAUSE: Outcomes of observation unit intervention

Evaluation of the patient with abdominal pain is very difficult. In the traditional approach in the emergency department evaluation the diagnosis is missed in 20% of patients with acute appendicitis[7] and > 50% of patients with cholecystitis.[8] 20-30% of appendectomy patients have normal appendix. With a period of observation, physician diagnostic performance can be improved with observation.[7]

During 12 hours of evaluation in emergency department observation unit, patients with appendicitis develop more signs and symptoms. Out of a 10 point scale, a patient with appendicitis typically has a score increase from a mean of 6.8 to 7.8 during observation.[12] In addition, those abdominal pain patients with abdominal pain without appendicitis usually have symptoms resolve during observation. Abdominal pain patients without appendicitis decrease their mean score from 3.8 to 1.6 during observation.[12]

Physician diagnostic performance also improves in appendicitis patients due to the ability to schedule diagnostic imaging. Rao et al examined the effect of CT scan on physician treatment plans with moderate probability of appendicitis patients (53 of 100 had appendicitis).[15] He prospectively recorded physician disposition decisions before and after CT scan results. Because of CT scan imaging results, 18 of the patients who were found to have appendicitis were admitted to the hospital for observation and then surgery who otherwise would have been released home after their emergency department evaluation (false negative decisions). Because of CT scan imaging results, 13 patients who were found to not have appendicitis were not taken to surgery who otherwise would have been taken to surgery after the surgeon's initial evaluation (false positive decisions).

Thus physician diagnostic performance improves as does the resultant patient outcome. False positive surgery rate decreases from 25% to 5%.[7,14] Thomson examined abdominal pain patient outcome when evaluated with and without observation.[16] He found that the normal appendix rate (false positive decisions) averaged 6% in the studies with observation compared with 20% in the studies without observation. Yet the rate of perforation was similar with and without observation. Banaszak et al[17] examined diagnostic performance at hospitals in Pennsylvania. They found those hospitals with observation units had significantly lower false positive surgery rate compared with those hospitals without observation units.

Missed diagnosis rate also improves with observation. Graff et al[7] examined the performance at hospitals with observation units versus hospitals without observation units. Hospitals using observation units for patients with abdominal pain have improved performance in evaluating patients for acute appendicitis with a 50% higher rate of extended evaluation of abdominal pain patients. They also had a 30% lower missed diagnosis rate, lower perforation rate and abscess rate.[7]

Evaluation of abdominal pain patients for cholecystitis also improves with observation. As in appendicitis patients, for many patients it is not possible to make the diagnosis of cholecystitis with any degree of certainty without imaging studies.[18-22] The traditional emergency department approach identifies only 28% of ED patients with cholecystitis at their initial evaluation.[8] There are 1.7 ultrasound tests performed for every case of cholecystitis diagnosed and the complication rate is 6.7%.[8] With observation more ultrasound testing can be scheduled (6 ultrasound tests for every case of cholecystitis diagnosed) and the diagnosis rate at the initial evaluation increased to 89%. This decreases the complication rate to 1.5%.[8]

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Observation and Abdominal Pain		
Inclusion Criteria		* symptoms suggestive of a possible serious acute abdominal condition (e.g. appendicitis, cholelithiasis/cystitis, diverticulitis) * non diagnostic initial testing * localization of abdominal pain * abdominal pain associated with anorexia and/or vomiting
Exclusion Criteria		* clear evidence of serious disease * surgical abdomen, unexplained rebound tenderness, unexplained mass * temperature > 40c or 103f * immunocompromised patient without surgical or oncological consultation * appendolith or free air on xray * unstable vital signs * need for continuous parenteral narcotics

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Upper Gastrointestinal Bleeding
Abhinav Chandra, MD

SUMMARY BOX
1) Patient Selection:
   Inclusion criteria of Upper Gastrointestinal Bleeding
   Exclusion criteria – Variceal Bleeding, age $\geq$ 70, pulse rate > 100 beats per minute, systolic blood pressure < 100 mm Hg, hemoglobin $\leq$ 10 g/dL, use of anticoagulants, abnormal mental status, bright red blood per rectum, co-morbidities (CAD, renal disease, hepatic disease, metastatic malignancy, or congestive heart failure)
2) Management - hydration, serial hemoglobin measurement, proton pump inhibitor infusion, serial orthostatics, gastrointestinal endoscopy
3) Outcomes – risk stratification is effective, cost of services lower, length of stay improved, proton pump inhibitors decrease rebleed rates

BACKGROUND
　　Upper gastrointestinal bleeding (UGIB) is a common emergency with an annual incidence of 50 to 150 per 100,000 of the population. Mortality from UGIB is around 10%, and may reach 35% in patients hospitalized with other concomitant medical condition. It results in 250,000 to 300,000 hospitalizations per year and costing $2.5 billion dollars.[1] Patient with UGIB may present in shock and require fluid resuscitation and admission; however, most episodes are self limited, and 70-80% of patients experience only a single episode. Failure to accurately identify those at high risk for rebleed may result in significant morbidity and mortality. As a result, many patients are admitted to the hospital at a significant cost.[2]

Patient Selection: Inclusion and Exclusion Criteria (Class B Recommendation [Fair Evidence to Support this] – Evidence II-2 [Well designed Cohort and Case-Controlled Analytic Studies])
　　Patients with UGIB may be appropriate for observation. After emergency department (ED) evaluation and resuscitation, those that require extended care, and are considered low risk by one of two validated scoring systems are ideal candidates. Though four risk stratification scoring systems are commonly mentioned (Rockall score, the Baylor bleeding score, the Cedars-Sinai Medical Centre Predictive Index, and the Blatchford score)[3], the Blatchford and Rockall scoring systems are the 2 validated tools which appear to be most commonly used to risk stratify patients. The objective of the Blatchford[4] system is to identify those patients who need endoscopy to control the bleeding. It is also different in that it is derived from initial triage history, physical exam, and laboratory data, without endoscopy data. The variables used to determine the Blatchford score are: blood urea nitrogen, hemoglobin, systolic blood pressure, heart rate, syncope, melena, heart disease, and liver disease. This system was derived from 1748 patients presenting with upper gastrointestinal bleeding at one of 19 hospitals in western Scotland. The logistic regression model was built by stepwise selection of explanatory variables – clinical and laboratory data obtained at the time of admission.[4] Next, they prospectively validated this derivation on a group of 197 consecutive adult patients admitted with upper-

gastrointestinal hemorrhage during a subsequent 3 month period in three hospitals in west Scotland. The ROC curve in the validation set was 0.92 (CI$_{95\%}$ 0.88-0.95). A score of 5 or less was associated with a less than 2% or less chance for need for intervention in the validation group.[4]

The Rockall score[5] was first reported in 1995 and is one of the best known. The data presented was prospectively collected over four months as part of a national audit of the management and outcome of acute upper gastrointestinal hemorrhage at 4 health regions in England. 74 hospitals participated in the initial audit, which lasted from June to October 1993. A total of 4185 cases of acute upper gastrointestinal hemorrhage were identified and 1625 cases identified subsequently over a three month period in 1994 were included in the study. This study identified five independent variables which were predictive of re-bleeding or death {age (points 0-2), presence of shock (points 0-2), co morbidity (points 0-3), diagnosis (points 0-2), and endoscopic stigmata of recent hemorrhage (points 0-2)}. The maximum possible score was 11 and, a low risk score was determined as a score of 0 to 2.[6] This was prospectively validated by Hay et al[7] in 299 patients and demonstrated 0.6% for subsequent complications. This was also validated by Tham et al[8] in a 102 patients. The low risk group of patients had no adverse outcomes. In summary, these two risk stratification systems may be utilized to identify patients at low risk and potentially able to be discharged after early endoscopy. Patients with portal hypertension, varicosities, taking anticoagulants, and unstable vital signs are not ideal candidates for a clinical decision unit. The ideal patients are less than 60 years old, without significant comorbidities, and felt to be reliable and compliant.

MANAGEMENT/INTERVENTION

Nonvariceal upper gastrointestinal bleeding patients can be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with hydration, proton pump inhibitors, serial hemoglobin/hematocrit measurements, serial orthostatics, and Gastroenterology consult for early endoscopy, as defined as within 24 hours of presentation.

The use of proton pump inhibitors (PPI) has been debated. Several trials have evaluated this. One trial which demonstrated this was performed by Dr. Alan Barkum[9] who analyzed data from the Canadian Registry on Nonvariceal Upper gastrointestinal Bleeding. The trial analyzed 1869 patients with UGIB. Decreased rebleeding was significantly and independently associated with PPI use (85% of patients, mean daily dose 56 ± 53 mg) in all patients regardless of endoscopic stigmata, (odds ratio (OR):0.53, 95% confidence interval, 95% CI:0.37-0.77). PPI use (OR:0.18, 95% CI:0.04-0.80) was independently associated with decreased mortality in patients.[9] Based on this and other trials, a Consensus Panel[10] recommended that PPI's should be provided, in the form of a bolus and then followed by an infusion, to patients with UGIB.

OUTCOMES

Though many clinical trials have been performed in the care and treatment of nonvariceal UGIB, none of them have been performed in an emergency department based clinical decision unit. Thus, the evidence about the success of observation care has been extrapolated from clinical trials performed around the world and performed by Gastroenterologists and other non-emergency medicine specialists.

Trials have validated scoring systems, demonstrated decreases in length of stay, demonstrated decrease in readmissions for bleeding, and subsequently a decrease in cost. Dr. Wrenn[11] and his team demonstrated the safety of rapid evaluation. Wrenn et al studied a cohort of 96 patients presenting with upper gastrointestinal bleeding and followed in the ED for 6 hours. Thirty-eight of 96 were considered low risk as defined by lack of orthostatics, lack of underlying significant co morbid disease, hemoglobin concentration greater than 10 gm/dL, less than 60 years old, and felt to be reliable and compliant. Thirty-three of 38 were discharged and 31 followed up. None of these patient required readmission or transfusion.[11]

A trial by Rockall et al[6] also evaluated the safety aspect of early discharge after endoscopy. They concluded that approximately 33% of initially low risk UGIB patients are eligible for discharge after endoscopic evaluation. The rebleed rate was less than 5% and a mortality rate in this group was 0.1%.[6]

In a trial by Longstretch et al[12], the investigators prospectively identified low risk upper gastrointestinal hemorrhage patients using Rockall's criteria. In his data set, he was able to reproduce the results with 1 patient in 34 was readmitted for rebleed and none died. He also calculated that approximately $1000 dollars was saved in hospital cost per outpatient treated.[12]

The key to the care of a patient with UGIB is appropriate risk stratification and endoscopic evaluation. The identification of low risk findings on endoscopy in the alimentary tract allows for discharge while the findings of high risk features support further care. These findings have been reported in prior publications. In an analysis of data from 37 prospective trials in which patients did not receive endoscopic therapy, Laine and Peterson[13] found that the rate of further bleeding was less than 5% in patients with a clean ulcer base and increased to 10% in patients with a flat spot. These patients would be appropriate for outpatient care after completion of observation. A consensus statement by Barkun et al[10] summarized high risk endoscopic features and their rebleed rates. The bleeding risks were 22% in those with an adherent clot, 43% in those with a nonbleeding visible vessel, and 55% in those with active bleeding (oozing and spurting). Other such endoscopic features at high risk for rebleeding include ulcer size (>1 or 2 cm) and the site of bleeding (the posterior lesser gastric curvature and posterior duodenal wall).[10]

In patients at low risk, Longstretch et al[12], Cipolletta et al[14], and Lee et al[15] demonstrated cost reductions of 43% to 91% with the use of early endoscopy in randomized controlled studies. In the trial by Longstretch's group, the investigators prospectively identified low risk upper gastrointestinal hemorrhage patients using Rockall's criteria. In his data set, he was able to reproduce the results with 1 patient in 34 was readmitted for rebleed and none died. He also calculated that approximately $1000 dollars was saved in hospital cost per outpatient treated.[12] Cipolletta team conducted a trial with patients at low risk for recurrent bleeding. Ninety-five consecutive patients were randomized for either early discharge and outpatient care (48) or hospital care (47) and then followed up at 30 days for morbidity and mortality. In their trial, all patients underwent endoscopy within 12 hours of the onset of hemorrhage, which should be easily accomplished from a clinical decision unit. No patient underwent surgery or died. Rates of recurrent bleeding were 2.1% in the early discharge group and 2.2% in the hospital-treated group (1 patient in each group). Median costs were $340 for the outpatient group and $3940 for the hospital group ($p = 0.001$).[14] Lastly, Lee's trial showed similar results. In his trial, all eligible patients with upper GI bleeding were randomized after admission to undergo endoscopy in 1 to 2 days (control) or early endoscopy in the emergency department. Patients with low-risk findings on early endoscopy were discharged directly from the emergency department and followed up at 30 days. In 110 consecutive patients with nonvariceal UGIB, after early endoscopy immediately discharge occurred in 26 of 56 (46%) patients. No patient discharged from the emergency department suffered an adverse outcome. The hospital stay (median of 1 day [interquartile range of 0 to 3 days] vs. 2 days [interquartile range of 2 to 3 days], $p = 0.0001$) and the cost of care ($2068 [interquartile range of $928 to $3960] versus $3662 [interquartile range of $2473 to $7280], $p = 0.00006$) were significantly less for the early endoscopy group.[15]

The future possibilities for increasing the CDU's role in managing gastrointestinal bleeding are numerous. Future investigations need to validate the prior trial experience from a clinical decision unit. Next, the understanding of lower gastrointestinal hemorrhage is in its infancy. Future directions are needed in the development of scoring systems to identify low risk patients. This needs to be followed by the identification of lesions at high risk for recurrence of lower gastrointestinal bleeding. Finally, trials need to be conducted to demonstrate to demonstrate the impact on cost as a result of observation care under the direction of emergency medicine.

In conclusion, patients may be placed in an observation unit for nonvariceal upper gastrointestinal hemorrhage. These patients can safely be stratified to discharge versus admission based on a validated, prognostic scoring system, can have early endoscopic procedure within 24 hours of observation care in a clinical decision unit.

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19

Urolithiasis

Sharon E. Mace, MD, FACEP, FAAP
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Urolithiasis: Summary (Level C recommendation, Class III strength of evidence)
IF adult patients after initial emergency department (ED) evaluation and management have a diagnosis of renal colic, unavailability of result of definitive diagnosis test due to time of presentation, and/or pain and/ or nausea/vomiting unrelieved by oral medication(s) and does not have fever over 38.6^{o}C or 101.5^o F, suspected pyelonephritis with known stone, high grade obstruction, sepsis with known stone, and surgical abdomen
THEN these patients can be further evaluated and treated in an ED based Clinical Decision Unit (CDU) for up to 24 hours with serial exams that include routine vital signs, parenteral analgesics, antiemetics, IV hydration, and appropriate diagnostic imaging.
BECAUSE CDU therapy is as effective as inpatient hospital services in treating and resolving problems related to urolithiasis.

BACKGROUND

Urolithiasis, the presence of calculi or stones in the urinary system, is a common disorder, with an estimated incidence up to 12 %.[1] Fifty percent of patients with a first time stone suffer from a recurrence within 5 years and one-third will experience a reoccurrence within 1 year.[1,2] In adults, there is a male predominance being 2-3 times more common in males than females.[2] In pediatric patients, boys and girls are equally affected.[3] Caucasians, Asians, and African-Americans are most affected in order of greatest to least. Urolithiasis is most common in young adults (in the third to fifth decades of life) but can occur at any age.[2]

The classic presentation of patients with ureterolithiasis (stones in the ureters) is unilateral flank pain and/or sudden onset of lower abdominal pain and/or groin and genitalia pain, which depends on the location of the stone in the ureter. Renal colic, defined as the pain and symptom complex caused by acute ureteral obstruction, is usually the rapid onset of an acute, unilateral, extremely severe pain.[4] Typically, renal colic is unilateral flank pain that radiates anterioinferiorly into the abdomen, which may proceed into or toward the ipsilateral scrotum or labium majorum. Frequently, the pain is so excruciating that the patient is unable to find a comfortable position ("writhing of renal colic") and is anxious, sometimes pacing the floor and hesitating to lie down on the examining table. The pain usually waxes and wanes, although some background pain generally persists, even with treatment. Diaphoresis and gastrointestinal symptoms with nausea and vomiting may occur. Passage of the stone or temporary relief of the obstruction generally provides immediate relief of symptoms.

The diagnosis of urolithiasis begins with a history that includes history of present illness with description of the pain (PQRST) including severity of pain, associated symptoms, and any patient/family history of calculi, while evaluating for any signs/symptoms of sepsis and/or other complications. Although mild pain on palpation over the site of the stone may be present, if peritoneal findings with guarding or rebound are noted, then other diagnoses should be considered including leaking/dissecting aneurysm or mesenteric ischemia. Examination of the groin, and in a male, the testes, should be done in order to rule out diagnoses in the differential including torsion, hernias, and infection. If the diagnosis is uncertain, a pelvic examination may be indicated in females and a pregnancy test is warranted in females of child bearing age.

Hematuria is very common, although microscopic hematuria is absent in 15% of patients with ureterolithiasis. A urinalysis should be done, not only to check for hematuria, but also to check for pyuria and infection. Fever and bacteruria are uncommon and usually do not occur unless an infection is also present.[4] Obstructing stones predispose to urinary tract infection and urosepsis. Renal function tests (eg, BUN and creatinine) may be helpful in at risk patients (elderly, diabetics, renal insufficiency, hypotensive or septic patients) and if a radiocontrast study is being done. If the patient is a diabetic or has significant nausea/vomiting/poor oral intake, then a blood glucose may be useful to detect hypoglycemia. Diagnostic imaging may be necessary to confirm the diagnosis, reveal possible complications, and to exclude other disorders that are in the differential, especially a leaking/dissecting aneurysm or mesenteric ischemia.

Pathophysiology

Ureteral obstruction, whether intraluminal (most common) or extraluminal, leads to renal colic. Although urinary tract stones are the most common causes of ureteral obstruction, there are other causes including: blood clots, sloughed renal tissue, pus, debris, strictures (whether from tumors or infections), and twisting or kinking of the ureters as with a mobile kidney.[4]

The afferent nerve impulses that are produced from renal colic travel to the spinal cord at the T11-L1 levels. This is why renal colic pain can be located in/referred to any structure(s) with the same innervation as the urinary tract including the gastrointestinal organs and other parts of the genitourinary tract system. Similarly, the nausea and vomiting that occurs with renal colic is presumed due to stimulation of the celiac plexus.

Renal colic pain is due to stretching of the ureteral mucosal nerve endings caused by an increase in intraluminal pressure from the ureteral obstruction. In addition, there is contraction of the ureteral wall smooth muscle as an attempt to move the stone. The ureteral wall smooth muscle will undergo spasm if the stone gets wedged and is unable to pass. This causes prolonged isotonic contraction and the production of lactic acid, which stimulates the A (slow-type) and C (fast-type) pain fibers. These afferent nerve impulses are transmitted to the spinal cord (T11-L1 levels) with the usual projections along the pain pathways to the central nervous system.[4,5]

Patient Selection – Inclusions

It is appropriate to admit a patient to an observation unit (OU) who presents to the ED with nonspecific abdominal pain/possible urothithiasis for diagnostic testing to establish a definitive diagnosis, which can usually be completed in 24 hours. Patients who also present with pain from renal colic and/or nausea/vomiting unrelieved by treatment in the ED should be considered for admission to the OU for pain management and fluids.

Patient Selection –Exclusions

        If a patient has a fever over 38.6^{o} C or 101.5^{o} F, suspected pyelonephritis with a known kidney stone, high-grade obstruction, sepsis, or a surgical abdomen, inpatient admission is indicated.

Management/Intervention

        Once in the OU, serial exams that include routine vital signs should be performed. Parenteral analgesics and antiemetics should be administered in addition to IV hydration. There are several options for diagnostic imaging. Noncontrast helical computed tomography (CT) may be the imaging technique of choice given its high sensitivity and specificity for urinary tract stones, although in patients in whom CT is contraindicated or if CT is unavailable, an ultrasound may be useful and can reveal hydronephrosis and other abnormalities.

        Inpatient admission may be warranted for patients who despite appropriate analgesics/antiemetics/IVFs in the OU are unable to maintain oral intake, have refractory nausea/vomiting, and/or severe pain that has not responded to appropriate management. Patients who are able to take oral fluids and medications and whose pain is controlled and do not have any complications; such as sepsis, pyelonephritis, persistent high fever suggesting serious infection (eg, pyelonephritis, bacteremia, sepsis), or acute renal dysfunction/failure; may be discharged home from the observation unit. Ambulatory management includes oral analgesia, timely urologic consultation, and close follow-up.

Outcomes

        Patients with urolithiasis have been successfully treated in ED observation units for years, although there has been limited outcomes research regarding observation unit management of urolithiasis.

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Pelvic Inflammatory Disease
Alison Lozner, MD

SUMMARY BOX

1) Patient Selection:
Inclusion criteria - presumptive diagnosis of PID and meet any of the following criteria:
1. are unable to tolerate oral antibiotics acutely
2. are dehydrated secondary to high fever or vomiting and require intravenous fluids
3. require serial abdominal exams to exclude other pathology such as appendicitis

Exclusion criteria – hemodynamic instability, sepsis, immunocompromised

2) Management -supportive therapies, such as intravenous fluids, pain control, and antipyretics, as well as antibiotics.
3) Outcomes – the majority of patients are successfully treated in the observation unit and avoid acute care hospitalization at ½ the cost of acute care hospitalization

BACKGROUND

Pelvic inflammatory disease (PID) is defined by the Center for Disease Control (CDC) as "a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometriosis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis" (1). Frequently, PID, which ascends from the cervix up into the uterus and peritoneal cavity, is caused by sexual transmission of the microorganisms *Chlamydia trachomatis* or *Neisseria gonorrhoeae*. However, other anaerobic and aerobic vaginal flora have also been associated with the disease (2).

A 2000 study in the journal *Obstetrics and Gynecology* noted that PID affects up to 1.5 million women in the United States annually. The morbidity of PID is significant and includes conditions such as chronic pelvic pain, infertility, and ectopic pregnancy. The same study found that the direct medical costs of PID and its sequelae totaled an estimated $1.88 billion per year (3). Strikingly, the study found that cases of PID treated initially as inpatients are significantly more costly than those treated as outpatients, $4673 average lifetime cost versus $777 (4). The Emergency Department Observation Unit offers another cost-saving option for patients with mild-to-moderate PID.

Patient Selection: Inclusion and Exclusion Criteria

Patients are appropriate for the observation unit if they have been given a presumptive diagnosis of PID and meet any of the following criteria:
1. are unable to tolerate oral antibiotics acutely

2. are dehydrated secondary to high fever or vomiting and require intravenous fluids
3. require serial abdominal exams to exclude other pathology such as appendicitis

The diagnosis of PID remains a challenge. Various studies have shown that the clinical exam may have a sensitivity of only 50-75% when compared with the gold standard of laparoscopic findings (5). Consequently, the CDC recommends empiric treatment for all young women who are sexually active and are at risk for sexually transmitted diseases if no other cause can be found for their pelvic pain and they have either cervical motion tenderness OR adnexal tenderness OR uterine tenderness.

The CDC also provides additional criteria that may be used to increase the specificity of the diagnosis:
1. oral temperature greater than 101F
2. abnormal cervical or vaginal mucopurulent discharge
3. presence of abundant numbers of white blood cells on saline microscopy of vaginal secretions
4. elevated erythrocyte sedimentation rate
5. elevated C-reactive protein
6. laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis* (6).

Management/Intervention
Management in the Observation Unit will include supportive therapies, such as intravenous fluids, pain control, and antipyretics, as well as antibiotics.
The following guidelines are taken from the CDC's *Updated recommended treatment regimens for gonococcal infections and associated conditions — United States, April 2007*. These recommendations notably exclude fluoroquinolones because of widespread resistance in gonococcal infections.

Recommended Parenteral Regimen A

Cefotetan 2 g IV every 12 hours
  OR
Cefoxitin 2 g IV every 6 hours
  PLUS
Doxycycline 100 mg orally or IV every 12 hours

Recommmended Parenteral Regimen B

Clindamycin 900 mg IV every 8 hours
  PLUS
Gentamicin loading dose IV or IM (2 mg/kg of body weight), followed by a maintenance dose (1.5 mg/kg) every 8 hours. Single daily dosing may be substituted.

Alternative Parenteral Regimens

Ampicillin/Sulbactam 3 g IV every 6 hours
  PLUS

Doxycycline 100 mg orally or IV every 12 hours

Recommended Oral Regimen

Ceftriaxone 250 mg IM in a single dose
    PLUS
Doxycycline 100 mg orally twice a day for 14 days

 OR

Cefoxitin 2 g IM in a single dose and Probenecid, 1 g orally administered concurrently in a single dose
    PLUS
Doxycycline 100 mg orally twice a day for 14 days

Of note, the CDC also recommends that physicians consider a regimen to cover anaerobic flora, such as Metronidazole 800 mg orally twice a day for 14 days (7).

There are no studies evaluating the appropriate point at which to transition patients from parenteral to oral antibiotics. Recommendations vary from making the switch at 24 hours after clinical improvement to a minimum of 72 hours after initiation of parenteral antibiotics. Patients who demonstrate clinical improvement after a 24-hour stay in the observation unit and are considered capable of completing an outpatient regimen can likely be discharged safely.

Outcomes

Evidence from the 2002 PEACH trial demonstrates that inpatient and outpatient therapies are equivalent for women with mild-to-moderate PID. Patients in this randomized control trial showed similar clinical improvement in the short-term. Moreover, the long-term sequelae of PID developed in similar proportions. (8)

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Pyelonephritis
Rebecca R. Roberts MD

Pyelonephritis: Summary (Level B recommendation, Class II strength of evidence)
IF adult patients with pyelonephritis are immune-competent, moderately ill, suspected E. coli or S. saprophyticus infection, taking po fluids, stable vital signs and have none of the following: immunocompromise such as cancer, sickle cell disease or trait, AIDS, cirrhosis, asplenia, and autoimmune disease, large renal abscess (>2-3 cm), perinephric abscess, unrelieved mechanical obstruction, functional obstruction, known single kidney, renal transplant, renal failure, renal foreign bodies such as nephrostomy tubes, prosthetic heart valves, vascular grafts, septic shock, altered mental status, metabolic acidosis, DKA, new renal insufficiency, hospital-acquired infection, recurrent infection, diabetes mellitus, congestive heart failure, elderly age or residing at a long-term care facility.
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with pain medicine, anti-emetics, antipyretics, hydration, and antibiotics such as fluoroquinolones, ampicillin-clavulanic acid, or TMP/SMX.
BECAUSE the therapy is as effective as inpatient hospital services in successfully treating 80% of low to moderate severity pyelonephritis at 1/2 the cost.

BACKGROUND

Urinary tract infection (UTI) is one of the most common bacterial infections seen by physicians. Though precise numbers are unavailable because UTI is not a reportable disease, as many as 8 million people are treated for UTI per year in the U.S.[1,2] In 2004, the CDC found that emergency departments (EDs) obtained nearly 5.5 million urine cultures and diagnosed 1.75 million urinary tract infections.[3] That same year, AHRQ reported 135,786 discharges for pyelonephritis with mean charges of $12,149 and a mean length of stay of 3.7 days.[4] Understanding the wide range of risk factors and diagnoses that both comprise and mimic UTI will lead to better observation unit (OU) decision making.

The spectrum of illness due to UTI is broad. At the mildest stage, individuals without symptoms but with $>10^5$ colony-forming units of bacteria/mL of urine are defined as having asymptomatic bacteruria.[5-7] Symptomatic UTIs include acute cystitis, acute pyelonephritis, and more severe syndromes.[7] Acute cystitis typically presents with dysuria, frequency, and urgency.[8] Acute pyelonephritis (APN), usually caused by ascending infection, involves the kidney parenchyma and collecting system. It is characterized by fever, flank pain, tenderness, and vomiting, often following a history consistent with cystitis.[6-9] Patients with APN may be only mildly symptomatic or in septic shock.[6,10] APN is five times more common in women than men.[6] Due to the development and more widespread use of imaging, it is becoming clear that many APN cases (up to 1/4) also involve renal parenchymal abscess formation.[7,11-13] There appears to

be a continuum between renal parenchymal infection and nephric abscess formation. The names "acute focal bacterial pyelonephritis" or "acute lobular nephronia" are sometimes used to distinguish formation of small parenchymal abscesses (< 2-3 cm) from frank renal suppuration or nephric abscess.[7,13,14] From the clinician's viewpoint, the major feature differentiating these entities is whether antibiotics alone, or antibiotics plus imaging-guided needle aspiration, placement of stents, nephrostomy tubes, or nephrectomy are needed for management.[11-13,15,16]

More severe suppurative manifestations of UTI include perinephric abscess, necrotizing papillitis, and emphysematous pyelonephritis.[6,7,16-18] All are associated with diabetes mellitus, sickle cell disease, immune-compromise and have high mortality rates. Emphysematous pyelonephritis in particular can have mortality rates as high as 30-70%, even with emergency nephrectomy, aggressive antibiotics and supportive care.[7,16,17,19]

Recurrent and relapsing infections may also complicate UTI. Up to 25% of women with UTI will have recurrences which are due to causes such as ureteral-vesicular reflux or other functional or structural abnormalities, bacterial colonization of periurethral areas, and use of contraceptive diaphragms and spermicides.[7,8,20-23] Recurrent infections are important because they are frequently associated with risk factors for poor outcome or caused by antimicrobial resistant organisms. Recurrent infection can be "reinfection" - an infection after culture-proven eradication of a UTI – or "relapse" - when the original infecting organism was never completely cleared.[20] "Relapse" should prompt consideration of a remaining nidus or risk for infection: infected stone, occult renal abscess, chronic prostatitis, diverticula, obstruction, incomplete bladder emptying, fistulas, or hematogenous spread from distant sources.[7,20,24]

Ideally, antibiotic treatment of UTI would be dictated by culture and susceptibility results, but clinicians must usually start antibiotics empirically.[2,25,26] It is therefore important to review the most common causative organisms, local antimicrobial resistance trends, and specific considerations for the urinary tract. By far, the most common organism is *Escherichia coli* (80-90%) followed by *Staphylococcus saprophyticus* (10-15%), then other gram negatives such as *Klebsiella pneumoniae*, *Proteus mirabilis*, and more rarely *Pseudomonas* species.[6-8,18,25,27-34] Gram-positive *enterococci* are uncommon and more often found in men with UTI.[7] *Staphylococcus aureus* or *Candida* species can spread hematogenously from occult bacteremia or ascend after introduction during instrumentation or colonization of urinary catheters.[6,7,16]

In decades past, the mainstays of UTI treatment have been trimethoprim-sulfamethoxazole (TMP/SMX), and beta-lactams such as ampicillin or amoxicillin and first-generation cephalosporins.[5,35] For additional parenteral treatment, aminoglycosides such as gentamicin and tobramycin have been highly effective.[5,36] These antibiotics achieve very high concentrations in the urine and urinary tissues due to renal excretion mechanisms.[5,25] In fact, high urinary antibiotic levels have been found to be more important than blood levels in successful treatment of UTI.[5,7,35] More recently, the fluoroquinolones such as ciprofloxacin and levofloxin have become the standard first-line therapy for both ambulatory and inpatient UTI due to high urinary levels, good oral bioavailability, infrequent dosing, and good activity against urinary pathogens.[5,7,18,25,35,37,38] However, not all fluoroquinolones share these characteristics; for example, moxifloxacin is not an effective drug for UTI.[5,35]

Now, the bad news. Around the world, *E. coli* resistance to TMP/SMX, ampicillin and amoxicillin has emerged and rates continue to increase; some reports show resistance rates as high as 30-50% to ampicillin.[2,5,18,29,32,33,36,39-42] More recently, *E. coli* resistance to the fluoroquinolones in community-acquired infections has been reported.[2,5,29,32,33,35,36,41-43] For example, at our hospital approximately 20% of community-acquired *E. coli* isolates are currently

resistant to ciprofloxin and levofloxacin.[44] Resistance of *E. coli* to TMP/SMX has been reported in diverse communities and in patients with Latin America origin or travel, and may be attributable to clonal dissemination.[5,39,45-47] It is recommended that if local resistance rates to an antimicrobial are more than 10-20%, an alternate antibiotic should be designated as the new empiric choice to prevent treatment failures and complications.[2,7,35,39,48] Cephalosporins have maintained in vitro effectiveness,[18,49-51] but oral treatment with first-generation drugs could be problematic due to the frequent dosing required, rapid clearance and short duration of high urinary levels, leading to some treatment failures or recurrences even for organisms that were susceptible in vitro.[5,7]

It is essential then, to maintain familiarity with the antimicrobial resistance spectrum in your area of practice. Most recommend using the facility "antibiogram" which is a compilation of antimicrobial susceptibility profiles for each bacterial species recovered from cultures, usually over a year.[32,35] The most useful report hospital-acquired and community-acquired profiles separately.[35] Some even specify bacterial susceptibilities by culture source (blood, urine, wound, etc).

A limit on the utility of the hospital antibiogram is that it may overestimate the burden of antimicrobial resistance. Most authorities have recommended sending urine cultures only in patients with complicated UTI.[1,22,35,52] Many causes of complicated UTI are also risk factors for antimicrobial resistance.[29] It is therefore likely that current antibiograms show higher resistance rates than actually occur among uncomplicated UTI patients.[29,35,44] Also, some high risk patients receive multiple cultures that amplify the effect of their susceptibility profile on the hospital antibiogram.[35] Paradoxically, using such an antibiogram may increase resistance by encouraging even more use of broad-spectrum agents in patients who do not need them.[29,35,44] Antibiotic sparing has become a public health issue that should also be taken into account when selecting empiric therapies.

