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Integrating Emergency Care with Population Health

Contents continued on page ii

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Table of Contents

continued

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Necessity of Lumbar Puncture in Patients Presenting with New Onset Complex Febrile Seizures

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Introduction: This study aims to characterize the population of patients presenting to a pediatric emergency department (ED) for a first complex febrile seizure, and subsequently assess the rate of acute bacterial meningitis (ABM) occurrence in this population. Furthermore, this study seeks to identify whether a specific subset of patients may be at lesser risk for ABM or other serious neurological disease.

Methods: This retrospective cohort study reviewed the charts of patients between the ages of 6 months to 5 years of age admitted to an ED between 2005 and 2010 for a first complex febrile seizure (CFS). The health information department generated a patient list based on admission and discharge diagnoses, which was screened for patient eligibility. Exclusion criteria included history of a complex febrile seizure, history of an afebrile seizure, trauma, or severe underlying neurological disorder. Data extracted included age, gender, relevant medical history, descriptions of seizure, treatment received, and follow-up data. Patients presenting with two short febrile seizures within 24 hours were then analyzed separately to assess health outcomes in this population.

Results: There were 193 patients were eligible. Lumbar puncture was performed on 136 subjects; it was significantly more likely to be performed on patients that presented with seizure focality, status epilepticus, or a need for intubation. Fourteen patients were found to have pleocytosis following white blood cell count correction, and 1 was diagnosed with ABM (0.5% [95% confidence interval: 0.0–1.5, n=193]). Forty-three patients had 2 brief febrile seizures within 24 hours. Of the 43, 17 received lumbar puncture while in the ED. None of these patients were found to have ABM or other serious neurological disease.

Conclusion: ABM is rare in patients presenting with a first complex febrile seizure. Patients presenting only with 2 short febrile seizures within 24 hours may be less likely to have ABM, and may not require lumbar puncture without other clinical symptoms of neurological disease. [West J Emerg Med. 2013;14(3):206–211.]

INTRODUCTION

Febrile seizures are seizures that occur in conjunction with high fever. They occur in up to 5% of children, typically between the ages of 6 months and 5 years.[1-2] Febrile seizures are classified as simple or complex. Simple febrile seizures are generalized, last less than 15 minutes, and do not recur within 24 hours. All others are considered complex and comprise 35% of first time febrile seizures.[3] Most children do not experience long-term effects due to simple febrile seizures.[4] However, complex febrile seizures may have been suggested to increase the risk of epilepsy in some children, particularly those with previously existing neurological abnormalities.[2]

A practice parameter developed by the American Academy of Pediatrics (AAP) for the treatment of children presenting with a simple febrile seizure (SFS) provides a guideline for treatment. The SFS practice parameter focuses on identifying the source of fever rather than performing a standard seizure work up, and examining for signs of encephalitis or meningitis by performing a lumbar puncture on children presenting with clinical signs of neurological disease.[4] No such guideline exists for children presenting with a first complex febrile seizure, and current treatment plans for this population vary greatly among pediatric emergency providers.[1,5] Medical providers often elect to perform lumbar punctures on these patients to rule out acute bacterial meningitis (ABM), although recent literature has shown that ABM is rarely diagnosed in the absence of other clinical signs and symptoms of serious neurological disease.[6-8]

Our study primarily aimed to characterize the pediatric population presenting with a first complex febrile seizure and determine the likelihood of ABM in these patients. Furthermore, recent literature has suggested that lumbar puncture may not be beneficial for patients presenting with two brief febrile seizures within a 24-hour period.[6] Our goal was to determine whether this specific subpopulation of patients is at a lesser risk of ABM or serious neurological disease.

METHODS

Study Design

This study was a retrospective cohort review of patients admitted to an urban pediatric emergency department (ED), which sees approximately 71,000 patients annually. This study was approved by the University of California, San Diego Institutional Review Board and the Rady Children's Hospital Research Administration office.

Study Setting and Population

This study retrospectively reviewed electronically available physician notes for patients who met study criteria. Inclusion criteria were being seen in the ED between January 1, 2005, and September 1, 2010, for availability of electronic physician notes; ED diagnosis of complex febrile seizure or status epilepticus; and 6 months to 5 years of age at the time of ED visit. We chose this age group in order to be consistent with the classic age range of a simple febrile seizure. All patients presented to the ED within 24 hours of the seizure, and had one or more features of a complex seizure. Patients were excluded if they had a previous history of afebrile seizures; did not meet criteria for complex febrile seizures; had a preceding history of trauma; or had a history of significant neurological abnormalities or a history of trauma.

Study Protocol

Patients were identified by the hospital's health information department, whichelectronically generated a list of patients seen in the ED with an assigned International Classification of Diseases (ICD)-9/10 code of either 780.32 for complex febrile convulsions or 345.3 for status epilepticus. This search included both admission and discharge diagnoses from the ED. It is unlikely to have excluded patients with a recorded diagnosis of bacterial meningitis rather than complex febrile seizure due to our institution's billing practices, which include a full listing of all diagnoses. This list was manually screened by both authors to ensure that the inclusion and exclusion criteria were met.

Data Extraction

Charts by the attending physician, nurses, and emergency transport staff, as applicable, were reviewed for each patient by both authors. However, as our research objective remains simply to characterize this patient population and compare to existing literature on this topic, we assert no investigator bias. Attending physician notes were surveyed for physical examination data, specifically the presence of macrocephaly, Todd's paralysis, petechiae, a prolonged postictal period, or a need for intubation. Each patient's record was screened for hospital notes, if admitted, and any subsequent follow up at our institution within 7 days of discharge.

Definitions

Cerebrospinal fluid (CSF) pleocytosis was defined as CSF white blood cell (WBC) count of > 7/μL.[6] In the case of blood-contaminated CSF samples, the authors used the correction equation: corrected CSF WBC count = (CSF WBC count - [CSF red blood cell count/500]).[6] Acute bacterial meningitis was defined as either bacterial growth from a CSF sample taken within a week of the ED visit, or CSF pleocytosis with bacterial growth from a blood culture within a week of the ED visit.[6] In the case of an uncertain ABM diagnosis, discharge diagnosis by the treating attending physician was considered final. Status epilepticus was defined as seizure activity without cessation for at least 30 minutes or recurrent seizures without regaining consciousness.[9]

Data Analysis

We performed data analysis using MYSTAT 12 (Chicago, Illinois), and calculated percentages and confidence intervals (CIs) using the Descriptive Statistics function. After characterization of the general population, we then analyzed separately patients presenting with 2 short febrile seizures within 24 hours to assess health outcomes in this population.

RESULTS

Case Identification

The subject list generated by the health information department listed 506 eligible patients; of those, 370 were between the ages of 6 months and 5 years of age. After screening for history of neurological abnormalities, afebrile seizure, complex febrile seizure, trauma, 193 eligible patients remained.

Table 1. Characterization of general population.

	n=193	%
Median age: 17.2 months (IQR=12.4–25.2)		
Female patients	99	51.3
Vaccination status reported	180	93.3
Vaccinations reported up-to-date	176	97.8
Patients returning from previous ED visit within 24 hours	39	20.2
Patients who received antibiotics < 24 hours before ED presentation	28	14.5
Patients with a history of simple febrile seizure	45	23.3

IQR, interquartile range; *ED,* emergency department

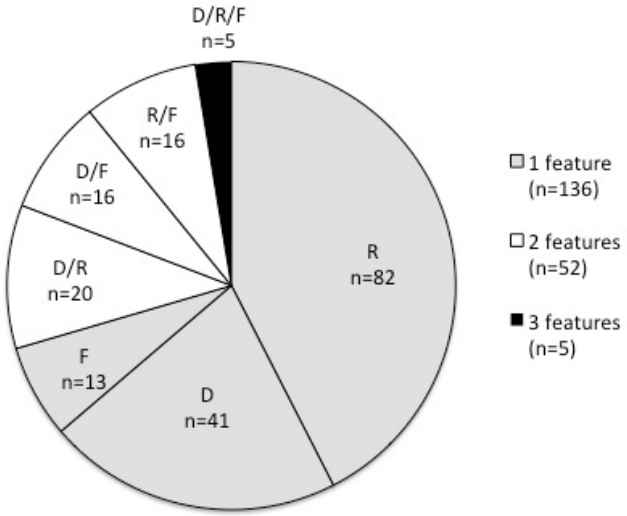
Table 2. Patients from the general study population with abnormal physical findings.

	n=61	%
Patients with 1 abnormal finding	56	91.8
Patients with prolonged postictal period only	11	19.6
Patients with Todd's paralysis only	7	12.5
Patients with petechiae only	1	1.8
Patients with macrocephaly only	1	1.8
Patients requiring intubation only	36	64.3
Patients with 2 abnormal findings	4	6.6
Patients with petechiae who required intubation	2	50.0
Patients with prolonged postictal period who required intubation	1	25.0
Patients with Todd's paralysis and a prolonged postictal period	1	25.0
Patients with 3 abnormal findings	1	1.6
Macrocephaly, petechiae, and intubation	1	100.0

Background information on eligible patients is outlined in Table 1. The majority of the sample (70.5%) had a febrile seizure with only 1 complex feature, 26.9% demonstrated 2 complex features, and 2.6% exhibited all 3 complex features. Figure 1 shows the further breakdown of complex seizure features. More than half (54.4%) of the population received medication for seizure cessation. The median highest recorded temperature was 39.3°C (interquartile range [IQR]: 38.5-39.9).

Upon physical exam, 132 patients (68.4%) had no notable manifestations of serious neurological disease; however, 40 patients required intubation in the ED. It can be difficult to determine whether the need for airway protection was a result of the natural course of the seizure, or an effect of the administration of anticonvulsants. We therefore recorded intubation as occurring before (n=5) or after (n=35) the administration of anticonvulsants to account for this uncertainty. The rest of these notable findings are outlined in Table 2.

The most common discharge diagnoses for patients seen



D, duration; *F,* focality; *R,* recurrence
Figure 1. Complex features of febrile seizures.

for a first complex febrile seizure were febrile illness (n=33), viral syndrome (n=26), and otitis media (n=24). Treating physicians admitted 139 patients; 131 were admitted to the hospital's inpatient services, and 8 were transferred to other institutions due to insurance requirements. Follow-up data were available for 170 patients (86%), and included inpatient discharge summary; imaging studies (computed tomography, electroencephalogram, or magnetic resonance imaging); or follow-up visit to our hospital. As the admitting facility for our region, we are aware of patients admitted in our area, and it is unlikely that any children were re-admitted without our awareness.

Lumbar Puncture Administration

Lumbar puncture was performed on 70.5% of subjects in our ED. Factors that were associated with lumbar puncture administration were no prior history of simple febrile seizure (75.6%), seizure focality (84.0%), status epilepticus (91.3%), and requiring intubation (100.0%). Fifty-seven patients did not receive a lumbar puncture. None of these patients returned to this hospital with a diagnosis of ABM. Further description of the 57 patients who did not receive lumbar puncture can be found in Table 3.

CSF Results

The median corrected CSF WBC count was 1/μL (IQR: 0–3). Fifteen subjects had CSF pleocytosis; 8 required the CSF WBC correction formula for blood-contaminated CSF samples. Fourteen subjects (7.3%) had pleocytosis after WBC count correction (95% CI: 4.1–10.1), 7 of whom were diagnosed at discharge by the attending physician with a serious neurological disease. Figure 2 shows the health outcomes of these subjects; only one was found to have ABM.

One 3-year-old male patient presented to our facility

Table 3. Patients who did not receive lumbar puncture in the emergency department.

	n=57	%
Patients who appeared with no abnormal physical findings	51	89.5
Patients who appeared with an abnormal physical finding	6	10.5
Patients with prolonged postictal period	3	50.0
Patients with Todd's paralysis	2	33.3
Patients with petechiae	1	16.7
Patients with macrocephaly	0	0.0
Patients requiring intubation	0	0.0
Patients who were admitted to inpatient services	25	43.9
Patients diagnosed with neurological disease	0	0.0
Most common discharge diagnoses		
Otitis media	9	15.8
Unspecified viral illness	8	14.0
Gastroenteritis	4	7.0

Table 4. Characteristics of sub-population with 2 febrile seizures.

	n=43	%
Median age: 17.2 months (IQR=12.8–24.2)		
Female patients	22	51.2
Vaccination status reported	40	93.0
Vaccinations reported up-to-date	40	100.0
Patients returning from previous ED visit within 24 hours	20	46.5
Patients who received antibiotics < 24 hours before ED presentation	9	20.9
Patients with a history of simple febrile seizure	14	32.6

IQR, interquartile range; *ED,* emergency department

after being previously seen in a different ED for a simple febrile seizure. He had a total of 4 febrile seizures, one of which lasted 30 minutes. He was intubated after receiving anticonvulsants, but had no other physical indicator of neurological disease. After receiving a lumbar puncture, he was found to have CSF pleocytosis (WBC=12). He lacked CSF or blood culture growth, but antibodies for a mycoplasma bacterial species were identified in the blood. The attending physician assigned this patient a discharge diagnosis of bacterial meningitis, for which he was treated during a month-long inpatient stay. Based on our review, we conclude that the rate of ABM in our overall patient population (n=193) is 0.5% [95% CI: 0.0%–1.5%]).

Of the 7 patients with CSF pleocytosis and serious neurological disease all were admitted to the hospital for treatment and observation; 1 was transferred to another facility for insurance purposes. One returned to the ED after hospital discharge for follow-up during recovery from viral meningitis; he was found to be stable and was discharged home.

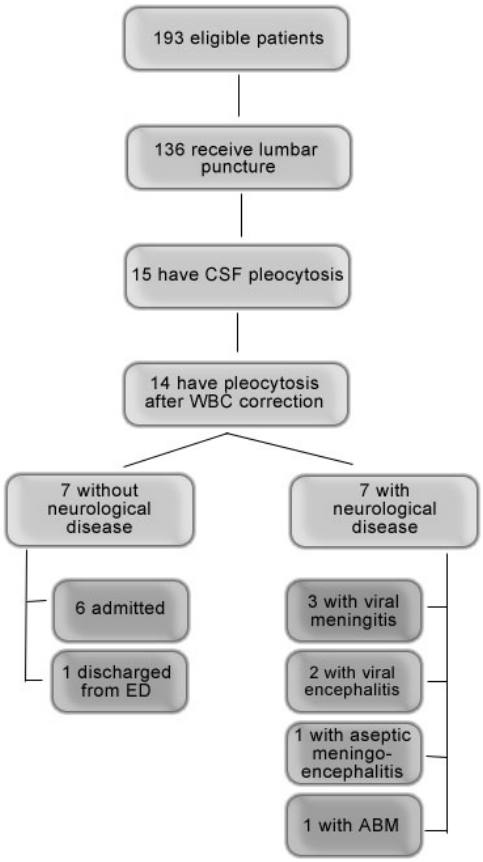


Figure 2. Patient outcomes after lumbar puncture.

Sub-analysis of Patients with 2 Brief Febrile Seizures

Of the 193 patients included in this study, 43 were identified to present with only 1 seizures, without any report of focality or prolonged seizure duration. Of these 43, 7 experienced their second seizure in the ED and subsequently received anticonvulsants. Twenty patients in this sub-population had already been seen in an ED for their initial febrile seizure, and were discharged home with a diagnosis of simple febrile seizure. Only 1 of the 20 received a lumbar puncture at the initial visit due to the presence of petechiae, but her CSF appeared normal and no other physical signs of disease were apparent upon presentation. She and 8 other patients were discharged from their initial visit with antibiotics. Background data on these patients is summarized in Table 4.

Lumbar puncture was performed on 17 of these patients, not including the patient who received LP during her initial ED visit. One subject was found to have pleocytosis (WBC=11), but lacked growth of any organism from CSF or blood cultures and had no other physical manifestations of neurological disease. None of the patients who underwent a lumbar puncture had any growth from a CSF culture. Blood culture was performed on 22 patients, and no organism was isolated from any of these samples. None was assigned an admission or discharge diagnosis of bacterial meningitis, or other serious neurological disease.

During the course of treatment in our ED for complex febrile seizure, 10 patients required supplemental oxygen, but 0/43 required intubation. None of the patients presented with Todd's paralysis or macrocephaly; however, 3 appeared to have a prolonged postictal period, and another previously mentioned patient presented with petechiae. Twenty patients were admitted for observation, including 2 by parental request. None of the patients had an additional seizure or any recorded adverse event during the course of inpatient stay. As in the patients who did not receive lumbar puncture, the 3 most common discharge diagnoses were unspecified viral illness (n=7), otitis media (n=6), and gastroenteritis (n=4); no child was diagnosed with a serious neurological disease. One patient returned after discharge due to complaints of herpangina. Follow-up data were available for all of the patients. None of the patients returned with reports of additional seizure or other neurological sequelae.

DISCUSSION

The importance of diagnosing acute bacterial meningitis in young pediatric patients is paramount; the disease progresses quickly and can cause long-term damage less than a day after symptoms arise.[8] Immediate medical attention is vital to the patient's survival and long-term well- being. Lumbar puncture is effective in diagnosing ABM and is therefore a standard procedure in differential diagnosis when a patient presents with a first complex febrile seizure.[10] However, lumbar puncture is invasive and can be traumatic, and there may be populations of patients that have a lower probability of serious neurological disease.[10] Sales et al[5] show a wide discrepancy of treatment plans between treating pediatric emergency physicians for patients presenting with complex febrile seizures. To better streamline patient care in a rushed pediatric ED, it's important to establish which patients may require lumbar puncture more urgently than others.

In our sample of 193 patients, only 1 was subsequently diagnosed with ABM. The incidence rate of ABM in our population is comparable to that of similar studies, and supports the assertion that ABM is uncommon in this population.[6,17] Therefore, it may be possible to identify a subset of patients presenting with a first complex febrile seizure who tend to be at lower risk of ABM or other serious neurological disease in order to administer appropriate treatment more efficiently.

Our analysis of the commonalities among patients who did receive lumbar puncture in our ED showed that these patients often presented with focality, status epilepticus, or a need for intubation. Seizure focality as a result of fluid accumulation in the subdural space may be an important indicator of ABM.[11] Convulsive status epilepticus has been found to be associated with increased rates of ABM.[12] Intubation rates for pediatric patients presenting with seizures vary, but have been reported up to nearly 50%, and clearly indicate a need for immediate medical attention.[13-16] These are not necessarily indications for lumbar puncture, but provide concrete evidence for the necessity of immediately ruling out bacterial meningitis or other neurological disease in these patients. While this may verge on common sense, the value of trained physicians' clinical bias should not be overlooked. With this in mind, our sub-population analysis of patients presenting with 2 brief seizures within 24 hours excluded any patients with focality or status epilepticus by definition, and none of the eligible patients required intubation during their treatment in our ED. The tendency of pediatric emergency physicians to treat patients with these specific clinical indicators of neurological disease reflects an existing perception of what serious neurological disease looks like upon presentation to a pediatric ED. In contrast, our sub-population may essentially represent the other end of the spectrum.

Our sub-population analysis included 43 patients, 17 of whom received lumbar puncture. No neurological disease was diagnosed in this group of patients, which is consistent with analyses in similar populations.[6] None of the patients in this population were found to have neurological sequelae in follow up. While each febrile seizure should be evaluated on a case-by-case basis, our data suggest that patients who fall into this sub-population may be at a lesser risk of ABM or other serious neurological disease. Patients with 2 short febrile seizures within 24 hours without other signs of neurological disease may not require lumbar puncture in the pediatric ED.

LIMITATIONS

Retrospective analyses often include several limitations. One important factor to consider in our analysis is that ABM rates are relatively rare, so studies of its incidence in a given population require a very large sample size. It is difficult to make any strong conclusions on the rates of ABM within this population of 193 patients; we can simply note that our findings appear to be consistent with similar studies and hope to supplement the existing literature on this topic.

Another consideration is that *Haemophilus influenzae* type B vaccines are usually administered in young children before the age of 6 months to prevent bacterial meningitis.[4] Status of this vaccine was not reported in patient charts, so we were unable to control for patients who had previously been vaccinated.

A final limitation was the use of ICD-9/10 codes for determination of our original subject list. Although we manually screened these patients' records to ensure that each met eligibility requirements, other children experiencing FCFS may have been miscoded. This may particularly apply to patients experiencing multiple febrile seizures within the duration of a febrile illness where no other complex feature was observed, as each seizure event may have appeared to be a simple febrile seizure. We attempted to control for this by ensuring that our search for patient charts was as comprehensive as possible. We also assume that all complex

features of the seizures were observed. This may not have been the case for children presenting with multiple seizures at home before presentation in the ED, or for patients who presented with focality that was not immediately recognized by the parent. These limitations are inevitable for this type of study. Future studies on this topic may focus on prospectively enrolling patients to gain a comprehensive understanding of febrile seizure presentation.

CONCLUSION

ABM is rare in patients presenting with a first complex febrile seizure. As Kimia et al[6] have suggested, patients presenting only with 2 short febrile seizures within 24 hours may be less likely to have ABM, and may not require lumbar puncture without other clinical symptoms of neurological disease. Furthermore, in patients with first complex febrile seizure, lumbar puncture is significantly more likely to be performed on patients that presented with seizure focality, status epilepticus, or a need for intubation.

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Abnormal Arterial Blood Gas and Serum Lactate Levels Do Not Alter Disposition in Adult Blunt Trauma Patients after Early Computed Tomography

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Introduction: Arterial blood gas and serum lactate (ABG / SL) values have been shown to be markers for occult shock and poor outcome following blunt trauma. However, the utility of ABG / SL in blunt trauma patients who also receive computed tomographies (CT) of the chest, abdomen, and pelvis (CT C&A) remains unknown.

Methods: A chart review was performed of all adult blunt trauma patients who received both CT C&A and ABG / SL upon presentation to our emergency department (ED) between January 1, 2007 and December 31, 2007. These patients (n=360) were identified from our institutional trauma registry database. Patients were divided into subgroups based upon whether they had a positive or negative ED evaluation for traumatic injury requiring hospitalization or immediate operative management. The expected course for patients with negative ED evaluations regardless of ABG / SL was discharge home. The primary outcome measure was the proportion of patients with a negative ED evaluation and an abnormal ABG or SL that were admitted to the hospital.

Results: 2.9% of patients with a negative ED evaluation and abnormal ABG or SL were admitted. Of these, none were found to have any post-traumatic sequalae.

Conclusion: We found that abnormal ABG / SL results do not change management or discharge disposition in patients without clinical or radiographic evidence of traumatic injury on CT C&A. Among patients who receive CT C&A, the routine measurement of arterial blood gas and lactate may be an unnecessary source of additional cost, patient discomfort, and delay in care.
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INTRODUCTION

Arterial blood gas (ABG) and serum lactate (SL) abnormalities have both been identified as markers for occult malperfusion and poor outcome following blunt traumatic injury.[1-5] This has led some authors to advocate the use of arterial blood gas with serum lactate (ABG / SL) as a screening tool for occult injury in all patients sustaining blunt trauma.[4] Our institutional protocol requires that ABG / SL be obtained on all Level I or Level II blunt trauma patients presenting to the resuscitation bay. However, cross-sectional computed tomography (CT) of the chest, abdomen and pelvis (CT C&A) is also obtained on many of these patients. It remains unclear whether or not ABG / SL adds any predictive or prognostic value in the detection of clinically-significant occult injury when early CT C&A is also obtained.

Routine laboratory testing in blunt trauma patients has been dramatically reduced over the past decade.[6] Studies have shown that the routine use of chemistry panels, amylase, and coagulation studies are of limited clinical value in the evaluation of blunt trauma patients, and merely add to overall hospital resource use.[6] Among those blunt trauma patients who also receive CT C&A imaging, routine ABG / SL testing may also be an unnecessary source of additional cost, patient discomfort, and delay in care. This study sought to determine

whether abnormal ABG / SL values change the emergency department (ED) disposition of patients who also receive an early CT of the chest, abdomen and pelvis.

METHODS

All Level I or Level II adult blunt trauma patients presenting to the ED resuscitation bay between January 1, 2007, and December 31, 2007, were identified from the institutional trauma registry. We considered patients ≥ 16 years of age adults for the purposes of this study. Exclusion criteria included the absence of an ABG or serum lactate level, the absence of complete CT C&A imaging while in the ED, concomitant penetrating trauma, transfer to or from another institution prior to hospital admission, or patients who left prior to completion of service.

The criteria for Level I and Level II trauma triage at our institution are shown in Figure 1. There is some discretion with regards to Level II triage criteria and some of these patients, as well as Level 3 trauma patients, are not seen in the resuscitation bay. Patients who are not seen in the resuscitation bay do not receive the same routine laboratory studies and therefore were not included in this study.

We developed a data abstraction tool to collect information, and instructed a research assistant on using the tool. All data were collected by the study authors and a single research assistant. This tool collected demographic data (age and gender), initial ABG and lactate values, results of all CT studies, mechanism and types of traumatic injuries, ED complications, and final disposition from the ED for all patients. Patients who were admitted to the clinical decision unit (CDU) for observation ≤ 23 hrs were considered to be hospital admissions for the purposes of this study, as they were not discharged home.

An abnormal ABG was defined as a pH of less than 7.35 or greater than 7.45, or a base deficit (BD) of ≤ -6. An abnormal lactate was defined as a serum lactate level > 1.8 mmol/L, which is the upper limit of normal at our institution.

We analyzed 2 patient subgroups. The first subgroup consisted of those patients with a negative ED evaluation for traumatic injury. By definition, these patients all had a CT C&A demonstrating no acute traumatic injuries, normal CT Head or Glasgow Coma Scale (GCS) of 15 and no clinical concern for head injury, and no radiographic or clinical evidence for any major traumatic injury requiring emergent operative intervention or hospital admission. In short, these patients had no traumatic sequelae identified that would have required hospital admission or emergent operative intervention.

The second subgroup consisted of those patients with a positive ED evaluation for traumatic injury. Patients in this group had either a CT C&A demonstrating significant acute traumatic injuries, or some other radiographic or clinical evidence of blunt traumatic injury requiring immediate operative intervention or hospital admission. In short, these patients would have required admission to the hospital for traumatic injuries regardless of ABG / SL results. For the purposes of this study, major injury was defined as blunt traumatic injury requiring immediate operative intervention or hospital admission.

The expected course for patients with a negative ED evaluation in the absence of the information provided by an ABG or serum lactate level would be discharge to home. Patient charts were reviewed looking for evidence of a change in expected management in both of these groups. The primary outcome measure was the proportion of patients with a negative ED evaluation and an abnormal arterial blood gas and/or lactate that were subsequently admitted to the hospital.

Secondary outcomes included the proportion of overall abnormal ABG / serum lactate results, and the proportion of patients with an abnormal ABG or serum lactate and a negative ED evaluation that subsequently sustained an ED complication. ED complications were defined as ED mortality, ED cardiac or respiratory arrest with successful resuscitation, or significant hypotension requiring the

Henry Ford Health System Trauma Criteria

Trauma Level I:
1. Systolic BP < 90
2. Respiratory rate < 10 or > 30
3. Glasgow coma score ≤ 10
4. Intubation in the field or respiratory compromise
5. Intubations prior to transfer from outside facilities
6. GSW to head, neck, trunk, including buttocks and perineum
7. Resuscitative blood transfusion during transport
8. ED Senior Staff Physician Discretion

Trauma Level II:
A. Mechanism of injury
1. High speed motor vehicle crash > 40 mph
2. Ejection
3. Rollover
4. Extrication
5. Death in same passenger compartment
6. Pedestrian or bicycle or motorcycle crash with victim thrown, run-over or with significant impact.
7. Fall > 10 feet
8. Burns: > 20% TBSA and any electrocution injury

Trauma Level II:
B. Anatomic criteria
1. All penetrating injuries to the extremities excluding those distal to the elbow and knee.
2. Flail chest or multiple rib fractures
3. Pelvic fracture
4. Two or more proximal long bone fractures
5. Amputation proximal to wrist or ankle
6. Focal neurologic deficit (paralysis, pain out of proportion, paresthesias, pallor, pulselessness)
7. Pregnancy (>20 weeks)
8. Extremes of age: < 10 yrs or > 65 yrs old

Figure 1. Trauma Criteria.
BP, blood pressure; *GSW*, gun shot wound; *ED*, emergency department; *TBSA*, total body surface area

Table 1. Patient characteristics (positive vs. negative emergency department [ED] evaluation).

	Positive ED evaluation	Negative ED evaluation	*P*-value
Number of patients	185 (51.4%)	175 (48.6%)	
Number admitted (%)	185 (100.0%)	11 (6.3%)	
Males (%)	138 (74.6%)	128 (69.2%)	
Mean age (years)	42.5	36.8	< 0.001
Mean pH	7.37	7.41	< 0.001
Mean carbon dioxide ($PaCO_2$, mmHg)	38.7	37.1	0.04
Mean oxygen (PaO_2, mmHg)	152.4	143.0	0.28
Mean oxygen saturation (%)	96.5	96.6	0.88
Mean lactate (mmol/L)	2.91	2.04	< 0.001
Mean base deficit	-2.97	-1.06	< 0.001

transfusion of blood products after the patient's initial resuscitation was completed.

RESULTS

We identified 464 adult blunt trauma patients from our institutional trauma registry who presented to the ED resuscitation bay between January 1, 2007, and December 31, 2007, . We excluded 104 patients from the study due to absence of CT C&A imaging (63 patients), transfer from or to another institution (28 patients), absence of either ABG or serum lactate value (6 patients), inaccurate patient identifier information (6 patients), or patient leaving prior to completion of service (1 patient).

Three hundred sixty adult blunt trauma resuscitation patients met inclusion criteria. We found significant differences in mean pH ($p<0.001$), mean partial pressure of carbon dioxide ($p=0.04$), mean serum lactate level ($p<0.001$), and mean base deficit ($p<0.001$) between groups. We found no significant differences between groups in regards to mean partial pressure of oxygen ($p=0.28$) or mean oxygen saturation ($p=0.88$). Patients with a negative ED evaluation were generally younger than patients with a positive ED evaluation (mean age 38.8 years vs. 42.5 years, $p<0.001$). This data is presented in Table 1.

Of these 360 patients, 175 (48.6%) had a negative ED evaluation, and 185 (51.4%) had a positive ED evaluation. Of the 175 patients with a negative ED evaluation, 104 (59.4%) had an abnormal ABG or serum lactate level. Of the 185 patients with a positive ED evaluation, 46 (24.9%) had a normal ABG and serum lactate level, although none were sent home (Figure 2). The laboratory and disposition results for patients with negative or positive ED evaluation are presented in Tables 2-4. The types of major injury identified on CT for all patients are presented in Table 5.

The sensitivity of an abnormal ABG or lactate level for blunt traumatic injury identified on CT of the chest, abdomen, and pelvis was 69.2%, with specificity of 43.5%. The positive predictive value (PPV) was 34.1%, with negative predictive value (NPV) of 76.9%. In identifying major blunt trauma injury, abnormal ABG (base deficit or pH < 7.35 or > 7.45) alone was found to have a sensitivity of 40.2%, and specificity of 79.8% (PPV 45.7%, NPV 75.9%). Abnormal serum lactate alone was associated with a sensitivity of 62.6%, and specificity of 50.6% (PPV 34.9%, NPV 76.2%) for major injury identified on CT.

The sensitivity of an abnormal ABG or lactate level for blunt traumatic injury requiring hospital admission was 73.2%, with specificity of 39.2%. The PPV was 58.4%, NPV of 55.6%. In predicting hospital admission, abnormal ABG (abnormal base deficit or pH) alone was found to have a sensitivity of 44.3%, and specificity of 68.1% (PPV 61.9%, NPV 51.1%). Abnormal serum lactate alone was associated with a sensitivity of 59.8%, and specificity of 54.2% (PPV 60.4%, NPV 53.6%). These results are presented in Table 6, including descriptive statistics for various combinations of abnormal lab values.