In most regions, fluoroquinolones maintain good activity.[2,18,28,32] Third generation cephalosporins such as ceftriaxone, aminoglycosides, and ampicillin-clavulanic acid are also still highly effective against the majority of *E. coli* isolates.[5,18,28,32,35,49,53,54] Aminoglycosides achieve high urinary levels and as low as 1 mg/kg of gentamicin or tobramycin every eight hours are highly active. However, a single high dose of gentamicin (3-5 mg/kg) or tobramycin (5-7 mg/kg) will result in prolonged effect with high urine levels and a significant post-antibiotic effect.[7] Another antibiotic maintaining good activity against uropathogens is nitrofurantoin.[5,21,30,32,37,41] Drawbacks for use in APN are the lack of parenteral formulations and its bacteriostatic action.[35] Other agents found to be successful in treating UTI are fosfomycin tromethamine and prulifloxacin.[55,56]

Another important step in APN decision-making is to evaluate for factors that predict poor OU outcome and infection with organisms that are resistant to first-line therapy. Many of the following risk factors are predictive of *both*.[6,10,15,34,50,53,57,58] The first predictor of poor response to antibiotics is obstruction to urinary flow. Common mechanical causes are renal stones, ureteral scars, strictures or valves, duplicate or abnormal collecting systems, prostatic hypertrophy or cancer, renal tumors and external compression from masses outside of the urinary system.[6,7,10,15,16,25,26,34,50,53,57-59] Functional causes include reflux, neurogenic bladder, multiple sclerosis, diabetic neuropathy, spinal cord syndromes, and treatment with medications such as antihistamines, anticholinergics, muscle relaxants, tricyclic antidepressants, narcotics, amphetamines, or beta-agonists.[6-8,10,25,26,35] Pregnancy is an important cause of functional urinary obstruction due to bladder relaxation and uterine compression.[6,7,25,31] Foreign bodies or invasive

procedures also predispose to intractable infection: indwelling catheters, renal stents, nephrostomy tubes, and frequent or recent instrumentation.[6,10,24,26,57,58,60] Underlying immunocompromise is a further risk for poor UTI outcome – HIV infection, diabetes, sickle cell disease, autoimmune diseases, cancer, immunosuppressive drugs, renal insufficiency, hepatic failure, alcoholism and advanced age.[7,8,10,16,17,25,26,34,35,57,58,61] Patients with polycystic disease are also at high risk of treatment failure due to limited diffusion of antimicrobials into renal cysts.[7] Of course, male gender, recurrent or relapsed UTI, or worsening renal function is a red flag signaling the possibility that one of the above problems has gone undetected.[14,15,26,62,63]

There are a host of disorders in the differential for UTI and APN that must be considered. Very commonly sexually transmitted infections present with clinical manifestations similar to UTI.[6,7,9,10,26] Acute urethritis, prostatitis, epididymitis, cervicitis, salpingitis, and tubo-ovarian abscess can cause urinary and flank symptoms along with white blood cells in the urine, so one must conduct an physical examination for these infections. The urinary system is a frequent site of extrapulmonary tuberculosis and clinicians should be alert for high risk patients exhibiting other signs of tuberculosis.[7,16,64,65] Appendicitis, especially if located in the retrocolic area can cause vomiting, flank pain, fever, leukocytosis and even a urinary sediment when overlaying the ureter.[6,9,26] Infective endocarditis frequently causes back pain, urinary sediment and fever and should be considered in anyone with a new cardiac murmur or damaged native valves, prosthetic valves, or vascular grafts.[26] Other renal events that mimic APN are xanthogranulomatous pyelonephritis, renal vessel dissection, renal infarct or papillary necrosis.[7,10,26] Patients with sickle cell disease or trait can have crises in the renal medullary regions due to the hypoxemia and acidosis normally occurring in this area. These conditions, if exacerbated by high altitude, heat illness or dehydration can precipitate local sickle cell deformity of red blood cells, ischemia and papillary necrosis, with tissue sloughing causing acute flank pain, hematuria, or even renal failure.[26] Flank pain can also be related to other structures in the area such as aortic dissection or aneurysm, pancreatitis, abdominal abscess, hepatic or splenic problems, penetrating peptic ulcers, subdiaphragmatic abscess, and thoracic maladies with pain referred to the flank such as pulmonary embolism, pneumonia, and pleural effusions.[6,9,10,26,66,67] Some autoimmune diseases can cause glomulonephritis which can mimic APN.[10,26] Patients are also taking immunosuppressive drugs and Crohn's disease sufferers are prone to large asymptomatic renal calculi.[18]

PATIENT SELECTION: Inclusion and Exclusion Criteria
Inclusion criteria:
immune-competent, moderately ill, suspected *E. coli* or *S. saprophyticus* infection, taking po fluids, stable vital signs

Exclusion criteria:
immunocompromise such as cancer, sickle cell disease or trait, AIDS, cirrhosis, asplenia, and autoimmune disease.[18,26,68] large renal abscess (>2-3 cm), perinephric abscess, unrelieved mechanical obstruction, functional obstruction, known single kidney[7,11,12,14,15,18,25,26] renal transplant, renal failure, renal foreign bodies such as nephrostomy tubes, prosthetic heart valves, vascular grafts,[7,18,26] septic shock, altered mental status, metabolic acidosis, DKA, new renal insufficiency, hospital-acquired infection,[7,25,26,57] recurrent infection, diabetes mellitus, congestive heart failure, elderly age or residing at a long-term care facility.[25,57,58,60,69]

MANAGEMENT/INTERVENTION

Patients with worse severity of illness, high-risk factors or unusual presentations may need renal, abdominal or thoracic imaging to exclude emphysematous pyelonephritis, nephric or perinephric abscess, unsuspected obstruction, or alternate diagnoses.[5,7,14,26,50,70] Imaging is also often recommended for male patients, those with diabetes, and children.[5-7,10,12,34,70] For a quick assessment of renal obstruction or abscess, ultrasound is good and many EPs are comfortable using this technology.[5-7,12,70] Spiral CT has largely replaced IVP as an accurate renal imaging modality that can also detect other abdominal processes in the differential diagnosis list.[5,7,11,12,18,70] More recently, low-dose, unenhanced spiral CT is gaining favor for the evaluation of the urinary system. The dose of ionizing radiation is a fraction of traditional scans, the risk of adverse reactions to contrast media is avoided and the accuracy is nearly the same.[71,72]

All patients with APN should receive urine cultures to identify causative pathogens and document antimicrobial susceptibility (or resistance).[1,5,6,25] However, most do *not* recommend blood cultures because they rarely result in a change in management.[6,61,73-75] Pain medications, antiemetics, and antipyretics are also recommended as needed.[7] Oral and intravenous fluids have always been a mainstay of APN treatment. However, *adequate* hydration of patients with dehydration is recommended. Forcing fluids to flush out the urinary system is not recommended because it can interfere with host immunity mechanisms and will dilute the antimicrobial urinary levels.[7]

Obtain results of a urine gram-stain as quickly as possible to guide initial empiric therapy while waiting for culture results. Most currently recommend an intravenous fluoroquinolone as the initial treatment of choice.[6,8,18,25,28,32,38] Alternative first choices are ceftriaxone with or without an aminoglycoside.[5-7,14,28,34,49,51,53] If the gram-stain suggests infection with gram-positive organisms or the patient is an elderly male at risk for *enterococci*, most would use ampicillin and an aminoglycoside while awaiting identification and susceptibilities.[7,8,18,76]

At discharge, continue oral treatment with fluoroquinolones.[5,25] Alternative oral medications include ampicillin-clavulanic acid or even TMP/SMX if regional and patient factors or a prior culture result indicate the infecting organism is susceptible.[7,28,41,50,53] Oral first-generation cephalosporins and nitrofurantoin are not currently 1st-line recommendations for APN treatment due to rapid urinary clearance and lack of bacteriocidal action, respectively. However, sometimes due to resistance, allergy, adverse reaction or pregnancy, these are the best choices.[29,30,34,37,49,51,77,78] Oral antibiotic treatment should be continued for at least 10-14 days to prevent relapse or recurrent infection and patients need close followup.[1,6,14,25,54,68,76,77]

During OU treatment for APN, patients should show improvement in symptoms including the ability to tolerate oral fluids, reduced pain and fever, stable vital signs and no signs of complication or alternate diagnoses.[69] The microbiology laboratory must be queried for preliminary culture results that may change management. Patient can be counseled on risk factors for UTI such as diaphragm use and the risk for relapse if they stop therapy too soon. Followup in 24 hours is recommended to check culture susceptibility results and to confirm that clinical improvement has continued with home care.[49,57] Additional followup is also required and it is recommend that followup urine cultures should be obtained to confirm bacterial cure.[7]

For those who do not improve sufficiently for discharge, renewed consideration should be given to the possibility of antimicrobial resistant organisms, occult obstruction, nephric abscess, and alternative diagnoses. Often renal imaging is indicated at this time and the clinician should be prepared to call other specialists if the need for abscess drainage, surgery, or intensive care is required. In fact, when developing protocols for OU, it is prudent to collaborate with key colleagues such as infectious diseases, urology, intensive care, and interventional radiology.[26]

OUTCOMES

Several authors have reported successful discharge of 72-95% of low to moderately ill APN patients after OU treatment.[9,51,79-83] More recently, there have been reports of ambulatory treatment for mild APN in early pregnancy.[8,49,77,78] Closer examination of these reports shows they are really reporting OU treatment. Pregnant patients in the first or second trimester were treated with one or two doses of parenteral ceftriaxone before conversion to oral cephalosporins and home discharge. In addition, OU treatment of APN has evolved rapidly without the benefit of randomized controlled trials. There are also studies of outpatient APN treatment.[6,84]

There are few cost studies in recent years and healthcare costs have tended to increase dramatically over time. However, we can extrapolate earlier reports in the following way. Let's postulate that 20% of the 135,786 APN patients hospitalized in 2004 could have been treated in the OU instead. That would be 27,157 patients avoiding initial hospitalization with 80% successfully discharged. An earlier cost study conducted (at this author's hospital) demonstrated a cost ratio of OU treatment to hospital treatment of $1587/$2784 (0.57).[81] If that cost ratio were applied to the current mean cost reported for APN ($12,149 in 2004), an estimated $6,925 could be saved per patient. That cost savings extrapolated to 27,157 potential OU patients would save the U.S. $188 million in one year. The current 3.7 day hospital length of stay for APN is similar to the 3.5 day length of stay reported in control group patients in the study we extrapolated and that study also demonstrated an 80% success rate for OU. This lends credibility to the above cost extrapolation.

In summary, OU treatment of APN presents challenges to the clinician. The kidney and its collection system are not accessible to a good physical examination. When one considers that calculi less than 2mm in diameter can cause havoc in the retroperitoneum, and that patients with seemingly mild cystitis can have occult renal abscesses with resistant organisms, it is clear that we are managing multiple uncertain probabilities at every decision point. There is a probability that a patient has complicated APN, an underlying risk for poor outcome, uncertainty about the infecting organism, and the risk for antimicrobial resistant organisms. In addition, many of the APN complications and alternate diagnoses require high suspicion and special tests to detect. Then, there is the additional public health civic obligation to preserve the effectiveness of our current antimicrobials for future patients while selecting the best therapy for patients in the present.[25,35,41,52] One must continue to consult the latest literature and local antibiograms because emerging resistance and new drug development ensure that our antibiotic recommendations will quickly become obsolete. In spite of these potential problems, we believe that OU treatment is an outstanding option for a significant proportion of patients with APN.

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25

Hypercalcemia
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SUMMARY BOX

Hypercalcemia: Summary (Level C recommendation, Class III strength of evidence)
IF adult patients with hypercalcemia after emergency department (ED) therapy require extended care and have none of the following: Calcium > 13.5 mg/dL, new EKG changes (shorten QT, prolonged PR, prolonged QRS), serious etiology of the condition such as malignancy
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with hydration, enhancement of renal calcium elimination, osteoclastic inhibitors, and treatment of the primary disorder
BECAUSE the therapy is as effective as inpatient hospital services in reducing the hypercalcemia and cost of services are lower than inpatient services.

INTRODUCTION

Calcium, one of the most critical elements in the human body, acts in cell signaling, muscle contraction, cardiac conduction, and other mechanisms of homeostasis. The skeleton binds 98% of calcium in the human body, or about 1200 grams. Half of the remaining circulating calcium is bound to proteins such as albumin and globulin, while the rest is free, or ionized, calcium, the only active form of the molecule.

Most clinical assays measure the total calcium levels, with normals ranging from 8 to 10 mg/dL or 2 – 2.5 mmol/L, with some variation for individual assays. Free calcium can be measured directly with an ionized calcium level, with normals ranging from 4 – 5.6 mg/dL or 1 – 1.4 mmol/L. Because about half of calcium is protein bound, variations in plasma protein levels may interfere with the measurement of calcium. Thus, all measurements of total calcium should be considered in light of serum albumin levels, with a conversion factor of 0.8 x measured calcium for every gram of albumin decrease below 4.0 g/dL.[1]

Calcium levels are tightly regulated by parathyroid hormone (PTH), excreted in response to low serum calcium. PTH increases release of calcium from bone via osteoclasts as well as increases tubular reabsorption of calcium by the kidney. Renal phosphate excretion is increased by PTH. PTH also facilitates the conversion of inactive vitamin D to 1,25 dihydroxyvitamin D, or calcitriol, to increase dietary calcium absorption from the small intestine. Calcitonin, secreted by the parafolicular cells of the thyroid gland, opposes osteoclast activity and the action of PTH on the kidney.

Hypercalcemia is defined as any elevation in the total serum calcium above 10.5 mg/dL or 2.63 mmol/L. Serum levels of greater than 14mg/dL are potentially life-threatening.[1]

Pathophysiology

The most common causes of hypercalcemia are primary hyperparathyroidism and malignancy, together accounting for about 90% of cases. Primary hyperparathyroidism is usually caused by a pituitary adenoma, less often parathyroid hyperplasia, and rarely a carcinoma of the parathyroid gland.

Malignancy can lead to hypercalcemia by a variety of mechanisms. In humoral hypercalcemia of malignancy, some solid tumors such as lung cancers, pheochromocytomas, and head and neck squamous cell cancers, may secrete PTH-related peptide (PTHrP), which binds at the PTH receptor and mimics the clinical effects of PTH. Patients may also have multiple endocrine neoplasia, and should be screened for other tumors in the appropriate clinical context. Humoral hypercalcemia often is a marker of terminal illness and suggests a limited life expectancy of a few weeks.

Additionally, lytic lesions in bone can occur with other cancers, such as multiple myeloma, lymphoma, or breast cancer. This increased bone turnover leads to hypercalcemia not related to humoral mechanisms. Prostate cancer is rarely associated with hypercalcemia despite frequent bony metastases. Hodgkin's lymphoma leads to hypercalcemia by means of increased calcitriol levels.

Granulomatous diseases such as sarcoidosis, tuberculosis, and Hodgkin's lymphoma, also produce hypercalcemia indirectly via macrophage mediated conversion of 25-hydroxyvitamin D to 1,25-hydroxyvitamin D.

Medications are a common etiology of hypercalcemia, especially thiazide diuretics, as they increase renal calcium reabsorption. Lithium and vitamin A analogues may also lead to hypercalcemia. Milk-alkali syndrome is a specific situation in which the consumption of large amounts of calcium-containing antacids leads to renal insufficiency, alkalosis, and hypercalcemia.

Other medical conditions may be the less common causes of hypercalcemia. Paget's disease and thyrotoxicosis both lead to increased bone turn-over and result in mild to moderate hypercalcemia. Familiar hypocalciuric hypercalcemia is an autosomal-dominant condition in which patients have moderately elevated calcium levels but low calcium excretion in the urine. Immobilization may also produce or exacerbate hypercalcemia.

Clinical Presentation

The clinical presentation may correlate to some degree based on the calcium level, but the patients' age, underlying medical conditions, rate of rise in the calcium level, and etiology of the hypercalcemia will also impact the presentation, making an absolute correlation inconsistent. Nonetheless, patients with a calcium level of 10.5 to 12 mg/dL are classified as having mild hypercalcemia, and patients in this range are often asymptomatic or mildly symptomatic. Patients with levels greater than 12 mg/dL are often at least mildly to moderately symptomatic, and those with levels over 13.5 mg/dL are at risk for serious complications or death.[1,2]

Patients with primary hyperparathyroidism generally have chronic, stable or slowly progressive hypercalcemia. These patients may come to medical attention only when hypercalcemia is detected on routine screening or testing for other purposes. Hypercalcemic crisis is not usually the initial presentation of a patient with primary hyperparathyroidism, as most of these patients have previously established diagnosis prior to crisis.

Hypercalcemia of malignancy may present in a variety of ways. Hypercalcemia may be quite severe in patients with established cancers. Humoral hypercalcemia is often developed in the terminal stages of cancer, and as such, hypercalcemia is not usually a presenting complaint. Patients with multiple myeloma may also have extremely high serum calcium levels.

The mnemonic "Stones, Bones, Abdominal Moans, and Psychic Groans" applies to the presenting complaints of patients with hypercalcemia. Neurologic symptoms can range from mild concentration difficulties, confusion, poor memory, and symptoms may progress to stupor and even coma. Patients may also complain of peripheral muscle weakness.

Abdominal symptoms are often nonspecific, including vague pain, nausea, vomiting, constipation, anorexia, and weight loss, but may hypercalcemia also lead to peptic ulcer disease and pancreatitis.

Nephrolithiasis may be a presenting symptom, and patients may also have nephrocalcinosis, nephrogenic diabetes insipidus, dehydration, and renal failure. Skeletal complaints such as bone pain, arthralgias, or arthritis may be present, as well as osteoporosis or osteoitis fibrosa cystica.

Patients may also have arrhythmias, and a shortened QTc on ECG is classic for hypercalcemia. The PR interval and the QRS complex may also be prolonged, and complete heart block may develop. Hypercalcemia potentates the effects of digitalis. Hypertension and vascular calcifications may also be present.

Evaluation

In critically ill patients in hypercalcemic crisis, the initial evaluation is the same as that for any other unstable patient, assessing airway, breathing, and circulation. In stable patients without a known origin for the hypercalcemia, however, the primary goal in evaluation is to find the underlying etiology, as appropriate care is best directed at treating the precipitating cause.

Patients should be approached with a thorough history, assessing for symptoms of hypercalcemia. Additionally, symptoms consistent with malignancy and associated cancer risk factors should be elicited. Taking a detailed medication history and checking family history for evidence of FHH or MEN syndromes, such as pituitary, adrenal, pancreatic, or thyroid cancers, may be helpful.

In patients with suspected hypercalcemia, checking an ionized calcium level is appropriate, as this measurement is most accurate. If an ionized calcium assay is not available, the serum calcium should be corrected for the albumin level to rule out factitious hypercalcemia or uncover a subtle hypercalcemia. In the acutely ill patient, an arterial or venous blood gas is a rapid means of obtaining the ionized calcium level at many institutions.

Levels of 25-hydroxyvitamin D will be elevated in patients with ingestions of Vitamin D containing compounds. Levels of 1,25-hydroxyvitamin D will be elevated in patients with granulomatous disease or other vitamin D mediated hypercalcemia.

Renal function, phosphorous, and other electrolytes such as potassium and sodium should be evaluated in all patients. Many patients with hypercalcemia have significant azotemia. Serum phosphate levels are low or normal in primary hyperparathyroidism and hypercalcemia of malignancy. Phosphate is elevated in granulomatous disease or thyrotoxicosis.

Patients should be screened for primary hyperparathyroidism by sending an intact PTH level. An elevated PTH in the face of hypercalcemia is strongly supportive of primary hyperparathyroidism. The next step is in this situation is screening for familial hypocalciuric hypercalcemia by collecting a 24-hour urine calcium. In this setting, the calcium excretion should be low as compared to the serum levels. Patients with normal or elevated urine calcium levels have primary hyperparathyroidism.

Patients with decreased PTH should be evaluated for malignancy in the appropriate clinical setting. Additionally, testing for other endocrinopathies, such as sending TSH and free T4 for thyrotoxicosis and checking a cortisol level may be indicated. Work-up for granulomatous disease such as sarcoidosis or tuberculosis should be guided by clinical suspicion.

In those patients with a presentation concerning for cancer, PTHrP should be checked. Additionally, in the rare scenario in which the patient has an elevated PTHrP but an unrecognized malignancy, the patient should undergo an oncologic work-up, with imaging and further labs as clinically indicated.

IF: Patient Selection

Patients are appropriate for observation who have acute hypercalcium after ED therapy, require further evaluation and therapy, and have no findings indicating a critical illness. Patients with a calcium level of greater than 13.5 mg/dL, whether symptomatic or not, are critically ill and should be admitted directly to the Intensive Care Unit from the ED. Those with new EKG changes (shorten QT, prolonged PR, prolonged QRS) should not be observed but admitted since they need therapy and evaluation beyond the observation time period to ensure they are safe for release home. When a serious etiology of the

hypercalcemic condition is evident (such as malignancy) then more treatment is required than can be provided in an observation unit.

Treatment

The assessment, treatment, and ultimate disposition of patients with hypercalcemia ultimately depend on three variables: the severity of the symptoms, the degree of hypercalcemia, and the etiology of the hypercalcemia. In acutely ill patients, assessment for protection of airway, breathing, and circulation are paramount. Patients with serum calcium levels of greater than 13.5 -14mg/dL or symptomatic patients with levels greater than 12 need immediate intervention.[1,2]

The primary treatment for hypercalcemic patients is aggressive IV hydration. All patients with moderate or greater hypercalcemia develop some degree of volume contraction. Normal saline should be used to increase the filtration and excretion of calcium, with a goal diuresis of 200 mL/hr.[1] Patients with moderate to severe symptoms may require 4-6 L/day and will often require multiple days of therapy. Diuresis will lower the serum calcium by 1-3 mg/dL.[1]

After intravascular volume is repleted, forced diuresis with a loop diuretic to inhibit the resorption of calcium in the distal renal tubule should be initiated. In patients naïve to these medications, low doses of furosemide, such as 10 – 20mg IV, may be effective, but some patients will require higher doses. Loop diuretics are especially important in cases of concomitant fluid overload or congestive heart failure. Diuresis also increases the excretion of potassium and magnesium, and these levels must be monitored.

The next line of treatment for moderate or severe hypercalcemia is antiresorptive medications. Bisphosphonates gradually decrease serum calcium levels by inhibiting osteoclasts and decreasing bone resorption. Effects are seen after 24 hours, but maximal effectiveness is not achieved until 72 hrs after administration. Despite a delayed onset of action, these medications are especially effective in cases of malignancy related hypercalcemia, but will also lower calcium in primary hyperparathyroidism. Pamidronate, an older medication, is given in doses of 15 – 90 mg IV over 4 hours. Pamidronate decreases the serum calcium by more than 1mg/dL per dose, and the average duration of action is 28 days. Zoledronic acid is a newer medication with a higher response rate, a faster onset, and longer duration of action than pamidronate, dosed at 4mg IV over 15 minutes. These should not be used in renal failure.[1,3,4]

Calcitonin acts on osteoclast receptors to decrease the release of skeletal calcium and inhibit renal resorption of calcium. It is the fastest acting antiresoptive medication but has only a minimal effect and a short duration of action. The maximal effect is seen within 6 hours, and the calcitonin will lower the calcium concentration by about 2mg/dL.[3] Additionally, tachyphylaxis usually develops to repeated doses. Thus, a practical approach in a patient with significant or refractory hypercalcemia is to give calcitonin for the immediate effects as well as give the bisphosphonate to have the greater, sustained effects.[5]

Hypercalcemia from hematologic malignancies and vitamin D mediated hypercalcemia respond to glucocorticoids, making them the first line medication after IV fluids in these situations. Malignancies may respond directly to the glucocorticoids, and these medications also inhibit 1-α-hydroxylase to decrease the conversion of 25-hydroxyvitamin D to calcitriol.

Hemodialysis with a low calcium or calcium-free dialysate is indicated in cases of life-threatening, resistant hypercalcemia or hypercalcemia with renal failure. Arrangements for emergent dialysis should be initiated as soon as a patient with potentially life-threatening hypercalcemia is recognized.

Primary hyperparathyroidism presenting with hypercalcemic crisis is rare, but when it does occur, is an indication for urgent parathyroidectomy.[1,3] Outpatient parathyroidectomy is also indicated in patients with nephrolithiasis, osteitis fibrosa cystica, neurologic complaints, serum calcium levels greater than 1mg/dL over normal, urine calcium excretion of greater than 400mg/day, a bone density T score of less than -2.5, a creatinine clearance reduced by 30%, or age greater than 50 years.[6]

THEN: Disposition

Patients with a calcium level of greater than 13.5 mg/dL, whether symptomatic or not, are critically ill and should be admitted directly to the Intensive Care Unit from the ED. Malignancy is the most common

etiology of severe hypercalcemia, but hypercalcemic crisis may also develop from primary hyperparathyroidism. These patients require aggressive therapy and frequent testing of electrolytes. Additionally, they may need hemodialysis or emergency parathyroidectomy, and the ICU is the best place for them to receive the monitoring that they require.

Conversely, patients with mild hypercalcemia, with levels of less than 12 mg/dL with mild or no symptoms, can often be discharged from the ED to follow up as an outpatient. This approach is generally safe for patients with a known underlying diagnosis and close follow up care. Patients should be screened for use of offending drugs, and the drug discontinued if applicable. Patients with known primary hyperparathyroidism should be referred back to an endocrinologist and possibly a surgeon for an outpatient parathyroidectomy. These patients may benefit from an outpatient sestamibi scan of the parathyroids to assist with operative planning.

Discharge planning for patients with an underlying malignancy should be made in conjunction with the patient's oncologist. Patients with a diagnosis that is associated with increased bone resorption, such as breast cancer, multiple myeloma, or lymphoma, may be started on a bisphosphonate in conjunction with the physician who will be following. Patients with a possible humorally mediated hypercalcemia, such as head or neck squamous cell or lung cancer, may be presenting with hypercalcemia as an early indicator of significantly progressing illness. As such, these patients may require admission for new surgical, radiation, or chemotherapeutic treatment, and should be discussed with the oncologist.

However, patients with mild hypercalcemia but no recognized underlying diagnosis may benefit from a protracted stay, either with admission to the medical floor or to the observation unit. The goal of this stay would be to begin the work-up for hypercalcemia in a patient without follow-up, monitor the patient for response to therapy, and arrange for further care after discharge. Depending upon different laboratory capabilities, a stay in the observation unit may allow time for assays such as PTH and PTHrP and thyroid function tests to return, as well as verifying ionized calcium levels and checking vitamin D levels. Depending upon institutional capabilities and policies, the patient may also undergo screening for certain conditions, such as chest imaging for sarcoidosis or PPD placement for tuberculosis. Additionally, patients with hypercalcemia due to medications can be observed off the medication while in the observation unit, and plans for starting a new medication can be made with the original prescriber. Lastly, screening for malignancy may be started, if it is felt that the patient is well enough to continue a cancer work-up as an outpatient.

These patients can be treated with IV fluids with or without diuretics, as indicated by symptoms, although there is no data to show that acutely lowering the calcium in an asymptomatic patient will have any effect on outcome.[1,2] These patients should have a calcium level checked before discharge to ensure that it is not rising despite adequate hydration. If outpatient follow up can be arranged, discharge of a patient with mild hypercalcemia and no known underlying diagnosis is reasonable.

All patients with mild hypercalcemia should be given good discharge instructions to maintain adequate hydration, about 3 L a day,[3] to avoid immobilization, to stop all offending drugs, avoid calcium and vitamin D containing foods, and to return for any neurologic changes, abdominal pain, nausea, vomiting, bone pains, or any other changes in their overall health.

The disposition of patients with mild symptoms and calcium levels of 12 – 13.5mg/dL is more complex, and largely depends on the etiology, the rate of rise of the calcium, and planned follow-up for the individual patient. These patients are far more likely to require an inpatient stay for continued treatment as compared to those with lower calcium concentrations. While there is little data on this topic, a reasonable approach for a patient with moderate hypercalcemia values and mild symptoms is admission to the observation unit or inpatient floor, as per institution, for aggressive IV hydration and loop diuretics. Patients with moderate hypercalcemia and moderate or greater symptoms warrant admission and further inpatient evaluation and treatment.

As with patients with mild hypercalcemia without an underlying diagnosis, admission to the observation unit may allow time to begin the work-up for the underlying etiology. However, in a patient with moderate levels of calcium and any symptoms without a diagnosis, the threshold for admission should

be much lower. Additionally, in those patients with a known etiology of hypercalcemia, disposition decisions should be made in conjunction with the physician following their condition.

Patients with known or suspected malignancy and symptomatic hypercalcemia should be regarded seriously. In addition to IV fluids and loop diuretics, bisphosphonates should be started early in the treatment. If the patient does not have a defined cancer or oncologist, but is symptomatic or ill-appearing, inpatient work-up for malignancy is appropriate. Additionally, moderate hypercalcemia in a patient with a known malignancy can be a very grave sign, and these patients should likely be admitted.
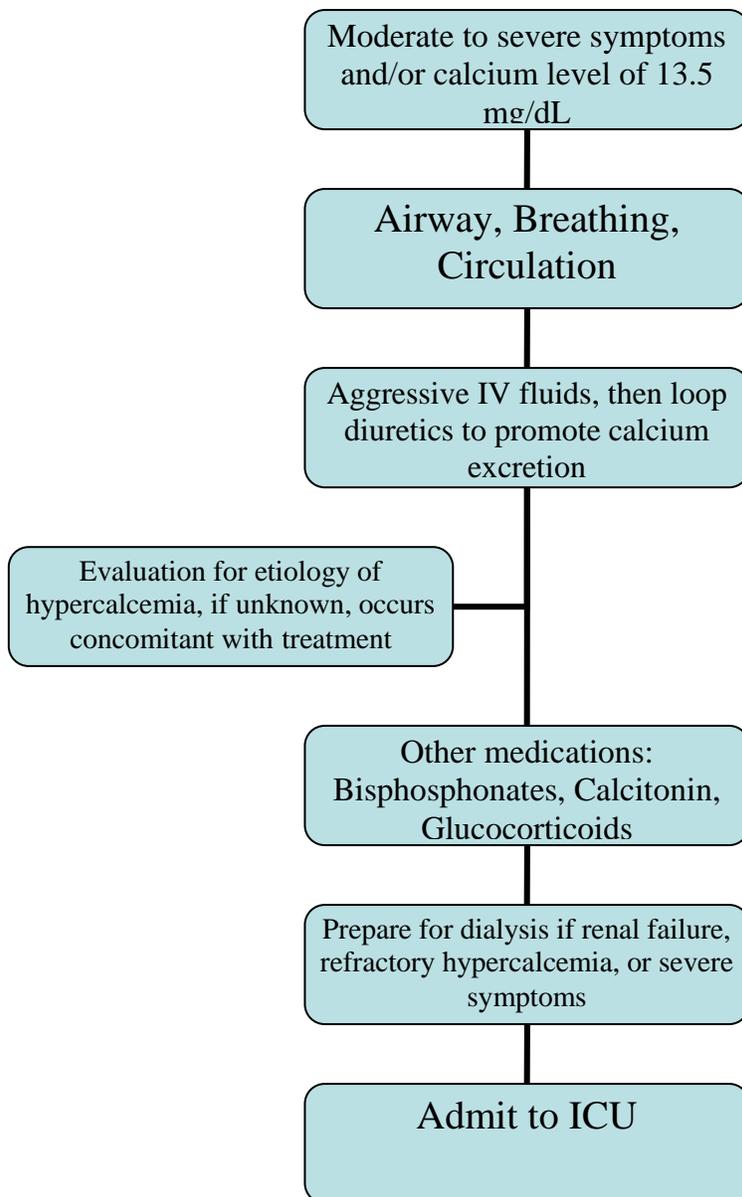
For all other patients, especially those with primary hyperparathyroidism, granulomatous disease, or other more benign etiology, re-evaluation after 12 to 24 hours of IV hydration and medications will determine further disposition. For patients who respond to therapy with a decrease in the serum calcium below 12mg/dL and are asymptomatic, discharge with very close outpatient follow up and strict discharge instructions may be reasonable.[7] All patients who fail to respond to IV fluids and diuresis or remain symptomatic will require more aggressive therapy and should be admitted.

Decisions to discharge patients on continued therapy, such as loop diuretics, bisphosphonates, or glucocorticoids should be made in conjunction with the physician who will be following the patient.

BECAUSE: Observation unit outcomes

Many observation units during a short term time period evaluate and manage patients with hypercalcemia. For selected patient the therapy is judged as effective as inpatient hospital services in reducing the hypercalcemia and cost of services are lower than inpatient services.

Management of Severe Hypercalcemia

Moderate to severe symptoms and/or calcium level of 13.5 mg/dL

Airway, Breathing, Circulation

Aggressive IV fluids, then loop diuretics to promote calcium excretion

Evaluation for etiology of hypercalcemia, if unknown, occurs concomitant with treatment

Other medications: Bisphosphonates, Calcitonin, Glucocorticoids

Prepare for dialysis if renal failure, refractory hypercalcemia, or severe symptoms

Admit to ICU

Management of Moderate Hypercalcemia

Mild symptoms and/or calcium level of 12 to 13.5 mg/dL

Known underlying diagnosis

No known underlying diagnosis

Aggressive IV fluids, then loop diuretics

Aggressive IV fluids, then loop diuretics

Other medications: Bisphosphonates, Calcitonin, Glucocorticoids

Other medications: Bisphosphonates, Calcitonin, Glucocorticoids

Patient with malignancy

Other etiologies

Evaluation for malignancy, primary hyperparathyroidism, other

Discuss with oncologist

Symptomatic

Asymptomatic

Likely admission for work-up for etiology, treatment

Likely requires admission

Likely requires admission

Admit to observation unit, reevaluate after hydration

Discharge to home only if asymptomatic and close follow-up arranged

Management of Mild Hypercalcemia

No or mild symptoms and calcium level less than 12mg/dL

- **Known underlying diagnosis**
  - **IV fluids +/- loop diuretics**
    - **Patient with malignancy**
      - **Discuss with oncologist**
      - **May start bisphosphonate in conjunction with oncologist**
        - **Asymptomatic**
          - **May be discharged with close follow-up**
        - **Symptomatic**
          - **Admit to observation unit or inpatient floor**
            - **May discharge if asymptomatic after fluids, and close follow-up**
    - **Other etiologies**
      - **Symptomatic**
        - **Admit to observation unit, reevaluate after hydration**
          - **Discharge to home only if asymptomatic and close follow-up**
      - **Asymptomatic**
        - **Discharge to home only if asymptomatic and close follow-up**

- **No known underlying diagnosis**
  - **IV fluids +/- loop diuretics**
    - **Evaluation for malignancy, primary hyperparathyroidism other**
      - **Symptomatic**
        - **May need admission for work-up of etiology**
      - **Asymptomatic**
        - **May be referred for outpatient evaluation for etiology**

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26

Observation Unit Toxicology
Jerrold B. Leikin, MD, FACEP

Toxicology: Summary   (Level B recommendation, Class II strength of evidence)
IF adult patients with toxicology exposure after emergency department (ED) evaluation and therapy require extended care and have none of the following: Respiratory depression, (PCO_2)> 45 mm Hg), Emergency Intubation, Seizures, Cardiac Arrhythmia, Hypotension (systolic blood pressure < 80 mm Hg), Unresponsiveness to verbal stimuli Second- or third-degree atrioventricular block, Emergent dialysis or hemoperfusion Worsening metabolic acidosis, Tricyclic or phenothiazine overdose manifesting with anticholinergic signs neurologic abnormality or QRS duration > 0.12 sec, or QTc duration > 0.5 sec, Administration of pralidoxime in organophosphate toxicity Pulmonary edema induced by drugs or toxic inhalation (ARDS), Drug-induced hypothermia or hyperthermia, including neuroleptic malignant syndrome Hyperkalemia secondary to digitalis overdose/ use of digoxin immune Fab fragments Body packers and stuffers, Concretions secondary to drugs, Emergent surgical intervention, Antivenom administration in *Crotalidae*, Elapidae or arthropod envenomation, Continuous arteriovenous hemofiltration, Exchange Transfusion requirement, Sustained-release beta-adrenergic blocker, calcium channel blocker, bupropion, lithium or oral hypoglycemic agent overdose, Cerebral edema Monoamine oxidase inhibitor overdose, Significant aspiration pneumonitis in the elderly Need for extracorporeal membrane oxygenation (ECMO), Delirium Tremens
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with Stabilization (Airway, Breathing/ventilation, Circulation, Supplemental oxygen (100%), Dextrose 50% in water (50 ml in adults; 2 ml/kg in children IV) or glucose evaluation, Thiamine HCL (50 to 100 mg) IV if glucose is administered, Naloxone (2 mg in adults; 0.1 mg/kg in children IV), History/physical examination of patient, with concentration on toxidrome (symptom complex), recognition, Decontamination/prevention of absorption (Gastrointestinal), Gastric lavage, Activated charcoal, Whole bowel irrigation, Antidote administration if necessary, Removal of absorbed toxic (Multiple dosing of activated charcoal, Forced diuresis (either saline or alkaline), hemodialysis, hemoperfusion, Monitoring for adverse side effects
BECAUSE the therapy is as effective as inpatient hospital services in evaluating and treating patients with toxicological exposures.