Table 2. Abnormal arterial blood gas and serum lactate (ABG / SL) by emergency department (ED) evaluation.

Lab abnormality	Positive ED evaluation (All were admitted)	Negative ED evaluation (Number admitted, %)	Total (Number admitted, %)
Alkalosis only (AL)	10	16 (1, 6.3 %)	26 (11, 42.3%)
Alkalosis + Lactate (A+L)	7	12 (0)	19 (7, 36.8%)
Acidosis only (AC)	10	10 (0)	20 (10, 50.0%)
Acidosis + Base deficit (AC+BD)	2	0	2 (2, 100.0%)
Acidosis + Lactate (AC+L)	17	11 (0)	28 (17, 60.7%)
Base deficit only (BD)	3	0	3 (3, 100.0%)
Base deficit + Lactate (BD+L)	4	1 (0)	5 (4, 80.0%)
Lactate only (L)	56	49 (1, 2.0%)	105 (57, 54.3%)
All abnormal (ALL)	31	5 (1, 20.0%)	36 (32, 88.9%)
Any abnormal (ANY)	139	104 (3, 2.9%)	243 (142, 58.4%)
All normal (NL)	46	71 (5, 7.0%)	117 (51, 43.6%)
Total	185 (100.0%)	175 (11, 6.3%)	360 (196, 54.4%)

Table 3. Percent of patients with abnormal arterial blood gas and serum lactate (ABG / SL) by disposition from emergency department.

Disposition	Number patients	Abnormal ABG (%)	Abnormal lactate (%)	Abnormal ABG or lactate (%)
Admitted	194 (53.9%)	86 (44.3%)	116 (59.8%)	142 (73.2%)
CDU	16 (4.4%)	3 (18.8%)	6 (37.5%)	6 (37.5%)
Floor	46 (12.8%)	13 (28.2%)	21 (45.7%)	28 (60.9%)
ICU	87 (24.2%)	50 (57.5%)	60 (69.0%)	72 (82.8%)
OR	45 (12.5%)	20 (44.4%)	29 (64.4%)	36 (80.0%)
Discharged	166 (46.1%)	53 (31.9%)	76 (45.8%)	101 (60.8%)
Total	360 (100.0%)	139 (38.6%)	192 (53.3%)	243 (67.5%)

CDU, critical descision unit; *ICU,* intensive care unit; *OR,* operating room

Table 4. Arterial blood gas and serum lactate (ABG / SL) results by finding of major injury on computed tomography (CT).

	CT chest			CT abdomen / pelvis		
	Negative	Positive	p-value	Negative	Positive	p-value
Number of patients	276	84		306	54	
Mean lactate (mmol/L)	2.36	2.90	0.03	2.36	3.18	0.01
Mean base deficit	1.63	3.41	< 0.001	1.73	3.75	< 0.001
All normal (%)	98 (35.5 %)	19 (22.6 %)		108 (35.3 %)	9 (16.7 %)	
Any abnormal (%)	178 (64.5 %)	65 (77.4 %)		198 (64.7 %)	45 (83.3 %)	

Table 5. Major injuries identified on computed tomography (CT) of the chest, abdomen, and pelvis.

Type of injury	Number (%) of all major injuries	Number (%) with abnormal ABG / SL
CT chest		
Hemothorax Hemomediastinum	12 (5.8%)	12 (100.0 %)
Multiple rib fractures/ flail chest	50 (24.3%)	36 (72.0 %)
Pericardial effusion	1 (0.5%)	1 (100.0 %)
Pneumothorax / Pneumomediastinum	26 (12.6%)	24 (92.3 %)
Pulmonary artery laceration	2 (1.0%)	1 (50.0 %)
Pulmonary contusion	31 (15.0%)	24 (77.4 %)
Transected aorta	1 (0.5%)	1 (100.0 %)
CT abdomen / pelvis		
Adrenal hematoma	2 (1.0%)	2 (100.0 %)
Bladder rupture	2 (1.0%)	2 (100.0 %)
Diaphragmatic rupture	1 (0.5%)	0 (0.0 %)
Free fluid in abdomen	9 (4.4%)	8 (88.9 %)
Free fluid in pelvis	9 (4.4%)	8 (88.9 %)
Gastric / bowel injury	7 (3.4%)	6 (85.7 %)
Kidney laceration	3 (1.5%)	3 (100.0 %)
Liver laceration / contusion	12 (5.8%)	10 (83.3 %)
Pancreatic injury	1 (0.5%)	1 (100.0 %)
Pelvic fracture	23 (11.2%)	17 (73.9 %)
Pneumoperitoneum	3 (1.5%)	3 (100.0 %)
Soft tissue hematoma	3 (1.5%)	2 (66.7 %)
Splenic laceration	8 (3.9%)	8 (100.0 %)
Total	206 (100.0%)	169 (82.0 %)

We found only 3 cases among the 360 patients included in our analysis that appeared to have a change in disposition from the ED due to abnormal ABG / SL values. The first of these patients was a 51-year-old male involved in a motor vehicle collision (MVC) who was admitted to the inpatient medical floor for known Atrial Fibrillation with Rapid Ventricular Response with an arterial pH 7.52 but otherwise normal ABG / SL. The second patient was a 33-year-old female involved in an MVC who was admitted for observation in the Clinical Decision Unit (CDU) for persistent abdominal pain with a lactate 2.4 mmol/L and discharged the following morning. The third patient was a 16-year-old male involved in an assault who was admitted to the CDU for an unexplained elevated lactate level (12.5 mmol/L) and base deficit of 9. He was also discharged home the following morning. All 3 patients had negative laboratory and radiographic evaluations in the ED with the exception of the ABG / SL. None of these 3 patients were found to have any post-traumatic sequelae during the time that they were monitored in the hospital.

Table 6. Abnormal laboratory values associated with hospital admission.

Abnormal lab value	Sensitivity	Specificity	PPV	NPV
Lactate (L)	59.8 %	54.2 %	60.4 %	53.6 %
ABG (pH or BD)	44.3 %	68.1 %	61.9 %	51.1 %
ALL (pH + BD + L)	16.5 %	97.6 %	88.9 %	50.0 %
ANY (pH or BD or L)	73.2 %	39.2 %	58.4 %	55.6 %

PPV, positive predictive value; *NPV,* negative predictive value

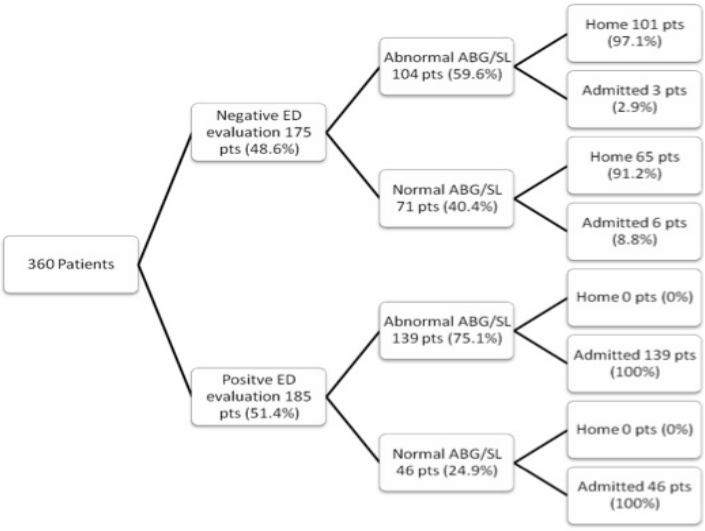

Figure 2. Study results.

Of the 175 patients with negative ED evaluations, 6 were admitted to the hospital despite normal ABG / SL values. One of these patients was admitted to the intensive care unit for a new diagnosis of atrial fibrillation, and 5 were admitted to the CDU for observation. Three of the 5 CDU patients were admitted for pain control, one was admitted for an elevated amylase level that normalized the following day, and 1 patient was observed for < 23 hours following infiltration of CT intravenous contrast. There were no ED complications identified in patients with a negative ED evaluation.

DISCUSSION

Arterial blood gases and serum lactate levels have been shown to be appropriate laboratory studies in the evaluation of select blunt trauma patients, especially those patients who have sustained significant traumatic injury. The utility of serial blood gases and lactate levels in assessing the adequacy of fluid resuscitation in blunt trauma patients has been well studied and is strongly supported by the current trauma and critical care literature.[7-8] Table 4 also demonstrates that patients in this study with major injury identified on CT generally have statistically-higher mean lactate levels and mean base deficits than patients in this study without major injury. However, in this study, the mean base deficit for patients with major injury identified on CT was still within normal limits for healthy individuals, and the mean serum lactate for uninjured patients was elevated above normal limits at our institution. This data suggests that ABG / SL levels are of limited value in detecting clinically-significant occult injury among patients with a normal CT evaluation of the chest, abdomen, and pelvis following blunt trauma.

CT has been shown to reliably identify major traumatic injury following blunt trauma.[9-10] ABG / SL levels can also play an important role in defining fluid resuscitation endpoints and evaluating the degree of post-traumatic malperfusion when followed over time. However, our data suggests that abnormal ABG / SL results do not alter discharge disposition or identify ED complications in those blunt trauma patients who also receive extensive CT early in their resuscitation. In this patient population, a thorough physical examination, appropriate CT, and other radiographic studies were adequate to identify injuries ultimately requiring immediate management or hospital admission. Based on these results, routine ABG / SL measurements should not be used as screening tests to identify occult injury in adult blunt trauma patients who undergo CT C&A.

Routine ABG / SL testing may not add any diagnostic value to a patient's ED evaluation, but is associated with additional costs to the patient, potential complications, and the misappropriation of already limited ED resources. The laboratory cost of an ABG / SL level at our institution is $216, which represents a cumulative cost of $77,760 for all 360 patients included in this analysis. Besides this additional cost, cannulation of the radial artery for sampling also carries the risk of certain complications, including bleeding, median nerve injury, pseudoaneurysm formation, and radial artery thrombosis.[11]

Based upon these results, we hope to defer ABG / SL testing on all patients who will be receiving early CT C&A at our institution until CT results are known, unless the patient is deemed clinically unstable or is expected to require hospital admission independent of CT findings. We believe that these changes to our institutional blunt trauma protocol will save our patients this unnecessary expense, while improving their risk profile without compromising the quality of the care provided in the ED.

LIMITATIONS

We faced the standard limitations of a retrospective study. However, these were mitigated by the fact that the trauma registry data is collected prospectively and the data points are readily found in the registry. The main limitation in this analysis was the inability to eliminate practice variation due to the retrospective nature of the study. The institutional trauma protocol requires that ABG / SL levels be obtained on all blunt trauma patients presenting to the resuscitation room. In reality, there was some variability in the frequency of ABG and lactate collection and this may have affected the results. We also did not evaluate how ABG / SL results may have affected intravenous fluid administration or other treatments provided in the ED. Lastly, the lack of complete follow up of discharged patients is a limitation of their true final outcome.

CONCLUSION

Abnormal arterial blood gas or serum lactate levels do not change the ED disposition of adult blunt trauma patients who also receive an early CT of the chest, abdomen and pelvis. The routine use of ABG / SL on these patients is not warranted.

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Oral and Intravenous Acetylcysteine for Treatment of Acetaminophen Toxicity: A Systematic Review and Meta-analysis

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Introduction: There are few reports summarizing the effectiveness of oral and intravenous (IV) acetylcysteine. We determined the proportion of acetaminophen poisoned patients who develop hepatotoxicity (serum transaminase > 1000 IU/L) when treated with oral and IV acetylcysteine.

Methods: Studies were double abstracted by trained researchers. We determined the proportions of patients who developed hepatotoxicity for each route using a random effects model. Studies were further stratified by early and late treatment.

Results: We screened 4,416 abstracts; 16 articles, including 5,164 patients, were included in the meta-analysis. The overall rate of hepatotoxicity for the oral and IV routes were 12.6% and 13.2%, respectively. Treatment delays are associated with a higher rate of hepatotoxicity.

Conclusion: Studies report similar rates of hepatotoxicity for oral and IV acetylcysteine, but direct comparisons are lacking. While it is difficult to disentangle the effects of dose and duration from route, our findings suggest that the rates of hepatotoxicity are similar for oral and IV administration. [West J Emerg Med. 2013;14(3):218–226.]

INTRODUCTION

Acetaminophen poisoning is the most common medication poisoning reported to United States (U.S.) poison centers and accounts for more than 30,000 hospital admissions every year in the U.S. alone.[1] Fortunately, acetaminophen-related hepatotoxicity can be prevented by early treatment with acetylcysteine. Acetylcysteine is administered by either the intravenous (IV) route or the oral route. The use of IV acetylcysteine was studied in Europe and Australia in the early 1970s, while the use of oral acetylcysteine was studied in the U.S. in the late 1970s.[2,3] Historically, IV acetylcysteine has been used in Canada, Europe, and Australia while oral acetylcysteine has been used in the U.S. In 2004, an IV formulation of acetylcysteine was approved for use in the U.S., and IV administration is now the most common route used in the U.S.[4]

As both IV and oral acetylcysteine are available in the U.S., clinicians must select one of these routes when treating an acetaminophen-poisoned patient. Unfortunately, there are no head-to-head trials comparing the efficacy of these 2 routes. The Cochrane Review of Interventions for Paracetamol (Acetaminophen) Overdose does not specifically compare IV and oral administration of acetylcysteine.[5] One previously published meta-analysis concluded that patients who present for treatment within 8 hours should be treated with IV acetylcysteine, but this analysis is now more than 10 years old and was performed before IV acetylcysteine was available in the U.S.[6] More recently, Yarema et al[7] compared the results of the U.S. National Multi-Center Trial of Acetylcysteine for Acetaminophen Overdose to the Canadian Acetaminophen Overdose Study. Their findings suggested that IV administration with a 21 hour administration

protocol was more effective for patients presenting within 12 hours of ingestion and that oral administration with a 72 hour administration protocol was more effective for those presenting more than 18 hours after ingestion. These results have stimulated interest in systematically evaluating the efficacy of the oral and IV routes using all published data.

The objective of this study is to determine the percentage of patients who develop hepatotoxicity during treatment with oral and IV acetylcysteine, and to explore the time-dependence of efficacy for the 2 routes.

METHODS

This was a systematic literature review and meta-analysis of studies reporting patients treated with IV or oral acetylcysteine for acetaminophen overdose. The study protocol was not registered. For included studies, the primary outcome measures were the percentage of patients who developed hepatotoxicity during treatment acetylcysteine by either oral or IV administration. Our secondary aim was to evaluate the time-dependence of efficacy for each route.

Definitions

Hepatotoxicity was defined as a post-baseline aspartate aminotransferase (AST) or alanine aminotransferase (ALT) level above 1000 IU/L. The definition of a toxic acetaminophen concentration varied among the studies; most non-U.S. studies used the original definition of toxicity (concentration above the line starting at 200 mcg/ml at 4 hours) while U.S. studies used the modified definition (concentration above the line starting at 150 mcg/ml at 4 hours). We included studies using either definition.

Literature Search and Data Abstraction

A literature search was performed using EMBASE, and MEDLINE and International Pharmaceutical Abstracts via Ovid. Articles were searched for acetaminophen key words using the terms acetaminophen, paracetamol, and CAS registry number 103-90-2, and for acetylcysteine key words using the terms acetylcysteine, n-acetylcysteine, and CAS registry number 616-91-1. The acetaminophen search was crossed with the acetylcysteine search using the Boolean operator "AND." The literature search was limited to human exposure and English language articles published between 1966 and 2009. Article flow is presented in Figure 1. Manuscripts were also reviewed to identify and exclude duplicate reports of studies.

All abstracts from resultant citations were reviewed by a single reviewer to identify articles containing potential efficacy data. Full articles were obtained for all selected abstracts and were further reviewed by 2 researchers for inclusion. The inclusion criteria applied at this step were: use of acetylcysteine for acute acetaminophen overdose, use of acetylcysteine subsequent to a 4 to 24 hour acetaminophen level above the Rumack-Mathews treatment line (either the "150 line" or the "200 line"), no evidence of hepatotoxicity prior to acetylcysteine treatment, and a reported AST or ALT activity post acetylcysteine treatment.