BACKGROUND

With emergency departments (EDs) playing an increasingly larger role in poison management, there are unique opportunities for observation medicine in the area of toxicology.[1-5] The observation unit may be used for monitoring and/or treatment of the poisoned or potentially-poisoned patient. Poisonings are a frequent category of illness utilized in observation units - especially pediatric units.[5] Twenty-two

percent of victims of potentially toxic exposures are evaluated in EDs annually, accounting for over 1 million visits. Sixty-seven percent of original toxicological research is published in emergency medicine journals. Emergency physicians diagnose and manage some of the sickest patients with toxic exposures.

Disposition of the toxicologic patient is frequently more challenging than in a similar patient presenting with a medical emergency. Most toxicological presentations involve an acute exposure, but the history is often vague or unreliable. Prolonged observation of even the most minimally symptomatic patient may be necessary. There may exist a significant delay from time of toxic exposure to onset of symptomatology (Table 19.1). During this "asymptomatic" interval, the practitioner may have only a nebulous history and a non-specific physical examination on which to rely. Furthermore, toxicological laboratory investigation may involve non-routine and sometimes esoteric testing procedures. Certain levels such as ethylene glycol or methanol may not be available for several hours, especially if they must be sent to an outside laboratory for processing. Patients may require monitoring or treatment during this time period.

Some patients meet criteria for intensive care monitoring (Table 19.2). Yet the majority of toxin-exposed patients do not require the intensive care unit and may be eventually discharged without acute care hospitalization if appropriately managed in the ED.[6-7] Observation of patients may take place in the ED over a number of hours but with the constraints of overcrowded waiting rooms and a limited amount of resources, this is often not feasible. Additionally, patients who need more services than can be provided in a couple of hours in the ED (such as prolonged antidote administration [Naloxone drips] or N-acetylcysteine administration or enhanced elimination of certain xenobiotics through multiple dosing of activated charcoal or whole-bowel irrigation), require admission. In many situations, the ED observation unit affords an appropriate and practical solution.

While improvements in the management of toxic patients have decreased mortality to less than 1%, there has been very little research into prolonged observation and monitoring of the toxic patient. How long to observe a potentially poisoned patient is often a challenging question. One of the most common complications of overdose patients is aspiration pneumonitis. Risk factors for development of aspiration pneumonitis include older age, a Glasgow Coma score under 15, spontaneous emesis (4 times the risk) seizures, delayed presentation to a healthcare facility (over 24 hours) and tricyclic antidepressant ingestion. The mortality in these patients can approach 9%.[9] In only few overdose/toxic exposure settings have treatment algorithms been studied dealing with observation and triage of these types of exposures.[10-13] Tokarski et al. noted that acute myocardial damage can occur in patients with cocaine-induced chest pain with normal or non-diagnostic ECGs.[10] They studied patients who reported onset of chest pain within six hours of cocaine abuse and who had normal or non-diagnostic ECGs. These patients were observed for 12 hours, with three creatinine kinase isoenzymes being obtained and utilized for admission criteria. Callaham et al. in a series of articles devised an admission and treatment algorithm for tricyclic antidepressant toxicity, which is summarized in Table 19.3[11, 12]

Smith et al. noted that alert patients with narcotic overdose did not experience delayed onset of pulmonary edema or recurrence of respiratory depression. They concluded that admission and prolonged observation is not warranted for opiate overdose patients who are awake and alert.[13] Furthermore, a recent study indicated that adult patients with opioid overdose may be safely discharged after about one hour post naloxone use if they can mobilize as usual, exhibit an oxygen saturation over 92% on room air, have a respiratory rate between 10 to 20 breaths per minute, have temperature between 35 and 37.5° normal heart rate (between 50 to 100 beats per minute) and a Glasgow coma scale score of 15.[14] Ingestion of about 5 mg/kg of codeine in toddlers requires a 4 to 6 hour observation time while propoxyphene and extended-release narcotic preparations require longer observation.[15] However, the observation unit may be appropriate for patients requiring repeated doses of naloxone or requiring a drip due to the longer half-life of certain substances such as methadone.

SELECTED EXPOSURES

Acute poison management is in the domain of emergency medicine. The basic tenets of acute poison management are listed in Table 19.4[1-5] Stabilization and decontamination of the toxic syndrome should always take place in the ED. Many antidotes (such as naloxone and the cyanide antidote) need to be administered as soon as possible for maximum effectiveness. In general, asymptomatic or minimally symptomatic patients being treated prophylactically or awaiting lab results will make appropriate observational unit patients.

Toxic Gas Inhalation

Toxic inhalants can be classified into four categories: physical asphyxiants, respiratory mucosal irritants, systemic toxicants and pulmonary sensitizers. It is important for the emergency physician to recognize the category of the inhalant in order to begin appropriate treatment (Table 19.5).[16-29] Since pulmonary edema may not manifest for 6 to 72 hours after exposure in 25% of smoke inhalation patients, it is important that symptomatic patients be observed for 24 to 48 hours (especially patients with upper airway burns or edema, hypoxemia, wheezes or rales, abnormal chest x-rays or tracheobronchitis).[19] Patients who have inhaled systemic toxicants are at high risk of complications and require observation if there exists any history or evidence of neurologic, cardiac, or hemodynamic abnormalities or a metabolic acidosis. Pregnant patients with serious systemic toxicant inhalation (ie, carboxyhemoglobin level greater than 20%) require observation. Asymptomatic patients without a remarkable physical examination and chest x-ray may be discharged after six hours of observation.

Acetaminophen

The recent introduction of continuous N-Acetylcysteine (intravenous administration of N-acetylcysteine over a 21 hour period or shorter[33]) allows the physician to complete an entire treatment protocol for this exposure within the observation unit.[30] In the acute (presentation within ten hours) exposure, individuals with potentially toxic acetaminophen ingestions (about 200 mg/kg or more), normal liver function tests, an acetaminophen blood level in the toxic range on the Rumack-Matthews nomogram can be considered for observation unit placement.

The dosing regimen for intravenous N-Acetylcysteine for adults (over 40kg in weight):

- Loading dose of 150 mg/kg in 200 cc of 5% dextrose infused continuously in 60 minutes
- Followed by a second dose at 50 mg/kg in 500 ml of 5% dextrose infused continuously over 4 hours
- Followed by a maintenance dose of 100 mg/kg in one liter of 5% dextrose solution infused continuously over 16 hours

In patients presenting with hepatic toxicity due to acetaminophen, the later infusion rate is continued until the liver function tests trends downward. Any patient demonstrating any signs of deterioration clinically or in the laboratory tests should be evaluated for transfer to higher levels of care (regular ward admission or intensive care unit). Due to cases of hyponatremia occurring in pediatric patients the intravenous volume is adjusted for individuals less than 40 kg. See Table 19.6

Substance Withdrawal

Minor withdrawal issues due to any substance (other than barbiturates) can be adequately addressed in an observation unit setting. Cocaine and amphetamine withdrawal are usually related to psychological dependence rather than a distinct physiological syndrome and thus prolonged therapy for clinical symptomatology is usually not required.

Adult opiate withdrawal can include agitation, nausea, vomiting, dysphoria, mild hypertension, tachycardia, diarrhea and pilo-erection. It usually starts within 24 to 30 hours upon cessation of use (heroin withdrawal may start within six hours of abstinence). Mental status changes and seizures do not

occur in adult opiate withdrawal (although it may occur in neonatal opiate withdrawal). The mainstays of therapy include benzodiazepines, an alpha-adrenergic agonist such as clonidine, anti-motility agents, anti-emetics and fluid/electrolyte replacement. Opiate withdrawal is rarely lethal.

Alcohol withdrawal syndromes usually begin within 24 hours of abstinence. Patients with normal mental status, no gastrointestinal signs, under age sixty years old, few co-morbid conditions and mild hyperadrenergic signs are appropriate for observation unit evaluation. Patients exhibiting alcohol withdrawal for the first time should also be considered for observation unit evaluation and those with Delirium Tremens should be admitted into an intensive care unit setting. Treatment centers on benzodiazepine therapy, fluid/electrolyte/vitamin replacement and a beta-adrenergic blocker if tachycardia/hypertension as adjunctive therapy in patients with coronary artery disease.[31]

Asymptomatic Pediatric Ingestions

Most asymptomatic accidental, single agent, pediatric ingestions can be managed in an emergency department (or even an outpatient) setting. An asymptomatic toddler, who is playful and eating well (with no emesis) about four to six hours post ingestion usually is indicative of low probability for serious delayed sequelae (with the exceptions of iron, lithium, salicylate and acetaminophen ingestions). Table 19.7 includes agents whereupon prolonged observation would be reasonable following single dosage from accidental ingestion in a toddler who is asymptomatic at the time of presentation. Symptomatic toddlers may require specific interventions along with prolonged observation.

Sulfonylurea ingestions

Well-appearing patients with persistent hypoglycemia requiring frequent glucose monitoring and dextrose and/or octreotide administration would be appropriate candidates to be managed in the observation setting.

Toxic Alcohol Ingestion

If the patient presents early (asymptomatic and without acidosis) after a reported ingestion of ethylene glycol or methanol, the patient may be monitored and given scheduled fomepizole dosing while awaiting laboratory results for levels of a toxic alcohol.

In summary, any patient who demonstrates any clinical deterioration or worsening laboratory parameters should be reevaluated and considered for transfer to the general floor, a step-down unit or the ICU. The observation unit should be reserved for those patients who appear well, are minimally symptomatic or asymptomatic, and are otherwise expected to fare well.[32] Patients who are flight-risks or at risk of self-harm should not be placed in the observation unit unless continuous one-to-one observation is available. Candidates for the observation unit should be selected on a case by case basis.

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Table 26.1 Examples of common drugs/toxins that exhibit delayed effects

Toxic Ingestion	Toxic Dose	Onset of Major Symptomatology (Latent Period)	Time to Determination of Toxic Serum Levels
Acetaminophen	140 mg/kg (adults) 200 mg/kg (children)	72 hr (hepatic phase)	4 hr
Salicylates	150 mg/kg	May not take place for 12-24 hr	6 hr
Iron	20 mg/kg	12 hr (shock, seizures)	2-4 hr
Theophylline			
Regular Formulation	10 mg/kg		5 (± 3 hr)
Sustained released	20 mg/kg		11 hr
Warfarin	0.5 mg/kg	36 hr (bleeding)	PT depression at 24 hr
Digoxin	2 mg (child) 5 mg (adult)	3-6 hr	4 hr
Ibuprofen	2.4 g (child) 24 g (adult)	Within 1 hr	1 hr
Phenytoin	Variable	1-2 hr	3-12 hr
Methanol	4 cc (100% methanol)	6-24 hr (visual)	1 hr

Table 26.2 Criteria for admission of the poisoned patient to the ICU

Respiratory depression (PCO_2)> 45 mm Hg)
Emergency Intubation
Seizures
Cardiac Arrhythmia
Hypotension (systolic blood pressure < 80 mm Hg)
Unresponsiveness to verbal stimuli
Second- or third-degree atrioventricular block
Emergent dialysis or hemoperfusion
Worsening metabolic acidosis
Tricyclic or phenothiazine overdose manifesting with anticholinergic signs neurologic abnormality or QRS duration > 0.12 sec, or QTc duration > 0.5 sec
Administration of pralidoxime in organophosphate toxicity
Pulmonary edema induced by drugs or toxic inhalation (ARDS)
Drug-induced hypothermia or hyperthermia, including neuroleptic malignant syndrome
Hyperkalemia secondary to digitalis overdose/ use of digoxin immune Fab fragments
Body packers and stuffers
Concretions secondary to drugs
Emergent surgical intervention
Antivenom administration in *Crotalidae*, Elapidae or arthropod envenomation
Continuous arteriovenous hemofiltration
Exchange Transfusion requirement
Sustained-release beta-adrenergic blocker, calcium channel blocker, bupropion, lithium or oral hypoglycemic agent overdose.
Cerebral edema
Monoamine oxidase inhibitor overdose
Significant aspiration pneumonitis in the elderly
Need for extracorporeal membrane oxygenation (ECMO)
Delirium Tremens

Table 26.3 Admission criteria for tricyclic antidepressant overdose_____

      A. Major signs of toxicity on presentation.
          1. Signs of anticholinergic toxicity
          2. Central nervous system toxicity
          3. Evidence of ECG abnormalities
          4. Hypotension
      B. Lack of peristalsis at six hours post-ingestion

      C. Clinical condition not improving at six hour post-ingestion

Table 26.4 Basic components of acute poison management_____

1. Stabilization
    b. Airway
    c. Breathing/ventilation
    d. Circulation
    e. Supplemental oxygen (100%)
    f. Dextrose 50% in water (50 ml in adults; 2 ml/kg in children IV) or glucose evaluation
    g. Thiamine HCL (50 to 100 mg) IV if glucose is administered
    h. Naloxone (2 mg in adults; 0.1 mg/kg in children IV)

2. History/physical examination of patient, with concentration on toxidrome (symptom complex) recognition

3. Decontamination/prevention of absorption (Gastrointestinal)

    a. Gastric lavage
    b. Activated charcoal
    c. Whole bowel irrigation

*4. Antidote administration if necessary

*5. Removal of absorbed toxic
        *a. Multiple dosing of activated charcoal
        *b. Forced diuresis (either saline or alkaline)
        *c. Hemodialysis
        *d. Hemoperfusion
*6. Monitoring for adverse side effects

* Appropriate components for the observation unit.

Table 26.5 Toxic inhalants

Category	Examples	Treatment Plan
Physical asphyxiants	Carbon dioxide Nitrogen Methane	Oxygen, respiratory support
Respiratory mucosal irritants	Ammonia Phosgene Chlorine	Bronchodilators, frequent tracheobronchial toilet, oxygen
Systemic poisoning	Carbon monoxide Hydrogen cyanide Hydrogen sulfide Methylene chloride	Hyperbaric oxygen (except for cyanide), appropriate antidotes
Pulmonary sensitizers	Toulene diisocyante Biologic dusts	Bronchodilators, corticosteroids

SOURCE: Kizer KW. Toxic inhalations. Emerg Med Clin North Am 1984; 2: 649-666. Adapted by permission.

Table 26.6 Dosing for patients less than 40 kilograms or on Fluid Restrictions

LOADING DOSE FOR PATIENTS LESS THAN 40 KILOGRAMS OR ON FLUID RESTRICTION

Body weight	Loading Dose: 150 mg/kg over 60 minutes	
	Acetadote ®	**5% dextrose**
30 kg	22.5 mL	100 mL
25 kg	18.75 mL	100 mL
20 kg	15 mL	60 mL
15 kg	11.25 mL	45 mL
10 kg	7.5 mL	30 mL

SECOND DOSE FOR PATIENTS LESS THAN 40 KILOGRAMS OR ON FLUID RESTRICTION

Body weight	Second Dose: 50 mg/kg over 4 hours	
	Acetadote ®	**5% dextrose**
30 kg	7.5 mL	250 mL
25 kg	6.25 mL	250 mL
20 kg	5 mL	140 mL
15 kg	3.75 mL	105 mL
10 kg	2.5 mL	70 mL

LOADING DOSE FOR PATIENTS LESS THAN 40 KILOGRAMS OR ON FLUID RESTRICTION

Body weight	Third Dose: 100 mg/kg over 16 hours	
	Acetadote ®	**5% dextrose**
30 kg	15 mL	500 mL
25 kg	12.5 mL	500 mL
20 kg	10 mL	280 mL
15 kg	7.5 mL	210 mL
10 kg	5 mL	140 mL

Table 26.7 Toxins/Medications that could cause fatality in a Toddler(under 20 kg weight) if ingested in a single dose form

A. TABLETS/CAPSULES

Amantadine
Amoxapine
Amoxipine
Amphetamines
Benzonatate
Beta-adrenergic blockers
Buspirone
Calcium channel Blockers
Chloroquine (>20mg/kg)
Chlorpramazine(>25 mg/kg)
Clonidine
Clozapine
Codeine
Colchicine
Cyclobenzaprine
Diflunisal
Diltiazem(>15mg/kg)
Disopyramide (>25mg/kg)
Haloperidol
Hydrocodone (>1.5 mg/kg)
Hydroxychloroquine (>20 mg/kg)
Hypoglycemic agents
Imipramine
Isradipine (>2.5mg)
Lithium
Lomotil®
Loxapine (>30 mg/kg)
Mefanamic acid
Meprobamate
Methadone (>1 mg/kg)
Mollindone
Monoamine oxidase inhibitors
Nifedipine (>15 mg/kg)
Olanzapine (>10 mg/kg)
Phenothiazines
Prazosin
Procainamide (>70 mg/kg)
Quinidine (>15mg/kg)
Quinine (>80 mg/kg)
Terazosin

Thioridazine (15 mg/kg)
Trazadone
Tricyclic Antidepressants (>5 mg/kg)
Verapamil (>15 mg/kg)

B. OINTMENTS/CREAM

Camphor (> 100 mg/kg)
Dibucaine (and other topical and local anesthetics)
Doxepin
Methyl salicylate (>200 mg/kg)
Podophylline 25% concentration (>15 mg/kg)
Theophylline

C. PATCHES

Clonidine   Nicotine
Fentanyl   Nitroglycerin

D. OPTHALMIC

Atropine
Imidazoline
Scopalomine

E. NON MEDICINAL SOLUTIONS

Acetonitrile
Ammonia (>10% concentration)
Ammonium Fluoride
Arsenic (inorganic)
Benzocaine
Butyrolactone
Diethylene Glycol
Ethylene Glycol (> 1 ml/kg)
Formaldehyde
Hydrofluoric acid
Hydrogen Peroxide (over 10% concentration)
Mercury (inorganic)

Methyl alcohol
Methylene Chloride
Nicotine Sulfate
Nitroethane
Pennyroyal oil
Selenious acid
Strychnine
Thallium
Toluene
Zinc chloride

E. MISCELLANEOUS

Boric Acid
Bromates (over 2% concentration)
Cigarette (one entire cigarette or three smoked butts)

27a

Hypoglycemia
Pawan Suri, MD
Taruna Aurora, MD

Hypoglycemia: Summary (Level C recommendation, Class III strength of evidence)
IF Adult diabetic patients who present to the emergency department (ED) with hypoglycemia secondary to insulin or oral hypoglycemic agents and have none of the following: Intentional drug overdose, acute renal insufficiency, persistent mental status changes despite glucose administration, impaired hepatic function or presence of an acute precipitating illness (CHF, sepsis, etc.)
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with serial blood glucose measurements, IV hydration, oral or parenteral glucose administration and IV octreotide administration if indicated.
BECAUSE carefully selected patients with hypoglycemia can be effectively managed and treated for the hypoglycemia and safely discharged from and observation unit, avoiding the costlier alternative of inpatient admission.

Background

Severe hypoglycemia is defined as an episode that is undetected by the patient or is detected so late that intervention by someone else is required to inject glucagon or take the patient to the hospital to receive IV glucose. Type I diabetic patients on intensive insulin therapy have a greater than threefold increase risk of severe hypoglycemia. Less commonly, severe hypoglycemia may also affect patients with type II diabetes who take either oral antidiabetic medications or insulin. In the DCCT trial, Type I Diabetics had a 65% incidence of severe hypoglycemia when followed over 6.5 years. In contrast, the cumulative incidence of hypoglycemia in Type II diabetics who were followed over a period of six years was 3.3% in patients taking sulfonylureas and 11.2% in patients taking insulin. Thus, hypoglycemia becomes a progressively more frequent clinical problem in Type II diabetics as they approach the insulin deficient end of the disease spectrum.

Risk factors for hypoglycemia include patients over age 65, those taking multiple medications and those who are frequently hospitalized. Commonly, patients have inadvertently taken excessive or ill-timed dose of their insulin or oral hypoglycemic agent. Decrease in exogenous

glucose delivery, as seen with missed meals, delayed gastric emptying or overnight state is a frequent cause of hypoglycemic episodes. Long acting agents like chlorpropamide and glyburide are more likely to cause hypoglycemia. Renal insufficiency is associated with a fourfold increase risk for hypoglycemia in patients taking sulfonylureas. Interaction of gatifloxacin with sulfonylureas can cause hypoglycemia.[1] This is unique to gatifloxacin and not a quinolone class effect. ACE inhibitors increase insulin sensitivity and glucose disposal, increasing the risk of hypoglycemia. Non-selective b-blockers can impair early warning symptoms leading to severe hypoglycemia.[2,3] One of the best predictors of severe hypoglycemia is a previous episode of severe hypoglycemia. The risk also increased in patients with high initial HbA1c levels that decreased quickly after intensive insulin therapy was begun. Other minor risk factors include male sex, higher insulin doses and adolescents.

Pathophysiology

In normal subjects the extracellular supply of glucose is carefully regulated by insulin and glucagon. Insulin acts to restore normoglycemia in three ways: (a) It decreases hepatic glucose production by inhibiting both glycogenolysis and gluconeogenesis, (b) Increased glucose uptake by skeletal muscle and adipose tissue by translocating glucose transporters from an intracellular pool to the cell surface, and (c) It diminishes the delivery of gluconeogenetic precursors alanine and glycerol to the liver via its antiproteolytic and antilipolytic actions.[4] Insulin also inhibits glucagon secretion by direct inhibition of the glucagon gene in the pancreatic alpha cells, [10] which further diminishes hepatic glucose production.

Response to hypoglycemia in normal subjects

The ability to suppress insulin release is an important component of the normal response to hypoglycemia. Another defense against hypoglycemia is the increased release of conterregulatory hormones, which raise plasma glucose concentration by stimulating glucose production and by antagonizing insulin induced increase in glucose utilization. In diabetics, since insulin is supplied exogenously and cannot be suppressed, the release of conterregulatory hormones becomes the primary defense against hypoglycemia. These hormones are, in order of importance, glucagon, epinephrine, cortisol and growth hormone. Glucagon acts only on the liver, increasing glucose production by stimulating both glycogenolysis and gluconeogenesis from amino acids, glycerol and pyruvate. Epinephrine, acting via b-adrenergic receptors has similar hepatic effects. It also increases the delivery of gluconeogenic substrates from the periphery, inhibits glucose utilization and via alpha-2 receptors inhibits insulin secretion. In addition, epinephrine induces early warning symptoms of hypoglycemia including anxiety and sweating. If the hypoglycemia is severe and persists for several hours, there is increased secretion of cortisol and growth hormone, which limit glucose utilization and enhance hepatic glucose production. It is important to understand that the actions of insulin and glucagon are closely linked. In the pancreatic islets of Langerhan, the insulin producing b-cells form the core, surrounded by glucagon producing alpha cells. Aterial blood enters the core of each islet, delivering substrates and information first to the beta cells and then to alpha and delta cells. The alpha cells rely heavily on the presence of functioning beta cells in order to function, a situation that is disturbed in diabetes.

<u>Glycemic thresholds in normal subjects</u>
- 80 mg/dl- Insulin secretion falls to very low levels
- 65-70 mg/dl - Release of glucagon and epinephrine, early protective response: sweating, anxiety, palpitations and tremors
- < 60 mg/dl – Early cognitive dysfunction and release of cortisol and growth hormone
- 45- 50 mg/dl – Lethargy and obtundation
- < 30 mg/dl – coma and convulsions

Response to Hypoglycemia in Diabetic Patients

The protective response to hypoglycemia is impaired in many diabetic patients. This is particularly true when hypoglycemia is induced either directly from exogenous insulin injection or indirectly from sulfonylurea stimulation. In these patients insulin release cannot be turned off and therefore glucose utilization and inhibition of hepatic glucose production continues. Further, both glucagon and epinephrine response to hypoglycemia are impaired in many diabetic patients. Diabetic patients who are well controlled (HbA1c levels <8%) may have few warning symptoms when their plasma glucose concentration falls below 60 mg/dl, The absence of epinephrine induced early warning symptoms can often lead to dangerously low blood glucose levels. The concept of hypoglycemia associated autonomic failure (HAAF) in type I DM,[5,6] posits that recent antecedent hypoglycemia causes both defective glucose counter-regulation and hypoglycemia unawareness, setting up a vicious cycle. Hypoglycemic episodes may lead to up regulation of glucose transport in the brain resulting in the maintenance of glucose uptake and therefore the prevention of warning symptoms of hypoglycemia. The compensatory increase in cortisol production during the first hypoglycemia episode may also play a critical role in minimizing the protective hormonal response during a subsequent episode. As few as 2-3 weeks of scrupulous avoidance of hypoglycemia reverses hypoglycemia unawareness and improves the reduced epinephrine component of defective glucose counter regulation.

Hypoglycemia is less common in type II DM because deficits in glucagon and epinephrine are much less prominent, and strict glycemic control is much more difficult to achieve. However, when hypoglycemia does occur in older patients, the glucose threshold for the onset of cognitive dysfunction may overlap with the onset of symptoms, thus limiting the time to initiate self treatment and increasing the risk of severe neurological events.

IF: Patient Selection

Hypoglycemic patients on long acting insulin or oral hypoglycemic agents who fail to respond to oral or parenteral glucose or show recurrence of hypoglycemia in the ED are often hospitalized for further management. While most of these patients can be successfully managed in an ED observation unit, some will require inpatient admission. These include, patients with intentional insulin or oral anti diabetic medication overdose, patients with acute or chronic renal or hepatic insufficiency, persistent mental status changes despite glucose administration or those with an acute precipitating illness like sepsis, CHF etc.

THEN: Observation Unit Management/Intervention

A thorough history is essential in determining the cause of hypoglycemia. The amount, timing and reason for any ingestion, what drug was taken, coingestants including other diabetic medications must be noted. Labs should include a basic metabolic panel and renal function with further testing as deemed necessary. Hypoglycemia will respond rapidly to IV Dextrose (D-glucose) 0.5-1 gm/kg available in 50 ml ampoules containing 25 g glucose in a 50% solution (D50). If thiamine deficiency from alcoholism or other forms of malnutrition is suspected, parenteral thiamine, 100 mg IV is given in conjunction with glucose.

Glucagon 5mg, given IM raises serum glucose levels slightly and is often used by EMS as a temporizing measure when IV access has not been established. The efficacy of glucagon is dependent upon hepatic glycogen stores, which may be depleted in the setting of prolonged hypoglycemia. Once the initial hypoglycemia is corrected, blood glucose should be measured twice more at 30 min intervals and if patient remains euglycemic, serum glucose can be checked every 4-6 hrs thereafter. If the patients respond to initial therapy with IV glucose based on clinical symptoms and serum glucose of more than 60 mg/dl, they should be fed a calorie rich meal.

If the hypoglycemia is due to an oral hypoglycemic medication, then holding the medication, feeding calorie rich meal and observation will suffice for the majority of patients. Role of Octreotide in the observation setting is less clear. If the patient develops a second episode of hypoglycemia, the authors have on occasion safely administered Octreotide, which is a somatostatin analog that inhibits insulin release from pancreatic beta islet cells. The drug is rapidly and completely absorbed when given subcutaneously, reaching 100% bioavailability within 30 minutes. In adults, the dose of Octreotide is 50-150 mcg administered by IM or SQ injection every 6 hours. It may also be given as an IV bolus over several minutes or by continuous infusion.

When discharging a diabetic patient with hypoglycemia from the observation unit, consider consulting with the patient's primary care provider or endocrinologist to determine the need for modification to the current antidiabetic regimen. Implementing a self management educational program can help the patient in control of their blood sugar.[7] Since the patient is at risk for recurrence of severe hypoglycemia following the initial episode, it is important to avoid tight blood sugar control for 1-2 subsequent weeks. Consider insulin regimens that minimize the risk of hypoglycemia.[6] In a split mixed insulin regimen, moving the dose of NPH insulin to bedtime has been reported to decrease the incidence of nocturnal hypoglycemia. Another alternative is the use of basal-bolus insulin regimen that involves the use of a long acting basal insulin analog once a day with rapid acting insulin analog with meals.

BECAUSE: Observation unit outcome

There are no randomized trials comparing outcomes for patients with hypoglycemia who are admitted to an observation unit versus inpatient service. In our experience, carefully selected patients are ideally suited to Observation management and can be safely discharged from a CDU. The controlled environment of the CDU also provides an excellent opportunity to further educate

the patients on their disease process as well as tips to avoid future hypoglycemic episodes. There could be potential cost saving for the hospital if the CDU can demonstrate earlier disposition as opposed to inpatient admission.

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27b

Hyperglycemia

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Hyperglycemia: Summary (Level C recommendation, Class III strength of evidence)
IF Adult patients who present to the emergency department (ED) with hyperglycemia and have none of the following: New onset DKA, venous Ph <7.2, acute mental status changes, End-stage renal disease, Blood glucose > 600 mg/dl, sepsis, acute CVA or acute MI
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with IV hydration, insulin, serial blood glucose and electrolyte measurements and diabetic teaching
BECAUSE carefully selected patients with hyperglycemia can be effectively managed and treated and safely discharged from and observation unit, potentially reducing costs and enhancing patient care.

Introduction

The clinical presentation of hyperglycemia in the ED varies greatly and can range from nonketotic hyperglycemia on the one end of the spectrum to diabetic ketoacidosis (DKA) on the other extreme. While some patients present with new-onset diabetes, most patients with hyperglycemia will have a prior history of type I or type II diabetes. Nonketotic hyperglycemia is also known as hyperosmolar hyperglycemic state (HHS) and differs from DKA due to the absence of ketoacidosis and the degree of hyperglycemia.[1,2] Approximately 33% of patient with hyperglycemia will have features of both DKA and HHS.[3] Regardless of the type of clinical presentation, the basic principles of hyperglycemia management are very similar.

While milder forms of DKA and HHS can be managed in an observation unit (OU), serious presentations carry significant morbidity and mortality require inpatient admission and occasionally intensive care unit admission. New-onset diabetics who do not have a primary care physician or health insurance coverage pose a unique disposition dilemma for the treating emergency physician. While these patients often do not meet acute inpatient admission criteria, it is unsafe to discharge them without proper diabetic teaching and resources to manage their disease. We find the OU especially useful for this cohort of hyperglycemia patients.

Clinical Presentation

Significant hyperglycemia classically presents with polydipsia, polyuria and polyphagia, with or without weight loss. DKA tends to develop rapidly over the course of a few hours to a day. The cardinal feature of DKA is the presence of an anion gap metabolic acidosis and ketonemia, both of which are absent in HHS.[2] Due to the metabolic acidosis, patients with DKA will often present with hyperventilation, abdominal pain and vomiting. The abdominal pain seen in DKA is thought to be due to delayed gastric emptying and ileus associated with metabolic acidosis and electrolyte abnormalities. It is rare to see abdominal pain in the absence of acidosis. In contrast, patients with HHS have a pH of > 7.30, negative urine and serum ketones and serum bicarbonate of > 20 meq/dl. While serum glucose concentration can exceed 1000 mg/dl in HHS, it is usually less than 800 mg/dl in DKA.[2] Patients with HHS are much more likely to exhibit neurologic symptoms like lethargy, confusion and obtundation because of higher plasma osmolality.[3] These symptoms do not develop till plasma osmolality exceeds 320-330 mosmol/kg. Therefore the presence of neurological deficits in diabetic patient with plasma osmolality below 320 mosmol/kg should prompt the search for alternate causes. Some patients with HHS can even have focal neurologic signs like seizures or hemiparesis.

When evaluating a patient with hyperglycemia for a possible admission to the Observation Unit, it is helpful to consider potential precipitating causes. The two most common reasons for hyperglycemia in the ED are non-compliance with antidiabetic regimen and infections.[1,3] Other causes include CVA, pancreatitis, acute MI, drugs like glucocorticoids, atypical antipsychotics and thiazide diuretics and insulin pump malfunction. Psychological problems associated with eating disorders that lead to poor compliance with insulin regimens and cocaine use may require additional resources like psychiatric consultation and substance abuse counseling.[5] The plasma osmolality can be calculated using the formula:

Effective Plasma Osmolality = [2 x Na (meq/L)] + [glucose (mg/dL) ÷ 18]

There are two main reasons for the increased plasma osmolality seen in DKA and HHS. The first is a rise in serum glucose and the second, more important reason is the loss of free water due to glucose osmotic diuresis.[2] Anuric end-stage renal disease patients with severe hyperglycemia do not exhibit the rise in plasma osmolality and rarely develop neurologic symptoms.

On physical exam, patients with DKA may have the classic Kussmaul respirations (rapid, deep breathing) and a "fruity breath" due to ketone production. The extent of dehydration in both DKA and HHS can be gauged from the physical exam, specifically looking for dry mucous membranes, decrease in skin turgor, dry axillae and hypotension.

In DKA, there are three ketone bodies produced, acetone, acetoacetic acid and beta-hydroxybutyric acid. In severe DKA, beta-hydroxybutyric acid is the predominant ketone. The commonly used nitorprusside test detects only acetone and acetoacetic acid and in rare circumstances it is possible to have a negative nitorprusside test in the presence of severe ketosis.[3] Some hospital labs offer beta-hydroxybutyric acid testing, but it is not widely available.

Serum sodium tends to decrease with rising serum glucose due to dilution from osmotic water movement out of the cells. Serum sodium concentration falls by approximately 1.6 meq/L for every 100 mg/dL rise in serum glucose.

There is an overall total body potassium deficit due to gastrointestinal losses, loss of potassium from cells due to glycogenolysis, urinary losses from glucose osmotic diuresis as well as hypovolemia-induced hyperaldosteronism. Despite a potassium deficit, the serum potassium concentration is either normal or

may even be elevated due to solvent drag from water movement out of the cell as well as insulin deficiency that impedes potassium uptake by cells. Further, acidemia plays a small role through a transcellular exchange of potassium with hydrogen ions resulting in a rise in serum potassium. Similarly, serum phosphate concentration is usually normal or high because of metabolic acidosis and insulin deficiency despite a total body phosphate deficit from osmotic diuresis and decreased phosphate intake. Insulin therapy can unmask this low phosphate that is usually asymptomatic. Clinically evident hemolysis as well as rhabdomyolysis with myoglobinuria are rare complications of the hypophosphatemia.[6]

There may be unexplained elevation of serum amylase and lipase in DKA without evidence of acute pancreatitis, therefore a diagnosis of pancreatitis in patients with DKA has to be made by clinical findings consistent with acute pancreatitis and abdominal CT scan. Leukocytosis, unrelated to infection often occurs in hyperglycemic patients but the exact etiology of this non specific leukocytosis is not known. Increase in white cell count corresponds to the degree of ketosis,[8] though WBCs> 25,000/microL or greater than 10% bands may favor an infectious etiology.