All articles meeting these criteria were further abstracted by 2 trained researchers for demographic data (i.e. age, gender, race), study characteristics (i.e. study type and inclusion and exclusion criteria), route of treatment, and which line on the Rumack–Mathews nomogram was used to qualify patients for treatment. When reported, rates of hepatotoxicity were stratified by time to ingestion. Reconciliation of abstracted data was performed by a single researcher and disagreements were resolved by referencing the primary source. Abstractors were not blinded to the study objectives.

All full articles were reviewed for references of interest. Abstracts and citations of selected references were obtained and reviewed according to the literature search procedure. In addition, a cited reference search using Web of Science was performed on all articles selected for abstraction. Full articles reviewed during any step of the literature search process were also reviewed for potentially relevant references.

Final criteria used to determine inclusion of an article for analysis were: 1) acetylcysteine treatment, with route specified, 2) absence or presence of hepatotoxicity, and 3) a toxic acetaminophen concentration, defined using either the "150 line" or the"200 line" on the Rumack-Mathews nomogram. Other stratification parameters were time to initiation of acetylcysteine and study size. For the primary analysis, we included studies that had consecutive enrollment and at least 20 subjects, as these criteria were used by the Cochrane Review to decrease the effect of small studies with a high probability of selection bias.

Analysis Plan

As formal comparison of treatments using meta-analysis

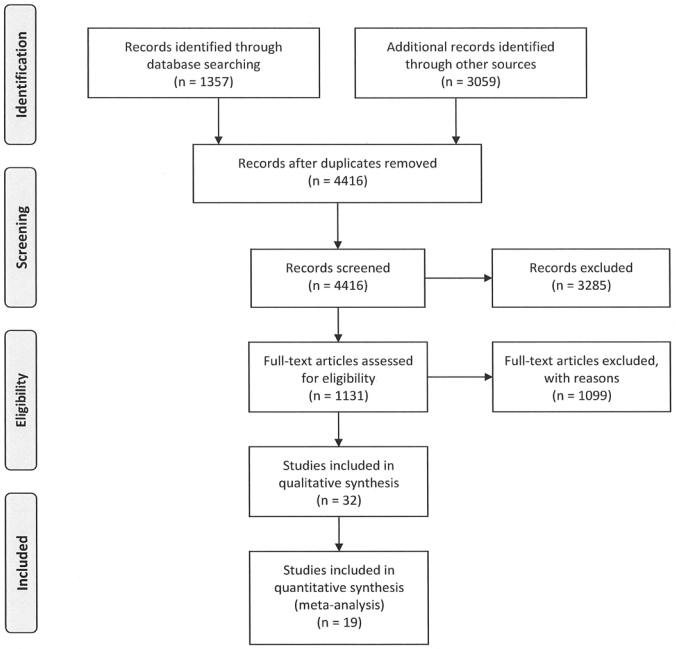

Figure 1. PRISMA diagram of articles identified during the article search and abstraction process.

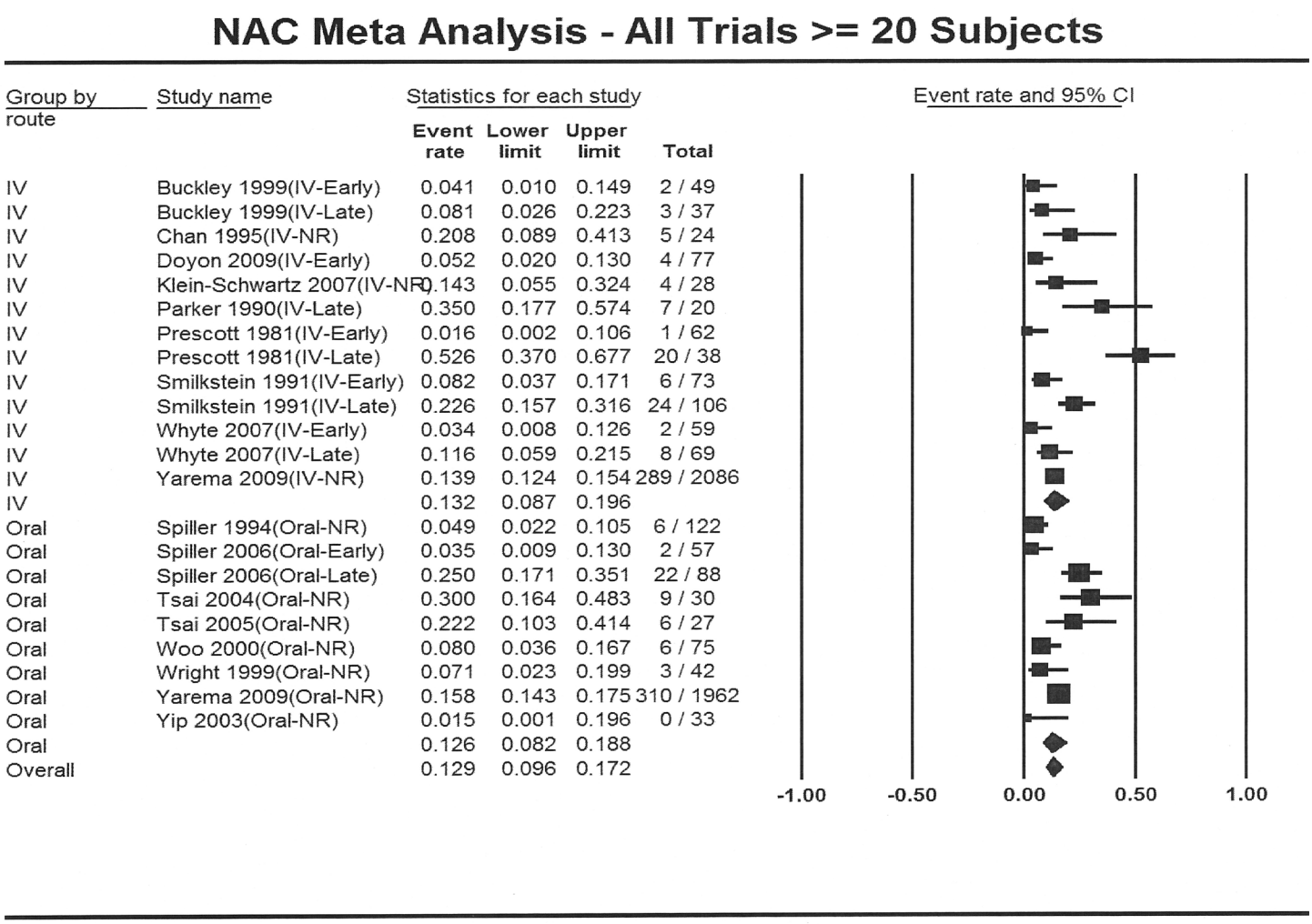

Figure 2. Forest plot showing proportion of patients with acetaminophen poisoning who developed hepatoxicity for intravenous and oral acetylcysteine treatment.

requires determining the differences in treatments using studies that directly compare treatments, we initially sought to identify studies that compared IV and oral administrations. As we did not find any studies meeting these criteria, we elected to present point estimates with 95% confidence intervals (CIs) for the outcomes of interest for each route rather than perform a formal meta-analysis comparing the routes.

Statistical Methods

The overall standardized estimates for event rates were determined for each route (IV or oral) and for time (early or late) subgroups. Event rates were defined as the number of subjects with post-baseline hepatotoxicity divided by the number of subjects included for a particular publication. Ninety-five percent confidence intervals were constructed on these estimates and compared across subgroups. Funnel plots were generated to investigate any publication bias. All meta-analyses, forest plots, and funnel plots were generated using "Comprehensive Meta-Analysis"® from Biostat™, Englewood, N.J., version 2.0.

The relationship between route (IV or oral) and time (early or late) of administration of NAC were explored using a multiple regression model. In order to construct estimable functions for route and time effects, we included only studies that reported both route and time. Time from acetaminophen ingestion to initiation of acetylcysteine therapy was abstracted as a binary outcome: "early" (less than 10 hours or as defined by the author) and "late" (greater than 10 hours or as defined by the author). A general linear mixed model (GLIMMIX procedure in SAS® version 9.2 Cary, N.C.) was applied to these data. Fixed effects were route, time, and the route by time interaction. Random effects were studied. Toxicity event rates were assumed to follow a binomial distribution. Main effects were considered significant if the *P*-value was < 0.05 and the interaction term was considered significant if the *P*-value was < 0.10. Standard meta-analysis techniques were used to summarize the data among the other citation subgroups. The meta-analysis was conducted using a random effects model.

Table 1. Demographics and study characteristics for citations reporting ≥ 20 subjects.

Short name	Study design	Treatment threshold[a]	Age mean (years)	Age range (years)	Age median (years)	Percent female	Race
Buckley[6]	Retro	150		0-89	24	64.0	NR
Chan[23]	Retro	200		Not at risk group: 14–78; At risk, no liver damage group: 14–85; At risk liver damage group: 16–34		76.8	100% Asian
Doyon [8]	Retro	150	28.3 ± 15.7	13–75	22		NR
Klein-Schawartz[9]	Prosp	150		15–74	34	57.0	NR
Parker[10]	Prosp	150	Women:37; Men:35	Women: 19-76; Men: 18–76		50.0	NR
Prescott[11]	Prosp	200	33	13–82		58.0	NR
Rumack[34]	Prosp	150		0.038–5		92.0	NR
Sivilotti[22]	Retro	150			22.1	69.0	NR
Smilkstein[24]	Prosp	150	21.3 ± 9.5			67.6	NR
Smilkstein[3]	Prosp	200[b]				69.2	NR
Spiller[13]	Prosp	150[c]	22.0 ± 0.9	2.0–84		68.9	NR
Spiller[14]	Prosp	200	26.1 ± 12.5	6.0–79		73.0	NR
Tsai[15]	Prosp	150	25.6 ± 8.8	2.0–60		84.0	NR
Tsai[16]	Retro	150	26.7 ± 10.2	12.0–60		88.9	NR
Whyte[17]	Retro	150	29.0 ± 12.9	0.1667–96			NR
Woo[18]	Retro	150		12.0–76		56.0	NR
Wright[19]	Retro	150[c]	High dose group: 20±10; Standard dose group: 24±10	2.0–45			NR
Yarema[20]	Retro	150					NR
Yip[21]	Prosp	150		13–48		85.3	NR

Prosp, prospective; *Retro*, retrospective; *NR*, no response

[a] Treatment threshold is the line on the Rumack-Mathew nomogram used to identify patients eligible for enrollment.

[b] The results of this study were stratified by time for the probable toxicity group (≥ 200) so this cutoff was used for the analysis.

[c] Study reported enrolling patients based on a "toxic concentration based on the Rumack-Mathew nomogram".

RESULTS

The primary literature search identified 1357 citations of interest. An additional 3059 citations were identified by the Web of Science and selected reference searches. Together, 4416 abstracts were screened for data, with 1131 meeting necessary criteria for further review. Of the 1131 full articles reviewed for data, 334 were selected for abstraction. The results of the literature search are presented in Figure 1. After applying final inclusion criteria, 19 articles were eligible and included in 1 or more analyses. The vast majority of the 315 articles that did not meet inclusion criteria were excluded because they included less than 20 subjects. Other reasons for exclusion were because subjects were selected based on outcome, the route of NAC administration was not reported, and stratification, or outcome data were not reported in a way that allowed us to include the studies in the analysis.

Meta-analyses

The characteristics of the patients included in the meta-analyses are shown in Table 1. Nineteen articles that met inclusion criteria and included at least 20 subjects were identified.[3,6,8-24] Sixteen articles reporting 5164 unique cases were included in the overall meta-analysis.[6,8-11,13-21,23-24] Three reports were excluded from this analysis as they were secondary data analyses or were included as a part of larger studies.[3,22,25] The overall proportion of patients who developed hepatotoxicity in the studies meeting criteria for inclusion in the meta-analysis was 12.9% (95% confidence interval: 9.6% to 17.2%). The percentages were similar when studies were stratified by route (Figure 2); the proportion for IV treated patients was 13.2% (95% CI: 8.7% to 19.6%) while the proportion for oral treated patients was 12.6% (95% CI: 8.2% to 18.8%).

Seven reports provided outcome data stratified by early (n=949) and late (n=1293) treatment.[3,6,10,11,14,17,24] Four studies

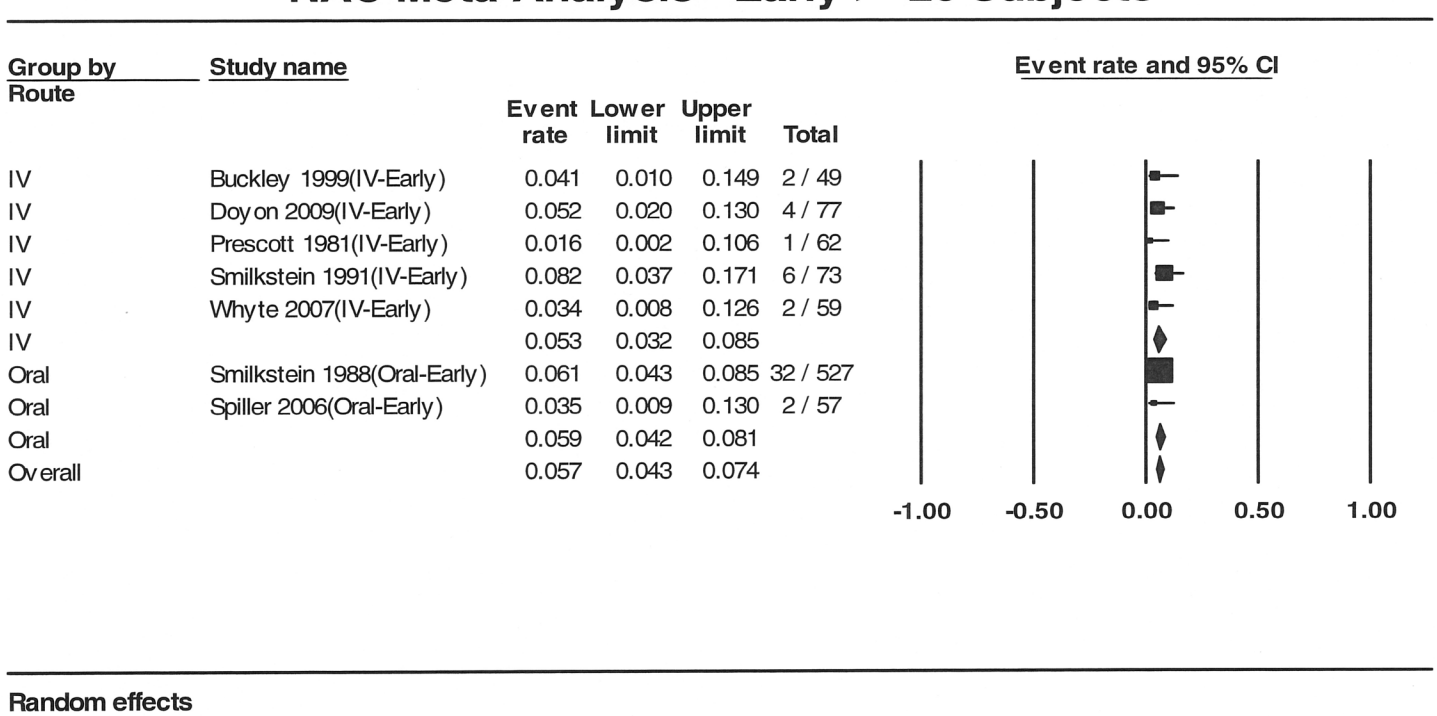

Figure 3. Forest plot showing proportion of patients with acetaminophen poisoning who developed hepatotoxicity for intravenous and oral acetylcysteine treatment when acetylcysteine was administered early (within 10 hours or as defined by author).

used a 10 hour cutoff and 3 used an 8 hour cutoff. Patients who received early acetylcysteine therapy had a percentage of hepatotoxicity of 5.7% (95% CI: 4.3% to 7.4%), compared to 26% (95% CI: 23.6% to 29.0%) in the late acetylcysteine group (Figures 3 and 4). When the analysis was stratified by route and time to acetylcysteine, the proportion of hepatotoxicity for IV-early and oral-early were similar: 5.3% (95% CI: 3.2% to 8.5%) and 5.9% (95% CI: 4.2% to 8.1%), respectively. The percentages for the 2 routes were also similar for patients treated late: 23.3% (95% CI: 11.7% to 41.1%) for IV treatment and 26.3% (95% CI: 23.6% to 29.0%) for oral treatment.

There was a marked difference in the percentage of patients who developed hepatotoxicity between early and late acetylcysteine administration. The regression analysis identified no significant route by time interaction (p=0.7516). However, there was a statistically significant effect due to time (p<0.001) and no significant effect due to route (p=0.7393). As a result of this analysis, it appears there is no difference in incidence of hepatotoxicity between acetylcysteine administered via IV or oral routes, but there is a difference between acetylcysteine administered early or late.

As we found a significant effect of time to treatment, the most relevant funnel plots to evaluate for publication bias must be stratified by route and time to treatment. This left only 2 studies in the oral group and 5 studies in the early/IV group, making formal analysis for publication bias impossible.

DISCUSSION

The percentage of patients who develop liver injury from acetaminophen poisoning is low for both oral and IV administration when acetylcysteine is administered early, generally defined as within 10 hours of ingestion. There is a marked increase in the percentage of subjects who develop hepatotoxicity when treatment is started more than 10 hours post ingestion, but the percentages for the oral and IV routes are similar in patients with delayed treatment. As the magnitude of the differences remained small, we feel the published literature reports similar rates of hepatotoxicity for the 2 routes.

The findings of our study are consistent with the findings of the previous meta-analysis, which reported an overall rate of hepatotoxicity with IV NAC of 3% with a 95% confidence interval of 0 to 6%, when treatment was initiated within 10 hours. Their results are based on 3 studies included in this meta-analysis. Our results include 2 additional studies with slightly higher rates of hepatotoxicity.

Our findings are also consistent with several studies that could not be included in the meta-analysis. Kerr performed a randomized controlled trial reporting 2 infusion rates of acetylcysteine. They noted no cases (0/58) of hepatotoxicity when acetylcysteine was infused within 8 hours and a hepatotoxicity rate of 9.8% (11/112) when treatment was delayed more than 8 hours after ingestion. Unfortunately, the study did not report how patients were risk stratified, so

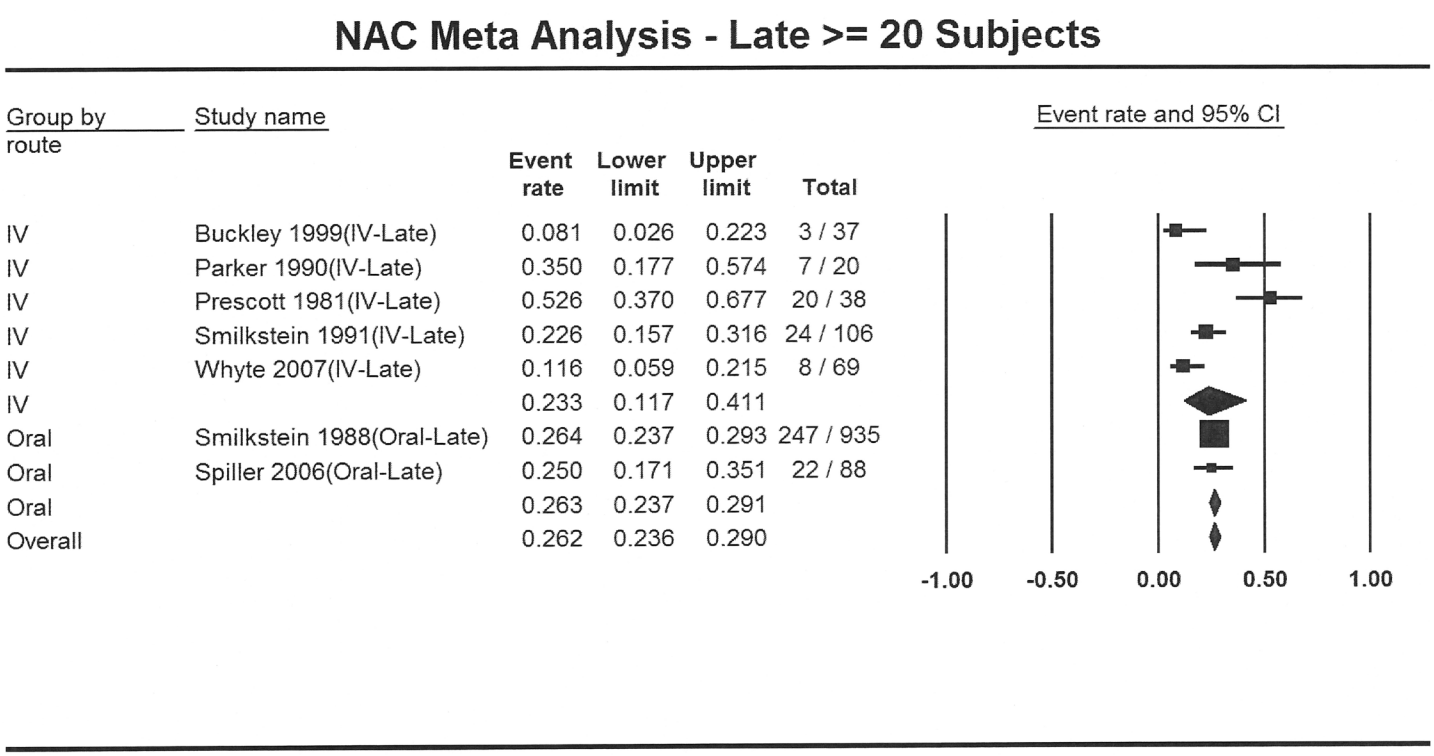

Figure 4. Forest plot showing proportion of patients with acetaminophen poisoning who developed hepatotoxicity for intravenous and oral acetylcysteine treatment when acetylcysteine was administered late (more than 10 hours or as defined by author).

we were not able to include this study in our meta-analysis.[26] Yarema et al[7] reported a lower risk of hepatotoxicity for the IV route when treatment was initiated within 12 hours of ingestion, and the relative risk of hepatotoxicity for patients treated with IV at 10 hours (the cutoff used in our study) was approximately 0.7 compared to oral NAC. While we found that the point estimate of the percentage of patients who develop hepatotoxicity was lower for the patients treated early with IV NAC, the absolute difference was very small (less than 1%) and there was substantial overlap of the 95% confidence intervals for the estimates for each route. Unfortunately, Yarema et al[7] evaluated time as a continuous rather than dichotomous variable, so we could not directly compare their findings to ours and were unable to include their full IV data in our comparison of time-stratified groups (a subset of the IV data was reported in another manuscript was included in our analysis).[22] Furthermore, in the study by Yarema et al[22] overall rate of hepatotoxicity (13.9%) was similar to our estimate (13.5%), suggesting that the populations were similar.

The efficacy of oral NAC using clinical (rather than time-based) endpoints has been described in several studies. Tsai et al[16] described no cases of hepatotoxicity among 17 patients treated with oral NAC (140 mg/kg followed by 70 mg/kg every 4 hours for a minimum of 20 hours) and stopped once the acetaminophen was undetectable and the transaminases were normal. Using a similar protocol, Betten et al[27-28] described no deaths and no cases of acute liver injury among 2137 patients. While the Betten et al[27] studies could not be included in the meta-analysis because the laboratory testing was not reported in a manner to determine the presence or absence of hepatotoxicity (our primary outcome), the lack of clinical liver disease suggests that serious outcomes are unlikely if these endpoints are used. Many toxicologists now use some variation of this approach.

While we did not evaluate safety, a recently reported study compared the rates and frequency of adverse events for IV and oral administration of acetylcysteine.[29] This study demonstrated that gastrointestinal effects (primarily nausea and vomiting) are common with both routes, but occur with a higher frequency with oral treatment, while anaphylactoid reactions were more common with IV administration. There were no acetylcysteine-related serious adverse events reported with either route. The authors concluded that the safety profile is acceptable for both routes. As our meta-analysis suggests that the efficacy of 21 hour IV and 72 hour oral acetylcysteine treatments are similar, we believe either route is acceptable depending on the patient's circumstances. Another consideration is cost. Two studies have reported that costs are similar or slightly favor the 21 hour IV protocol over the 72 hour oral protocol. While there are several methodological limitations to these studies, they suggest that there is not a major difference in cost between the IV and oral route. Clinicians should select a route based on individual patient

Table 2. Factors for clinicians to consider when selecting a route of administration for acetylcysteine during treatment of acetaminophen poisoning.

Patient characteristics	Comment
Liver failure	Only IV administration has been shown to be effective for treatment of liver failure.[35] The efficacy of oral administration has not been evaluated.
Vomiting	Vomiting may impede delivery of oral medications.
Altered mental status	Oral administration increases the risk of aspiration.
Hypotension/GI tract dysfunction	Oral medications (including acetylcysteine) may not be absorbed effectively.
Severely atopic, severe asthma or prior allergic reaction to IV acetylcysteine	Life-threatening anaphylactoid reactions have occurred in patients with history of atopy or asthma treated with IV acetylcysteine.[36]
Candidate for outpatient therapy	Oral administration may allow outpatient therapy in selected cases.[37]
Cost	The costs benefit of a particular route is not clear. Costs are lower when the 20 hour IV protocol is compared to the 72 hour oral protocol.[38-39] However, many clinicians use shortened oral treatment protocols which reduce costs.[29]

GI, gastrointestinal; *IV*, intravenous

and institutional characteristics. We have listed several factors that clinicians should consider when determining the route for a particular patient (Table 2).

LIMITATIONS

There are limitations to any meta-analysis. The first limitation is that the studies included in the meta-analysis may be subject to publication bias. We identified a large number of studies, and our results suggest that there is little heterogeneity among the studies. In fact, the search results from this study are similar to the results reported in the Cochrane Review. Also, we may have missed some publications, as our search terms did not include the trade names (Acetadote, Fluimucil, Lysox, Mucolysin, Mucomyst, Parvolex) in the search terms.

A second limitation to any meta-analysis is that patient-level data is unavailable. Without patient level data, we could not account for several potential confounders that may be associated with outcome from acetaminophen poisoning. These confounders include age, sex, amount ingested, acute ethanol intoxication, chronic ethanol abuse, pre-existing liver disease, as well as the use of gastric decontamination and co-ingestions. It is also possible that there is residual confounding due to time from ingestion to treatment.

While our objective was to determine the rates of hepatotoxicity for the 2 routes, the optimal meta-analysis would compare oral and IV administration. However, we found no reports of trials with a direct comparison. An alternative to a head to head comparison would be to compare outcomes where each therapy was compared to placebo. However, there have been no placebo controlled trials of acetylcysteine, so this analysis was also impossible. Our analysis determined the overall rates reported for each route, but we did not perform a formal comparison of the rates.

Another limitation is that our analysis was focused only on route and did not account for dose. The large number of studies using different durations makes disentangling the effect of dose and duration from route in a meta-analysis very difficult. While we could have stratified by planned duration (i.e. 72 hour oral, 20 hour oral, 48 hour IV, 21 hour IV etc.), it is clear that even studies using "fixed" time points actually had variation in treatment duration. For example, patients treated with the "21 hour" IV protocol who develop hepatic injury will receive therapy beyond 21 hours and many of the studies evaluating oral administration used variable dosing duration rather than a fixed time.[7,30-32]

When the acetylcysteine treatment protocols are followed as approved, the oral treatment protocol provides approximately 5 times the amount of acetylcysteine as the IV treatment protocol over a 72 hour period. However, due to first pass effects, only a small percentage of the oral product is systemically bioavailable and systemic concentrations are likely substantially higher in the first 21 hours with IV dosing.[33] The relative importance of hepatic and systemic concentrations is not known. As we observed very similar proportions of patients who developed hepatotoxicity for the oral and IV routes, we conclude that the effectiveness of published IV and oral protocols are similar.

A final limitation is that several of the identified studies did not report time to acetylcysteine in a way that allowed us to apply our early-late stratification scheme; therefore, several studies could not be included in the time-stratified analysis. This change in the data set produced point estimates of hepatotoxicity that were higher for IV administration (13.2% vs. 12.6%) in the overall analysis, but higher for oral administration in both early (5.9 vs. 5.3%) and late subgroups (26.3% vs. 23.3%). As the magnitude of the differences remained small, we feel our overall conclusions that the 2 routes have similar efficacy remain valid.

CONCLUSIONS

Studies report similar rates of hepatotoxicity for IV and oral acetylcysteine, but direct comparisons are lacking. Delays in treatment are associated with a dramatic increase in the rate of hepatotoxicity for both routes. While it is difficult to disentangle the effects of dose and duration from route, our findings suggest that the rates of hepatotoxicity are similar for oral and IV administration.

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Conflicts of Interest: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. This study was supported by Cumberland Pharmaceuticals (a manufacturer of IV acetylcysteine). All authors are employees of Denver Health. Denver Health has clinical, consulting and research contracts with Cumberland Pharmaceuticals (a manufacturer of IV acetylcysteine), Cadence Pharmaceuticals (a manufacturer of acetaminophen products) and McNeil Consumer Healthcare (a manufacturer of acetaminophen products). The investigators received only their salaries for work performed on this project. The sponsors had no role in the study design, performance, analysis or authorship of the article. The sponsor reviewed the final manuscript, but the authors are responsible for the final content. KH was also supported by Award Number K08DA020573 from the National Institute on Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Drug Abuse or the National Institutes of Health.

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Financial Implications for Physicians Accepting Higher Level of Care Transfers

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Introduction: Higher-level-of-care (HLOC) transfers to tertiary care hospitals are common. While this has been shown profitable for hospitals, the impact on physicians has not been described. Community medical center call panels continue to erode, in part due to the perception that patients needing transfer are underinsured. Surveys show that the problematic specialties to maintain call panels in community hospitals are neurosurgery, otolaryngology, plastic surgery, orthopedics and ophthalmology. This places greater stress on tertiary care hospitals' physicians. The objective of this study is to describe the financial consequences to physicians who care for HLOC transfers across specialties and compare these with all patients from each specialty and specialty-specific national reimbursement benchmarks.

Methods: Financial data were obtained for all HLOC transfers to a single tertiary care center from January 2007 through March 2008. Work relative value unit (RVU) and reimbursement were taken from a centralized professional fee billing office. National benchmarks for reimbursement per RVU were calculated from the 2006 Medical Group Management Association (MGMA) Compensation and Production Survey.

Results: In this period 570 patients were transferred, 319 (55.9%) through the emergency department (ED). Reimbursement per RVU varied from a high of $74.93 for neurosurgery to $25.91 for family medicine. Reimbursement to emergency medicine (EM) for HLOC patients was 16% above the average reimbursement per RVU for all ED patients ($50.5 vs. $43.7). Similarly, neurosurgery reimbursement per RVU was 22% above the reimbursement per RVU for all patients ($74.93 vs. $61.27). The remainder of specialties was reimbursed less ($25.91 vs $69.60) per RVU for HLOC patients than for all of their patients at this center. All specialties at this site were reimbursed less for each HLOC patient than national average reimbursement for all patients in each specialty.

Conclusion: Average professional fee reimbursement for HLOC patients was higher for EM and neurosurgery than for all other patients in these specialties at this site, but lower for the rest of the specialties. Compared to the national benchmarks, this site had an overall lower reimbursement per RVU for all specialties, reflecting a poorer patient mix. At this site HLOC transfers patients are financially advantageous for EM and neurosurgery. [West J Emerg Med. 2013;14(3):227–232.]