The combination of insulin deficiency and increase in ACTH, glucagon, growth hormone and catecholamines in DKA and HHS leads to lipolysis and marked hypertriglyceridemia and hypercholesterolemia. These abnormalities start to resolve within 24 hours of insulin therapy.

IF: Patient Selection

Hyperglycemic patients presenting to the ED with blood glucose level <600, and a pH >7.2 can be successfully managed in an ED observation unit provided they do not have new onset DKA, acute mental status changes, End-stage renal disease, sepsis, acute CVA or acute MI. Patients who do not meet the blood glucose and pH criteria upon ED presentation and have treatment initiated with fluid replacement and insulin are often able to meet these criteria upon reevaluation if they remain in the ED.

THEN: Observation Unit Management/Intervention

Even though patients with hyperglycemia who are admitted to an observation unit are carefully selected to exclude seriously ill patients who may require inpatient or ICU management, it is imperative to repeat a thorough history and physical exam upon transfer to the OU to identify and treat any precipitating events that may have been missed on initial ED presentation.

The primary goals of treatment of both DKA and HHS are frequent monitoring, administration of IV fluids and insulin therapy to correct hypovolemia, hyperglycemia, heperosmolality, electrolyte abnormalities and in the case of DKA, correct the metabolic acidosis.

All patients with hyperglycemia should get a complete blood count, serum electrolytes including serum glucose, BUN and creatinine, urine analysis and an EKG. If there is an anion gap or presence of ketones in the urine, patients should get an ABG and serum ketones. Optional tests may include a chest x-ray, blood and urine cultures, cardiac enzymes, amylase and lipase. For patients with new-onset hyperglycemia obtain a baseline weight and consider sending HbA1C, liver function (for Type 2), c-peptide and insulin antibodies. Even though these test results may not be available prior to discharge, they will help follow up care. Most patients will have an elevated BUN and creatinine. DKA presents with a high anion gap metabolic acidosis and low serum bicarbonate. Sometimes DKA can present with serum glucose that may be only slightly elevated or even in the normal range. This occurs in patients with poor oral intake or pregnancy.

Check serum glucose every hour while the patient is on intravenous insulin infusion. Serum electrolytes, blood urea nitrogen, creatinine should be measured every four hours.[3,9] We do not repeat ABGs during treatment and elect to rely on serial bicarbonate measurements and anion gap do determine the extent of acidosis. If needed, venous pH can be checked instead, which is about 0.03 units lower than arterial pH and is less painful for the patient.[10]

Fluid replacement - The osmotic diuresis seen in DKA and HHS leads to significant volume depletion that can average up to 6 L in DKA and 10 L in HHS.[1,3,9] In addition, for each liter of fluid lost, there is concomitant loss of approximately 70 meq of sodium and potassium. Hence one of the most important goals of therapy is to replace the intravascular volume and electrolytes. If this is done too rapidly, it can lead to precipitous lowering of plasma osmolality and cause cerebral edema. Isotonic saline (0.9% sodium chloride) is the fluid of choice and is given at a rate of 10 to 15 mL/Kg per hour, not to exceed 50 mL/Kg in the first four hours[9] with a goal of replacing estimated deficits within the first 24 hours. Response to fluid replacement can be judged by hemodynamic monitoring and urine output. As renal perfusion increases, serum glucose is further reduced by increasing urinary loss of glucose. While isotonic saline is the appropriate fluid for initial hydration, one-half isotonic saline can be used if the corrected serum sodium is normal or elevated and if concurrent potassium replacement is needed.[9] The serum creatinine is initially elevated out of proportion to the fall in glomerular filtration rate, because acetoacetate artifactually raises measured creatinine in the standard colorimetric assay. With fluid replacement, as the glomerular filtration rate rises, BUN and creatinine fall to normal levels.

Insulin therapy - Insulin remains the cornerstone of therapy for treating hyperglycemia. For treating DKA a continuous IV regular insulin drip can be started at 0.14 U/Kg per h. Alternately, the patient can be given a bolus of 0.1 U/kg followed by a continuous infusion at 0.1 U/Kg per h.[11] Both the approaches are equally effective. Contrary to popular belief, insulin lowers serum glucose primarily by decreasing hepatic glucose production rather than enhancing peripheral utilization. Insulin, in relatively low doses exerts a potent antilipolytic affect. Insulin infusion is started after ensuring that serum potassium is above 3.3 meq/L since insulin will worsen the hypokalemia and may lead to possible arrhythmias, cardiac arrest, and respiratory muscle weakness.[9]

Initial fluid repletion will reduce serum glucose by 35 to 70 mg/dL per h by increasing urinary losses and hemodilution. Addition of insulin will further reduce serum glucose. If the serum glucose does not fall by 50 to 70 mg/dL in the first hour, the insulin infusion should be doubled every hour until a steady decline in serum glucose is achieved. Higher doses of insulin will not produce greater than 50-70 mg/dL fall because the insulin receptors are already saturated.

When the serum glucose reaches 200 mg/dL in DKA or 250 to 300 mg/dL in HHS, the insulin infusion rate can be reduced by half to 0.05 U/Kg per hour and the intravenous saline solution is switched to dextrose in saline.[3] Any further reduction in the serum glucose at this time below 200 mg/dL in DKA or 250 to 300 mg/dL in HHS may promote the development of cerebral edema. Newer insulin analogs like glulisine insulin are equally effective in treating hypoglycemia. Another alternative for treating uncomplicated, mild DKA is the use of subcutaneous insulin analogs (insulin lispro and aspart).[12,13]

Insulin infusion causes a rapid reversal of potassium distribution from extracellular to the intracellular space and it is very important to carefully monitor serum potassium. If the serum potassium is initially elevated despite substantial total body potassium deficit, repletion is not begun until the serum potassium concentration falls below 5.3. The use of one-half isotonic saline is preferred when adding potassium (20-40 meq/L) since it is osmotically active and if added to isotonic saline; it will yield a hypertonic solution that will be unable to correct the hyperosmolality. The goal is to maintain serum potassium between 4.0 and 5.0 meq/L. Reversing the hyperglycemia with insulin will lower the plasma osmolality, which will

cause water to move from the extracellular fluid into the cells, thereby raising the serum sodium concentration.[9]

Bicarbonate therapy is usually not needed in the stable hyperglycemic patients admitted to an OU, though it may be indicated in severe cases with a serum pH<6.9 or severe hyperkalemia. Side effects of bicarbonate therapy include reduced respiratory drive, increase in pCO2 and paradoxical CNS acidosis. Bicarbonate administration can also slow down the rate of recovery of the ketosis and lead to a post treatment metabolic alkalosis.

Despite the hypophosphatemia accompanying insulin therapy, routine use of phosphate replacement is not recommended because of potential side effects like hypocalcemia and hypomagnesaemia. Phosphate replacement in the form of 20-30 meq/L of potassium phosphate added to replacement fluids is reserved for patients with a serum phosphate of < 1.0 mg/dl or patients who show signs of cardiac dysfunction, hemolytic anemia, or respiratory depression.

Cerebral edema and noncardiogenic pulmonary edema are rare complication of the treatment of DKA and HHS. Most cases of cerebral edema are seen below the age of 20.[14] OU management should include looking for symptoms like headache that may develop within 12 hours of therapy. Once developed, cerebral edema can progress rapidly to obtundation, seizures and death, with an overall mortality between 20 and 40 percent.[9] Ensuring that initial fluid replacement does not exceed 50 mL/Kg in the first four hours and not letting the blood glucose fall below 200 by switching replacement fluids to dextrose (see above) are two strategies used to prevent cerebral edema. Both mannitol and hypertonic saline have been used to treat cerebral edema.[14]

New-onset Diabetics- All the new-onset diabetics in our observation unit get a literacy test. We use REALM-R (Rapid Estimate of Adult Literacy in Medicine, Revised) available at adultmeducation.com to gauge the ability of English speaking patients to understand diabetes teaching packet instructions. Low literacy instruction pamphlets are available. Patients also get a visual acuity to determine if they are able to measure insulin accurately. Insulin pens are preferred for visually impaired patients. If available, a diabetes educator (usually a nurse or a mid-level provider) are excellent resources and should be involved in patient management.

For all Type 1 diabetics, who are usually thinner and insulin sensitive we start insulin at a total daily dose of 0.3 units/kg/day[15] and recommend an endocrinology consult. We use a single daily subcutaneous injection of the long acting Glargine insulin (Lantus) along with 4 units of Humalog at the largest meal. If the patient is unable to afford the Lantus, we start NPH insulin twice a day in divided doses of 0.15 Units/kg/day. We ensure the patient can perform self glucose monitoring and is able to self administer insulin and provide the patient with a blood glucose meter or a prescription to get one.

For Type 2 diabetics, who are typically obese and insulin resistant we use oral antidiabetic medications and insulin, either alone or in combination. For patients with blood glucose <200, start monotherapy with metformin 500mg twice a day unless there is a contraindication (serum creatinine >1.5, CHF, elevated liver enzymes, alcohol abuse or IV contrast within 48 hours). Patients with blood glucose>200 can start once daily Lantus at 0.4 units/kg/day and metformin 500mg twice a day. Another option is to start NPH insulin 0.2 units/kg twice a day along with metformin 500 mg twice a day.[16] All patients must have access to a glucose meter and be able to use it.

BECAUSE: Observation unit outcome

There are no randomized trials comparing outcomes for patients with hyperglycemia who are admitted to an observation unit versus inpatient service. Patients with uncomplicated DKA or HHS respond well to Observation Unit management with fluid replacement and insulin and can be safely discharged. The OU also provides an opportunity for diabetic teaching that includes self blood glucose monitoring and insulin administration.[17] There could be potential cost saving for the hospital if the CDU can demonstrate earlier disposition as opposed to inpatient admission.

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28

Confusion
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Confusion: Summary (Level C recommendation, Class III strength of evidence)
IF adult patients with confusion after emergency department (ED) therapy require extended evaluation and care and have none of the following: abnormal vital signs, visual hallucinations, elderly, new EKG changes or positive biomarkers, known organic disease, seizure, history of headache, loss of coordination, focal neurologic findings
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with further evaluation and medications to control the symptoms
BECAUSE the therapy is as effective as inpatient hospital services in evaluating and treating the confusion and cost of services are lower than inpatient services.

Goals

The physician has two goals in his approach to the confused patient. The first goal is to identify patients that are confused. The changes in higher neurologic function may not be evident to the physician and only become apparent on questioning the patient's family or friends. The physician's focus may be on other aspects of the patient's condition and the confusion not identified. A patient should be considered confused if he has two or more of abnormalities of the neurologic functions listed in Table 1. Another method of detecting the confused patient is the confusion assessment method (CAM).[1] A patient is considered confused who these abnormalities in neurologic functions: acute onset and fluctuating course, inattention, disorganized thinking, and altered level of consciousness.[1] Medical terms frequently used to describe the confused patient are delirium or acute organic brain syndrome.

The second goal is to discriminate which of the patients are seriously ill and need hospitalization. Delirium is common among elderly emergency department patients and a predictor of poor outcome.[2-3] In hospital mortality for the patient with confusion ranges from 25% to 35%.[4-6] The initial physician's evaluation is often inadequate. From 32% up to 76% of patients with a state of acute confusion are not correctly identified during the first physician's evaluation - the confusion is not recognized, the patient's symptoms are ascribed to another problem, or the physician diagnoses the wrong cause of the confusion.[7-10]

Yet, many patients with acute confusion are not seriously ill. Many patients have a benign and treatable cause. Thus many patients with confusion do not need to be hospitalized if the benign aspect of their condition can be identified during a short period of observation.

IF: Patient Selection

Observation should be considered after initial emergency department evaluation for any

patient who does not have a clearly identified cause of their confusion and is judged to have a possible pathologic cause of their confusion. For those patients with confusion who have clear evidence of a pathologic condition the patient should be admitted (eg, abnormal vital signs, visual hallucinations, elderly, new EKG changes or positive biomarkers, known organic disease, seizure, history of headache, loss of coordination, focal neurologic findings).

THEN: Approach to the Patient with Confusion
The assessment, treatment, and ultimate disposition of patients with confusion is dependent upon a thorough evaluation for serious dangerous conditions. Every patient with confusion needs a complete history and physical. Screening tests should include CBC, lytes, blood sugar, U/A, selected toxic screens, serum calcium, oximetry (or ABG), EKG, CXR, and lumbar puncture (unless counterindicated). Selected cases should have a head CT scan or head MRI or EEG.[11] The physician should be hesitant to ascribe the patient's confusion to functional disease when there are any findings suggestive of organic disease (Table 2). A psychiatric or benign cause of the confusion should not be assumed until all organic causes have been ruled out. When there is a high degree of suspicion the patient has a serious condition, the patient should be admitted to the hospital.

Differential Diagnosis
The causes of acute confusion are listed in Table 3. The physician's emergent evaluation is focused on identifying those patients with a serious or dangerous cause of their confusion.

Meningitis
Patients with meningitis often present with confusion, especially the elderly. Classic symptoms of meningitis are fever, confusion, repeated vomiting, seizure, headache, chills, stiff neck. Physical findings common in the more advanced cases of meningitis are stiff neck (80%), change in consciousness (96%), and neurologic symptoms (50%) such as seizures, babinski sign, doll's eyes, fixed pupils, hemiparesis, nystagmus, abnormality of cranial nerves.
Unfortunately the presentation of the patient with meningitis is often subtle[12]. In 50% of patients meningitis presents subacutely over 1 to 7 days with one third having respiratory symptoms. In 20% of patients the meningitis presents over 1 to 3 weeks, usually with respiratory symptoms. One fourth of patients with meningitis present acutely without prodrome.
The physician must have a low threshold for considering the diagnosis of meningitis if to not miss the diagnosis since many patients with meningitis do not have the classic signs and symptoms.[12-14] Meningitis should be considered in any patient with altered level of consciousness, unexplained seizure, severe unexplained headache, neck stiffness, unexplained fever, or new onset focal neurologic deficit. Meningitis should be considered in any patient with risk factors for developing meningitis such as immunosuppressive treatment, diabetes mellitus, alcoholism, recent neurosurgery, hematologic malignancy, transplantation, or AIDS. In the elderly the physician always must have a high suspicion of meningitis since it often presents subtly. Symptoms are often nonspecific symptoms such as somnolence, decreased intake by mouth, or low grade fever.[12-14] Suspicion of meningitis must be high in small children. Symptoms are also often nonspecific such as fever, repeated vomiting, seizure, irritable, or headache. Any child less than 2 months old with a fever should have a lumbar puncture test.[15-16] Any child 2 to 6 months old with a fever should have a lumbar puncture test if the child appears ill without evident cause or has signs of sepsis (high fever, high white blood count).[15-16]

Early diagnosis and treatment is the key to preventing serious or fatal pathology. The physician must have a very low threshold for doing a lumbar puncture to diagnose meningitis in many patients – the clinical pearl expressing this need for a low threshold is "if you think of doing a lumbar puncture, do it." For some patients, especially the elderly, the physician will not think of the need for lumbar puncture without a period of observation. During observation the data base on the patient expands and the differential diagnosis is revised.

Subdural Hematoma

Chronic subdural hematoma is known as the "great masquerader" because of the protean manifestations of the disease. Often the physician cannot find a history of the patient having a fall. Often the symptoms do not focus the physician on a central neurologic cause of the patient's illness. It should be considered in any patient with confusion or headache, especially if the patient is elderly, or on chronic anticoagulants.

Subarachnoid hemorrhage

Usually the patient with a subarachnoid hemorrhage will have a severe headache. At times the predominant complaint of the patient is confusion. There is further discussion of subarachnoid hemorrhage in the headache chapter.

CVA

A CVA should be considered in any patient with acute confusion. Focal neurologic findings may be present as a clue to the diagnosis, eg, hemiparesis or aphasia. In other patients there will be no focal neurologic deficits and the physician must rely on a low threshold for CT scan imaging of the head.

Toxic Effects

Almost one third of episodes of acute organic brain syndrome are due to the effects of toxic agents, abused substances, or adverse reactions to prescribed medications.[17-18] The most common substances are hallucinogens (LSD, PCP), and anticholinergic drugs (tricyclic antidepressants, atropine, antihistamines, phenothiazines). A toxic screen may identify the substance that the patient and family will not or cannot identify. Confusion is often a prominent component of the symptoms of withdraw from alcohol, amphetamines, and barbiturates.

Thiamine deficiency

Thiamine deficiency is a common treatable cause of confusion in the elderly and the alcoholic. When confusion is associated with nystagmus and oculomotor palsies, the diagnosis is Wernicke's encephalopathy. A bolus of glucose can precipitate the encephalopathy. Thus a bolus of intravenous thiamine (100 mg) should be given in the confused or high risk patient before a bolus of intravenous glucose.

Metabolic Abnormality

Many metabolic or endocrine abnormalities present as confusion. In the initial evaluation of any patient with acute confusion a series of blood tests should be ordered to rule out a metabolic cause of the patient's disease. The changes in higher neurologic function may only be evident to the family or friends for the patient with a mild to moderate abnormality, eg, sodium 115.

Infection

Confusion can be a toxic sign of infection or pre septic shock. Fever, chills, and rigors are other clues to the presence of sepsis. Selected infections often have neurologic symptoms in their clinical presentation, eg, legionella pneumonia.

Tumor

Confusion is one of the most common findings in the patient with a brain tumor. 60% of patients with brain tumor have signs of confusion by the time the diagnosis is made. Other findings suggestive of tumor are headache, vomiting, seizures, or focal neurologic findings.

Treatment

Costs

The cost savings with comprehensive observation programs are quite substantial for patients with confusion. The presence of confusion in patients in the emergency department has been shown to significantly increase hospital length of stay and thus costs.[19] A short period of observation can reduce cost by prevent admission for many patients by showing they do not have a serious dangerous disease. For other patients, observation can reduce cost by reducing length of stay by more rapidly identifying the patient's serious dangerous cause of their confusion and more rapidly initiating needed therapy.

Table 1: Findings suggestive of a confusion state

Judgment poor
Orientation poor
Intellect worsening
Memory (recent) worsening
Calculating ability poor
Learning difficulties
Affect labile
Personality change

Table 2: Findings suggestive of organic disease

Abnormal vital signs
Visual hallucinations
Elderly
On medications
Known organic disease
Alcohol or substance abuse
History of headache
Loss of coordination
Focal neurologic findings

Table 3: Differential diagnosis of confusion

Organic

Drug Effects:
opiates, barbituates, bromide, thallium, cimetidine, lead, tricyclic antidepressants, caffeine, theophyline, antichlinergics (atropine), hallucinogens (LSD,PCP), CNS stimulants (cocaine)

Infections:
systemic, CNS (meningitis, encephalitis, abscess)

Withdrawal:
alcohol, barbiturate, amphetamine, etc.

Metabolic:
hyponatremia, hypoglycemia, hyperglycemia, hypoxia, hypercapnia, liver failure, uremia, acidosis, alkalosis

CNS:
seizures, post-ictal, infections (meningitis, abscess, encephalitis), tumor, subarachnoid hemorrhage, subdural hematoma, cerebral contusion, epidural hemorrhage, heat stroke

Deficiency:
thiamine, niacin, vitamin B12

Cancer:
primary, metastasis

Psychiatric

Acute schizophrenia
Manic state
Paranoid state
Grief reaction
Depression
Conversion reaction

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Headache

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Headache: Summary   (Level C recommendation, Class III strength of evidence)
IF adult patients after initial emergency department (ED) treatment require further therapy and have none of the following: abnormal CT scan demonstrating lesion requiring immediate surgical intervention, evidence of intracranial or subarachnoid hemorrhage, evidence of bacterial CNS infection (bacterial meningitis, CNS abscess), hypertensive crisis, or features of high-risk headache such as acute altered mental status, seizures and headache (in a patient not known to have epilepsy), acute loss of vision (consider acute glaucoma or stroke), AIDS or other significant comorbidity, new focal neurological signs, nuchal rigidity, abnormal vital signs, and abnormal ophthalmic findings (eg, unequal or sluggishly reactive pupils).
THEN these patients can be further evaluated and treated in an ED based Clinical Decision Unit (CDU) for up to 24 hours with additional treatment for the headache and diagnostic evaluation, as warranted.
BECAUSE CDU therapy is as effective as inpatient hospital services in treating and resolving the headache, and the evaluation can be accomplished in the CDU as easily and safely as in the inpatient hospital, and the cost of services in the CDU are lower than inpatient services.

BACKGROUND

Headache is a relatively common presenting complaint making up 1% of all ED visits.[1,2] Fortunately, most of the complaints stem from benign causes. The challenge in the ED is to identify patients with serious or life-threatening causes of headache. A period of observation will aid in the screening process, and provide symptomatic relief to the patient.

Migraine is a relatively common disorder, affecting about 18% of American women and 6% of American men.[3] Migraine patients usually present to the ED because of a severe attack, or have failed medications at home. Typically, they suffer from repeated episodes of unilateral throbbing headaches associated with nausea, vomiting, photophobia, phonophobia, and an aura.

Tension headache is an extremely common headache with an estimated annual prevalence of 11% and up to 78% of the adult population suffering from a tension headache at some point in time.[2]

Patient Selection: Inclusion and Exclusion Criteria

Patients are appropriate for observation who have a headache after ED therapy, require additional treatment of their headache pain, and/or further diagnostic evaluation; and have none of the following: abnormal CT scan demonstrating lesion requiring immediate surgical intervention, evidence of intracranial or subarachnoid hemorrhage, evidence of bacterial CNS infection (bacterial meningitis or CNS abscess), or hypertensive crisis.

Patients who have features of high-risk headache should not be admitted to the observation unit. Signs and symptoms of high-risk headache include acute altered mental status, seizures and headache (in a patient not known to have epilepsy), acute loss of vision (consider acute glaucoma or stroke), AIDS or other significant comorbidity, new focal neurological signs, nuchal rigidity, abnormal vital signs, and abnormal ophthalmic findings (eg, unequal or sluggishly reactive pupils).

Patients who have symptoms that can be explained by other disease processes should be managed accordingly, and may not require observation based on their headache symptoms.

The clinical decision unit (CDU) or observation unit (OU) is beneficial:

- To evaluate the patient who is considered low risk for serious causes of headache, but whose symptoms cannot be explained by another disease process.
- To treat certain patients with a secondary cause of headache.
- To evaluate and treat the patient with a clinically benign headache, but in which the severity may render the patient not ready to be discharged.
- To observe and treat the patient who was initially assessed to have a possible high-risk headache, but has a negative CT and negative LP, and is still symptomatic.

Management/Intervention

The goal of the CDU is to treat the patient's headache pain, to do further evaluation in order to make a specific diagnosis for the headache, and identify patients with a serious cause of headache, which may not have been apparent at the initial presentation.

The CDU serves to further evaluate patients who do not have high-risk features of headache, and do not have symptoms that can be explained by other causes, such as: known migraines, or sinusitis. A period of symptomatic treatment and observation would provide additional information to make a more definitive diagnosis. Most of them have primary headache, of which migraine most common. If, however, during the period of observation, the patient develops any high-risk features, he/she should be investigated urgently and appropriately.

Pathophysiology: Migraines

The mechanisms underlying the etiology, pathophysiology and progression of migraine headaches are not fully understood. Migraine symptoms are the result of a complex interplay of genetic factors, the trigeminovascular system, peripheral and central neuronal dysfunction, and brainstem pain modulating systems. The early "vascular" hypothesis proposed migraine as a vasoplastic disorder, initiated by vasoconstriction in the cranial vasculature. However, vasodilation alone cannot explain the local swelling and tenderness of the head that sometimes accompanies migraine.

Migraine is now considered a neurovascular pain syndrome.[4,5] Reduced levels of magnesium and increased levels of calcium and glutamate are thought to cause abnormal neuronal excitability, leading to depressed electrical activity spread to adjacent areas of the cortex (a phenomenon called cortical spreading depression) and peripheral sensitization of the trigeminal vascular system. Abnormal neuronal excitability in the caudal nucleus is linked to central sensitization. Prostaglandin is thought to aid in maintaining central sensitization. Cutaneous allodynia (the perception of pain resulting from ordinarily painless stimulation of normal skin or scalp) has been associated with central sensitization.[6] Prostaglandins and cyclo-oxygenase enzymes play a key role in establishing and maintaining central sensitization.[7,8] The termination of migraine in patients with ongoing allodynia is achieved through suppression of central and peripheral sensitization.[9]

Pathophysiology: All Headaches

Currently, the pathophysiology of all headaches is thought to result from traction or inflammation of any of a number of structures including intracranial structures: the main arteries at the base of the skull, the basal dura/dural arteries, the great venous sinuses and their branches, and the large intracranial arteries and veins; and extracranial structures: skin, mucosa, blood vessels, nerves, muscles and fascial planes.[1] Surprisingly, the brain parenchyma itself, pia mater, and most of the dura (exception is the dura at the base of the skull) are unable to produce painful stimuli.

Four pathophysiologic mechanisms are implicated in causing headaches: tension, traction, inflammation, and vascular processes. Tension occurs from contraction of muscles of the head and/or neck and is implicated as the main reason for tension headaches. Stretching of intracranial structures causes traction, which is due to a mass effect, as occurs with a tumor, an intracranial bleed (eg, subdural hematoma, epidural, or intracerebral hematoma), or an abscess. Inflammation can occur with intracranial or extracranial structures, as with subarachnoid hemorrhage, meningitis, sinusitis, mastoiditis, and possibly neuralgias. Distension/dilatation of vascular structures accounts for the vascular mechanism, which occurs with headaches from severe hypertension and migraines. It should be remembered that any given headache may be due to one or a combination of these four pathophysiologic mechanisms.[1]

Specific Headache Therapy

For headache patients with continued pain and/or protracted vomiting despite ED therapy, intravenous fluids and antiemetics in addition to specific medications for the headache pain is beneficial. A quiet and dimly lit room in the CDU would make the headache sufferer (especially those with migraines) more comfortable.

Specific Headache Therapy: Migraines

Parenteral therapy is generally warranted for ED patients with migraine headaches since the majority have already tried (and failed) oral medications.[2] NSAIDS eg, ketorolac, which act as prostaglandin inhibitors, may be given parenterally at a dose of 30 mg.[9] Ketorolac may be given again 6 hours later, if needed. It may be given with a dopamine antagonist, eg, metochlorpromide or prochlorperazine.

Abortive therapy in migraine aims to stop the inflammation mediated by 5-hydroxytryptamine $(HT)_{1D}$ and $5HT_{1B}$ receptors. Ergot alkaloids have a long history in the treatment of migraine. Intravenous dihydroergotamine (DHE) has been shown to abort central

sensitization of the trigeminovascular pathway in animals[10] and is useful when administered during the migraine prodrome at the time the headache starts, and once allodynia is established.[4] A systemic review found that DHE was not as effective as sumatriptan or phenothiazines as a single agent in the treatment of acute migraine, but when combined with an antiemetic, it was as effective as opiates, ketorolac or valproate.[11] As such, most treatment regimens include metochlorpromide or prochlorperazine as an adjunct. DHE may be repeated 1 hour later, if needed. DHE should be avoided in pregnancy, ischemic heart disease, and peripheral vascular disease, because of its vasoconstrictive properties.

Triptans act peripherally to block the transmission of pain signals from nociceptors of the dura. Triptans are effective in terminating the throbbing and positional pain of migraine attributable to peripheral sensitization. Triptans are more selective $5HT_{1D}$ agonists than DHE, and cause less nausea and vomiting. Sumatriptan administered subcutaneously at doses of 4 or 6 mg was found to be well tolerated and efficacious in treating acute migraine in the ED.[12,13] It may be administered again 1-2 hours later, with a maximum of two injections per day. Triptans should be used only after the diagnosis of migraine has been established. Contraindications to the use of triptans are similar to those for DHE and for the same reason. Since both cause vasoconstriction, sumatriptan should not be given within 24 hours of the administration of DHE or other ergots.[14]

Dopamine antagonists have been used successfully to alleviate the nausea and vomiting associated with migraine. Commonly used as antiemetics in combination with DHE or ketorolac, they may also be used as inexpensive monotherapy alternatives. A meta-analysis of 13 trials found that metoclopramide was effective in improving pain, nausea and relapse outcomes in acute migraine when compared with placebo, and the authors recommended metoclopramide as a primary agent in the treatment of acute migraine in the emergency department.[15]

Neuroleptics can be used to treat nausea and vomiting in acute migraine attack. Their effects are mediated via the dopamine-2 receptor blockade.

Magnesium has been proposed to play a role in the pathophysiology of migraine. Intravenous magnesium has been studied in several trials, with varying results.[16-21] In a trial comprising 120 patients, magnesium was found to significantly improve the pain and associated symptoms of migraine only in patients who had migraine with aura.[16] The counter-therapeutic cerebral vasodilatory effects of magnesium was proposed to be contributory to the variable results of magnesium therapy for headaches.[16-21]

The use of intravenous valproate has been used in the abortive treatment of acute migraine and other primary headache disorders and for migraine prophylaxis.[22-24] When compared with the combination of intramuscular DHE and metoclopramide, intravenous valproate showed similar effectiveness in aborting nausea, photophobia and phonophobia associated with migraine in patients with prolonged moderate to severe symptoms.[23]

Intravenous corticosteroids such as dexamethasone or methylprednisolone may be an option for intractable migraine,[25,26] and intravenous dexamethasone has also been shown to reduce headache recurrence at 48-72 hour follow-up.[27]

Concern for addition should not be a consideration in using opioids to treat acute episodic headache in the ED.[1] However, because of the low success rate and the high reoccurrence of headaches with opioid use, opioids should be used when other therapies have failed or are contraindicated.[1] Opioids are rarely indicated for the treatment of chronic headache pain since daily opioid use can cause analgesic rebound headaches and there is the possibility of narcotic abusers in this patient population.[1,28]

Unconventional approaches have been described in the treatment of headaches. Complete relief occurred in 65.1% and partial relief in 13.7% of patients treated with bilateral lower cervical paraspinous intramuscular injections with 0.5% bupivacaine.[29]

Relief was rapid, usually within 5-10 minutes. Associated symptoms of nausea, photophobia, and allodynia were also commonly relieved. The mechanism of relief is thought to be secondary to calming of the trigeminocervical complex.

Nerve blocks for the treatment of headache have been reported. Supra-orbital and greater occipital nerve blockage by pain specialists in migraine patients are reported to be effective.[30] Greater occipital nerve block and trigger point injections are also reported to be effective in reducing the pain of migraine and brush allodynia.[31] Greater occipital nerve blockades have also been used to alleviate symptoms of postconcussive headaches.[32]

Currently, the triptans and the phenothiazines are the most effective drugs for the treatment of migraine headaches.[1]

Specific Headache Therapy for Headaches Other than Migraine Headaches

Patients with post-LP headache may be relieved with hydration, lying supine, and medications. Caffeine may be given intravenously as a bolus or through a drip. Epidural blood patch is considered if other treatment measures fail to provide relief.

High-flow oxygen inhalation is the first-line of treatment for cluster headaches but sumatriptan is also effective[33] and dihydroergotamine may also be employed.[34]

Patients who have had a negative CT scan and a negative lumbar puncture, but who are still symptomatic may be admitted for further evaluation and may be given symptomatic treatment and observed in the CDU.

Patients with chronic daily headaches (CHD) may frequent the ED with headache complaints. Many of these patients began with episodic headache attacks which increase in frequency over time, often in association with medication overuse. Episodic tension-type headaches can evolve to chronic tension-type headaches, and episodic cluster headaches may progress to chronic cluster headaches. Establish if there has been an overuse or abuse of analgesics, as this may perpetuate the chronic pain cycle. Parenteral and intranasal DHE, NSAIDs, dopamine antagonists, and parenteral divalproex (valproic acid) are often useful symptomatic treatments with little potential for causing medication-overuse headaches.[35] Management workup includes eliciting any psychiatric overtones and concurrent substance abuse and preventive treatment.

When indicated, consultation with appropriate headache or neurology specialists may be obtained in the CDU and initiation of prophylactic therapy for headaches may be started upon discharge from the CDU.

Disposition after Observation

Most patients with headache can be discharged after a period of time in the CDU. If, however, the patient develops any high-risk signs or symptoms, or the pain remains unchanged or worsens with therapy, he/she should undergo further evaluation and therapy, as an inpatient.

SUMMARY

The goal in the evaluation of headache in the ED is to obtain early diagnosis and management for patients with headaches. A period of observation in the CDU aids in the process, by diagnosing patients who may have been undiagnosed in the initial brief ED visit, and

by treating those with continued pain and/or vomiting despite ED therapy. Symptomatic treatment, observation, and further diagnostic evaluation in the CDU is appropriate for patients with severe symptomatic but benign headaches.

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Seizures

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Seizures: Summary   (Level C recommendation, Class III strength of evidence)
IF adult patients after initial emergency department (ED) evaluation and management have a normal or baseline neurologic examination and a history of epilepsy with breakthrough seizures, alcohol withdrawal seizures, uncomplicated febrile seizures, new onset seizures, and posttraumatic seizure after blunt head trauma and none of the following: a CT scan demonstrating need for immediate surgical intervention, status epilepticus, acute cerebrovascular accident, bacterial meningitis, subarachnoid hemorrhage, delirium tremors, eclampsia, patients with focal deficits unless explained (eg, hemiplegic migraines), persistent altered mental status, and AIDS.
THEN these patients can be further evaluated and treated in an ED based Clinical Decision Unit (CDU) for up to 24 hours with serial examinations including neurologic checks and vital signs, pulse oximetry and EKG/rhythm strip monitoring, intravenous fluids, and medications including anticonvulsants as needed and diagnostic evaluation such as CT scan, EEG, MRI, laboratory studies, and neurology consultation.
BECAUSE CDU therapy is as effective as inpatient hospital services in treating and resolving the seizures, in diagnosing events that mimic seizures, to confirm whether or not a seizure did occur, and if yes, rule out secondary causes of the seizure, classify the seizure, and begin treatment. This evaluation can be accomplished in the CDU as easily and safely as in the inpatient hospital, and the cost of services in the CDU are lower than inpatient services.

Background

Patients with seizures or presenting complaints related to seizures represent approximately 1% to 2% of all ED visits in the United States.[1] About 5% of the population will experience a non-febrile seizure during their lifetime.[2] Febrile seizures are the most common seizures seen in children younger than 5 years old.[3] Febrile seizures occur at some point in 2% to 4% of children worldwide.[4] Epilepsy is defined as recurrent unprovoked seizures. There are an estimated 2.5 million patients with epilepsy in the United States with a prevalence of about 6.6 per 1,000 Americans.[5,6] Outcomes successful observation unit management of patients with seizures has been documented. However, specific outcomes research is not available.