INTRODUCTION

The federal Emergency Medical Treatment and Active Labor Act (EMTALA) mandates that all patients presenting to an emergency department (ED) must have a medical screening evaluation, and that emergent conditions must be treated within the capacity of the ED and hospital, regardless of ability to pay. If a patient's emergency medical condition cannot be stabilized, often due to lack of specialist availability, then the patient may be transferred to another ED for higher level of care (HLOC). Conversely, hospitals with tertiary care capacity, often academic institutions, must accept these patients. Failure to comply with EMTALA carries civil fines and suspension from Medicare reimbursement.

Community hospitals have increasing problems maintaining specialist panels for their EDs.[1,2] The cause is multi-factorial, including erosion of the willingness of specialists to take ED call. This in turn is fueled by the perception that ED patients carry greater liability risk, and that specialists receive inadequate reimbursement from these patients or their often-underfunded insurance. The availability of on-call specialists to EDs has received attention from the media in recent years. The *New York Times* in 2004 stated "fewer and fewer doctors are willing to be on call to ERs given the high insurance premiums they must pay and, in many cases, the lack of reimbursement for treating the uninsured."[3] The Institute of Medicine in 2007 concluded that the lack of on-call specialist availability was "one of the most troubling trends" in emergency care.[4]

The American College of Emergency Physicians (ACEP) surveyed 442 national ED directors in 2008, and 74% reported on-call specialist coverage problems,[5] with the most problematic specialties of neurosurgery, plastic surgery, hand surgery, and orthopedics. A similar survey by the California chapter of ACEP found that 80% of ED physicians reported that on-call physicians were less willing to see underinsured or uninsured ED patients. Plastic surgery, head and neck surgery, neurosurgery, ophthalmology, and orthopedics, in that order, were the most problematic specialties for emergency physicians (EP) to obtain an admitting physician or secure follow-up care.[1]

A 2006 survey of 243 California ED directors found that rural EDs have the greatest problems obtaining specialty care.[6] They reported long delays for transfer to HLOC. Interestingly, specialist physician availability in community hospitals was not found to be associated with the payer mix of the ED patients.

HLOC transfers to tertiary hospitals are common. A previous study performed at the same academic health center as this paper, showed that transfers for HLOC resulted in a net financial gain to the hospital, although reimbursement varied dramatically by insurance type.[7] State (Medicaid) and county insurance reimbursements resulted in net losses to the hospital, comparable to the completely uninsured. Conversely, these losses were more than compensated for by reimbursement from private insurance carriers. For this same group of patients, the hospital realized a net profit of reimbursement over cost of $2,586,200.

The purpose of this study is to estimate the financial consequences to physicians who care for HLOC transfers. We specifically describe professional reimbursement, by specialty, and compare with all patients from each specialty during the same time period. Finally, we compare HLOC patients to specialty-specific national reimbursement benchmarks.

METHODS

The study used the same group of 570 HLOC patients to examine professional reimbursement as the previous study, which looked at hospital reimbursement.[7]

We identified all transferred patients (regardless of HLOC status) from 3 different sources. First, the county government Emergency Medical Services Agency maintains an Interfacility transfer (IFT) report with patients who were initially seen at a primary paramedic receiving center ED, but then sent immediately with the same ambulance to a designated specialty center (n=90 patients). Second, this hospital's transfer center maintains a log of phone requests for transfer into this tertiary care facility (n=457 patients). We verified that patients on the IFT list came to this tertiary ED via this hospital's electronic medical record and this log book. Finally, we queried the ED tracking board at this tertiary care hospital to identify referrals for HLOC that came directly to the EP, rather than the transfer center (n=185 patients). Duplicates were identified and removed from the list, resulting in 570 patients. Of these, 319 (55.9%) were transferred to this tertiary center through the ED, while 251 (44.0%) came to the tertiary center as direct admits from another inpatient setting.

Research assistants identified patients for the study who came to the tertiary center from another ED or inpatient setting via ambulance over a 14-month period (1/1/2007 to 3/31/2008). Since patients are never transferred to our tertiary center for elective reasons (physician preference, managed care or other insurance reasons, or for lateral levels of care), we are confident that all patients transferred were for HLOC. The time period examined was chosen such that all 570 patients' billing and reimbursement activities were complete, with accurate information regarding charges and reimbursement. Through these mechanisms, we are confident that we captured all HLOC transfer to the institution during this time period.

Each specialty department's centralized professional fee billing office used the list of patients, dates of birth, date of arrival and medical record numbers to provide admission service, length of stay, principle diagnosis, procedures performed, primary payer (insurance profile), charges, relative value unit (RVU) and reimbursement data. Data were entered and analyzed with purely descriptive statistics with Excel (version 12.3.0, Microsoft, Redmond, WA). We determined total patients, RVUs and charges and reimbursement by specialty. We calculated charges, reimbursement, and RVUs per patient. In order to compare to national benchmarks, we calculated reimbursement per RVU and average percent of Resource-Based Relative Value Scale (RBRVS) for all patients within each specialty.

Table 1. Reimbursements, charges, and number of patients, RVUs, average RVUs per patient, % RBRVS, and reimbursement per RVU by specialty for HLOC transfer patients across 12 specialties, organized from highest to lowest by reimbursement per RVU.

Specialty	Number of patients	Total charges in dollars	Charges per patient in dollars	Total reimbursement in dollars	Reimbursement per patient in dollars	Total RVUs	Average RVUs per patient	%RBRVS	Reimbursement per RVU in dollars
Neurosurgery	87	323,927	3,723	117,082	1,345	1563	17.96	196.73	74.93
Obstetrics/ Gynecology	13	85,530	6,579	25,540	1,964	367	28.23	182.74	69.60
Head and neck surgery	32	143,271	4,477	37,884	1,183	627	19.61	158.74	60.38
Orthopedics	39	80,433	2,062	23,213	595	402	10.30	151.77	57.81
Ophthalmology	41	167,498	4,085	45,785	1,116	833	20.33	144.23	54.93
Neurology	81	103,117	1,273	30,466	376	571	7.05	140.09	53.36
Emergency medicine	319	422,558	1,324	104,668	328	2071	6.49	132.70	50.54
Plastic surgery	9	92,065	10,229	8,890	988	181	20.07	129.23	49.22
Surgery with trauma	294	1,592,232	5,415	336,306	1,144	7157	24.34	123.38	46.99
Internal medicine	238	604,733	2,540	148,764	625	3576	15.03	109.21	41.60
Pediatrics	121	344,278	2,845	69,314	573	1672	13.82	108.84	41.45
Family medicine	6	3,126	521	530	89	20	3.42	68.03	25.91
Total	570 patients with 1280 pro fee bills	3,962,768	6952	948,450	1,663	19,040	33.40	n/a	49.81

HLOC, higher level of care*; RVUs*, relative value units; *RBRVS*, resource-base relative value scale

National benchmarks for reimbursement per RVU were calculated from the 2006 Medical Group Management Association (MGMA) Compensation and Production Survey.[8] Since an RVU in 2007 was reimbursed according to RBRVS at $38.0870, if the account were paid this, we considered that reimbursement to be 100% of RBRVS. Therefore, we calculated percent of RBRVS by specialty by dividing the reimbursement per RVU by $38.0870.[9]

If reimbursement per RVU for HLOC transfers were found to be low compared to national benchmark, this could be explained by genuine poor reimbursement for HLOC transfers, or by global or specialty-specific low reimbursement specific to our institution alone. To determine which of these was the case, we compared each specialty's payer mix from this study site (reimbursement per RVU) with national benchmarks. The study was approved by the local Institutional Review Board.

RESULTS

We present our reimbursement data comparisons for HLOC patients in 4 ways.

1. Reimbursement per RVU for each group of HLOC patients by specialty (n=12) (Table 1, Figure 2).
2. Percent RBRVS reimbursement for HLOC patients by specialty (n=12) (Figure 3).
3. Reimbursement per RVU for HLOC patients compared to all of this tertiary center's patients by specialty (n=8) (Figure 4).
4. Reimbursement per RVU for HLOC patients by specialty (n=12) compared to national benchmarks and all of each specialty's patients at this study site (Figure 5).

Finally, to isolate the potential effect of HLOC status alone vs. overall payer mix of our tertiary care center, we present reimbursement per RVU for this study site (not only HLOC patients) vs. national benchmarks (Figure 6).

In this period 576 patients were transferred, or 1.6 per day. The number of patients per specialty ranged from a low of 6 for family medicine to a high of 319 for emergency medicine (EM) (Figure 1). The remaining 251 patients were transferred directly to an inpatient unit, and so did not trigger any ED charges. Total RVUs for all patients at the receiving center were 19,040, or 33.40 RVU per patient. RVU per patient varied from a low of 3.42 for family medicine to a high of 28.23 for obstetrics/

Table 2. Reimbursement per RVU for all HLOC study site patients by specialty. National benchmarks of reimbursement per RVU from the 2006 MGMA Survey. Specialities are organized from highest to lowest according to reimbursement per RVU as in Table 1.

	Reimbursement per RVU	
Specialty	All study site patients n=570 ($)	National benchmarks ($)
Neurosurgery	61.27	97.66
Obstetrics/Gynecology	n/a	88.42
Head and neck surgery	n/a	106.55
Orthopedics	n/a	103.21
Ophthalmology	61.07	90.68
Neurology	61.96	81.53
Emergency medicine	43.69	54.78
Plastic surgery	n/a	107.29
Surgery with trauma	51.50	60.39
Internal medicine	46.08	56.11
Pediatrics	42.74	54.06
Family medicine	32.95	83.74

HLOC, higher level of care*; RVU*, relative value unit; *MGMA,* Medical Group Management Association

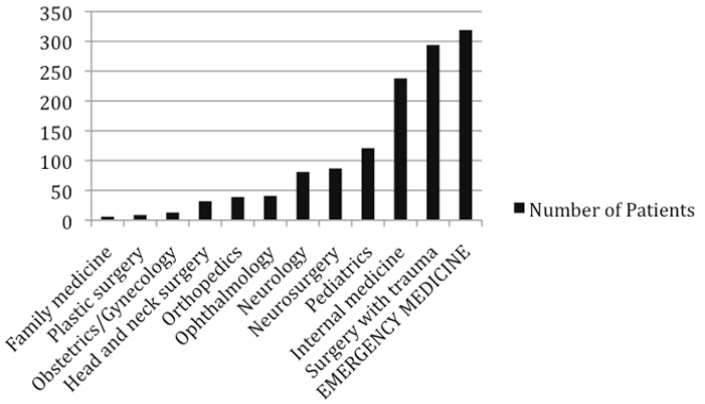

Figure 1. Number of higher level of care (HLOC) transfer patients per specialty for 12 specialties at one tertiary care site over 14 months. N=570 total patients billed 1280 times by specialty services.

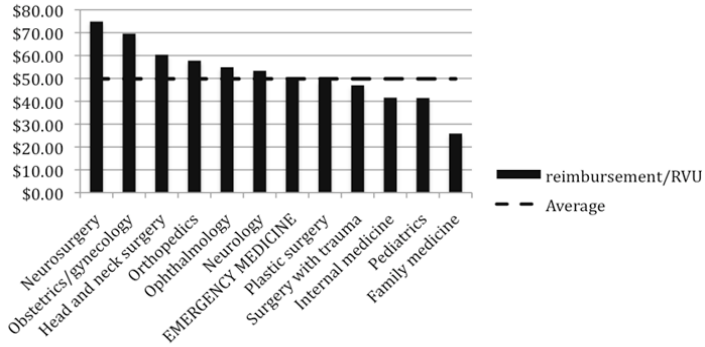

Figure 2. Reimbursement per relative value unit (RVU) for higher level of care (HLOC) transfer patients for 12 specialties. Average reimbursement per RVU for all specialites = $49.81.

gynecology (Table 1) (e.g. normal spontaneous vaginal delivery= 26.80 work RVU). EM had 6.49 RVU per patient (e.g. evaluation and management code level 5= 3.80 RVU).[10]

Total reimbursement from all payers (government, private and self-pay) was $948,450 (Table 1). Reimbursement per RVU varied from a high of $74.93 for neurosurgery to $25.91 for family medicine (Table 1, Figure 2). The average reimbursement per RVU for all HLOC transfer patients was $49.81. Five of the 6 specialties shown by hospital surveys to have the most trouble maintaining call panels (neurosurgery, head and neck surgery, orthopedics, ophthalmology, and plastic surgery) had higher-than-average reimbursement per RVU compared to other specialties. The sixth, plastic surgery, had lower-than-average reimbursement per RVU.[1,2]

We also compared specialties using the 2007 RBRVS as determined by Centers for Medicare and Medicaid Services (CMS). The percent RBRVS ranged from a high of 197% for neurosurgery to 68% for family medicine. Percent RBRVS for EM was 132.7% (Table 1, Figure 3).

Not all specialties at this tertiary center had billing data available for reimbursements per RVU for all of that specialty's patients during the same time period. Head and neck surgery, obstetrics, orthopedics, and plastic surgery were unavailable from the billing group.

Looking more closely at the individual specialties, EM had $50.54 reimbursement per RVU for their HLOC transfer patients (Table 1, Figure 2). Reimbursement to EM for transferred patients was 16% above the average reimbursement per RVU for all ED patients for the period (Figure 4). Compared to national data from the 2006 MGMA survey, reimbursement to EM for transferred patients was 8% below the national EM average (Figure 5).

For the most problematic specialties, neurosurgery transferred-patient reimbursement per RVU was 24 % above the average patient reimbursement per RVU for all neurosurgery patients at this center ($75.93 vs. $61.27 per RVU) for the period (Table 1 and 2, Figure 4). However, compared to national data, reimbursement per RVU at this center was 22% lower ($97.66 nationally) (Figure 5).

The remainder of specialties were reimbursed less per RVU for HLOC patients than for all of their patients at this center (Figure 4). The largest loss was seen in family medicine patients. For surgery with trauma (the second highest volume specialty for HLOC transfers after EM), reimbursement per RVU was 8.9% less than for all Level I Trauma Center patients combined (Table 1 and 2, Figure 4).

Compared to the national average, this study site had an overall lower reimbursement per RVU for all specialties. This demonstrates that this study site likely has a lower payer mix than national average, leading to lower reimbursements per RVU (Figure 5).

Figure 6 is a graphical representation of this tertiary center's

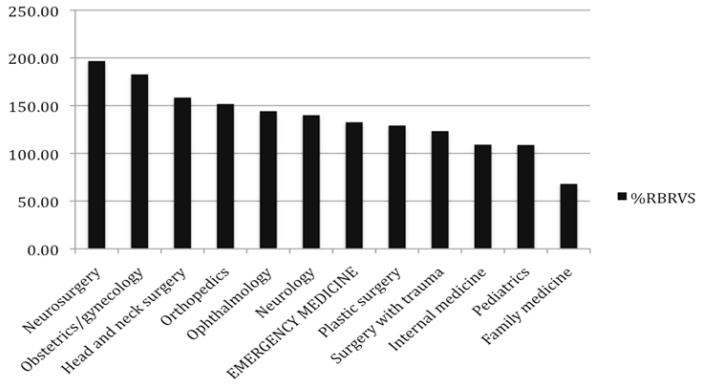

Figure 3. Percent resource based relative value scale (%RBRVS) by specialty (n=12) for higher level of care (HLOC) transfer patients (N=570).

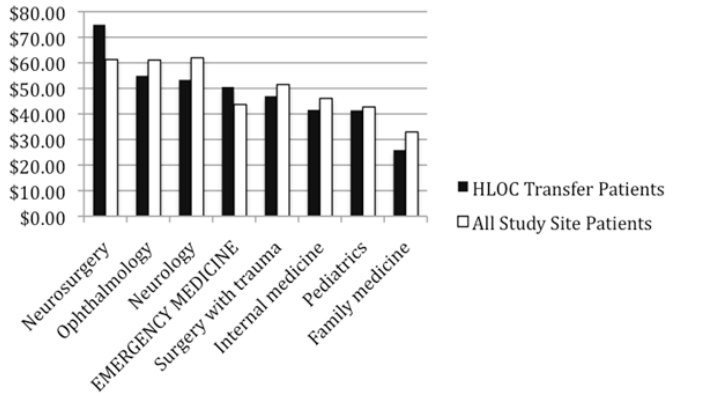

Figure 4: Reimbursement per relative value unit (RVU) for higher level of care (HLOC) transfer patients vs. all study site patients by specialty (n=8 specialties). All patient data not available at study site for 4 specialties: obstetrics and gynecology, head and neck surgery, orthopedics and plastic surgery.