Seizures are classified as primary or secondary seizures. Primary seizures (epilepsy) are seizures that occur without a known cause. Secondary seizures are a result of specific brain irritants. Both primary and secondary seizures may be partial or generalized. The first task is to determine whether the acute episode is a seizure. Not all paroxysmal events are seizures. Common mimickers include syncope, hyperventilation syndromes, migraine attacks, breath-holding spells, sleep disorders, movement disorders,

and psychogenic seizures. Once the diagnosis of seizure is made, the next step is to classify the seizure and rule out secondary causes of the seizure.

Patient Selection: Inclusion and Exclusion Criteria

Patients are appropriate for observation who have a history of epilepsy with breakthrough seizures, alcohol withdrawal seizures, uncomplicated febrile seizures, stable adults with new onset seizures, and posttraumatic seizure after blunt head trauma with normal or baseline neurologic examination.

Seizure patients are not appropriate for a clinical decision unit who have a CT scan demonstrating need for immediate surgical intervention, status epilepticus, acute cerebrovascular accident, bacterial meningitis, subarachnoid hemorrhage, delirium tremors, eclampsia, patients with focal deficits unless explained (eg, hemiplegic migraines), persistent altered mental status, and AIDS.

Management/Intervention

The goal of the CDU is to continue the treatment of the patient's seizures that was begun in the ED, and continue the evaluation of the patient for serious dangerous causes of their symptom. This includes serial examinations with neurologic checks and vital signs, pulse oximetry and EKG/rhythm strip monitoring, intravenous fluids, and medications including anticonvulsants as needed. It also includes diagnostic evaluations such as CT scan, EEG, MRI, laboratory studies, and neurology consultation can be done. Such an evaluation may be able to diagnose events that mimic seizures, to confirm whether or not a seizure did occur, and if yes, rule out secondary causes of the seizure, classify the seizure, and begin treatment, if indicated.

Laboratory studies are not always indicated in patients who have returned to their normal mental status with an intact neurological examination.[7-9] Labs should be targeted at patients who are at risk. For example, bedside capillary sugar for hypoglycemia in a diabetic patient, electrolytes in renal failure patients, and lumbar puncture for suspected meningitis even if lumbar puncture is not immediately performed but is done after antibiotics are administered.

Neuroimaging is generally performed as part of the evaluation of a first seizure. This procedure may be performed as part of the initial ED or observation unit (OU) evaluation.

Many patients with seizures can be adequately assessed and treated in an ED observation unit. These are the patients with stable vital signs, a single seizure episode, a normal or baseline neurologic examination, and a normal mental status. They should have a low probability of significant secondary causes and should be able to be discharged after 24 hours of observation.

The most common cause of breakthrough seizures in a known epileptic is poor compliance with established medication regimes, therefore, the level of prescribed anticonvulsants should be measured. Once the secondary causes have been ruled out and if the antiepileptic drug level shows sub-therapeutic levels, the patient may be safely admitted into the OU for antiepileptic drug loading and observation. The patient may be discharged with instructions and neurology follow-up if there are no further seizures in the OU and return of normal mental status.

There is always a question whether the first seizure is really a seizure. A prospective descriptive study demonstrated that only 52% of the 232 patients referred to the neurology clinic had a specialist diagnosis of seizure. Among these: alcohol, sleep deprivation and recreational drugs were the most common precipitating factors cited.[10] Thus, the admission of a young and/or "previously healthy" patient with a single first episode of seizure into an OU is appropriate provided there is full recovery to normal or

baseline neurological status. With the use of extended observation and screening, the ED physician could correctly identify the patient's need for hospitalization in 90 of 91 patients (99%) presenting with first major motor seizure and helped ruled out any serious cause.[11] EEG and imaging can be done in the OU if indicated.

The psychological, social, and legal implications of the new diagnosis of a seizure disorder should not be underestimated. The use of an ED OU will allow the physician more time to confirm the diagnosis (less likely to erroneously label a patient with a seizure disorder), and discuss and counsel the patient on the above issues.

Simple febrile seizures may be admitted to the observation unit for further observation, parental assurance, and education. Treatment is aimed at lowering the temperature and treating any secondary cause of fever. Children with simple febrile seizures can usually be sent home with antipyretics for the duration of the illness and adequate discharge advice and follow-up with a primary care physician. Febrile seizures generally have a benign prognosis and prophylactic anticonvulsants and antipyretics are not indicated.[3]

Alcohol related seizures could arise form acute intoxication or withdrawal from alcohol. Antiepileptic drugs are not needed. A short course of benzodiazepines may help ameliorate withdrawal symptoms. A CT scan of the head may be indicated to rule out structural lesions especially in the context of focal signs, an altered mental status (not due to alcohol or drugs), or significant head injury; since the history may be difficult to obtain and patients may not be cooperative with examinations. The OU also allows the physician time to observe the patients for the development of delirium tremors (DT) which carries a high mortality if not treated.

Post traumatic seizures occur in as many as 10% of children after head injury.[12] A CT scan of the head is frequently used to evaluated children with blunt head injury. Routine use of CT scans of the head, however, has disadvantages, including an increased risk of later malignancy.[13] This makes observation of such patients (at low risk of traumatic brain injuries after blunt head trauma) in the OU with frequent neurological checks a useful management strategy. This option would eliminate the risk of radiation from a head CT.[13]

Discharge Criteria include: no seizure recurrence, no deterioration in clinical status, therapeutic levels of anticonvulsants if indicated, correction of abnormal laboratory studies, and accompanied home by a responsible adult to an appropriate home environment.

Hospital Admission Criteria include: deterioration in clinical status, identification of exclusionary causes, and inappropriate home environment.

Outcomes

The ED OU can improve patient care while decreasing the cost of hospitalization by allowing the physician additional time for diagnostic evaluation and management. Extended screening and observation has been shown to improve diagnostic accuracy and determine the need for hospitalization.[11] Concerns over long term effects of radiation from CT scans especially in children and infants has led to the use of observation as an option for low risk patients status post blunt head trauma.[12,13]

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Transient Ischemic Attack
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TIA: Summary   (Level A recommendation, Class I strength of evidence)
IF adult patients with TIA after emergency department (ED) evaluation and therapy require extended care and have none of the following: a positive CT Scan (mass lesion, bleed, large stroke), hypertensive crisis (diastolic BP >120 with symptoms), deteriorating neurological symptoms, depressed Level of Consciousness, or more than one seizure;
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with neuro checks every two hours, frequent vital sign measurement, neurologist consultation, initiation of antiplatelet therapy, and testing as needed (MRI, echocardiogram, carotid Doppler, EEG);
BECAUSE the therapy is as effective as inpatient hospital services in clearing the asthma, patient satisfaction is higher than inpatient hospital services, and cost of services are lower than inpatient services.

BACKGROUND

Transient Ischemic attacks (TIAs) represent more of a diagnostic dilemma than a management issue. Unlike acute stroke or active cardiac disease, the treatment strategies for TIAs are generally limited to neuroprotective agents. As such, inpatient admissions for management of TIA predominately involves diagnostic strategies to determine the extent of suspected underlying cerebrovascular disease. A two-year trial of TIA admissions reported that 95% of the inpatient costs were attributed to the inpatient bed cost, suggesting that if an outpatient system could significantly reduce the cost of management.[1] If an outpatient observation pathway can provide similar diagnostic strategies to inpatient care without compromising patient safety, then a process of observation services would likely reduce the costs of TIA diagnosis and management.

The body of literature specifically related to managing TIAs in observation centers is limited, but the characteristics of presentation and management of TIAs are favorable in the observation setting. Observation medicine is optimal for acute diseases that[1] are commonly seen in EDs and without a process are usually admitted[2] are associated with high risk disease[3] strategies can be developed to distinguish high risk from low risk disease, and[4] these strategies permit a majority of patients excluded from high risk disease to be safely discharged for outpatient management.

The resource reductive benefits of outpatient observation medicine are particularly effective when the disease commonly presents to the ED. Nearly 3% of all ED visits are for stroke and TIA,[2] making suspected TIA one of the more common disease presentations. Comparatively, 7% of ED visits are for estimated for chest pain.

TIAs precede 15 to 20% of strokes.[3] As a result, admission rates for suspected stroke and TIA are high, with one trial of 15 hospitals[2] reporting 86.3% of suspected TIA and minor strokes requiring admission. However, only 18% of those admitted with suspected stroke in this trial had a TIA or were

stratified as high risk. Nearly one-third of those admitted (n=272) with an initial suspicion for stroke or TIA were found to have another diagnosis by discharge. Since TIA presentations are common in EDs, an early aggressive process for risk stratification would likely improve resource utilization by identifying alternative diseases without requiring inpatient resources.

Inpatient death rates for TIA are low (0.2%)[4] suggesting that a TIA management strategy results in a low probability of a life threatening event after the early diagnostic and management phase. Without this risk stratification process, 4-8% of TIA patients had a stroke within 1 month,[5,6] emphasizing that the risk of bad outcomes outweighs the practice of discharging acute TIA without a diagnostic workup. Recognizing the need for an early diagnostic process for suspected TIA, The American Heart Association's Stroke Council guidelines suggest that inpatient admission is 'often justified to expedite evaluation.'[7] The Task Force on Hospital Utilization for Stroke of the American Academy of Neurology concurs with the AMA's recommendation for admission. Both organizations acknowledge that the evidence basis for the recommendation for inpatient admission is based on the need to exclude high risk disease and not based on any reliable clinical or evidence based data.

There is no evidence that inpatient admission provides any therapeutic or safety benefit over similar outpatient diagnosis and management. A survey examining admission practice patterns among neurologists evaluating two TIA scenarios resulted in wide variability (11-87%) as to which cases required inpatient admission.[8] If a diagnostic strategy comparable to inpatient admission can be performed through short term observation, than the resultant practice standard would likely reduce unnecessary admissions while improving care.

IF: Patient Selection

IF a patient has a transient neurologic finding without a positive CT Scan (mass lesion, bleed, large stroke), hypertensive crisis (diastolic BP >120 with symptoms), deteriorating neurological symptoms, depressed level of consciousness, or more than one seizure;

THEN: Observation Unit Management/Intervention

THEN the patient may be observed up to 24 hours with neuro checks every two hours, frequent vital sign measurement, neurologist consultation, initiation of antiplatelet therapy, and testing as needed (MRI, echocardiogram, carotid Doppler, EEG);

Management strategies for TIA require a coordinated process for exclusion of high risk cerebrovascular disease.[9-13] This process includes review of risk factors including organized stroke prevention care,[14] patient assessment [brain imaging[10] (CT, MRI, and/or ultrasound,[10,15,16] basic laboratories and ECG)],[17] risk factor management (aspirin or antithrombotic therapy, glucose and cholesterol control, blood pressure monitoring), and primary or secondary prevention (eg, pharmacologic management such as statin therapy,[18] management of atrial fibrillation). Delays from inpatient admission length of stay (LOS) occur largely due to lack of coordination of studies. The median time from arrival to the ED to the inpatient floor or CT scanner was 2.6 and 2.7 hours respectively[2] suggesting that significant time is spent processing patients for admissions or obtaining tests.

BECAUSE: Outcome of Observation Unit Intervention

BECAUSE a period of observation is effective in identifying serious underlying cause of the patient's symptoms at significantly lower costs than hospital admission. The need for an ED based outpatient process is supported by data from a trial of recent stroke and TIA management by outpatient primary care physicians.[19] Outpatient diagnosis and management reduced the need for acute inpatient management to about 6%. However, many of the critical tests necessary to exclude high risk underlying disease were omitted, such as brain imaging or carotid ultrasound. More than 60% in this trial required admission within the following 30 days, suggesting that difficult to obtain diagnostic tests, that may only be immediately available in an ED or hospital, must be available to fully categorize the disease.

With a comprehensive diagnostic strategy, more than 92% of TIA presentations are eligible for discharge within a reasonable observation period.[1] In a large trial of 137 community hospitals, the mean inpatient length of stay for TIA (n=7861) was 3.4 days in community hospitals and 4.9 days in major teaching hospitals compared with 5.9 and 10.8 days for ischemic stroke.[4] Censori et al commented, "the cost of [TIA] management is mostly due to the type of investigations that are carried out and the number of days necessary for the completion of the diagnostic workup."[20] The trial concluded that LOS may be reduced in TIA when an accelerated diagnostic workup can be provided.[20]

Because TIA diagnosis requires an early aggressive diagnostic strategy with little pharmacological management, the nature of an ED based observation center could optimally fulfill the requirements of this process. Evidence supporting an ED based TIA process that can be designed within the recommended time frame for observation (6 to 23 hours) is lacking. However, data supporting improved hospital utilization of resources through outpatient TIA diagnosis and management[4,20] by early risk stratification[7] is supported in the literature.

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Observation and TIA		
Inclusion Criteria		* transient neurologic finding * small stroke (normal examination or questionable finding on sensory or motor examination) * unreliable history of events
Exclusion Criteria		* Positive CT Scan * Hypertensive crisis (diastolic BP >120 with symptoms) * Deteriorating neurological symptoms * Depressed Level of Consciousness * More than one seizure * New objective findings (hemiparesis, aphasia, hemianopsia, gait disturbances) * Embolic origin of stroke symptoms

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Sickle Cell Anemia

Sharon E. Mace, MD, FACEP, FAAP
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Sickle Cell: Summary   (Level C recommendation, Class III strength of evidence)
IF adult patients after emergency department (ED) evaluation and therapy have symptoms of a vasocclusive sickle cell crisis, or a history of sickle cell disease with dehydration, nausea/vomiting, and minor infection (ie, upper respiratory infection) and have none of the following: Presence of aplastic, hyperhemolytic, and acute splenic sequestration crisis, serious infection (ie, meningitis, sepsis, pneumonia, and osteomyelitis), acute chest syndrome, pregnancy, CHF, lung infarction, priapism, high fever (40° C or 104° F), hepatic crisis, cholangitis, and cholecystitis.
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours beginning analgesic drug therapy promptly and consistently, reassessing pain frequently (as often as every 30 minutes), using adjunctive drugs in addition to opioids (if no allergies or contraindications), avoidance of meperidine, and fluid replacement
BECAUSE available studies suggest that selected patients with sickle cell disease including those with a vasocclusive crisis can be safely and effectively managed in an observation unit (OU) since it allows for extended pharmacologic management and observation.

BACKGROUND

Approximately 8-10% of African-Americans have sickle cell trait,[1] while about 70,000 – 100,000 Americans have homozygous hemoglobin S and suffer from sickle cell disease.[2] Sickle cell anemia is more common in certain ethnic groups, affecting approximately 1 in 500 African Americans.[3]

PATHOPHYSIOLOGY

Sickle cell disease, an autosomal recessive inherited disorder of hemoglobin structure and function, results from the presence of hemoglobin S instead of hemoglobin A caused by the substitution of valine (in hemoglobin S) for glutamic acid (in hemoglobin A) in position 6 of the globin beta-chain. Under oxygenated conditions both hemoglobin S and hemoblobin A have similar function, while in the deoxygenated state hemoglobin S leads to red blood cell sickling.

Individuals with sickle cell disease are homozygous for the sickle gene (SS) and their erythrocytes contain at least 90% hemoglobin S. Those who are heterozygous for the sickle cell gene (SA) have sickle cell trait and their erythrocytes contain both hemoglobin A (about 50-60%) and hemoglobin S (about 30-40%). Sickle cell trait is a carrier state that is clinically benign except under conditions of severe acidosis or low ambient oxygen concentrations. Individuals with a variant of sickle cell disease, including sickle thalassemia and SC disease (heterozygous for hemoglobin S and

hemoglobin C), have lower levels of hemoglobin S and less morbidity than those with (SS) sickle cell disease.

There are several types of crises that occur in patients with sickle cell anemia (SS disease). Vasocclusive crises occur when sickle cells occlude blood vessels and cause acute painful crises. A hemolytic crisis occurs when there is excessive breakdown of damaged red blood cells. A splenic sequestration crisis, which generally only occurs in infants and young children, occurs when the spleen enlarges and traps the abnormal sickled red blood cells. An aplastic crisis results when an infection, to which sickle cell patients are especially susceptible since they are immunosuppressed, causes the bone marrow to stop producing red blood cells.

Occluded blood vessels can cause acute painful episodes, or "vasocclusive crises," which are the most common cause of emergency department (ED) visits and hospitalizations among sickle cell patients.[4] Repeated crises can cause damage to almost any organ but especially the kidneys, lungs, heart, bones, eyes, and the nervous system.[2]

The hallmark of a sickle cell vasocclusive crisis is vascular injury caused by the sickle cells occluding small and sometimes, large blood vessels. During a vasocclusive crisis, sludging of the abnormal hemoglobin S in the small capillaries leads to a decrease in flow and a decrease in ambient oxygen; resulting in greater deoxygenation of hemoglobin and further sickling of the erythrocytes. A viscous cycle of sickling, hypoperfusion and ischemic injury results.[2]

Complex interactions between the sickle cells, vascular endothelial cells, and constituents of the plasma are responsible for initiating and maintaining a sickle cell vasocclusive crisis.[5] Deoxygenation of sickle cells causes the efflux of potassium, which in turn, increases cell density and leads to the polymerization of hemoglobin S. Injury to the cell membranes allows the sickle cells adhere to the vascular endothelial cells and impair blood flow and oxygenation.

The sickled red blood cells also alter the normal homeostasis or balance between vasoconstrictors and vasodilators in the plasma. Recent research has documented impaired vasodilatation occurs in sicklers during a vasocclusive crisis. Nitric oxide (NO) is the mediator of vasodilation. NO is formed from the substrate, L-arginine. The hemolysis of red blood cells that occurs during a vasocclusive crisis releases free hemoglobin, which in turn neutralizes NO, resulting in vasoconstriction. During a vasocclusive crisis, levels of the biochemical mediators, NO and L-arginine, are destroyed, which leads to the vasoconstriction characteristic of this type of sickle cell crisis.[2]

Hydroxyurea has been suggested for the prevention of vasocclusive crisis.[6] Hydroxyurea is a substrate precursor for L-arginine, which results in increased NO levels, which counteracts the uninhibited vasoconstriction seen during a vasocclusive crisis. It also stimulates fetal hemoglobin levels (up to 20% of all hemoglobin) which inhibits sickling of red blood cells.[2]

Patient Selection – Inclusions

Physical evaluation to determine admission to the clinical decision unit (CDU) should include vital signs, hydration status, degree of pallor, scleral icterus, spleen size, cardiopulmonary status, neurologic exam, and evidence of infection. Admission criteria to the CDU include symptoms of a vasocclusive sickle cell crisis with stable vital signs and no significant infection(s). Patients with sickle cell disease who have minor illnesses or injuries that are expected to resolve with therapy within 24 hours may also be admitted to the CDU. This includes sickle cell patients with mild dehydration, nausea/vomiting or acute gastroenteritis (but not an acute abdomen or ileus), or a mild upper respiratory infection. Such sickle cell patients should be hemodynamically stable without a serious infection (such as pneumonia or meningitis).

The history, physical examination, and laboratory studies (eg, CBC and reticulocyte count) may be helpful in determining what type of acute sickle cell crisis is present. Specifically, whether a vasocclusive (the most common type of sickle cell crisis), splenic sequestration (which usually only occurs in infants and young children), aplastic, or hyperhemolytic crisis is present.

Patient Selection – Exclusions

Patients who should not be admitted to the CDU include those in asplastic, hyperhemolytic, and acute splenic sequestration crisis or patients with acute chest syndrome. Patients with serious infections; such as meningitis, sepsis, pneumonia, and osteomyelitis are candidates for inpatients admissions. Pregnant patients also should not be admitted to the CDU. Patients with congestive heart failure, lung infarction, priapism, high fever (40° C or 104° F), altered mental status, cholangitis, and cholecystitis should not be admitted to the CDU.[7]

Patients should be considered for inpatient admission after appropriate CDI therapy within 24 hours, if any of the following are present: severe persistent pain, inability to take oral medications, clinical deterioration, unstable vital signs, and significant fever/serious infection.[7]

Patients who have improvement in pain, are able to take oral medications, and are clinically stable without significant infection(s) can be discharged from the CDU.[7]

Management/Intervention:

Upon admission to the CDU, serial exams including vital signs can be performed and therapy for the underlying illness/injury including painful vasocclusive crisis can be given. Although the details of the management of sickle cell vasocclusive pain crises are debated, all treatment protocols recommend beginning analgesic drug therapy promptly and consistently, reassessing pain frequently (as often as every 30 minutes), using adjunctive drugs in addition to opioids (if no allergies or contraindications), avoidance of meperidine, and fluid replacement.[2,5,7] Many experts recommend ongoing pain medication administration, as well as needed (prn) orders for breakthrough pain.[2] PCA pumps have also been used for treatment.[2,5] Although opioids drugs are the mainstay of treatment for vasocclusive crisis, other drugs, such as acetaminophen and nonsteroidal anti-inflammatories (NSAIDs) (eg, ketorolac), and antihistamines can be used in combination with opioids for pain relief.[2,5,7]

Of the opioids, meperdine should not be used given its long-acting metabolite that is known to lower the seizure threshold. It is also contraindicated in patients with impaired renal function, and in combination with monoamine oxidase inhibitors or antidepressants.[2]

The patient can be placed on supplemental oxygen. Although oxygen has been recommended as a baseline therapy for years, there is no evidence-based data showing a definitive benefit.[2] Fluids should be given, but the specific type and amount are controversial. "Liberal" fluid therapy has been suggested by some,[5] although excessive amounts should not be given because of a danger of volume overload and precipitating congestive heart failure. Generally, fluids are given at 3-4 liters a day for an adult or about one and a half time maintenance, which is about 150 cc/hour for an adult.[7] The commonly used intravenous fluid is D5 ½ normal saline.[7] Hydration should be initiated and maintained and titrated depending on the presence of dehydration, ongoing losses, respiratory symptoms, cardiovascular status, and other factors.

In patients of any age, frequently reassessment is crucial in determining the dose of opioids needed, the dosing schedule, need for adjunctive medications, hydration status, response to therapy, and whether inpatient hospitalization is required.

Outcomes:

The foundation of sickle cell pain management is analgesics. The pharmacological management of a sickle cell vasocclusive pain crisis requires a special combination and titration of NSAIDs, opioids, and adjuvant medications that requires continuous monitoring, which makes CDU management ideal.

An 18-year study of the evaluation and management of sickle cell disease in the emergency department (ED) found that painful episodes are the most frequent complaints with 75% requiring admission to the hospital for further care.[8] In this 15-year follow-up of this 18-year prospective study, they found that results similar to that achieved as an inpatient can be attained with ED protocols.[8]

A study of 363 patients at an urban tertiary care ED of patients 18-45 with typical symptoms of sickle cell pain crisis found that an OU facilitated treatment of patients with sickle cell pain crises in an area other than the main ED, although it did not affect the inpatient admission rates or the return visits.[9]

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37

Psychiatric Problems and Needs

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SUMMARY BOX

1) **Patient Selection:**
Inclusion criteria – Patient exhibits active emotional illness (psychiatric symptoms such as psychosis, mania, agitation, intoxication, withdrawal, combativeness, confusion, self-destructive behaviors or other behavioral problems) and one or more goals can be identified for their period of observation.
Exclusion criteria – Patient requires medical, surgical, or neurologic diagnostic evaluation, observation, or treatment.
2) **Management** – Assessment, evaluation, containment, elimination of intoxicating substances and withdrawal symptoms, psychiatric or other specialty consultations, and therapeutic interventions
3) **Outcomes** – Psychiatric stabilization with potential for discharge to a treatment setting less "restrictive" than a psychiatric inpatient unit.

BACKGROUND

Goals of Observation

Over 6% of patients who present to an emergency department (ED) have a psychiatric problem. Most patients with psychiatric problems will be managed as outpatients. Admissions to psychiatric hospitals have been severely restricted and the number of psychiatric hospital beds in the United States have decreased by 62% per capita since 1970.[1] On initial evaluation of a patient with psychiatric complaints it is often difficult to develop a workable, safe approach to the patient's problem. The ED observation unit is an appropriate setting to manage many patients who would otherwise require acute hospitalization.[2]

The patient with psychiatric complaints admitted to the observation unit undergoes a series of evaluations and therapeutic interventions. Most efforts are focused on the patient's safety and determining the most appropriate disposition for the patient. Initial steps are aimed at medical clearance, safe containment, initiation of psychotropic medication, elimination of intoxicants and resolution of withdrawal symptoms. By talking with the patient and obtaining information from other sources, the physician clarifies the patient's intent regarding injury to self or others while continuously evaluating the safety of patient discharge. The physician can schedule services for the patient and observe the patient until sustaining relationships, such as those with the patient's therapist, family members or halfway house, can be reestablished. The physician may arrange alternatives to psychiatric hospitalization by making appointments for outpatient psychotherapy, placement in a residential or day treatment facility, home visitation by psychiatric personnel, or admission to drug and alcohol treatment centers. Patient needs can extend from individual care to assistance with financial and work problems.[3]

It is important to note that the patient's stay in the observation unit does not replace psychiatric treatment. The emergency physician *should not* attempt "psychotherapy" with these patients. A brief, focused visit to assess the patient's physical, anxious, suicidal, violent, and psychotic symptoms is sufficient.

Legal Issues

Restrictions on personal freedom and violations of privacy are "permitted" in the ED when done in the interest of establishing whether the patient is critically ill or a danger to himself or others. Once the patient is admitted to the observation unit, much stricter laws may govern a physician's actions. These laws differ depending on the state, the type of observation, and the type of unit.

Observation unit directors should review state statutes with a forensic psychiatrist to develop clinically relevant policies that adhere to the law. The hospital lawyer and risk manager should also be involved.

Patient Selection: Inclusion and Exclusion Criteria

Psychiatric patients are appropriate for observation when they have an active emotional illness and one or more goals can be identified for their period of observation. Some patients require a medical workup (medical clearance) to rule out an organic cause of psychiatric symptoms. Others are intoxicated or in withdrawal and can be safely managed in an observation unit. The physician must distinguish between functional psychiatric illness and drug-induced symptoms and, in the case of a suicide or self-mutilation, attend to medical complications. Some patients may be unable or unwilling to cooperate with an adequate psychiatric examination but may be adequately evaluated with a short period of observation. Patients needing social service intervention often need, not hospitalization, but time to get help.

Key factors in determining the appropriateness of observation include:

1. **Availability of adequate information** – Can information regarding the patient's illness be obtained from the patient, his/her physicians or family? Such information will help the physician determine the severity of the patient's current condition.
2. **Role of medication** – Did the patient's problems occur following discontinuation of psychotropic medication? The patient may require only a short period of observation to reinstitute his/her medication.
3. **Physical environment** – Does the observation unit provide adequate stability and containment for the patient? If it is open to the ED, has only curtains separating cubicles and is staffed by different ED nurses on each shift, emotionally unstable patients may experience the unit as chaotic.
4. **Medical needs** – Does the patient need primarily medical or surgical care? Some psychiatric units specialize in the care of medically ill patients, while others can manage only medical/surgical patients with outpatient problems.
5. **Psychiatric services** – How available are psychiatric consultation-liaison services? Some hospitals have a team of consultation-liaison psychiatrists available 24 hours a day. Others provide non-medical, non-psychiatric social service consultation only during normal business hours. Specialized psychiatrists can help with the initial evaluation in the ED and provide ongoing psychiatric treatment to patients admitted to the observation unit. They can help the nursing staff on these units create a "mini-psychiatric unit" in the patient's room.

Management/Intervention

Security and Safety

Observation unit staff must be equipped and trained to manage severely disturbed patients in order to ensure the safety of the patient, other patients, staff and visitors. Safety measures should include:

1. **Restricting the patient to the observation unit** – The unit's perimeter should be clearly demarcated, with access through a single, locked, alarmed door controlled by staff. The patient should leave the unit only for medical testing/treatment and only when accompanied by a staff member knowledgeable about the patient's potential for dangerous or unpredictable behavior.
2. **Searching body and belongings** – While preserving modesty, patients should be asked to change into a hospital gown in the ED at the time of medical clearance. Patients may secrete sharp objects, drugs and other items in their possessions. Items brought by visitors should be searched. Patients with histories of violence require more thorough and intrusive searches. Those with a history of swallowing sharp objects or secreting them within their bodies should be screened using metal detectors, X-ray and inspection of body orifices.
3. **Conducting nursing checks** – Nurses should check patients every five to 30 minutes, depending on the degree of concern. Even patients on one-to-one constant observation will probably require nursing staff checks.
4. **Creating a safe environment** – Trained staff should directly supervise the patient when using objects such as shaving implements and dinner utensils. Smoking materials should be taken from the patient at admission. Suicidal patients may overdose, cut, burn, hang, suffocate and electrocute themselves. Violent patients grab items they can use to threaten others. Patients may attempt to harm themselves or others while in the observation unit. Medication must be locked up. Patients must not have access to items such as needles, glass objects, soda cans, loose screws, sharp edges, tubing, belts, bathrobe ties, shoe laces, call-light cords, plastic bags or loose/uncovered electrical circuitry. The unit should be evaluated by a psychiatric nurse specialist or other psychiatric expert to identify potential risk areas and develop a safety protocol for high-risk patients.
5. **Employing physical restraints when needed** – Specially designed wrist and ankle restraints should be used to restrain patients who are not safe and cannot be contained by one-to-one observation or tranquilization. They should be restrained on beds rather than stretchers. Staff should be trained by psychiatric personnel in the safe use of restraint, and techniques should be practiced regularly.

Therapeutic Setting

Psychotic, manic, agitated, intoxicated, withdrawing and combative patients are calmed by a low-stimulus environment featuring elements such as a private room, dim lights, reduced noise and minimal interpersonal interactions. Depressed, anxious and traumatized patients are better served by preserving their connections to the hospital staff. Confused patients require a setting that helps orient them to time, place and important people.

Behavioral Management

When non-psychotic patients with behavioral problems are admitted to the observation unit, staff members should gather together and develop a simple behavioral management plan. This plan:

1. **Specifies behaviors that will or will not be tolerated** – Difficult patients took a lifetime to develop their style of behavior. Dramatic change cannot be expected during their observation unit stay, especially with the added stress of illness and hospitalization.
2. **Specifies recommended interventions** – The plan outlines staff interventions that reward good comportment and neutralize or ignore annoying behavior. Staff are less likely to feel helpless or retaliate and patients benefit from a predictable, caring staff that provides a consistent message.

Specific Categories of Patients

Suicidal or Self-Destructive
When admitting these patients to the observation unit, it is best if the emergency physician has adequate psychiatric back-up to assist in assessment, treatment, and discharge planning. The physician must keep the patient safe and assess the likelihood that the patient will hurt himself if discharged.[4] Specialized psychiatric consultants aid the physician in this evaluation, but the emergency physician remains the responsible physician.

Information in the patient's history and mental status examination can help the physician gain a sense of the patient's original, current and future (within 24 to 48 hours of discharge) lethality.[5] Questions to be explored include:

1. What is the lethality of the currently proposed method of self-harm? Have the means been obtained? How complete is the plan? Has the patient carried out parts of the plan? Does the patient believe he will die as a consequence of this plan?
2. Has the patient recently made arrangements for the time following his death? Has he completed a will, cleaned up a study or workshop, distributed personal goods, taken insurance policies out of a vault, made good-bye calls or written letters?
3. Has the patient taken special precautions to remain undiscovered?
4. Were previous suicide attempts potentially lethal and well planned, or were they impulsive and non-lethal?
5. Does the patient still want to be dead?
6. Is the patient psychotic and therefore experiencing a distorted perception of reality? Was he experiencing "command hallucinations" telling him to kill himself? Does his paranoia make his answers incomplete, so that the physician cannot tell what information is being withheld?
7. Did the patient's physical state on arrival in the ED suggest a serious suicide attempt, despite the story the physician hears?
8. People do not usually try to hurt themselves in an emotional vacuum. What are this patient's emotional precipitants for these feelings, and are any of the other people involved in these relationships available to talk with the physician and the patient?
9. How worried are the people with whom the patient lives? Patients are not safe if returned to a setting in which others do not realize what has happened or are indifferent.
10. Are significant caretakers or others away?
11. Does the patient seem honest and forthcoming or remote and superficial?
12. What does the patient's therapist want done?
13. Is the patient intoxicated or withdrawing from drugs or alcohol? A useful examination cannot be performed until these states have resolved.

Affirmative answers to the first seven questions place the patient in a high-risk group. Other patients at high risk include middle-aged and older men, recently separated or widowed, who have lost their jobs and have a problem with substance abuse. Young, intoxicated men who will be detained in jail are also at increased risk. All high-risk patients should be transferred to a psychiatric unit as soon as they are medically cleared.

Agitated
Agitation is a non-specific term describing patients who are loud, physically disruptive, and upsetting to others. The physician first determines which conditions are contributing to the patient's presentation. These may include psychosis, mania, character pathology, anxiety, drug or alcohol intoxication or withdrawal and organic causes. Once organic, intoxication, and withdrawal states have been ruled out, the physician must determine whether the patient has psychosis, mania or a character disorder.

I. *Psychotic patients* – Characteristics may include prominent hallucinations and delusions, poor personal hygiene, bizarre behavior, incoherent speech, hypervigilance and attendance to non-existent stimuli.

Treatment: A selected group of patients with psychosis can benefit from an observation unit admission. They include patients who:
1. Have mild or chronic psychotic symptoms or mild decompensation attributable to a change in life events that can be readily solved with social service assistance.
2. Have acute exacerbations in their symptoms, are well known to the ED staff and are known to respond quickly to treatment. These patients can quickly recompensate in the observation unit with structure and medication. They should have an intact outpatient treatment program.
3. Need a period of observation for their intoxication or a withdrawal state to resolve.
4. Need a more comprehensive medical clearance before a decision is made on their need for hospitalization.

Every psychotic patient must undergo a thorough physical, neurologic and mental status examination, as well as a search by history and urine and blood analysis for alcohol and substance abuse. A more comprehensive medical clearance evaluation should be done on all patients with findings that suggest an organic cause of their symptoms. Such findings include: (1) a first psychotic break, (2) new onset psychosis in a middle-aged or older patient with a normal premorbid history of functioning, (3) symptoms suggesting a delirium, including clinical features that develop over a short period of time (hours to days), tend to fluctuate over the course of a day, cause fluctuations in the level of consciousness, disturb the sleep-wake cycle, disorient the patient or impair the memory, (4) abnormalities on the medical or neurologic history and physical examination or screening laboratory studies or (5) non-specific findings on initial examination, leaving the physician with the sense that this is not a functional or substance-related psychosis.

The management of the patient with psychotic symptoms should be individualized. Physical restraint should not be used prophylactically, as this may panic and enrage the patient, but should be used when necessary for safety and containment. "Worry" on the part of the emergency physician or members of the nursing staff should be used as a barometer to assist in the decision to restrain a patient. Since the behavior of psychotic patients is unpredictable, it is best, when in doubt, to restrain the patient.

Medications, including antipsychotics and sedatives, should first be offered orally in liquid or sublingual form. They may be given intramuscularly (IM) for safety and containment. When possible, patients should be restarted on their correct psychotropic regimen. Many patients improve on 2-10 mg/24 hour of haloperidol (Haldol) or its equivalent (Table 37.2). Occasional patients may need up to 20 mg of haloperidol or its equivalent per 24 hours. The sedative properties of neuroleptics work immediately. The antipsychotic properties take days to weeks to work. The more sedating, lower potency, neuroleptics drugs are usually more anticholinergic and may cause hypotension, placing medically compromised patients at risk. More commonly, the physician will use a less sedating neuroleptic (haloperidol) plus a short-acting benzodiazepine (lorazepam/Ativan) or diphenhydramine (Benadryl) for sedation. Diphenhydramine or benztropine (Cogentin) can also prevent dystonic reactions. Either IM Zyprexa 10 mg or IM Geodon 20mg could be substituted for IM Haldol for patients who are taking no antipsychotic medication upon presentation. A suggested protocol is listed in Table 37.2. IM Zyprexa must not be given together with IM Ativan as serious respiratory depression may occur.[6, 7]

The goal of this regimen is to *calm* the patient, *not* rid him of psychotic or manic symptoms. The *minimum* amount of medication should be used to achieve the desired effect. Many patients can readily be converted to a regimen of PO or IM neuroleptics BID and Ativan 1 to 2 mg PO or IM every 4 to 8 hours with Benadryl 25 to 50 mg PO or IM QID, or Cogentin 1 to 2 mg PO or IM BID, used to prevent dystonic reactions from Haldol or the older neuroleptics. Second generation neuroleptic agents are much less likely to cause dystonia or EPS. At the four-hour mark, if no benefit has been achieved, the physician should search for overlooked organic causes of agitation and lengthen the dosing interval to every two to four hours for additional doses of Ativan or Haldol. A potential ceiling for Haldol is 20 mg/24 hr, though rare

patients will require more. The use of Ativan is limited by the potential for respiratory suppression. When the patient is calm and compliant with treatment, control should be gradually returned to the patient who has required restraint. Restraints should be removed from one extremity at a time, every 30 minutes, starting with one leg and then the opposite arm. Routine restraint loosening or release should be built into all physical restraint protocols even when the restraints are not being discontinued.

The dose and frequency of administration of neuroleptics and sedatives need to be reduced in patients who (1) are elderly, (2) have cardiopulmonary compromise, (3) have vasomotor instability, (4) have hepatic dysfunction, (5) have organic brain syndrome, dementia, or a history of strokes, and (6) who have HIV-related disease. A dose of Haldol, 0.5 to 1 mg PO or IM every 2 to 4 hours to a maximum of 10 mg/24 hours, should be sufficient. Sedatives may be unnecessary and may complicate the picture by causing confusion or respiratory suppression. With the exception of patients with HIV-related disease and patients receiving doses of more than 5 mg/24 hr of Haldol, Benadryl and Cogentin need not be used prophylactically, since dystonic reactions are less likely.

Table 37.1 Dosage equivalency of oral antipsychotic agents[8]

Proprietary Name	Generic Name	Approximate Equivalent Oral Dose
Haldol	Haloperidol	2mg
Prolixin	Fluphenazine	2 mg
Navane	Thiothixene	4 mg
Stelazine	Trifluoperazine	3-5 mg
Trilafon	Perphenazine	8-10 mg
Thorazine	Chlorpromazine	100 mg
Risperdol	Risperidone	2 mg
Zyprexa	Olanzapine	5 mg
Geodon	Ziprasidone	60 mg
Seroquel	Quetiapine	75 mg
Abilify	Aripiprazole	7.5 mg

Table 37.2 Regimen for control of the agitated, psychotic, or manic patient [9, 10, 11]
Select one regimen. Haldol + Benedryl + Ativan **or** Geodon + Ativan **or** Zyprexa alone

Time of Dosing	Drug	Dose	Route
0 hr	Benadryl (Not required with Zyprexa or Geodon)	50 mg	PO or IM
	Ativan (not used with Zyprexa)	1 mg	PO or IM
	Haldol/Zyprexa /Geodon	5 mg/10mg/20mg	PO or IM
1 hr	Ativan (Not used with Zyprexa)	1 mg	PO or IM
2 hr	Haldol	5 mg	PO or IM
3 hr	Ativan (Not used with Zyprexa)	1 mg	PO or IM
4 hr	Haldol/Zyprexa/Geodon	5 mg/10mg/20mg	PO or IM

II. *Manic patients* – Are euphoric and grandiose. Their behavior is energized and intrusive. Their speech is loud, rapid and uninterruptible.

Treatment: These patients may need a more comprehensive medical clearance than can be performed on the initial evaluation, need a period of observation to monitor and wait for the effects of intoxication or withdrawal to resolve. They may be hypomanic, well known to the ED, exhibiting behavior that will not disrupt the observation unit, but will get the patient into trouble as an outpatient (eg, speeding, excessive spending). With the exception of antidepressants, this patient can have outpatient medications restarted under supervision in the unit after lithium and anticonvulsant blood levels have been determined. The blood levels will indicate the patient's medication compliance. Lorazepam (Ativan) and haloperidol (Haldol) may be beneficial for patients who are taking no psychotropic medications, who cannot tell what regimen has been helpful in the past, or who are manic for the first time. The goal of this regimen is to *calm* the patient, *not* stop manic or psychotic symptoms. Many manic patients can be managed on larger doses of short-acting benzodiazepines (Ativan) and smaller doses of neuroleptics (Haldol) than can psychotic patients (Table 37.2). Lithium or other antimanic agents requiring blood levels should be started under the direction of a consulting psychiatrist as soon as the patient is willing to take oral medication and cooperate with blood drawing

If minimal response is achieved at the four-hour mark, the physician should refer to the previous section describing treatment of the psychotic patient (Table 37.2). The dose and frequency of administration of neuroleptics and sedatives should be reduced in selected patients (see section on the psychotic patient). When the emergency physician is having to observe acutely manic or psychotic patients awaiting an opening in a psychiatric hospital, recommendations on safety and containment given earlier should be followed.

III. *Patients with character disorder* – Appear either "hysterical" or like an adult having a temper tantrum. Their behavior seems purposeful and designed to provoke onlookers. These patients are *engaged* in a relationship with their caretakers rather than being disconnected or oblivious to them as seen in psychosis and mania.

Treatment: Decompensating patients with unstable personalities should be treated with short-acting benzodiazepines (eg, lorazepam (Ativan) 1 mg. PO or IM q 1 hour) until calm, to a maximum of 4mg. If symptoms have not resolved or disinhibition ensues, the protocol for the agitated psychotic and manic patient should be used (Table 37.2).

When one cannot distinguish among these three diagnostic possibilities in the agitated patient, the aggressiveness of the treatment protocol selected should reflect the degree of dyscontrol and the danger posed to the patient and caretakers.

Sexually and Physically Traumatized

Traumatized patients come to the ED following suicide attempts, self-mutilating episodes or outbursts of rage. Decompensation occurs in the context of medication changes, life transitions, losses, return to substance abuse, events – such as rape or assault – that recapitulate their abuse or when the abuser returns to their lives. They may complain of depression, anxiety, psychotic-like symptoms such as hallucinatory events, rage, flashbacks, nightmares, or memory loss. Often these patients' bodies were violated first as children. Usually the perpetrator was an adult in a caretaking role, so these patients are exquisitely attuned to their bodies and to the behavior of their caretakers. They may view the physician with fear and suspicion, expecting the physician to, at best, not protect them and, at worst, hurt them. They may have strong preferences about the gender of their physician. Physical symptoms, along with intrusive examinations and procedures, may bring back unbearable memories. Sharp objects such as needles and IVs may be frightening. Restraint of movement and sedation may leave the patient feeling there is no escape. Giving oral medication – "putting something in their mouths" – without discussing it beforehand may terrify them.

If the physician knows the patient's history in advance, he or she can anticipate or ask for the patient's help in predicting which situations will provoke anxiety. More often, their history is a private shame, and the physician must make the connection that their "irrational" response has an understandable cause. To give up in frustration is to repeat the history of their early abandonment. Treating them requires patience and the capacity for safe compromise. Many traumatized patients will not require hospitalization but will benefit from a psychiatric or social service evaluation in an observation unit. The unit is used to provide safety and an evaluation for violent and self-destructive potential as outlined previously. Drug- and alcohol-induced intoxication and withdrawal states should be considered. It is especially important that the patient be given a respite from her unsafe world. When thinking clearly, she can get assistance in arranging for an alternate living setting or legal protection for herself and her children. Patients who have severe psychotic-like symptoms or are self-destructive, homicidal or unable to function may need admission to a psychiatric unit.

Other Problems Unique to Psychiatric Patients

Akathisia – This extremely uncomfortable motor restlessness manifests itself as restlessness of the extremities, inability to sit still or pacing. It is caused primarily by antipsychotic drugs, may be seen in patients taking serotonin reuptake inhibitors, and is rarely caused by tricyclic antidepressants. It is dose-related and reversible with discontinuation of the drug. The best treatment is propranolol, 20 to 120 mg/day orally in divided doses. If benzodiazepines or benztropine (Cogentin) is being used for other purposes, these drugs too may provide relief. For patients in whom propranolol is contraindicated, clonidine, 0.05 to 0.1 mg PO BID is also effective.[12]

Acute Dystonic Reaction – These are severe involuntary contractions of the muscles, especially in the region of the face, mouth, jaw and eyes. They are caused by antipsychotic medication and are reversible with discontinuation of the drug. The most rapid treatment is with Benadryl (25 to 50 mg IV or IM) or Cogentin (1 mg IM). To prevent recurrence, Benadryl or Cogentin should be used for at least two days after discontinuation of the offending agent.[12]

Serotonin Syndrome – There is no expert consensus regarding diagnostic criteria for serotonin syndrome. Criteria published in 2003 recommends the diagnosis of serotonin syndrome be based upon the development of either four major or three major and two minor symptoms following an increase in dosage or addition of another serotonergic agent in a patient already on serotonergic treatment. Symptoms include:

1. Mental symptoms:
      Major: coma, semi coma, confusion, elevated mood
      Minor: agitation, insomnia, nervousness
2. Autonomic symptoms:
      Major: fever, sweating
      Minor: diarrhea, tachycardia, hyper- or hypotention, tachypnea
3. Neurologic symptoms:
      Major: clonus, chills, tremor, muscle rigidity, hyper reflexia
      Minor: akathisia, poor coordination, mydriasis

Other medical, neurologic, psychiatric and toxic causes must be ruled out, and the patient must not have been started on antipsychotics or had the dose of antipsychotic increased prior to the development of symptoms. There have been no consistent laboratory findings in patients with serotonin syndrome. The disorder is generally self-limiting, but some patients may require admission to intensive care units. Most patients will improve within 24 hours of discontinuation of serotonergic agents.

Cyproheptadine in doses of 4-8mg repeated at one- to four-hour intervals up to 32 mg daily has been reported effective in reversing the symptoms rapidly.[13]

Neuroleptic Malignant Syndrome (NMS) – NMS usually develops over the course of one to three days following the initiation or increase in the dosage of an antipsychotic medication. Older high potency antipsychotic agents (Haldol, Prolixin) given via the oral or intra-muscular route are the most common agents causing NMS. The newer atypical antipsychotic agents may cause NMS or a sub-syndromal or atypical condition.[14] The main clinical features are motor symptoms (muscular rigidity, dystonia, akinesia), hyperthermia to 107/F, sweating, mental status changes (confusion, agitation progressing to obtundation and coma) and autonomic instability. Laboratory findings include leukocytosis, elevated creatinine phosphokinase levels and elevated liver enzymes. The most severe forms of this syndrome are complicated by rhabdomyolysis leading to acute renal failure, respiratory failure, seizures, severe hyperthermia and circulatory collapse. Prior to the recent interest in and study of this syndrome, the mortality rate approached 20%. Treatment includes immediate discontinuation of antipsychotic medication, the institution of supportive care, including IV hydration and the treatment of complications. In patients not taking depot formulations of antipsychotics, symptoms can reasonably be expected to resolve within five days of discontinuing antipsychotics. Patients may be given Benztropin (Cogentin) 2 mg IVP to help distinguish NMS from extrapyramidal stiffness. If there is no response and symptom severity includes lead-pipe rigidity, trismus, facial spasm, or autonomic instability; Dantrolene 1 mg/kg PO QID or 2 mg/kg (1 to 5 mg/kg) IV QID plus lorazepam (Ativan) 1mg PO TID may decrease the muscular rigidity. If the muscle rigidity is accompanied by diaphoresis and high fever ($\geq 102º$ F) or diaphoresis is profuse relative to temperature, Bromocriptine 2.5 to 5 mg PO TID should be added to the regimen of Dantrolene and Ativan.[15]

Interactions with Monoamine Oxidase Inhibitors – Patients on MAO inhibitors (phenelzine/Nardil, tranylcypromine/Parnate, isocarboxazide/Marplan) are at risk for two serious and potentially fatal complications of medication: hypertensive crisis and meperidine (Demerol) MAOI interaction. Hypertensive crisis can occur when the patient taking an MAO inhibitor eats tyramine-containing foods or takes any of a number of drugs, such as amphetamines, cocaine, ephedrine, pseudoephedrine, procaine preparations with epinephrine, methyldopa and phenylpropanolamine. The treatment of choice for the hypertensive crisis in the ED is phentolamine.[16] All patients on MAO inhibitors or who have taken an MAO inhibitor within two weeks should be on a tyramine-restricted diet. If patients taking MAO inhibitors must be treated with pressor agents, one-quarter the usual dose should be tried as a test dose and titrated accordingly. These patients will require ICU monitoring and the availability of the appropriate antihypertensive agents.

MAO inhibitors in combination with narcotics may lead to a syndrome characterized by restlessness, agitation, tremulousness, myoclonic jerking, sweating, high fever (to 109^0 F), stupor, seizures, coma, and death now known to be the Serotonin Syndrome. In particular, this syndrome has been reported with Demerol and dextromethorphan. Treatment entails discontinuing the offending agents and providing supportive measures. Patients who must be treated with a narcotic should receive agents other than Demerol. Treatment should be initiated with a quarter-strength test dose, after which the dose is increased incrementally to full strength as tolerated.

Outcomes

There have been few clinical trials of psychiatric evaluation, treatment, and release from emergency rooms let alone CDU's. Psychiatric CDU care remains largely driven by the limitations in private insurance and public funding for both inpatient and outpatient treatment. Thus, psychiatric patients for whom safety mandates more than outpatient office-based care often await openings in inpatient units, day treatment programs, residential programs, rehabilitation centers, and "wrap-around"

home services as CDU patients. The therapeutic setting, evaluation and treatment options outlined in this chapter will assist the emergency room physician with the initial stage of care.

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Asthma
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Asthma: Summary   (Level A recommendation, Class I strength of evidence)
IF adult patients with acute asthma after emergency department (ED) therapy require extended care and have none of the following: pregnant, new EKG changes, respiratory rate >40, impending respiratory failure, evidence CHF, inability to perform spirometry, O2 sat < 90% room air, temperature > 101 F, pCO2 > 45, pH < 7.3;
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with hydration, steroids, nebulizer treatment q 3h & peak flows
BECAUSE the therapy is as effective as inpatient hospital services in clearing the asthma, patient satisfaction is higher than inpatient hospital services, and cost of services are lower than inpatient services.

BACKGROUND

Asthma is a chronic inflammatory disorder of the airways that causes recurrent episodes of wheezing, breathlessness, chest tightness, and coughing usually associated with widespread but variable airflow obstruction that is often reversible spontaneously or with treatment.[1] In the United States nearly 15 million people have asthma and in 1995 exacerbations of this disease accounted for over 1.5 million ED visits, 5000,000 hospitalizations, and over 5,500 deaths. The estimated direct and indirect costs of this disease in 1998 totaled $11.3 billion.[2] Nearly one third of these costs are attributable to hospitalization alone and it is estimated that 20% of all asthmatic patients account for 80% of the direct costs for managing this problem.[3] Also the prevalence of asthma increased in all age, sex, and racial groups from 1980-1994, a trend that appears to be continuing today.[2] Thus the ability to successfully manage the majority of acute attacks in a novel outpatient environment (ED based CDU) has significant ramifications in decreasing the costs associated with managing this disease.

IF: Patient Selection

Patients are appropriate for observation who have acute asthma after ED therapy, require extended care, and have none of the following: pregnant, new EKG changes, respiratory rate > 40, impending respiratory failure, evidence CHF, inability to perform spirometry, O2 sat < 90% room air, temperature > 101 F, pCO2 > 45, pH < 7.3 (See Table).

In the late 1990's prospective randomized trials[4] were done to evaluate the medical and cost-effectiveness, patient satisfaction, and quality of life of patients receiving CDU care for acute asthma compared to inpatient therapy. Patients (not critically ill or with complications of asthma) not meeting pre-established discharge criteria after receiving 3 hrs of standardized, aggressive ED care were randomized to either further aggressive CDU care for 9 hours or to routine inpatient ward care. Fifty-nine % of CDU randomized asthmatics were discharged home while the remaining patients were admitted to the hospital. All patients were closely followed up for 8 weeks after hospital discharge. There were no

differences in the 2 groups during the follow-up period in relapse rates or in any other morbidities. There were significant differences in the length of stay (8.8+-3.6 h v 59.0+-35.9 h), patient satisfaction on 4 of 7 global satisfaction indicators,[5] and quality of life measures (physical, emotional, social functioning, mental health, and vitality), all favoring the CDU pathway. The mean costs per patient in the CDU group was $1202.79 +-$1343.96 compared with $2247.32+-$1110.18 for the inpatient group.[6] The authors concluded that CDU care for selected asthmatics not adequately responding to 3 hours of ED therapy resulted in the safe discharge of most patients and that quality gains and cost-effective measures can be achieved by the use of CDU like units.

Selected patients are unlikely to be successfully treated during observation and should be admitted to the hospital from the ED. There have been a number of studies of acute asthma[7-9] that have shown that a minimal response in airflow improvement after 20-30 minutes of beta agonist administration indicates resistant disease that will require extended care beyond the ED. Recent studies[10] have clarified which of these patients have the highest likelihood of successful discharge home from the CDU. Asthmatics achieving a peak expiratory flow rate (PEFR) of 40% or higher after 3 beta-agonist treatments have a high probability of CDU discharge success, while those that achieve a PEFR of less than 32% need inpatient care as they have a low probability of CDU discharge. The remaining patients (PEFR between 32 % and 40%) have an intermediate probability of CDU success.

THEN: Observation Unit Management/Intervention

Asthma patients can be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with hydration, steroids, nebulizer treatment q 3h* and peak flows.* They should receive oxygen therapy and be monitored with oximetry.

BECAUSE: Observation unit outcome

Many clinical trials (including one randomized clinical trial) have shown a short period of observation (less than 24 hours) can be used successfully. 80% of patients treated in observation units are successfully treated and released home without hospitalization. Reports documenting successful ED based CDU management of acute asthma have been recorded in the medical literature since the 1970s[11] when the specialty of emergency medicine was just beginning. At that time, like today, the use of the CDU for asthma management was mostly driven by a desire to limit the more costly inpatient hospitalizations. Acute asthma was the most common diagnosis entering the CDU and the successful discharge rate to home for this disease was 76% of cases. In the 1980's other retrospective chart audits[12] concluded that the CDU was an appropriate, safe, and less expensive than inpatient admission place ($459.43 v $1347.97 respectively) to treat acute asthma attacks and that its use decreased the hospitalization rate[13] for this problem.

The economic advantages of CDU management of acute asthma may be derived as follows. A recent study[14] of a variety of hospitals in the USA found that for 2149 patients who had an ED visit for asthma-related problems, the average cost per visit was $234. The same paper reported that for 1074 patients that required admission for acute asthma the average length of stay was 3.8 days and the cost was $3103 (range $2200 to >$15000). Approximately 60% of CDU treated non-complicated asthmatics can be successfully discharged without adverse consequences.[4] If 500,000 asthmatics are admitted in the USA per year it is likely that 10% are complicated, leaving 450,000 uncomplicated admissions. Of these 60 % or 270,000 can be managed in the CDU and thus avoid admission. The admission costs would have been 270,000 x $3103 = $837,810,000 for these patients. CDU costs for these same patients would have been 270,000 x $1202.70 = $324,729,000.[4] Thus the national savings per year on a national basis for CDU care of these patients is estimated to be the difference or $513,081,000.

The positive outcome seen with the use of CDU like units for managing asthmatic attacks has attracted international attention. Foreign language journals[15] indicate similar trends for asthma management – no health outcome differences between CDU treated patients and those cared for in

ordinary hospital units, no increased CDU complication risks, and CDU patients having a reduction in length of stay and decreased hospital costs.

The future possibilities for increasing the CDU's role in managing acute asthma attacks are attractive. Patients with asthma exacerbations need further education about their disease and a plan developed with them for future exacerbation assessments and home management strategies. This can be done in a more effective and complete fashion if they are managed in a CDU type unit with systems in place to maximize this educational process. More severe or complicated asthma patients with severe and none responding airways obstruction, but not ill enough to go to an ICU, may be best managed in a ED based CDU as the physicians and nurses there are comfortable with very frequent inhalation therapies and airway/ventilator management, in contrast to the situation on most hospital wards.

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Table: Asthma Inclusion and Exclusion Criteria

Observation Asthma		
Inclusion Criteria		* Shortness of breath * Mild to moderate use of accessory muscles * Wheezing * Fair to good air exchange * Stable blood pressure * Normal mentation
Exclusion Criteria		* Peak flow < 20% predicted or < 20% improvement 1st Neb * Pneumonia * New EKG change (except sinus tachycardia) * RR >40 * Impending respiratory fatigue/failure * Evidence of CHF * Inability to perform spirometry * ABG's (if obtained) 7.30 < pH > 7.50, p02 < 70, pc02 >45 * Pulse oxymeter < 90% on room air * Bronchospasm due to epiglottitis, aspiration, FB * Temp > 101F * COPD * EKG changes

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Abdominal Trauma

Robert D. Welch, MD, FACEP

Summary: Penetrating Abdominal Trauma Level B, Class I Strength of Evidence
Summary: Blunt Abdominal Trauma Level B, Class IIa Strength of Evidence
IF a patient has sustained an abdominal injury (either blunt or penetrating), is hemodynamically stable, has normal initial diagnostic studies that may include abdominal and pelvic computed tomography (CT), focused assessment by sonography for trauma (FAST), or diagnostic peritoneal lavage (DPL) and has a low probability of having sustained a serious injury
THEN the patient should be evaluated by a period of observation, repeat exam, and possibly repeat diagnostic studies such as the FAST exam (if available), or (if indicated) repeat CT of the abdomen and pelvis.
BECAUSE certain injuries may result in delayed findings and serious pathology of which the vast majority of occult injury will be detected by a period of observation that includes serial exams and further diagnostic study dependent upon physical findings and the level of clinical suspicion for significant intra-abdominal injury.

BACKGROUND

It is important for patients with abdominal injuries to be evaluated promptly to identify the presence of significant abdominal injuries. Delays in diagnosis or intervention can lead to significant patient morbidity and mortality. The conventional approach to evaluate patients with suspected abdominal injury includes history (if possible), physical examination, ultrasonography (FAST), and focused CT scan of the abdomen and pelvis. An accurate history provides the mechanism of injury and guides the examiner's clinical suspicion for significant abdominal injury. There is consensus in the literature about the unreliability of initial examination of the abdomen following acute blunt injury. However, one study did show a high negative predictive value of normal physical findings in patients with isolated abdominal injury or lower rib fractures due to low energy impact.[1] A more recent prospective study reported a pre-test sensitivity and specificity of physical examination to detect intra-abdominal hemorrhage to be 39 and 90% respectively.[2] This same study showed the sensitivity and specificity of emergency physician's FAST examination to detect intraperitoneal hemorrhage to be 86 and 99%, respectively. FAST is a quick, non-invasive, repeatable, and an inexpensive tool that is used in the setting of potential traumatic abdominal injury to detect the presence of free intraperitoneal fluid (hemorrhage) as an indicator of organ injury. A positive FAST proves the presence of intraperitoneal injury, but a negative scan fails to confidently exclude traumatic organ injury. A recent Cochrane review of emergency ultrasound-based algorithms for diagnosing blunt abdominal trauma states that due to its poor overall sensitivity, ultrasound cannot be used to rule out abdominal injury.[3] CT scan remains the diagnostic study of choice to detect intra-abdominal injury in traumatized patients.

Abdominal injuries are generally divided by mechanism into blunt or penetrating injuries because the clinical evaluation, diagnostic tests, and treatment may differ. When considering management pathways for the observation unit, these differences must be considered and, therefore, management goals

here are divided in an injury specific format. The ability to observe abdominal injuries at specific institutions should be based on that institutions ability to care for trauma patients. These institutions must insure that repeat clinical evaluation of patients occurs, and that personnel with decision-making capability are immediately available to begin necessary treatment, including potential operative intervention. An analysis of errors that occurred in the management of trauma patients in San Diego County found the single most frequent error was failure to properly evaluate the abdomen.[4] This should be considered when evaluating and managing trauma victims with the potential for abdominal injury. Finally, although DPL has been all but abandoned in many centers it still is an effective diagnostic aid under certain circumstances.

Penetrating Abdominal Trauma
IF: Patient Selection

Patients selected for possible observation include only stable patients without multiple injuries and not requiring hospital admission for any other reason. Penetrating abdominal wounds result from a variety of mechanisms that include stab wounds, gunshot wounds, or others mechanisms (for example impalement injuries). Stable patients with anterior abdominal stab wounds and no signs of serious injury on exam are well suited to observation.[5] Some patients will have wounds that penetrate the peritoneum but do not cause abdominal organ injury. It is the goal of observation to determine which patients with peritoneal penetration have significant injury requiring laparotomy and which patients can be managed non-operatively, thereby reducing the rate of nontherapeutic laparotomy. Similarly, many stable patients with penetrating flank wounds can be observed.

Nonselective immediate laparotomy for penetrating abdominal trauma results in up to a 30-40% incidence of unnecessary surgery.[6-8] Many confirmed solid organ injuries (liver, spleen, kidney) can be observed. Demetriades reported on patients with solid organ injury who were hemodynamically stable without peritonitis and who were evaluated with CT scan. In the absence of CT evidence of hollow viscus injury, patients were observed with serial clinical examinations, hemoglobin levels, and white cell counts. Overall, 27% of patients with solid organ injuries were successfully managed non-operatively, including 18 cases with grade III to V injury.[9] However, there is no good evidence that patients with this type of injury can be appropriately cared for in a short-term emergency department based observation unit.

Selected gunshot wounds to the abdomen can be observed (possibly with DPL as an adjunct), but this should only be done in experienced trauma centers.[10-13] In one study, stable patients who presented with superficial or tangential injuries were able to be evaluated and subsequently discharged from the ED on the basis of physical examination and plain radiographs.

THEN: Observation Unit Management / Intervention

Patients should be evaluated during their period of observation with repeat exam, and one of various methods used to determine the need for laparotomy including selective observation (repetitive physical exam in alert patients),[14-18] local wound exploration (evaluation of the wound for peritoneal penetration, [LWE]) and DPL if penetration occurs,[6, 19-25] CT scan[26-28], laparoscopy (with or without DPL as a primary indicator)[29-32], or FAST. Laparoscopy requires a patient being taken to the operating suite likely precluding ED observation. As already discussed low thoracic or upper abdominal wounds that penetrate the diaphragm may not cause immediate problem and are candidates for observation even when initially clear of abnormal clinical findings.[33-35]

BECAUSE: Outcomes of observation unit intervention

Serial physical exam and selected diagnostic studies can be unreliable, particularly when the possibility of diaphragmatic injury exists, making observation and the use of more sophisticated studies necessary in certain cases of lower chest or upper abdominal (thoracoabdominal) stab wounds.[25]

Many centers have adopted LWE and DPL or simple observation of the alert stable patients to evaluate anterior abdominal stab wounds, but observation with serial physical exam is a critical aspect of

these pathways. Using LWE has certain advantages. Patients with a clearly negative LWE can be discharged after good local wound care and do not require observation. For patients with demonstrated peritoneal penetration, or if the examiner is unsure if penetration occurred, further observation and DPL if a diaphragm injury is suspected is critical.[22, 23, 25] It has been suggested that abdominal stab wound patients that are hemodynamically stable can be sent home from the emergency department if DPL counts are less than 1000 red blood cells/cubic millimeter[36] but others have demonstrated that using such a low number results in non-therapeutic laparotomy.[37]

Abdominal computed tomography has been evaluated and may be an effective diagnostic study, but it has not been directly compared to the simpler and less expensive alternatives described above.[27, 38] However, one study did show CT to have a 100% negative predictive value in hemodynamically stable patients with anterior abdominal stab wounds.[39] In this study, 19 out of 67 patients that had a CT had positive CT findings, leading to laparotomy in 10 patients.

The evaluation of deep posterior (back) or flank wounds is different because LWE is useful in wounds with only superficial penetration. If the injury has penetrated the muscle fascia, the potential for serious injury is increased and it is very difficult to judge the full depth of wound penetration. When the patient has no evidence of significant blood loss, shock, or peritonitis (is "asymptomatic") the literature and experience indicates that observation and serial physical exams will be effective in both diagnosing occult injury and reducing the rate of non-therapeutic laparotomy.[22, 40] Some authorities prefer the use of abdominal computed tomography (CT)[41, 42], later refined to "triple contrast" CT (3-CT, defined as intravenous, oral, and rectal contrast), to look for intra-abdominal as well as retroperitoneal injuries.[27, 43-47] Stable patients with penetrating flank wounds can be divided into low, moderate, or high risk based on 3-CT findings. Low risk findings are those demonstrating no penetration or penetration into subcutaneous tissue only. The moderate risk group had penetration into muscle or a retroperitoneal hematoma not near a critical structure. Finally, the high risk 3-CT demonstrates extravasation of contrast from the colon or kidney, hematoma near a major vessel, fluid in the peritoneal cavity, free air in the retroperitoneal space, or injury above and below the diaphragm.[45] This scheme was modified by Kirton[46] to low risk (no or subcutaneous injury only) and high risk (deep muscle or any other injury). This algorithm can be supplemented by DPL in certain cases. Albrecht [47] felt that patients with isolated back or flank wounds who are stable and had a low-risk 3-CT could be immediately discharged. Patients with the higher-grade 3-CT findings or other potential for serious occult injury should be observed for 6 - 24 hours. Others have argued that the routine use of CT scanning is too costly for the yield of significant injury and observation alone is more appropriate as the CT did not alter routine care.[48] Macleod reported that initially asymptomatic and stable patients admitted for observation with penetrating wounds to the flank developed signs and symptoms of injury requiring laparotomy within 18 hours, the majority (94%) within 6 hours. Patients undergoing observation for penetrating wounds to the flank require diligent frequent examination, especially during the first 6 hours.[49]

For patients with penetrating abdominal, thoracoabdominal, or flank wounds, no single course of action or algorithm is optimal for every patient (as is true for the other injuries discussed here). In some cases, observation alone may be appropriate, particularly in patients who are alert, not intoxicated, and have no other serious distracting injuries. Imaging the diaphragm is difficult, and LWE may not be definitive. In many patients with penetrating flank wounds the use of 3-CT coupled with observation (and occasionally DPL) appears to be a safe and effective manner to manage these types of injury. The single unifying aspect of all the different management schemes is the need for observation. Finally, if exam or diagnostic studies are or become equivocal during observation, admission and possible laparotomy should be strongly considered.[50]

Ultrasound has been evaluated as a screening tool for penetrating injuries. Its use in stable, asymptomatic patients sustaining anterior abdominal stab wounds by surgical residents using an 8mHz probe to detect fascial defects has shown promise, with 59% sensitivity and 100% specificity (PPV 100%, NPV 59%).[51] In patients with no observable fascial defect, LWE is not indicated. However, sufficient data is not yet available to make sound recommendations.[52]

Blunt Abdominal Trauma

IF: Patient Selection
      A patient is appropriate for observation who has possible sustained a blunt abdominal injury, is hemodynamically stable, has normal initial diagnostic studies that may include abdominal computed tomography (CT) or , focused assessment by sonography for trauma (FAST), and has a low probability of having sustained a serious injury.

THEN: Observation Unit Management / Intervention
      The management of blunt abdominal trauma differs from penetrating trauma. It is important to realize that most authorities feel observation alone is not considered adequate when evaluating patients with blunt abdominal trauma or suspected injury. The physical exam may be unreliable in intoxicated, head injured, multiply injured patients, or those with spinal injuries. Many patients with abdominal tenderness will not have serious intra-abdominal injuries and some patients with significant intra-abdominal injury will not have abdominal tenderness or other physical signs of injury.[1, 53, 54] A large multi-center study of patients with potential blunt abdominal injury that excluded serious head injury cases (defined as a GCG <14) found that 19% of patients with no tenderness on abdominal exam had a positive CT scan for significant abdominal injury, and 11% of patients who had a CT scan based solely on the mechanism of injury had a an abnormal scan. In addition, 16% of patients who had an initial negative chest and pelvic x-ray had a positive CT scan.[55] These findings require that diagnostic testing and/or observation are necessary to both reduce the incidence of unneeded surgery and to avoid missing serious abdominal injury. Due to the potential for "missed injuries", hospitalization for observation has been the standard for patients who have sustained potential abdominal injuries that do not have obvious pathology noted on initial examination or initial diagnostic studies.[55] The choice of diagnostic study should be based on each institution's expertise. Some commonly used studies will be considered here.
      Computed tomography, DPL, and ultrasound (US) are among the diagnostic modalities used in the evaluation of blunt abdominal trauma. Each modality has its own advantages and disadvantages (an in-depth discussion is beyond the scope of this section) but no study is 100% sensitive in the diagnosis of significant intra-abdominal or retroperitoneal injury. The diagnostic test used should be based on the sensitivity and specificity of the study at that institution, the prevalence of blunt abdominal trauma, and the intended goal of the diagnostic study (to diagnose those who require laparotomy or diagnose all intra-abdominal injuries).[56]
      In many centers, ultrasound and CT have virtually replaced DPL as the initial method of evaluating stable abdominal injury patients.[55, 57] Not only has the accuracy of abdominal CT been studied in trauma centers, but it has also been reported to be accurate in low volume non-designated trauma centers.[58] DPL still has a place in the evaluation of the unstable blunt trauma patient when the possibility of hollow viscus injuries exists.[59-62]
      Helical or spiral CT scanners provide faster scanning times and improved image quality. The concept of whole body imaging (pan scanning) involves CT imaging of the head, cervical spine (including the cranio-cervical and cervical-thoracic junction), chest, abdomen and pelvis. This approach may be justified as a screening tool in patients with severe trauma (ISS of 16 or greater), but due to the potential consequences of exposure to increased levels of radiation, may not be justified as a screening tool in lesser traumatized patients.[63] Study authors site an increased rate of identification of injuries that were not identified by either physical exam or plain film x-rays of the cross-table lateral c-spine, chest, and pelvis. In addition, the speed with which injuries are identified allows for rapid development and implementation of treatment plans. The necessity of identifying clinically significant injuries has to be weighed against the concern for increased radiation exposure.[64]
      Two recent studies (one retrospective[65] and one prospective[55]) suggest that some patients with suspected blunt abdominal injuries and negative abdominal CT scans can be discharged without observation. In the large prospective study, only 25 of 2744 patients were ultimately diagnosed as having

bowel injuries. Of these 25 cases, three abdominal CT studies were negative for injury (a miss rate of 12%). Extra-abdominal injuries were found in almost all (97%) of all study patients.[55] In the accompanying discussion, the authors estimated that 40% of their patients with normal abdominal CT studies could have been sent home. Due to the potential for missed bowel injuries and other factors such as the associated injuries and drug or alcohol intoxication, it is not yet clear that it is safe or even possible to immediately discharge all patients with negative abdominal CT scans from the emergency department. The care and disposition of minimally injured patients with negative abdominal CT scans may be streamlined in the observation unit by using a critical path that identifies the needs of these patients early in their observation course.[66]

The ability of CT scan to diagnose bowel and mesenteric injury is not totally clear but most studies suggest it is not 100% sensitive. Recent studies show that computed tomography may be reasonable accurate for the diagnosis of bowel and mesenteric injuries when specific signs of bowel or mesenteric injury are present.[67, 68] When only nonspecific signs of bowel or mesenteric injuries are seen on CT images, correlation with clinical findings is necessary. A repeat CT scan after 6-8 hours in stable patients may help determine the significance of these nonspecific findings. Others also suggest CT may be "reasonably" accurate for small bowel or mesentery injury[69, 70] but some data does not support this conclusion.[71-74] Regardless, CT scan is not 100% sensitive for injury and observation should be the norm for any patient with a mechanism or exam consistent with the possibility of hollow viscous or mesenteric injuries despite the results of a CT scan.