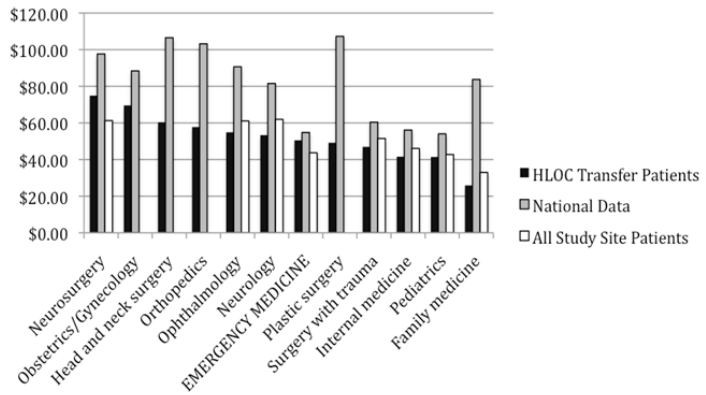

Figure 5. Reimbursement per relative value unit (RVU) for higher level of care (HLOC) transfer patients vs. national benchmarks vs. study site patients.

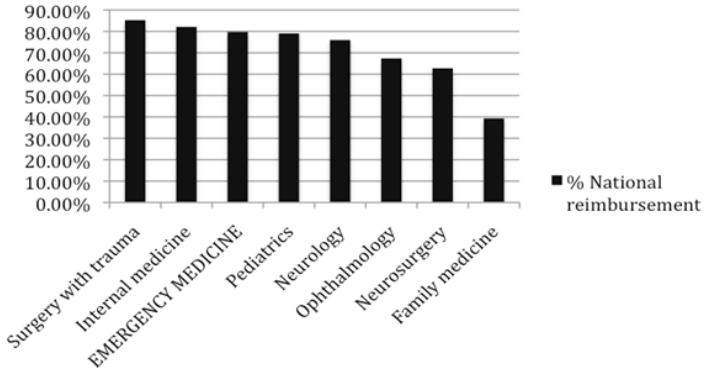

Figure 6. Reimbursement per relative value unit (RVU) for all study site patients by specialty, as a percentage of national reimbursement per RVU from Medical Group Management Association (MGMA) data for 8 specialties. All patient data not available at study site for 4 specialties: obstetrics and gynecology, head and neck surgery, orthopedics and plastic surgery.

overall reimbursement by specialty (not just HLOC patients) vs. the national benchmark. This illustrates the degree to which average reimbursement at our center lags behind national norms.

DISCUSSION

According to a recent national survey, maintaining on-call specialist panels has become an increasing problem nationwide, with 74% of ED directors reporting problems.[5] Between 2000 and 2006, surveys of California EPs indicate increasing problems obtaining timely specialist care for 9 of 20 specialties (mostly surgical), and that the number of specialty call panels for community hospitals is, on average, declining. Community practitioners who care for underserved populations reported the most problems.[1,2]

Although we obtained billing data for 12 specialties, including internal medicine, pediatrics and family medicine, the HLOC service required of the transfer was most often a surgical subspecialty. Furthermore, the 41 ophthalmology patients in our system were admitted to internal medicine or pediatrics. Consequently, the most common services required for HLOC transfers were surgery with trauma (including burns) at 52% (294/570), neurosurgery 15% (87/570) and neurology 14% (81/570). This in turn reflects our tertiary center's status as an American College of Surgeons Level I Trauma Center, and The Joint Commission-certified Primary Stroke Center. The next most common groups of patients were ophthalmology, orthopedics and head and neck surgery (at 6-8% each).

At our tertiary care center, specialties that hospital surveys indicate have the most trouble maintaining call panels (neurosurgery, otolaryngology, orthopedics, and ophthalmology), paradoxically had higher-than-average reimbursement per RVU compared to other specialty's higher level of care patients. Plastic surgery had lower-than-average reimbursements per RVU, but this is likely inconclusive with only nine HLOC patients (Figure 2, Table 1).

For specialties with complete reimbursement data (n=8), average professional fee reimbursement for HLOC patients was higher than all-patient reimbursement rates only for EM and neurosurgery. Of the other problematic surgical subspecialties (head and neck surgery, orthopedics and ophthalmology),

HLOC transfer reimbursement was lower for ophthalmology, but unavailable for the other 2. This implies that neurosurgery and EM may benefit from accepting HLOC patients, but not ophthalmology. At our center 319/570 (56%) patients arrived through the ED, and though they may contribute to crowding and flow problems, these patients appear to reimburse better than the average ED patient (Figure 4, Table 1 and 2).

For HLOC transfer patients, all specialties studied at this center (n=12) had lower reimbursement per RVU than national benchmarks [$49.81 vs. $65.62 (weighted average of national RVU/patient reimbursements proportional to the number of HLOC transfers by specialty in this data set)]. Therefore, our site had substantially lower reimbursements compared to the national data, likely a reflection of our challenging payer mix as an academic institution. Previous studies have found that receiving hospitals have a poorer payer mix than transferring hospitals, which in turn shifts the burden for care of these patients from the private to public/academic sector.[6]

While the hospital realized $2,586,200 in profit from these 570 patients, the total professional fee reimbursement was $948,450, or $1,663 per patient.[7] We have no way of calculating professional costs to care for these patients, so cannot comment on physician "profit," but reimbursement per RVU was $49.81, or 131% of RBRVS. Some specialties may consider this attractive, while others not. From an ED perspective, HLOC transfers generate 133% of RBRVS compared with 115% for all other patients, and are therefore economically advantageous at this site. Couple this with the obvious patient need for special expertise in the tertiary center, as well as provision of patient material to support training and procedural needs, and these HLOC transfers should be viewed as desirable.

LIMITATIONS

We acknowledge several limitations and recommend further study. Billing data were unavailable at our center for some of the specialties we were most interested in, including orthopedics, head and neck surgery, and plastic surgery. These are specialties often cited by EPs as the most problematic for obtaining consultation, admission, or follow-up care.

Also, the number of HLOC patients for some specialties was low, and comparison to national data and to all of our tertiary care patients for that specialty is inexact (eg. plastic surgery and family medicine).

We used 2006 MGMA national benchmark data for 2007-2008 patients, as this was the latest available at the time of data analysis.

We believe this is a consecutive patient sample, but acknowledge that some transfers may have occurred that were not discovered in our screening process. Conversely, some revenue could have been lost due to inaccurate billing practices in our centralized university billing center.

Finally our data would not be generalizable to other tertiary care centers with varied HLOC transfer patient proportions by specialty, differing payer mixes, billing efficiencies, and direct admission practices.

CONCLUSION

Higher-level-of-care transfers (HLOC) to one tertiary center were found to be economically disadvantageous overall, but reimbursement varied widely among specialties. Neurosurgery and EM were reimbursed better for HLOC transfers than for all of the other patients in these specialties at this site, but HLOC transfer-patient reimbursement was worse than national benchmarks for all services. This reflects a poorer patient mix at this site than nationally. Whether the teaching and procedural value of these patients compensate for financial liability is a matter of institutional purpose and professional priority.

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Conflicts of Interest: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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Pneumothorax in Liberia: Complications of Tuberculosis

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Tuberculosis (TB) is a known cause of secondary pneumothorax. In areas with endemic TB, complications from the disease, including pneumothorax, are increasing in prevalence. We present the cases of 3 patients (ages 32 years, 17 years, and 3 months) seen in the emergency department at John F. Kennedy Medical Center in Monrovia, Liberia, West Africa. Each presented with shortness of breath and cough, and with some degree of respiratory distress. Airway compromise was present with tracheal or mediastinal deviation. Each patient underwent tube thoracostomy with improvement in pneumothorax and respiratory status. [West J Emerg Med. 2013;14(3):233–235.]

INTRODUCTION

Tuberculosis (TB) is a long-recognized and well-documented cause of secondary spontaneous pneumothorax,[1,2] with an incidence of approximately 5% in postprimary (pulmonary) TB patients.[3] Pleural infection results from rupture of subpleural caseous lesions, resulting in accumulation of a chronic empyema. A bronchopleural fisutla may occur spontaneously during the natural history of the disease, though it is more frequently caused by trauma or attempted surgical intervention. Both chronic empyema and bronchopleural fistula may result in spontaneous (and subsequent tension) pneumothorax, the latter with a more acute presentation. Tube thoracostomy is the indicated treatment, in conjunction with appropriate pharmacologic management of TB and other infections.[3–5]

CASE 1

A 32-year-old male, with known human immunodeficiency virus (HIV), presented to the emergency department (ED) with progressively worsening difficulty in breathing. Chest radiograph showed pneumothorax and air-fluid level on the left side. Tube thoracostomy was performed, with improvement in symptoms and pneumothorax (Figure 1).

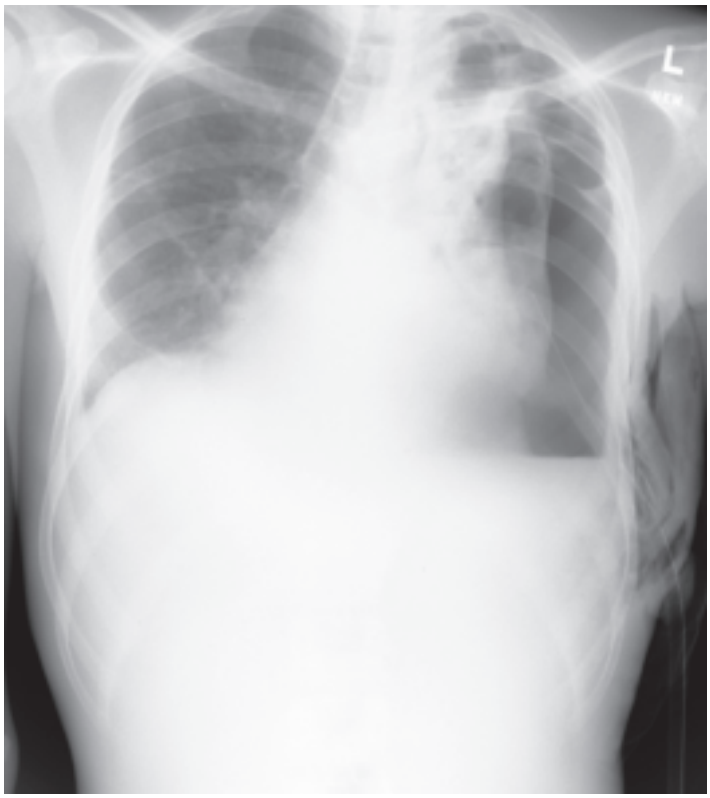


Figure 1. Chest radiograph after tube thoracostomy of a 32-year-old male with shortness of breath, with improvement in respiratory status and lung expansion with persistent left-sided air-fluid level and pneumothorax. (All patient images taken with permission of patient or accompanying guardian.)

CASE 2

A 17-year-old male presented to the ED, via referral from an affiliate health center, with fever, cough, dyspnea, and tachypnea. Initial evaluation of the patient showed a young man

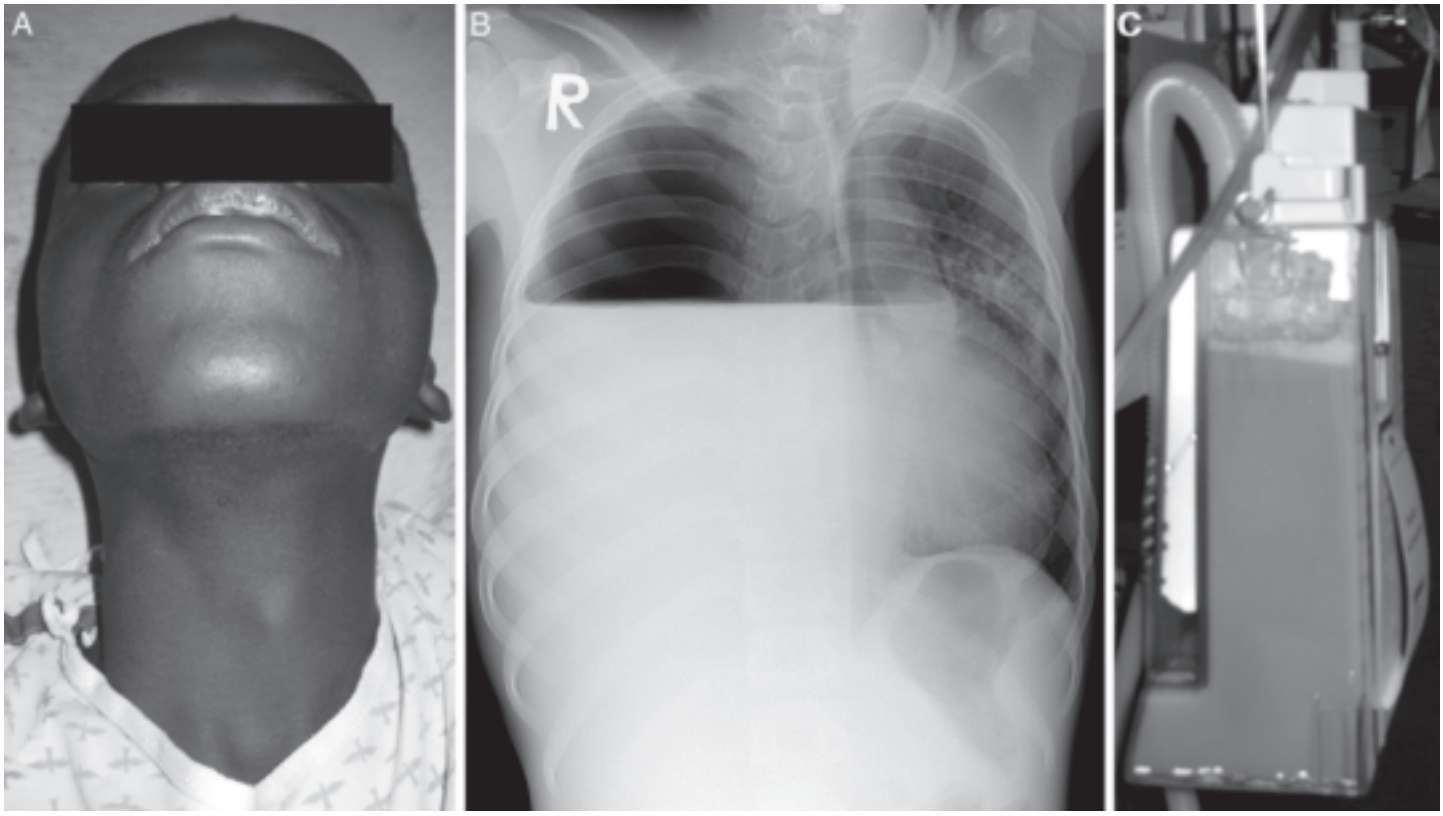
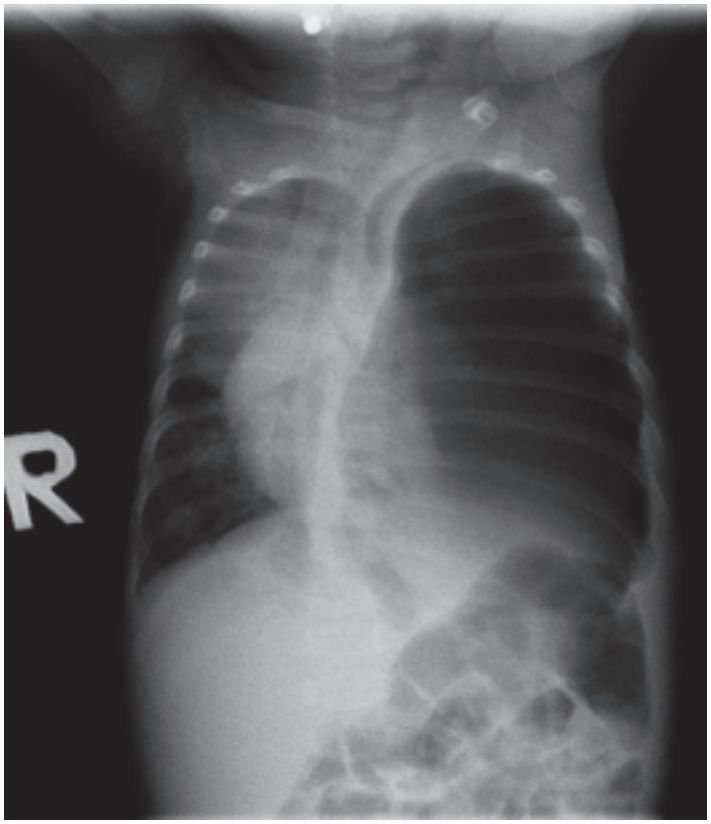


Figure 2. A, A 17-year-old male referred from the tuberculosis (TB) clinic for shortness of breath with evidence of tracheal deviation on examination of neck. B, Chest radiograph of 17-year-old male referred from TB clinic for shortness of breath reveals right-sided air-fluid level with pneumothorax and mediastinal shift. C, Purulent drainage from tube thoracostomy of patient with presumed TB effusion and pneumothorax. (All patient images taken with permission of patient or accompanying guardian.)



in respiratory distress with tracheal deviation (Figure 2A). Chest radiograph (digital) confirmed tension pneumothorax with air-fluid level on the right side (Figure 2B). Tube thoracostomy was performed with copious purulent output under pressure (Figure 2C).