Some have advocated managing intoxicated blunt abdomen trauma cases without CT scan[75] and others suggest patients do not need observation based on alcohol alone.[76] Other studies have looked at the possibility of reducing the high frequency of negative abdominal CT scans by considering predictors of abdominal injury[77, 78] and practice guidelines that allow some patients to be observed with serial exam.[79-81] These concepts are still in the early stages and not considered to be of proven efficacy. Use of short-term observation is very useful should the physician choose to adopt any of these strategies.

Ultrasound (US) has become the initial diagnostic study of choice for screening blunt abdominal trauma victims at many institutions in the United States.[82-87] A consensus paper and now general terminology has labeled this study the "focused assessment by sonography for trauma" or FAST exam.[88] An important aspect of the use of the FAST exam is its limitations. Ultrasound may miss injuries that are retroperitoneal, bowel injury, and intraperitoneal solid organ injury without hemoperitoneum.[89, 90] Ultrasound was found to be only moderately sensitivity for detecting free fluid and/or parenchyma injury.[91-93] It may also miss injuries in patients with pelvic ring fractures.[94] If done immediately after an injury, US will miss small amounts of free intraperitoneal fluid but as bleeding continues the threshold for a positive study can be reached.[95, 96] Indeterminate scans mandate alternative diagnostic studies to search for abdominal injuries.[95, 97]

A meta-analysis of the diagnostic utility of the FAST for blunt abdominal trauma found that a positive study was very good for ruling-in injury but a negative study was not sufficient to rule-out serious injury (negative likelihood ratio (LR) 0.23 for organ injury; negative LR 0.24 for free intraperitoneal fluid).[98] These aforementioned studies confirm the need for observation and possibly repeat FAST exam or other studies if the FAST exam is used as a primary screening modality. There is suggestion that the contrast-enhanced US (FAST using contrast)[99, 100] or tissue harmonic imaging[101] may be a useful alternative method to evaluate abdominal trauma but this remains to be proven.

In the future, randomized clinical trials comparing emergency department observation unit compared to in-patient based evaluation and treatment would benefit patient care and could possibly result in cost savings and decreased radiation or contrast agent use among abdominal trauma patients.

Observation and Abdominal Trauma Penetrating		
Inclusion Criteria		* Stable patients with anterior abdominal stab wounds * Low probability of having sustained a serious injury
Exclusion Criteria		* signs of serious injury on exam

Observation and Abdominal Trauma Blunt		
Inclusion Criteria		* Stable patients with blunt abdominal injury * Low probability of having sustained a serious injury
Exclusion Criteria		* signs of serious injury on exam * signs of serious injury on abdominal computed tomography (CT), focused assessment by sonography for trauma (FAST), or diagnostic peritoneal lavage (DPL)

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Chest Trauma and Observation
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Summary: Penetrating chest trauma Level A recommendation, Class II strength of evidence Summary: Blunt chest trauma Level C recommendation, Class II strength of evidence
IF a patient has sustained a penetrating or blunt chest injury that has the potential to result in serious injury, has normal initial diagnostic studies (that may include chest radiography, electrocardiography, or other studies), O2 saturation $\geq$ 94%, GCS >14, and has a low probability of having sustained a serious injury,
THEN the patient should be evaluated by a period of observation with serial physical examination, oximetry, and other diagnostic tests as indicated (ie, repeat chest radiograph or FAST exam for pericardial fluid)
BECAUSE observation improves physician decision making (some injuries result in occult serious damage and nearly all of these will be detected during observation by serial exams and further diagnostic study) and may improve cost effectiveness.

BACKGROUND

Between 1984 and 1986, an estimated 52% of trauma care expenditures were utilized for patients with minor injuries.[1] This trend has continued with data from 2003 to 2005 showing the economic burden of blunt and penetrating trauma continues to be high.[2] The National Study on Costs and Outcomes of Trauma (NSCOT) was undertaken to address the needs for better information on trauma care.[3] The NSCOT cost data has yet to be published but clearly the costs of treating victims of blunt and penetrating trauma remain very high. The use of efficient short-term observation will help reduce the cost of treating patients with minor injuries.

Because it can be difficult to diagnose certain occult injuries upon initial presentation, many trauma patients require repeat exam and diagnostic tests. It has been noted that minimally injured patients often remain hospitalized beyond 24 hours for a variety of reasons including the need for repeat exam and diagnostic studies.[4] Additionally, some patients are intoxicated with drugs or alcohol precluding immediate discharge. There are very few studies that look specifically at the outcomes and costs of observation unit based management of traumatically injured patients. Most of the following discussion is based on exiting literature of specific injuries and is not related to the actual location of the observation period.

Patients who sustained chest injuries are uniformly evaluated and treated in the emergency department (ED). There were an estimated 41.9 million injury-related visit to EDs nationally in 2005 (over one-third of the total 115 million visits). Of those 4.24 million were for motor vehicle crashes and almost 2.2 million visits were for intentional injuries like cutting, piercing, or other mechanisms (which include firearms and explosives).[5] These mechanisms, and others not listed here, can result in serious chest injuries. In the instance of penetrating chest injury, potentially life-threatening complications such

as pneumothorax or cardiac tamponade may be either very occult or absent on presentation. Physical examination alone is unable to detect hemopneumothorax in patients sustaining penetrating chest injury, with sensitivities of 50% for auscultation, 25% for pain or tenderness, and 32% for tachypnea. The negative predictive values of these tests were <91%.[6] For this reason, all patients with penetrating chest injury require, at a minimum, a chest x-ray.

Patients with blunt thoracic trauma are also at risk for intra-thoracic injury. Myocardial contusion is one type of cardiac injury seen in patients with blunt thoracic trauma. This condition has fostered a great amount of debate in the literature. Since the outcome of hemodynamically stable and arrhythmia free patients with isolated blunt chest trauma and suspected myocardial contusion is excellent, many authorities question the importance of a prolonged hospital stay and the multiple diagnostic studies previously advocated to diagnose this injury in stable patients.[7-11] A stable patient with blunt chest trauma and no other serious injuries in whom the potential for cardiac contusion exists may be a candidate for short-term emergency department observation. Additionally, those with uncomplicated chest wall contusions or rib fractures may benefit from short-term observation, pain, control, and pulmonary care prior to discharge.

Penetrating Chest Trauma
IF: Patient Selection
IF a patient has sustained a penetrating chest injury that may result in serious injury, has normal initial diagnostic studies (that may include chest radiography, electrocardiography, or other studies), O2 saturation $\geq$ 94%, GCS >14, and has a low probability of having sustained a serious injury,

THEN: Observation Unit Management / Intervention
THEN the patient should be evaluated by a period of observation with serial physical examination, oximetry, and other diagnostic tests as indicated (repeat chest radiograph, echocardiogram of the heart, or chest CT). Patients having normal physical examinations and diagnostic studies at prescribed follow-up time periods can be safely discharged from the ED.

BECAUSE: Outcomes of observation unit intervention
BECAUSE observation improves physician decision making (some injuries result in occult serious damage and nearly all of these will be detected during observation by serial exams and further diagnostic study) and may improve cost effectiveness.

Asymptomatic stab wounds to the chest (negative initial CXR) are well suited to evaluation and management in an observation unit. A number of studies have demonstrated this group can be managed without hospitalization if a six-hour post-injury chest radiograph is normal.[12-14] Two observational studies found that there was only a 0 - 4% rate of pneumothorax discovered on a three-hour post injury chest radiograph.[15, 16] A prospective study of 10,544 patients with stab wounds to the chest found 4,106 patients with "asymptomatic wounds" and a negative initial chest radiograph. The negative predictive value for a single chest radiograph was 87.4% indicating that the low predictive value precluded immediate outpatient management.[17] Delayed injuries were found in 519 patients (12.6%). All of these injuries were diagnosed within an eight hours observation period and almost 88% of all cases could be managed as outpatients after a repeat chest radiograph at six-hours and a total of eight hours of observation.

The use of advanced imaging has blossomed over the last decade but the cost-effectiveness of utilizing imaging techniques such as CT scan for asymptomatic patients has yet to be determined. Non-contrast chest CT was found to be as reliable as a 6-hour chest x-ray to rule out delayed pneumothorax in stable patients who sustained a penetrating chest injury. All hemodynamically stable patients with initially negative chest x-rays were immediately sent for chest CT and, if no abnormal findings, observed until a repeat 6-hour chest x-ray was completed. CT identified six pneumothoraces and one hemothorax. Two patients required operative intervention. There were no delayed chest x-ray findings provided the CT was negative.[18] This approach may, in the future, allow for the rapid disposition (discharge) of patients

with penetrating chest injury who have a negative chest CT thereby reducing ED length of stay. Until these findings are confirmed an observation period of three to six-hours is still warranted.

Certain stab wound injury patterns warrant more extensive evaluation with other diagnostic studies and possibly longer observation periods (up to 24-hours).[19] Central chest wounds (defined as between the nipple lines) are more prone to cardiac injury with a mortality rate of 22% if there is a cardiac wound.[20] Cardiac ultrasound is effective in excluding cardiac injury.[19, 21, 22] Immediate ED ultrasound to evaluate for potential cardiac wounds (pericardial effusion) is accurate[23, 24] and improved outcomes among patients with cardiac injuries.[25] Emergency department limited echocardiography is now a primary study in many trauma centers and should be performed on all patients with penetrating thorax or thoracoabdominal wounds (below the nipple line anterior and below the tip of the scapula posterior).[26]

Thoracoabdominal wounds also can result in diaphragm penetration and intra-peritoneal injury.[27-30] Ultrasonography has been studied as a noninvasive screening modality to determine clinically significant truncal visceral injury.[31] Ultrasonic examination of four quadrants around each truncal wound was performed. The skin, fascia, and muscle planes were studied and compared to the analogous contralateral quadrants on the same patient, looking for the greatest depth of fascia violation or muscle edema. There were no false negatives in this study, which had a sensitivity and negative predictive value of 100% in determining clinically significant truncal visceral injury in penetrating truncal trauma. Diagnostic peritoneal lavage (DPL) can also be used to evaluate this type of injury.[13, 27, 32, 33] Patients with negative initial studies are appropriate for observation with repeat radiographs and exam.

Another diagnostic approach for penetrating thoracoabdominal wound is laparoscopy[30, 33, 34] or angiography to exclude significant injury. Laparoscopy has been shown to be an important and safe modality for the evaluation of diaphragmatic injuries in penetrating thoracoabdominal injuries.[35] Patients undergoing laparoscopy will generally be cared for by the surgical trauma team and admitted for an observation period if the examination finds no serious injury.

Regardless of the penetrating chest injury location and mechanism all patients with initially negative studies will still require a period of observation and repeat exam.[13, 16] We utilize a strategy of repeat radiographs and ultrasound (if indicated) at six-hours and a minimum six-hour observation period.

There is a lack of randomized clinical trial information but, as will be described later, cost savings appear to be significant for patients with traumatic chest injuries who are evaluated in observation units or by a critical path that is applicable to observation units.[4, 36, 37]

Blunt Chest Trauma
IF: Patient Selection
IF a patient has sustained a blunt chest injury that may result in serious injury, has normal initial diagnostic studies (that may include chest radiography, electrocardiography, cardiac biomarkers, or other studies), O2 saturation $\geq$ 94%, GCS >14, and has a low probability of having sustained a serious injury.

THEN: Observation Unit Management / Interventions
THEN the patient should be evaluated by a period of observation with serial physical examination, oximetry, and other diagnostic tests as indicated (repeat chest radiograph, echocardiogram of the heart, or chest CT). Asymptomatic or minimally injured patients can be evaluated during a period of observation and avoid hospitalization if their evaluation remains negative.[38, 39]

BECAUSE: Outcomes of observation unit intervention
BECAUSE observation improves physician decision making (some injuries result in occult serious damage and nearly all of these will be detected during observation by serial exams and further diagnostic study) and may improve cost effectiveness.

The incidence of myocardial contusion continues to be difficult to determine despite advances in biomarkers and imaging studies. There is no "gold-standard" for making the diagnosis other than direct examination of the heart[40] but a reasonable estimate of the incidence among blunt chest trauma patients is

around 15%[38, 41-43] It is also difficult to determine the rate of delayed cardiac complications in blunt chest injury patients. Studies have attempted to relate cardiac dysrhythmias, myocardial infarction, pericardial effusions, and hypotension as markers of the complications of cardiac contusion. Many patients in these studies had serious co-morbidities making it difficult to clearly define a cause and effect link for these cardiac complications. Foil et al found a 5% incidence of cardiac related complications but it was not clear all were the result of myocardial contusion.[8] Fulda determined that of 17 patients with initial normal ECGs, seven (41%) developed clinically significant abnormalities (six required intervention).[44] Another study of 342 patients with blunt trauma admitted to an intensive care unit found a 13% incidence of myocardial contusion. Twenty-seven (61%) of the patients with myocardial contusion developed arrhythmias or cardiogenic hypotension and cardiac injuries contributed to six deaths.[45]

The ideal cardiac diagnostic study to predict cardiac complications in patients with blunt chest trauma is unclear.[46] Historically, serial creatine kinase–MB (CK-MB) were used to diagnose myocardial contusion. It has been suggested that a total CK-MB greater than 200 mg/dl was 100% sensitive for predicting cardiac complications.[45] Unfortunately, virtually all other studies have determined that CK does not predict the development of cardiac complications and is of little value.[8, 9, 39, 40, 46-52] A meta-analysis did support the use of ECGs and CPK-MB measurement to predict complications. It is difficult to interpret studies in this area because of differences in the definitions of patient populations, complications, the reporting of diagnostic test results, and the treatments.[53]

The cardiac troponins are more sensitive and specific for diagnosing myocardial contusion than many other tests.[44, 49, 54, 55] These markers however, do not aid in the prediction of complications.[44, 55-57] In animal studies, the troponins were better able to detect the degree of myocardial damage and were superior to other markers of cardiac injury.[58, 59] A normal troponin level in stable patients four to six hours post-injury excluded significant blunt cardiac injury.[60] Salim has suggested that the combination of EKG abnormalities and troponin I are 100% sensitivity for detection of clinically significant blunt chest trauma (defined as cardiogenic shock, dysrhythmias requiring treatment, or structural cardiac abnormalities related to trauma).[61] The finding of 100% sensitivity is highly likely not accurate. For seriously injured patient, this is a recommended study but, because of the very low pre-test probability of serious complications, the need to employ any of the biomarkers of cardiac injury in stable patients with normal presenting ECGs remains controversial.

Radionuclide cardiac imaging studies have been investigated in patients with suspected myocardial contusion. The bulk of the evidence suggests that they do not predict complications in the asymptomatic patient.[62-76] The same meta-analysis discussed above found that radionuclide scans are not predictive of complications.[53] An individual case may warrant one of these studies, but none of these should routinely be used in patients with suspected myocardial contusion.

Echocardiography has been utilized to diagnose myocardial contusion.[8, 77, 78] Transesophageal studies are not limited by rib fractures, chest tubes, or other problems that can be associated with transthoracic studies. Transesophageal echocardiography seems to be the best tool for diagnosis and could be considered for patients with high clinical suspicion of cardiac contusion.[79] Transesophageal studies result in improved image quality and it can be done at the patient's bedside.[78, 80, 81] Although there are those who advocate echocardiography to aid in the diagnosis and management of myocardial contusion[77, 82], most authorities do not routinely use echocardiography as a screening tool for low-risk patients.[10, 45, 46, 78, 83] Maenza, et al[53] could not determine the diagnostic value of echocardiography from their meta-analysis. The value of echocardiography is most obvious for its ability to rule out other structural cardiac abnormalities (valve injury, pericardial effusion, etc.) and providing a general sense of cardiac filling and function in the critically ill patient. Formal echocardiography, in most cases, should be reserved for patients at higher risk for other potential cardiac injuries.[9, 38-40, 78, 81, 84-87] In institutions where the focused assessment by sonography for trauma (FAST) is done, the subxyphoid view can be done to rule out pericardial effusion or poor cardiac function.[23, 24, 88]

Reviews of myocardial contusion still recommend asymptomatic patients should be monitored for 24-48 hours[40, 85], but most studies do not find this duration necessary and consider it excessive and

expensive.[8, 10, 38, 39] Expert opinion and study has shown that asymptomatic patients can be observed in the emergency department or short-stay unit and, if the patients remain stable, they can be discharged. Recommendations as to the length of monitoring time vary, and include "brief"[10], less than six hours[8, 60], six to 12 hours[7], 24 hours[51, 85, 89], or as much as 48 hours.[40] Patients over age 50 (or 55) years of age may require the longer monitoring periods[10] but there is no definitive data to substantiate this claim. The longer observation times and multiple tests for all patients seems to be is based on the worry of liability and rare delayed complication.[90] Delayed complications have still warranted report in the literature.[47, 50, 91-95] These events should not be the overriding factor used to determine the need for hospitalization. It has been shown that proven myocardial contusion virtually always resolves leaving no functional impairment.[96]

Other injuries must also be considered with blunt chest trauma. CT scan of the thorax has been found to be significantly more effective in detecting intrathoracic injuries such as pneumothorax, hemothorax, pulmonary contusions, and mediastinal hematomas than chest x-ray.[97, 98] Chest CT also was more reliable the pain chest radiography for detecting fractures of the rib, scapula, sternum, and vertebra. Since even minor rib fractures may be complicated by pneumothorax.

Cost savings appear to be significant for patients with traumatic chest injuries who are evaluated in observation units or by a critical path that is applicable to observation units.[4, 36, 37] For all types of trauma cases evaluated in ED observation units in the 1980's, 80% were ultimately discharged home without a hospital admission resulting in over 50% in cost savings. In addition, in-patient beds are preserved for the sicker patients treated in a busy trauma center.[36]

In the future, randomized clinical trials formally evaluating the outcomes and costs of observation unit-based management of patients with chest injuries would help optimize patient management utilizing the most cost-effective strategies.

Observation and Chest Trauma Penetrating		
Inclusion Criteria		* Stable patients with asymptomatic stab wounds to the chest * Normal initial diagnostic studies (that may include chest radiography, electrocardiography, or other studies), O2 saturation $\geq$ 94%, GCS >14 * Low probability of having sustained a serious injury
Exclusion Criteria		* Signs of or associated serious injury on exam * O2 saturation < 94% and symptomatic or O2 saturation < 90%

Observation and Chest Trauma Blunt		
Inclusion Criteria		* Stable patients with blunt chest injury * Normal initial diagnostic studies (that may include chest radiography, electrocardiography, cardiac biomarker testing, or other studies), O2 saturation $\geq$ 94%, GCS >14 * Low probability of having sustained a serious injury
Exclusion Criteria		* Signs of or associated serious injury on exam * O2 saturation < 94% and symptomatic or O2 saturation < 90%

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Mass Casualty Injuries
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Mass Casualty Injuries: Summary   (Level C recommendation, Class III strength of evidence)
IF adult patients with blast injuries after emergency department (ED) evaluation and therapy have no apparent or minimal (abrasions, lacerations) injuries, but with risk of exposure to primary blast forces (location history and/or tympanic membrane rupture)
THEN these patients should be optimally managed initially in an ED based Clinical Decision Unit (CDU) for up to 24 hours with cardiac and pulmonary monitoring, frequent neurologic exams, and serial exams for evolving abdominal tenderness
BECAUSE the therapy is as effective as inpatient hospital services

BACKGROUND

There currently exists almost no evidence-based information in the available literature on the role of the short-term observation unit in the management of mass casualties. The few articles that have some basis in evidence concern blast injuries; the most common mass casualty situation. Mass casualties would occur most commonly from terrorist-related events, large industrial events, or from natural disasters. Terrorism or industry-related events have, in the past, been most commonly 'sentinel' events leading to an acute surge of victims, usually to the geographically closest hospitals.[1, 2] Surge management evolving form sentinel events is a topic currently undergoing study my multiple medical and government agencies and organizations. However no one yet has, in evidence-based fashion, addressed possible roles for the short-term observation unit during acute surge situations.[2] Since one of the major functions of short-term observation units is to offload pressures on in-patient beds, and one of the severe problems of hospital surge management is the intense overcrowding, it would seem logical that there would be a role for such units during these surge events.

Patient Selection

There is little or no truly evidence-based literature currently available concerning a role for short-term observation management for such weapon of mass destruction (WMD) injuries as chemical, biological, or nuclear/radiation. Concerns over contamination and latent/prodrome periods of greater than 23 hours may make short-term observation for many of these conditions less than optimal. There is, however, some literature concerning periods of observation for the most common WMD-related injury group - Blast Injuries.

In an article published in *Clinical Decisions in Emergency Medicine*, I reviewed the available literature concerning periods of proposed observation for various blast injuries [2,] and developed the following conclusions:

Disposition

In scenarios where there are small numbers of blast-related patients and the ED/trauma center is functioning in a normal (non-disaster) fashion, disposition of patients should follow normal trauma guidelines. Patients with destabilizing injuries should receive immediate stabilizing interventions by the trauma team and rapidly moved to definitive care areas such as the operating room, or intensive care units.

In most blast situations, closed-area blasts being a possible exception, the vast majority of presenting victims will have only minor 2nd or 4th degree injuries, frequently limited to simple superficial lacerations, abrasions and/or contusions to non-critical or non-"specialty" areas. Review of previous blast events suggest that as few as 15% of patients assessed in the ED will generally require in-hospital admission.[3] If there is no risk of potential exposure to primary blast forces, patients with minor injuries should be able to be discharged from the ED after local wound care with the appropriate follow-up and wound care instructions. More complicated lacerations with contamination and/or penetrations may require intra-operative or other significant interventions and/or delayed closures, and dispositions will be individualized for such patients. Additionally, there may be follow-up needs for psychological and other social issues evolving from the blast event.

Observation for patients with no apparent or minimal (abrasions, lacerations) injuries, but with risk of exposure to primary blast forces (location history and/or tympanic membrane rupture) has been recommended by various authors.[4-9] There are general recommendations that such patients should, after initial evaluation, be observed and reexamined periodically for evolution of symptoms.[4] The most common delayed symptoms are respiratory. Delayed pulmonary symptoms "blast lung" are reported to evolve insidiously and take 12-to48 hours to fully manifest.[4,10] Delayed AGE symptoms can be sudden and profound in onset. Primary blast-related abdominal injuries are also reported as potentially having delayed appearance.[7,9-12] Intestinal perforations are reported as being delayed as long as 5-13 days after injury.[11,12] There is no current consensus on minimum or appropriate time periods for observation of various presentations. Kiser has recommended observation of all blast-injured patients for 6-12 hours.[5] Stapczynski recommends observation for all blast-exposed patients for variable periods.[8] He notes that for those with only soft-tissue findings, the observation period would be as long as the treatment period in the ED before discharge.[8] He recommends observation during the first 24 hours for those with signs of blunt-force trauma and those with tympanic membrane rupture.[8] One report noted overnight observation of victims suffering emotional shock sufficient to require sedation.[13] The same article recommended overnight observation for those with only minor injuries but with a history of transient loss of consciousness.[13] Outcome data for these presentations was not reported. Wightman recommends admission for 1 to 2 days for those with loss of consciousness.[9] Wightman has suggested observation of 6 hours for those with minimal pulmonary symptoms but with risk of exposure to primary blast forces. He however notes that there are no studies to determine risk factors for the sequellae of delayed pulmonary and

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abdominal PBI, and other authors have recommended observation periods of up to 48 hours for those with risk of delayed PBI presentations.[9] Phillips and Wightman suggest observation of 48-72 hours for all patients with pain, tenderness, or other indications of potential abdominal injury.[7,9] Leibovici and colleagues studied survivors of terrorist bombings with isolated TM rupture admitted for at least 24 hours of hospital observation noting that no such patients in the study developed later signs of pulmonary or intestinal blast injury.[6] The authors therefore concluded that such patients could be safely discharged from the ED after chest radiography and a brief observation period, though the specific observation time was not further defined.[6] There is little other discussion concerning observation for blast injury in the literature. Disposition for surviving patients with more significant injuries including 1st and 3rd degree, and more serious 4th degree injuries will be admission, often to intensive care settings, often by way of the operating room.

Management

Management algorithm for observation of blast and other mass-casualty injuries have not yet been defined. In available literature on blast related injuries, most proposals for 'observation' focus on ruling out occult primary blast injury, (PBI). The most common rapidly evolving manifestations of PBI are cardiorespiratory and neurologic. Therefore, those patients being observed for these injuries should have cardiac and pulmonary monitoring and frequent neurologic exams. Gastrointestinal PBI is more rare and evolves more slowly, but those at risk for PBI should have serial exams for evolving abdominal tenderness.

Outcomes

In 2005, I again searched for available literature in this topic area and studied the levels of evidence existed concerning observation for the different injuries described above. These results were presented at the 3rd European EM Conference in 2005 and are as follows:

Results

Manual review of journal articles obtained by repeated computerized searches over the study period produced 19 articles for review. Manually cross-referencing reference lists from obtained journal article and other manual searches produced an additional 6 articles and 2 Emergency Medicine textbook chapters. The 27 articles (25 journal articles and 2 textbook chapters) were then reviewed for content related to discussions of management of blast injuries that included observation. Fourteen articles mentioned the term "observation" in contexts other than medical management and were excluded from further review. Ten of the reviewed references had some discussion concerning observation for medical management of blast-injured victims, (9 journal articles and 2 textbook articles). The 9 journal articles became the final review group.[2,4,6,7,9,14-17]

The 9 journal articles were found to be of the following types; 1 was a prospective, non-randomized observational study,[2] 4 were retrospective blast event case reviews,[4,14-16] and 4 were retrospective reviews and discussions of blast injury management.[2,7,9,17] Only 1 of the journal articles, the prospective study, had observation as one of the primary questions of the article.[6] The 1 prospective article and 1 case report article described actual observation times and outcomes of victims.[6,14] Each of the 9 journal articles recommended or discussed some type of

observation for various types of blast-injured patients. Four articles presented hypothetical observation times for certain types of blast presentations based on anecdote and review case-report data.[2,7,9,17] However, several of the articles commented that exact observation times were unknown, anecdotal, and not prospectively researched.[2,9] In some presented case-report situations, the observation period significantly exceed typical periods seen in ED-based observation units.[7,9]

Discussion

There is currently little evidence-based data concerning appropriate utilization of short-term observation units during mass-casualty surge-management conditions. There is certainly no consensus in available literature concerning appropriate utilization.[2] Current literature, however, suggests observation units might play a specific role in management of certain blast-injury and other mass-casualty presentations.

Could short-term observation units play a role in offloading surge stress on in-hospital units? It is well recognized that Surges from blast injuries occur within the first several hours of the event. One of the major roles of the observation unit has always been to offload stress on inpatient beds. Thus the observation unit should be potentially perfectly positioned to assist in handling such a surge. As previously noted 85-to-90% of casualties will be 'walking wounded'. For those victims who are stable on initial exam but have risk factors for possible evolving injury, or are felt to need further attention at some point, short-term observation might be a reasonable option.

Of greater immediate importance are the approximately 15% of presenting victims who are more seriously injured. This number becomes critically important to the hospital if this is 15% still represents dozens or hundreds of patients. In most studies these victims are noted to arrive within the first 90 minutes to three hours and often represent a second surge that comes after the primary surge of 'walking wounded' has inundated the ED. Here the observation unit would be perfectly positioned to off-load in-hospital bed demands during this surge period by handling lesser-injured victims or those who need short-term observation for potential evolving injuries.

Recommendations

Blast and other mass-casualty injuries can be studied to determine optimal periods of observation. Investigations can then determine the optimal location for such observation, whether short-term or in-hospital-based. The dynamics of surge presentations should be prospectively studied to determine optimal methods of hospital-based response and intervention for such events.

As the majority of victims presenting to hospitals after any mass-casualty event will appear to be minimally injured, the initial care and final disposition of the majority if not all presenting victims will be the responsibility of the ED. However, criteria could be developed and quantified, based on good research, to rapidly determine during triage or initial ED interventions which patients would benefit from short-term periods of observation.

Short-term ED-based observation units would be excellently suited and located for such a purpose and are already designed to handle flow of patients on an hour-by-hour basis when requiring frequent re-evaluations for a variety of indications. In the chaos of a mass-casualty victim surge or recurrent surges, the role of the ED-based observation units could possibly be

emergently expanded to handle victims for periods longer than 23 hours during the crisis, thus offloading in-hospital service beds for victims who require specific interventions rather that observation. Such possibilities need to be further researched.

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Structure and functions of Observation Units in Australia/New Zealand

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Introduction: Cultural differences

Australia and New Zealand are linked by geographic proximity, by the British Commonwealth, and by a similar accent. Residency programs in both countries are conducted under the auspices of the Australasian College for Emergency Medicine (ACEM) which has its headquarters in Melbourne, Australia. A proportion of consultant positions in New Zealand and a number in Australia are temporary locum-tenens positions filled by non-natives, especially American ABEM-boarded physicians. An ordinary citizen of either country is likely to refer to the "ED" instead of the "A&E", as a British native would, or the "ER", as an American would. A "consultant" is roughly similar to an "attending" in US parlance.[1] In emergency medicine such a consultant is often called a "FACEM", meaning a physician certified as a "Fellow of the Australasian College for Emergency Medicine", the equivalent of the US FACEP. But the post-graduate clinical training of consultants is most similar to the British Commonwealth sequence of House surgeon-Registrar, except that in Australia and New Zealand the House surgeon part of training is initially referred to as an intern (for the first year) and then a resident (for the second and subsequent years until registrar training). Registrar training in Australia and New Zealand is the equivalent of residency in the US, but better paid and of variable duration, and always longer than standard 3 or 4-year EM residencies in the US. The ACEM mandates a period of provisional training as a registrar prior to sitting the Primary Examination, a theory exam based on pathology, pharmacology, physiology, and anatomy. Trainees cannot progress in training until that exam is completed. Once done, there is another mandatory minimum of five years of training before the final Fellowship Examination can be undertaken. A freshly minted FACEM thus has considerably more experience in the ED than a US residency graduate. Consultancy positions are less prevalent, not guaranteed after training, and tend to be well-paid and competitive. Unlike the US, even community hospital EDs without academic connections tend to be staffed by more trainees than consultant-level physicians.

History of Observation Units

Observation units have a long history in Australia. One of the first such units was associated with the Fremantle Hospital ED in Perth, Western Australia, ca. 1986. A national survey in 1989[2] found that about half of EDs had such a unit, and most of the rest were planning to have one. Though there has not been a

recent published national survey, experience suggests they are now more widespread, with at least 90% of EDs using them to expedite the care of selected patients.

Structure and functions of Observation Units

Observation units are usually administered by the ED rather than by inpatient departments. There are exceptions: In Hawkes Bay, NZ, the unit is a purpose-built 20-bed observation ward, of which 15 beds are controlled by the hospital internal medicine department. A single acute medicine consultant rounds daily with a team of post-graduate trainees, without a rigid 24-hour stay limit. The other 5 beds are controlled by the ED. This form of observation practice is more like the increasingly common "acute medicine" concept pioneered in the UK.[3]

As in the US, the criteria for observation unit admission in Australia and New Zealand vary geographically. But Australian units are more likely than US units to care for persons with toxicologic problems, (eg, overdose, intoxication, and unique to Australia: the consequences of living among numerous poisonous creatures) and psychosocial problems, (eg, situational crises, suicidal ideation, frail elderly persons without specific treatable conditions). At Sir Charles Gairdner Hospital, for example, the usual morning observation unit rounding team includes an attending physician, a toxicologist, social workers and allied health workers, and drug rehabilitation personnel.

The ratio of ED visits to observation unit beds in Australian hospitals tends to be around one obs bed per 2,500 visits, (eg, 16 beds for 50 thousand annual ED visits at Sir Charles Gairdner) similar to this ratio in most US hospitals. In Hawkes Bay, however, with its UK-style "acute medicine" observation beds, this ratio is about one bed per 1,500 visits (20 beds for 30,000 visits).

Unlike the US, observation units in Australia and New Zealand are not frequently used to risk-stratify chest pain patients at low risk for acute coronary syndrome. Among the few low-risk chest pain patients who are not discharged, the most likely provocative test performed the next day is the standard graded exercise test, rather than a radionuclide scan or stress echocardiogram, as would be typical in the US Since the primary care infrastructure is perhaps more reliable than the US, most low-risk chest pain patients are referred from the ED to their GP for further workup.

Summary

ED observation units have become essential and dependable components of care in all but the smallest hospital s in both Australia and New Zealand. The biggest differences between US and Australia/NZ observation units are the common use of such units to manage psychosocial problems, and the infrequent use of such units to manage low-risk chest pain patients.

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Observation Unit in Emergency Department in India: An Overview

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Emergency care in India is primarily provided by the Urban-based Government Hospitals, and Medical College Hospitals. The over crowding of patients seeking emergency in these hospitals has become an insurmountable challenge to health authorities. Moreover, lack of inter-hospital referral and transfer protocols compound the problems of emergency department overcrowding. Therefore there is a need to adopt and develop new approaches that have the potential to streamline patient flow and deliver timely, effective and cost-efficient care.

Unlike in the USA and UK where emergency services of the hospitals are designated as Department of Emergency Medicine and Department of Accident and Emergency respectively, in India emergency services area is still referred to as 'Casualty.' There is variation in staffing and administration of Casualty in government and private hospitals. By and large the Casualty is managed by resident doctors, who are either pursuing their post graduate course in medicine, surgery, or orthopedics or those who, after their graduation, join as house officers for six months to one year. The administrative requirements of the Casualty center are provided by chief-medical officer and a specialist who are posted in the Casualty from various departments by rotation. The nurses are posted to Casualty as permanent staff for longer period of time. Barring few hospitals, there is no Attending Physician coverage in the ED.

The patients coming to Casualty for emergency care are attended by the resident doctors posted there, and if specialist consultation or admission is required, then the appropriate specialist is called from the ward to assess and further manage the patient. In their initial assessment and management, one of the most difficult decisions faced by the Casualty doctor is whether the patient being attended to can be managed at home or must be admitted to the hospital. The doctor may be reluctant to send a patient home, fearing that he may worsen at home. This dilemma can be resolved by keeping such patients under observation for some time in an observation unit (OU).

However, there is paucity of literature in India about the role of observation units in casualty. There is one retrospective study by Aggarwal[1] tried to evaluate whether an observation unit attached to the emergency department (ED) of a tertiary care hospital in India is safe, is effective in minimizing hospitalization of acutely ill patients and is acceptable to the patients. In this study, 115 916 patients who attended the ED, 11 130 (9.6%) were observed in the OU. The average period of observation was 7.74 hours. Of the patients observed, 21.3% required inpatient care, while 78.5% were discharged after treatment. Twenty-four patients left the hospital against medical advice, and three patients died in the OU. The study concluded that an OU in the ED is safe in treating acutely ill patients, is effective in reducing substantially the number of patients requiring admission to the hospital, and is acceptable to the patients.

Krome[2] published a review of short stay observation unit (SOU) publications spanning 15 years and identified the following consistencies in what had been written about SOUs:

- they have been shown to be a safe place to initiate treatment until a final decision can be made about admission;
- they must be under the administrative and medical control of the emergency department;
- they must have a time limit for patient observation that is strictly enforced;

- repeated observations of the patient must be made and documented;
- there must be a clear objective for each patient admitted to the unit; and
- the unit cannot function in lieu of inpatient beds.

Krome concluded that there was little left to be learned about their use.

Goodacre[3] examined the use of short-stay units in the United Kingdom. He found that use of these facilities is highly variable and concluded that further comparative studies were required to define the role of the short-stay ward.

While the literature[4-7] regarding the value of such units is also increasing, most reports to date describe the impact of such units on single disease or presentation management, such as chest pain or asthma. These studies have shown the benefit of OU in terms of short stay, quality of care, and patient satisfaction.

The studies included in this review were conducted outside India, so the findings may not be able to be generalized to the Indian context. For example comparative studies reveal that management through observation units was driven by clinical protocols, where as in India protocols are lacking. Secondly, and it is not known what proportion of the observed benefits could be attributable to the clinical protocol alone. Studies[8-9] of clinical protocols compared with routine care has shown similar benefits with respect to length of stay, costs and patient outcomes. So even if protocols are developed in India, further studies are required to establish whether Observation Units and clinical protocols have a synergistic effect.

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Observation Units in Singapore
Malcolm Mahadevan MD

The first formal observation unit in Singapore was set up in the National University Hospital (NUH) in 2004 by Dr. Malcolm Mahadevan. Prior to that, some ED's had an area for observing patients, but there was no funding, entry criteria, or exit criteria. Any observation in the emergency department was an informal process. There was also no availability of extended therapy or diagnostic testing than what was available in the ED.

The model adopted for emergency observation medicine in Singapore has been the American model. Dr. Mahadevan successfully completed a fellowship in 1999 in observation medicine with Louis G. Graff, MD, FACEP at the University of Connecticut Medical School in Hartford, Connecticut. Subsequently 2 nurses and another emergency physician completed training at the Cleveland Clinic's Observation unit with Sharon Mace, MD, FACEP, FAAP.

Since inception in 2004 as a pilot project, observation medicine and units have gained acceptance in other hospitals in Singapore. The first major hurdle was getting governmental support for reimbursement for observable conditions. It was accepted that conditions requiring more than 9 hours but less than 24 hours could be admitted and managed in an EDOU with utilization of the individual's savings scheme for payment.

The observation unit at NUH initially started with 8 observable conditions. Since then, this has expanded to a list of 24 conditions. In 2008 approximately 250 patients per month were evaluated and managed in the 8 bed observation unit. Three hospitals in Singapore now offer formal observation services. All of these observation units are operated adjacent to the ED's and are staffed and run by the ED's.

NUH's observation unit is called the EDTU (emergency diagnostic and treatment unit). The list of conditions currently judged suitable for admission has been broadened to include the following:

1. Anaphylaxis
2. Appendicitis
3. Asthma
4. Backpain
5. Cellulitis
6. Chest Pain
7. Colorectal problems such as prolapsed hemorrhoids
8. Congestive Heart Failure
9. COPD
10. Dengue Fever
11. Dyspepsia
12. Gastroenteritis
13. Upper Gastrointestinal Bleed
14. Headache
15. Hyperglycaemia
16. Hypoglycaemia
17. Pneumonia
18. Apical Pneumothorax
19. Homogeneous RIM Pneumothorax
20. Stable Head Injury
21. Seizure
22. Syncope
23. Transient Ischemic Attack (TIA)
24. Vertigo

Evaluation and management of emergency department patients is much improved by enlarging the time period for services to 24 hours by the use of the observation unit. A major tool used in managing patients in the observation is 'tincture of time.' In contrast to the short time period of the emergency department (2 to 4 hours), with the added time the patient's clinical condition often changes with repeated physical exams and clarifies the patient's diagnosis. In addition many clinical conditions can be successfully treated over 24 hours that cannot be successfully treated during the short time period of in the emergency department. Another important focal point for care in the observation unit is consultation from coordinating care. To standardize care, order sets for all the different conditions are available on the hospital intranet and are downloadable. Examples of some of the protocols for some of these conditions are reviewed below.

Dengue

We found that during outbreaks that occurred each year, admissions for dengue would escalate. During these outbreaks many patient would occupy precious beds in the hospital when they only needed bed rest and daily platelet counts. Emergency medicine and infectious disease physicians concurred on criteria for selected patients to be observed rather than admitted. High risk features which excluded patients from observation and required hospitalization included extremes of age (<18, >60), immunocompromised, diabetes mellitus, significant co-morbidities, confusion, severe abdominal pain, suspicion of significant bleeding or shock and platelet count less than 50,000. Patients with platelet counts between 50,000 and 80,000 are managed in the observation unit for 24 hours with repeat platelet count and symptomatic treatment such as fluid hydration. This helped cut down on dengue admissions especially during the outbreak periods.[1]

Pneumothorax

Another novel and emerging management strategy that we implemented was in the management of primary spontaneous pneumothorax. We started off trying to aspirate some them and observe them for 24 hours. From the lessons we learnt we improved this by utilizing a Seldinger type drain that allowed for repeat aspirations and greater success. With this approach many patients avoid hospitalization.

Chest Pain

Other example of integration of care is collaboration with cardiologists in the development of a chest pain pathway and order set. This initially included electrocardiographic monitoring, serial ECGs, serial cardiac biomarker testing. It now includes emergency physician ordering outpatient treadmill exercise testing and / or MIBI scans for patients suspected of having acute coronary syndrome. This program has resulted in significant reduction in use of inpatient hospital beds as well as reduced attendances at the cardiology outpatient services.

Other examples of integration of care have occurred with the implementation of order sets for different clinical conditions. CHF patients being seen in the OU by a heart failure nurse who participates in education as well as arranging follow on care for the patient in the heart failure clinic. Asthma and COPD nurses help care for their respective OU patients as well. Patients with back pain are seen by physiotherapists to help them to manage their acute low back pain.

Looking forward we are now working on engaging the help of a geriatric nurse as well as physical and occupational therapists to help evaluate and intervene in care of the elderly OU patients.

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Observation Medicine in Taiwan
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Outline
Introduction
Background- the state of Taiwan health care system and its influence on the observation practice in the ED
Development of observation medicine in the Taiwan
Structure and function of observation rooms in Taiwan
The severe stasis/overcrowding of observation rooms in Taiwan and its cause
Summary

Introduction
In Taiwan, observation practice in the emergency department (ED) is very common and nearly all EDs in large teaching hospitals have observation units,[1] although observation medicine is still not well recognized. Severe patient stasis and overcrowding is very common in ED observation unit of large teaching hospitals. In this chapter, we will discuss the development of observation medicine and the operation of the observation unit in Taiwan, and explore the factors causing patient stasis and overcrowding in the observation unit and specific points of observation medicine in the ED of its large teaching hospitals.

Background- the state of Taiwan health care system and its influence on the observation practice in the ED
The healthcare system of Taiwan provides a service of a relatively high quality-to-expense ratio to its people, although it is a governmental, generalized health insurance system covered by the Bureau of National Health Insurance (NIH). People here pay a relatively low insurance fee and a low fixed deductible/copay in each outpatient visit, ED visit and hospitalization. Under this insurance system, patients can visit any hospitals, including EDs, without any limitations. The malpractice lawsuit rate against the hospitals and physicians is very low compared to that of the United States. The low lawsuit rate is one of the causes of low medical expense in this country. Partly owing to the convenience of the medical access and the custom of local medical usage, many patients have no fixed visiting hospitals or clinics and physicians. Mainly because of the factors mentioned above, abuse of the medical resource and inadequate patient information are always the problems in our medical system.

Development of emergency medicine in Taiwan
About the ED system, most EDs are staffed by well trained board-certified emergency physicians (EPs), a medical subspecialty recognized by the Department of Health. And the ED provides a relatively good quality of patient care. Due to the frequent overcrowding state, EPs are very accustomed to a high patient volume and flow and well-trained to manage patients in a highly efficient way. Most EDs of large teaching hospitals have a formal EP training program and many are university affiliated, and also provide a formal emergency medicine course in the medical school. The Taiwan Society of Emergency Medicine, a counterpart of ACEP in the US, helps to set medical and administrative guidelines for the ED, under the supervision of the Department of Health. EDs in Taiwan set no threshold or limitation for patients' access to the ED and patients need no worry of refusal by EDs or the Bureau of NIH. There is no ED refusal of case by the Bureau of NIH. This

convenience also explains partially the high patient flow and overcrowding in many EDs and inadequate hospitalization beds. Because of medical trend not to encourage the small hospitals to care critical patients (because of a low fee and a higher risk), it is common for those hospitals to transfer complicated cases to large teaching hospitals. Additionally, the medical pay by the Bureau of NIH encourages hospitals or clinics to see patients in outpatient basis. These factors cause the medical systems to become a extreme state that only small hospitals or clinics or large teaching hospitals can survive and small or middle-size hospitals have little room. Therefore, transferring complicated cases, "dumping" the cases, through the EDs without notice is common, and "the patient required the transfer for better care" and "the patient is your old patient" are the common reasons.

The influences of our healthcare system on our observation practice in the ED

Under the above mentioned conditions, many patients have to stay in ED observation rooms. A large observation unit which includes several observation rooms and temporary observation areas over the hallways or other regions within the ED seems to be the common scene in many EDs of large teaching hospitals. Overcrowding and patient stasis in the observation unit is very common and severe in EDs of large teaching hospitals. Sometimes the average number of patients staying in the ED observation unit might be over 100, even more. In our 2001 study in Veterans General Hospital in Taipei, the average daily number of patients admitted to observation unit was 41 and the mean length of stay (LOS) in the observation room was around 30 hours; therefore, it is estimated that the average number of patients staying in observation room at any time was around 50.[2]

The generalized insurance system and low medical fee might encourage the patients to ask for hospitalization. Therefore, if observation is suggested, some patient might choose the alternative, hospitalization.

Severe overcrowding in most large ED in Taiwan makes the most patients to ask for admission or leaving EDs for home treatment or observation when EPs suggest an observation management.

However, in the chaotic appearance, there seems to be a regular and orderly functioning in the observation rooms.

Development of observation medicine in the Taiwan

Observation Medicine is not well recognized in Taiwan with only a few large teaching hospitals having a formal protocol for the observation room practice and even fewer hospitals having policy about observation medicine. However, observation practice has been common in many EDs.

To discuss the development of observation medicine in Taiwan, we set three stages about the development of observation (observation practice, the development of observation room, and the development of observation medicine). Since the beginning of emergency medicine in Taiwan, most hospitals have had the practice of observation. The patients are kept in the hands of EPs and given intravenous fluid and observed for his abdominal pain and fever, etc. It is an informal process that no formal order or sheet is needed for the observation. Later, many hospitals have "observation rooms" in the ED. If strictly defined, an observation unit should have some criteria: patients needing observation (not a space just for waiting for hospitalization), a process of shifting patients to the observation room, fixed physicians or nurses, and a formal documentation for the observation. Under these criteria, not all "observation rooms" in Taiwan were fit for the definition of observation units in that time. Only after the development of emergency medicine in late 1980s, some well-run observation units have been developed. Regarding the emergency medicine (the presence of the observation unit, quality control guidelines, and a formal daily ward round), only a few EDs of large teaching hospitals have developed it since early 1990s. After 1999, with IOM issuing the "To err is human", a goal of setting 48 hours as the upper limit of patient staying in the ED observation unit has seemed to be a consensus between the member of Taiwan Society of Emergency Medicine.

To alleviate the observation unit overcrowding and patient stasis, some hospitals put the 48-hour-upper-limit as a quality indicator in their ED quality control list and began to collect data of observation unit. However, because observation medicine is not well recognized as a specialty medicine in Taiwan, variations in implementation are common about quality control, observation room statistics collection, and the improvement process. In 2005, a standard protocol for the observation unit was set for the patient safety in the annual meeting of the Taiwan Society of

Emergency Medicine. In 1992, Veterans General Hospital in Taipei set an "intensive care area" within the observation units because of the risk of keeping high-risk patients in the ED and inadequate intensive care unit (ICU) beds. In 1995, this hospital set a formal ICU, the first ICU in the ED in Taiwan, within the ED observation unit. Thereafter, ICUs have been set in several other EDs of large teaching hospital, also within the original observation rooms.[1] Although setting an ICU in the ED should not include in the development of observation medicine, it has decreased the risk of the observation unit and also provided a notion that stratifying the patient risk is an important part in observation rooms. Keeping high-risk patients in the observation room without trying to stratify their risk, consultations, or without supervision from a subspecialty consultant, if available and indicated, would decrease the care quality of observation units and prolong the patient stay in the observation units, as well as exaggerate the patient stasis in the observation units. In the our 2001unpublished data, we found patients having good and specific consultations before entering the observation room had a shorter stay (26 hours vs. 34 hours) and less patients staying over 48 hours (14% vs. 19%) than those without.[2]

Structure and function of observation units in Taiwan

In Taiwan, observation units are very common in EDs of many hospitals in Taiwan. In smaller hospitals, patients might be moved rapidly to the observation areas (or rooms) for intravenous fluid treatment or observation of some symptoms such as dizziness, for examples, when EPs cannot discharge the patients immediately. The observation rooms are like a temporary treatment or observation areas. Sometimes it is difficult to differentiate ED and observation room patients because they are both cared by the same on-duty EP in the same area. In these hospitals, a lower threshold of criteria of hospitalization is usually present. Thus, for patients needing more prolonged observation for symptom (possibly more than several hours) and to the response to treatment, such as chest pain, mild congestive heart failure or urinary tract infection, might be admitted to regular wards due to more availability of beds and the "longer" stay of the patients. (Some of these cases might be kept in ED observation units for observation in some large teaching hospitals in Taiwan.) Their LOS's in the ED observation room are short (the mean LOS was around 4 hours in one study),[3] as compared to those of large teaching hospitals (around 30 hours in one study).[2]

In large teaching hospitals with frequent overcrowding, ED patients are not so easily moved to the observation unit. A formal observation can only be made after an initial evaluation and treatment are done and the patient's condition is made clear. A move to the observation unit should be done not only with a change of new area, also with a new note and order for observation. So before patients are admitted to observation units, more time have been spent for the make-clear process. So for patients entering the observation units, the status of patients (patients of pure observation, patients of waiting admission or operation, patients needing management of their social problems, etc.) might be defined. The observation units are usually supervised independently by EPs with on-duty residents. A large proportion of observation room patients are waiting for hospitalization. However, the definition of patient status (observation or waiting for hospitalization) is not clear in some patients sometimes. For some patients listed in the waiting-for-hospitalization status, they may be discharged in short time. But for some patients thought to be of the "observation" status, they actually need hospitalization. The LOS's are much longer for most patients. In our previous 2001 unpublished results, the mean LOS was 26.7 hours for patients of pure observation and around 30 hours for those who need hospitalization.[2] Below is the discussion of observation units of large teaching hospitals. In the EDs of large teaching hospitals, patients needing intravenous fluid treatment (cases of acute gastroenteritis, for example) may be kept in EPs' hands for several hours and might not be admitted to the observation room.

Why are patients admitted to the observation unit? Many patients were admitted to observation units are waiting for formal hospital beds, while a large number of patients were also for the "observation purpose." Sometimes the purpose of staying in the observation room is not specified, because the EPs think that "there is no bed now and all patients have to stay in the observation room." Some patients with multiple problems or nonspecific presentations, especially older patients, are frequently kept in the observation unit for further making-clear and observation, if no evidence of severe diseases is noted. Some patients with social or care problems are frequently kept in the observation unit for further arrangement of their deposition.

What kinds of patients kept in the observation unit for "pure" observation? Chest pain/tightness is the commonest clinical condition for patients to stay in the observation room. Serial follow-up of cardiac enzyme (including Troponin I) and symptoms are done. With negative results and relief of symptoms, most patients are discharged in the next day. Patients with mild upper gastrointestinal bleeding (UGI bleeding) without active bleeding are always kept in the observation for the next-morning endoscopic examination. Those without evidence of (recent) active bleeding by the endoscopic results might be discharged after supportive care. Minor stroke (cerebral infarct) is also a common clinical condition for observation. After serial work-up, aspirin, and hydration are given, patients without worsening of symptoms and signs might be discharged. Syncope is also a common symptom for observation. Some mild to moderate infectious conditions (urinary tract infection, pneumonia, fever in elderly patients, and cellulites etc.) and pulmonary conditions (chronic obstructive pulmonary diseases with acute exacerbation or mild 2nd infection and bronchial asthma with an acute attack) are also common diseases for observation to the treatment response.

When patients are admitted to the observation unit? In most EDs, the patients were admitted to the observation room after EPs make it clear some clinical conditions (more critical or severe conditions not suited for pure observation). In many hospitals, the decision of needing and waiting hospitalization is determined by solely the EP who sees the patient before entering the observation unit, and, thereafter, these patients enter a waiting list and are admitted automatically when appropriate hospitalization beds are available. Informing the subspecialty is not a must. However, consultation of subspecialty before hospitalization or admitting to the observation is done in many EDs. In these hospitals, many internal factors complicate the hospital admission process of ED patients and cause the overcrowding and patient stasis of observation rooms

Who cares the patients in the observation unit? A fixed EP with on-duty resident(s) take care of observation unit patient care in most EDs. However, an EP who is on duty for ED patient care might also care patients of the observation room at night in some hospitals, depending on the size of the observation room (or number of the patient).

Who take responsibility of the patients in the observation unit? Many patients do not have their own family physicians in Taiwan. Therefore, when the patients are admitted to the observation room, EPs take the most responsibility for the patients. This means EPs have to take the legal responsibility of the patient when any adverse events occur because the patients were not yet admitted. In some hospitals, the physicians of the subspecialty take the responsibility of the patients when their patients stay in the observation unit. However, consultants might just provide opinions on the care but not take responsibility in many patients in many hospitals.

Where the observation unit? In most situations, observation units are located in the ED and are several large rooms with a capacity to keep 6-8 patients and with only curtain for isolation in Taiwan. And, because these spaces are easily occupied and full, other "temporary regions" are created to meet the need. Hallways or regions near the observation unit are the most common. Sometime the scene is like a market.[1] Few hospitals have a dependent unit for the observation process.

What care provided in the observation unit? The care intensity in the observation units is mild to moderate partly because there are some patients needing hospitalization. Patients in critical conditions have to be kept in the resuscitation area and moved to the ED ICU for close monitoring. During the patient stay in the observation unit, most examinations could be arranged and performed in a higher, "emergency" priority. In some hospitals, a next morning ED endoscopic examination can be done for some patients with UGI bleeding to determine the necessity of hospitalization. But not all examinations can be done in the ED observation unit, because some examinations are considered to be hospitalization processes and some are of different financial systems.

When to discharge, hospitalize, or transfer the patients? In most situations, the attending EPs round the observation unit in the morning and make the decision about the deposition of the patients of most patients, with the help of lab tests and by following the symptoms, as well as with the opinions of subspecialty consultants. Sometimes, the initial decisions (waiting for hospitalization or pure observation) for some patients might be changed. Because patients had no limitation in selecting the hospitals (all under the coverage of the Bureau of NHI), transfer of the patients, due to unavailability of beds or a change in the clinical condition, is not uncommon. However, when patients visit the large teaching hospitals, "terminals" in the one-way ED healthcare system, it is difficult for them to be transferred due to the common overcrowding problem in those large hospitals.

Who and how to pay for the observation care? Only a low daily doctor fee, nurse fee and bed fee are paid for the ED observation practice. The Bureau of NHI sets 6 hours as the minimal time to pay the observation doctor fee for patients who initially stay in the ED. After the patients enter the observation unit, a daily doctor fee is paid to the physician who sees the patients. Although The Bureau of NHI pay for most examinations arranged in the observation unit, some special tests cannot be paid, even done, in the ED.

What the quality control and quality improvement of the observation unit? There is a consensus within the Taiwan Society of Emergency Medicine that 48 hours is the maximal time limit for patient stay in the ED. In Veterans General Hospital in Taipei, a 5% is the set as upper limit of the percentage of patients in observation unit staying over 48 hours. They set the time limit not only because of emphasis of observation medicine, but also because of the overcrowding problem. The management of the observation room is thought as a part of the total solution to the ED overcrowding. Collection of observation unit data (LOS's, mortality cases, cases of respiratory and cardiac arrest, cases of adverse events most commonly) is occasionally performed for special purposes. In Veterans General Hospital in Taipei, facilitation of admission process and transfer of patients to the cooperative hospitals are the main solutions to patient stasis in the observation room. Other quality improvement processes include limitation of patient numbers in each observation room (decreased from 8 to 6) increasing the efficiency of patient transfer or patient settlement for patients with social or care problems, and diversion of patients.

The specific points of observation in Taiwan

Because of the ED overcrowding and frequent inadequacy of hospitalization beds, some variations have developed in practice of observation medicine in Taiwan. For example, in Veterans General Hospital in Taipei, a teaching hospital with the observation unit protocol, some modifications of observation practice have been done. A short stay observation for minor stroke (cerebral infarct) is a common practice in the ED observation unit. Patients are administered hydration and aspirin, arranged a carotid Doppler's examination, and observed for any neurological progress. The majority of patient could be safely discharged in the next day or within 48 hours without major sequelae and then an outpatient follow-up is arranged. Another example is mild UBI bleeding. For most patients without severe and active UGI bleeding, a "next-morning" endoscopic examination is arranged in the ED. A large proportion of patients could be safely discharged after an overnight treatment and observation and if the endoscopic result show no evidence of (recent) active bleeding. A 48-hour is set as upper limit of keeping patients in the observation unit, and more clinical conditions are manageable and discharged within this period. In 1995, Veterans General Hospital in Taipei has set a formal ICU in the observation unit and thus patients with unstable conditions can be admitted if ICU beds are not available in the ICU upstairs.

Differences in observation medicine between Taiwan and the United States

Some differences about the status of observation medicine are present between Taiwan and United States. Some of the differences are developed from the reality (severe overcrowding and absence of admission beds in Taiwan), some from the absence of recognition and notion of observation medicine. EPs in Taiwan seem to get accustomed to the overcrowding and patient stasis and develop their own efficiency in manage the observation patients. But because of the overcrowding and large rooms for 6-8 patients, the environmental condition seems to be suboptimal in the observation units in many teaching hospitals in Taiwan. Furthermore, observation medicine is not well recognized in Taiwan, and no special board of observation medicine exists in the Society of Emergency Medicine or the governmental health department. A clear policy and documentation of the observation unit is always absent in many large teaching hospitals. Additionally, some EPs have no adequate notion about observation practice. They might think keeping the patients in the observation room is a loading and they try only to discharge or admit patients. Regarding to the payment from the Bureau of NHI, only a low doctor and nurse fee are paid for observation practice, because observation medicine is not well recognized as a subspecialty care. Also because of these factors (the lack of establishment of observation medicine in Taiwan and low pay for observation patients), no chest pain unit has developed in Taiwan.

The severe stasis/overcrowding of ED observation units in Taiwan and its cause

Overcrowding and patient stasis are common problems in observation units of most large teaching hospitals in Taiwan.[4] In our 2001 unpublished study in Veterans General Hospital in Taipei, 22.6 % of ED patients were admitted to the observation unit. Of them, 48 % were considered to be patients waiting of hospitalization and 52 % considered to be patients for observation, and 15 % stayed in ED observation room for more than 48 hours.[2] In addition, EPs usually kept high-risk patients (eg, pneumonia, urinary tract infection, fever without a definite sources, chronic obstructive pulmonary diseases, severe UGI bleeding, etc.) in the ED observation unit without initial subspecialty consultation or trying to admit the patients.[2]

Many factors are causing patient stasis and overcrowding in the ED observation units. External factors determine the input of patients to the ED and are not controlled by the hospitals. Internal factors are problems within the ED and hospitals and considered manageable by the hospitals themselves, although difficult to be managed.

External factors (Table 1)

A changing policy of the governmental health department is thought be an important cause. The Bureau of NHI changes their policies mostly because of economic factors frequently, thus the ED and hospitals always to consider "economic" factors before considering the solution of overcrowding and patient stasis in the ED.

The most important factors are the development of hospitals at the two extreme ends of the spectrum of capabilities. At one end are large hospitals with strong intensive care and at the other end are small hospitals/clinics that care only outpatient patients. There is no barrier to patient transfer between hospitals. The small-or medium-size hospitals have limited role in the Taiwan health care system. They develop their unique healthcare characteristics and are dependent on getting their revenue from outside the Bureau of NHI. For critical patients in their EDs and ICUs, the tendency is to transfer the patients after getting the initial evaluation and management. These costs are not commonly rejected by the Bureau of NHI. They avoid prolonged care of complicated cases for which they will not receive payment. These cases are under strict review of the Bureau of NHI and thus small and medium size hospitals avoid the risk of caring complicated cases.[1] The incomes from these complicated, critical cases are usually cut by the Bureau of NHI. Additionally, there is no set limitation or barrier of patient transfers which makes their transfer more easy and "reasonable." Therefore it is common to see aggregation of complicated and severe cases in ED and ED observation units of large teaching hospitals. Patients in Taiwan seems also understand this situation and tend to visit EDs of large teaching hospitals when they think they may have severe problems. Even after visiting small- or medium ED, they might ask for transfer when stabilized or told to have severe problems and need transfer. Under this situation, a sound development of critical care system (including ED care) seems to be "unnecessary" in small-and medium-size hospitals and, thus, a vicious cycle of "care quality-patient transfer-patient recognition" develops.

Table 1. External factors of patient stasis and overcrowding in the ED observation units of large teaching hospitals in Taiwan

- **Changing policy of the health department**
- **Extreme development of hospitals in patient care**
- **No barrier of patient transfer in one-way ED healthcare system**
- **Patient tendency to visit larger hospitals with severe problems**

Internal factors (Table 2)

Many internal factors are contributing to overcrowding in hospitals. A fundamental factor in overcrowding is inadequate hospitalization beds in the large hospitals. Additional factors are the elderly age of many observation patients, the determination of many emergency physicians to try-to-treat-and-try-to-discharge patients, and intrinsic slow pace of evaluations in the observation unit. These account for some of the long LOS's of patients in the observation unit.

Some factors may be manageable with the correct approach. Most observation rooms in the large teaching hospital EDs have some of these problems. Those ED needing subspecialty

consultation for hospitalization decisions and with more complicated subspecialty systems suffer the patient stasis most. Those ED's suffer less patient stasis that have decisions on hospitalization left solely to the discretion of EPs are able to arrange the hospitalization automatically (by the entering order in the computer system). Below are the factors that have some influence on overcrowding:

- **EPs' no clear-cut purpose of observation/initial clarification in some patients[2] (Table 3)**
  Many patients enter the observation unit without a plan (at least without a note) and longer LOS's are expected in these cases, a result shown in our unpublished data. In these cases, stratification of patient risk is not done and intention to admit the patients, if needed, is not present. Many factors (mechanisms) might be present. The EPs might not have a clear-cut idea of observation and they admit these patients to observation room just because the patients cannot be discharged from the ED, especially when the hospitalization beds are full. Patients with some diseases (pneumonia, infection of unknown origin, urinary tract infection, UGI bleeding, chronic obstructive pulmonary disease with acute exacerbation, acute coronary syndromes, congestive heart failure, etc.) are frequently kept in the observation room due to the absence of hospitalization beds, and EPs might have no motivation to admit them even when they need and might also lose the definition of who needs hospitalization or observation. In addition, many patients who have clear indication of hospitalization are still kept in the observation unit and admitting-the-patients action is still not done. This might be because they have too complicated conditions that are difficult to define which subspecialty department to care the patients, they have several severe diseases that all subspecialty departments involved refuse to care the patients, or they have a single disease (a diabetic foot for example) that subspecialty departments involved always consider the cases should be cared by other department. After entering the observation unit, these cases without initial clarification or clear observation purpose might have a lower priority of hospitalization, need more consultations, need more examinations, and need more waiting time to complete examinations and consultations, just because they have no subspecialty or assigned subspecialty in charge. Sometimes, a new condition may develop in these cases and the condition becomes more complicated.
- **Work-ups are not available all time in the observation unit**
  Some examinations, subspecialty consultations, and decisions might be postponed in the observation room, especially at night and in the weekend and holidays, because the care intensity is low to moderate.
- **Consultations' requirement for making-clear actions[4]**
  Cases kept in the observation unit without initial assignment to a subspecialty or with initial consultation might be considered to be patients belonging to the ED. Subspecialty consultants might stand in passive altitude and ask for more examinations and consultations if required to take over the patients.
- **Subspecialty consultants' negative impact in the observation stasis[4]**
  In Taiwan, not all ED of large teaching hospitals need subspecialty consultants to make decision of hospitalization or before patients entering the observation unit. However, if the consultants are involved in this process, they usually have a negative impact on patient stasis in the observation unit. They usually refuse to take over the patients with complicated conditions and just accept their regular follow-up patients and "clean" cases with a single active problem. For cases with multiple active problems and chronic conditions, physicians from subspecialty often offer opinions and hesitate to admit these cases to their wards. To determine an "appropriate" department to care the patients, multiple consultations usually have to done in many cases in the ED observation unit. Even accepting the patients before patients enter the observation room or take over the patients in the observation unit, they sometimes hesitate to admit the patients to their wards. Some of these cases (eg, vegetative patients of old cerebral infarct with a pneumonia or urinary tract infection) are usually kept in the ED observation room because of their lower priority of admission. Trying to cure and discharge the patients is one of the reasons. But in most times, they worry about "bad patients" might make another stasis in their wards and set a lower priority of hospitalization for those "bad cases."

- **Trying to treat and try to discharge the cases in the observation unit**
  Poor management of the observation room and an initial inappropriate judgment before patients enter the observation room might play a role in patient stasis in the observation unit. Under treatment, the patients always show some improvement after entering the observation unit, but always in an equivocal state between hospitalization and observation. A treat-and-discharge is usually tried in these patients, but it sometime ends up with prolonged stay of patients in the observation unit.
- **Imbalance of beds distribution**
  In large teaching hospitals with too many specialty departments, beds might be available in many subspecialty departments and inadequate in many other subspecialty ones. It is difficult to admit a pneumonia patient (thought to belong to department of infection or chest medicine that has a very high possibility of "no bed" in most times) to the department of cardiovascular surgery.
- **Inadequate general wards**
  Most hospitals in Taiwan try to open more common wards that accept patients of mixed subspecialty departments. But the supply always cannot catch up the need.

Table 2. Internal factors of patient stasis and overcrowding in the ED observation unit
- **Inadequate hospitalization beds (the fundamental factors)**
- **Congenital factors (that are not manageable)**
  Older age of many patients
  A try-to-treat-and-try-to-discharge intention for observation unit patients
  Intrinsic slow work in the observation
- **Factors related to poor management**
  No clear-cut purpose of keeping patients in the observation unit
  No all work-up in all time (postpone some decision until the next daytime, holidays)
  Subspecialty consultations for making-clear actions
  Subspecialty consultants' negative impact in patient stasis
  Trying to treat and try to discharge the cases in the observation unit
  Imbalance of beds distribution
  Inadequate general wards

Table 3. Effects of no initial clarification of patient status in the observation unit
- **Lower priority of hospitalization**
- **Needing more consultation or tests and needing more time in doing them**
- **Keeping high-risk patients needing hospitalization patients in the ED**
- **Subspecialty consultants' passive altitude to these patients**
- **The possibility to develop new diseases**

Summary

In Taiwan, observation is a very common practice and observation units are also very common in emergency department (EDs) of many teaching hospitals, but observation medicine is still not well recognized. Only a few university-affiliated teaching hospitals have more formal observation protocols that accept observation medicine a formal practice and have policies about the observation in ED. Some EPs and EDs even think keeping patients in the ED observation unit is a loading. This can be seen that they try to keep the observation patient number as low as possible and discharge or admit patients as rapidly as possible. Many patients also might have a negative impression about observation units and observation. Some factors contribute to this state. If "observation" is a considered management modality, many patients might choose or ask for hospitalization partly because the National Health Insurance covers most expense of medical management and partly because severe overcrowding in the observation units in most large teaching ED in Taiwan makes the most patients to ask for hospitalization or leaving EDs for home treatment or observation. Overcrowding and patient stasis in the observation units of large teaching hospital is common. The most important two factors are the development of hospitals to the two extreme ends that one end is large hospitals with strong intensive care and the other end small hospital/clinics that care only

outpatient patients and no barrier of patient transfer. Therefore, aggregation of complicated and severe cases in ED and ED observation units of large teaching hospitals is a common scene. However, some internal factors also exacerbate the condition. Those ED needing consultation of subspecialty for hospitalization decision and with a more complicated subspecialty system suffer the stasis most. Subspecialty consultants always have a negative impact in patient stasis in the observation unit. They usual select "clean" cases and refuse to take over the patients with complicated conditions and/or require more examinations and consultation before taking over the patients. EPs' no initial clear-cut purpose of observation and clarification of clinical conditions before patients entering the observation is also an important cause of stasis. Longer LOS's are expected in these cases, and patients would undergo more examinations and consultations. In addition, under the upper limit of 48-hour observation room staying time, EPs and consultants of subspecialty might try to treat and discharge some patients from the observation unit. However, prolonged stay might be possible when this intention is poorly managed. Under this difficult condition, though, some possible modifications of observation medicine have developed in Taiwan. A next-morning endoscopic examination for mild UGI bleeding and keeping minor stroke patients (cerebral infarct) for observation and treatment in the ED observation room seem to have an effect in decreasing hospitalization and patient stasis in the observation room. And setting an ICU in the ED observation unit has an effect to decrease the risk of caring high-risk patients. In Taiwan, a policy of try-to-treat-and-discharge in 48 hours in the observation unit, although somewhat against observation medicine principles, also could avoid hospitalization in some cases.

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