CASE 3

A 3-month-old female, brought in to the ED by her mother, had acute onset shortness of breath and respiratory distress after several weeks of cough and fever. Chest radiograph (digital, 2 views) revealed tension pneumothorax with mediastinal deviation (Figure 3). Tube thoracostomy was performed under intramuscular ketamine sedation, with purulent drainage and subsequent improvement in pneumothorax.

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Figure 3. Chest radiograph of 3-month-old infant with shortness of breath reveals presumed tuberculosis-related pneumothorax and resultant mediastinal shift. (All patient images taken with permission of patient or accompanying guardian.)

DISCUSSION

These patients were suffering from spontaneous tension pneumothorax with empyema secondary to presumed pulmonary TB. The patient in case 2 was sent from the TB treatment facility. All 3 patients improved after tube thoracostomy and drainage (via suction when available or gravity when not available) of the empyema. No acid-fast stain or culture test was available at John F. Kennedy Medical Center to confirm TB, although given the comorbidities and exposure, this was the presumed diagnosis.

Other causes of secondary spontaneous pneumothorax include chronic obstructive pulmonary disease with emphysema, cystic fibrosis, lung cancer, other infection (including coccidioidomycosis, aspergillosis, histoplasmosis) and, in HIV-related disease, pulmonary *Pneumocystis jiroveci*.[6]

In Liberia, West Africa, with a population of approximately 3.8 million, TB has an estimated prevalence of 420/100,000,[7] indicating a total population of approximately 16,000 active TB patients. TB incidence is growing at 2% annually in the general population. However, in the HIV population, the incidence of TB is growing at a much steeper 6.9%.[8] TB and HIV are independently associated with spontaneous pneumothorax; however, in HIV patients with TB, the rate of pneumothorax increases dramatically.[9] Thus, in Liberia, as in countries where TB is prevalent and HIV is growing, spontaneous pneumothorax will become an increasingly common pathologic condition and a cause of respiratory distress.

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Computer Simulation as a Tool for Assessing Decision-Making in Pandemic Influenza Response Training

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Introduction: We sought to develop and test a computer-based, interactive simulation of a hypothetical pandemic influenza outbreak. Fidelity was enhanced with integrated video and branching decision trees, built upon the 2007 federal planning assumptions. We conducted a before-and-after study of the simulation effectiveness to assess the simulations' ability to assess participants' beliefs regarding their own hospitals' mass casualty incident preparedness.

Methods: Development: Using a Delphi process, we finalized a simulation that serves up a minimum of over 50 key decisions to 6 role-players on networked laptops in a conference area. The simulation played out an 8-week scenario, beginning with pre-incident decisions. Testing: Role-players and trainees (N=155) were facilitated to make decisions during the pandemic. Because decision responses vary, the simulation plays out differently, and a casualty counter quantifies hypothetical losses. The facilitator reviews and critiques key factors for casualty control, including effective communications, working with external organizations, development of internal policies and procedures, maintaining supplies and services, technical infrastructure support, public relations and training. Pre- and post-survey data were compared on trainees.

Results: Post-simulation trainees indicated a greater likelihood of needing to improve their organization in terms of communications, mass casualty incident planning, public information and training. Participants also recognized which key factors required immediate attention at their own home facilities.

Conclusion: The use of a computer-simulation was effective in providing a facilitated environment for determining the perception of preparedness, evaluating general preparedness concepts and introduced participants to critical decisions involved in handling a regional pandemic influenza surge. [West J Emerg Med. 2013;14(3):236–242.]

INTRODUCTION

The probability of a highly pathogenic influenza pandemic has been a topic of interest among healthcare providers, the public, and health policy personnel at regional, state, national and international levels. Since the first influenza pandemic was described in 1580, over 30 recognized influenza pandemics have occurred. Three, occurring in the last century, varied in lethality from 1 million deaths worldwide in 1968 to 50 million deaths worldwide in 1918.[1] The Influenza A virus (H5N1), or Avian influenza, and H1N1, or Swine Flu, have been of more recent concern. First identified in Hong Kong in 1997, the outbreak of the H5N1 flu strain ultimately resulted in 18 infections and 6 deaths.[2] Since its original mutation, the H5N1 avian flu virus has spread to over 15 countries, infecting 552 people and killing 322 as of April 2011, a mortality rate of approximately 58%.[3] If the H5N1 strain had mutated and developed the ability to transfer via human contact, the world could have been on the brink of a pandemic.[4] More currently, the H1N1 virus was declared a pandemic in 2009

with an estimated amount of infected persons between 43 to 89 million, through April, 2010.[5]

The civilian population depends on the preparedness and response of the medical community for significant illness management and crisis mitigation, yet preparing for, and handling any pandemic influenza outbreak is a difficult task. Methods to enhance preparedness may include educational sessions, as well as table-top and large-scale exercises. Current literature has shown that computer-based high-fidelity simulations may be effective as training tools.[6] A computer-based simulation of an influenza outbreak provides a repeatable approach to stimulate integrated decision-making, and discuss thought processes.[7] Reports demonstrate that their use may be an authentic, low-risk learning environment that teaches teamwork competencies and promotes insightful and systematic practice.[8] Higher-fidelity simulations (i.e. those that produce a realistic experience for trainees through use of multimedia inputs) have also been shown to receive more positive feedback from participants than lower-fidelity simulations (e.g. slower paced, pre-determined table-top and paper-based exercises), suggesting that they are a more effective method of training and education, stemming from their authentic nature and real time decision-making components.[9] By definition, high-fidelity simulation more closely resembles the actual event it is representing, such as using realistic materials, equipment, story boards, sounds, and visual aids. Since high-fidelity models represent scenarios in a more realistic fashion, in theory, they are more likely to produce results similar to real life.

We report briefly on the development and initial testing of this computer-based simulation for a putative pandemic influenza outbreak. We used a Delphi-method for initial development and prioritization of learning principles. We then tested the simulation on regional hospital participant volunteers, in order to quantify the before-and-after simulation knowledge about 7 key areas.

METHODS

Development

We used a Delphi-method, or structured communication technique with content and regional experts and using the federal assumptions of the 2007 National Incident Management System (NIMS) for a pandemic outbreak, to derive key categories and decisions to build into the computer programming. Three to six rounds of subject and key role-player expert scenarios were performed with subject matter experts (SMEs) until the computer program was finalized and placed into a run-mode. The final simulation intended to produce documentable and reproducible actions that could be performed during these trainings. These were not intended to teach definitive care should an actual outbreak occur. These practice decisions were intended to broaden trainees' understanding of evolving crises, enhance insight into current preparedness gaps, and allow them to test their own strategies for response, prior to an incident. The main objective was to employ this simulation and assess participants' beliefs regarding their own hospitals' mass casualty incident preparedness, which was measured using pre- and post-event surveys.

Table 1. Description of simulation student participants by self-declared job category.

	Students
Hospital providers	146
Emergency medical technician	1
Government health department	2
Indicated "other" or undeclared	6
Total students	155

Participant Population

Employees of 7 hospitals within south central Pennsylvania, not part of the development team, were participants in testing this system. All participants were volunteers who were invited to attend the educational session. The study group totaled 155 personnel. The group was comprised of hospital-based personnel (Table 1). Participating hospitals ranged from a small community hospital of 125 beds to much larger medical facilities located in micro-metropolitan settings.

Simulation Workshop Session

The primary goal of this simulation testing experience was to introduce personnel to the critical decisions involved in handling a pandemic influenza surge with overwhelming patient volume and assess their opinion of current preparedness models at their home institution. Methods to improve decision making or how to impact home institution current models, was not part of this model of education. The session represented an introductory exercise intended to inform and raise awareness about organizational surge preparedness gaps. Desired outcomes were that attendees: (1) understand that mitigation is highly interdependent because effects of decisions cascade to affect other responders in the surge response; and (2) will stimulate potential ideas for creating and implementing policies and procedures for community mitigation strategies during an outbreak. All simulations took place in conference rooms within the hospitals where participants could sit at a desk in front of a simulation computer. In instances where there were more participants than leadership positions, participants were encouraged to work in small groups and make decisions together.

Training goals were identified, discussed, and deliberated throughout the session, and further emphasized in the post-simulation discussion. During this post-simulation discussion, the death toll, surge percentage, and the 7 critical success factors were discussed. Each participant was asked to

Table 2. Sample survey data collection tool used in the simulation workshop sessions.

Healthcare Facilities Partnership of South Central Pennsylvania PanFlu Simulation What type of organization do you work for? Circle one: EMA EMT Hospital Government Health Department Other (specify):_____			
Critical Success Factors	Importance	Preparedness	Recommendation
Working with external organizations. Clear policies and procedures for working with external organizations during a mass casualty incident / surge event (MCI/SE) with upwards of 500 or more casualties.			
Internal policies and procedures. Clear policies and procedures for how your organization will operate differently during an MCI/SE than it would during normal times.			
Maintaining supplies and services. Policies and procedures for maintaining adequate and dependable sources of supplies and outside services.			
Technical infrastructure. Dependable voice and data communications equipment that works 24/7 both within and across organizations during an MCI/SE.			
Staff support. Policies and procedures for supporting the physical and mental health of the staff, and providing means for them to meet the needs of their families. Ability to integrate volunteers and temporary personnel into the work flow and to make volunteers available elsewhere.			
Public relations. Policies and procedures for keeping the public informed and for advising them of critical procedures which need to be followed during an MCI.			
Training. Courses and facilities that provide training and practice on all of the critical success factors described above.			

EMA, emergency medicine agency; *EMT*, emergency medical technician

complete a pre- and post-simulation confidential questionnaire that examined their perspective regarding influenza- response importance and preparedness. A sample survey used in the simulation workshop sessions can be found in Table 2. This questionnaire also assessed the simulation influence on participant awareness of cascading-effects of decision making, and additionally gauged participants' beliefs surrounding the 7 success factors. The participant provided a self-assessed measure for each of the factors, ranging from low (1), to essential (5). A recommendation section similarly asked participants to rank how quickly they felt their organization should take steps to correct gaps identified during the simulation (within each key factor), ranked on a scale of 1 (deserves immediate attention) to 3 (does not need attention at this time). This study was approved by the local institutional review committee. We performed comparison of before and after simulation perceptions, using a student's t-test with $p<0.05$ considered significant.

RESULTS

We surveyed 155 hospital personnel both before and after the simulation training, and then compared and analyzed their responses. Of the 42 possible questions, evaluation data were only considered if at least 80% of the questions were completed per survey; this included 133 (86%) participants, and these subjects formed the sample population. Hospital personnel comprised the majority of the people surveyed, at 124 out of 133 (93%). A comparison of the pre-simulation and post-simulation preparedness data is presented in terms of perceived own facility preparedness (Table 3) and personal importance (Table 4) in 7 key categories/factors (external organization, operations, supplies, communication, mass casualty incident planning, public information, and training). While preparedness ratings were stable and not statistically different, there was a trend toward declined preparedness perception in 2 of the 7 key factor areas—supplies and communication, post training. Otherwise stated, after the simulation, they felt their facility is less prepared than originally thought (before the simulation). The authors interpreted this to mean that the articipants realize that they were less prepared to manage supplies and use voice and data communication systems after they had completed the simulation (Table 3). Similarly, pre-simulation and post-simulation total scores for the "importance" subsection (Table 4) revealed that there was a statistical increase in mean

Table 3. Pre- and post-course preparedness ratings for 7 key factors in pandemic influenza training,using a Likert scale, 1-5.

Factor	Pre-simulation Mean t (SD)	Post-simulation Mean t (SD)	Change score (post-pre) Mean t	Paired-t (p-value)
1. External Organization	3.34 (0.68)	3.36 (0.76)	0.02	0.304
2. Operations	3.48 (0.72)	3.35 (0.78)	-0.13	0.255
3. Supplies	3.31 (0.77)	3.22 (0.77)	-0.09	0.035
4. Communication	3.57 (0.81)	3.44 (0.81)	-0.13	0.035
5. Mass Casualty Incident Planning	3.05 (0.74)	3.02 (0.82)	-0.03	0.369
6. Public Information	3.39 (0.71)	3.50 (0.77)	0.11	0.075
7. Training	3.22 (0.74)	3.27 (0.85)	0.05	0.338

SD, standard deviation

Table 4. Pre- and post-course importance ratings for 7 key factors in pandemic influenza training, using a Likert scale, 1-5.

Factor	Pre-simulation Mean t (SD)	Post-simulation Mean t (SD)	Change score (post-pre) Mean t	paired-t (p-value)
1. External Organization	4.65 (0.65)	4.81 (0.46)	0.16	0.000
2. Operations	4.56 (0.69)	4.72 (0.54)	0.16	0.003
3. Supplies	4.49 (0.67)	4.73 (0.54)	0.24	0.000
4. Communication	4.63 (0.64)	4.74 (0.53)	0.11	0.019
5. Mass Casualty Incident Planning	4.33 (0.80)	4.67 (0.53)	0.34	0.000
6. Public Information	4.12 (0.91)	4.42 (0.74)	0.30	0.000
7. Training	4.37 (0.78)	4.63 (0.62)	0.26	0.000

SD, standard deviation

Table 5. Pre- and post-course recommendation ratings for 7 key factors in pandemic influenza training, using a Likert scale, 1-5.

Factor	Pre-simulation Mean t (SD)	Post-simulation Mean t (SD)	Change score (post-pre) Mean t	paired-t (p-value)
1. External Organization	2.24 (0.67)	2.31 (0.79)	0.07	0.136
2. Operations	2.25 (0.62)	2.34 (0.72)	0.09	0.076
3. Supplies	2.16 (0.67)	2.26 (0.82)	0.10	0.139
4. Communication	2.20 (0.78)	2.31 (0.82)	0.11	0.030
5. Mass Casualty Incident Planning	2.06 (0.67)	2.23 (0.83)	0.17	0.004
6. Public Information	2.06 (0.60)	2.30 (0.68)	0.24	0.001
7. Training	2.09 (0.63)	2.26 (0.77)	0.17	0.011

SD, standard deviation

ratings in all key factors for successful management of a pandemic influenza outbreak (all p-values <0.05). In the third evaluation domain, recommendations ratings (by trainees), 4 of the 7 factors—communication, mass casualty incident planning, public information, and training (Table 5) achieved statistical significance. Finally, participants reported that their perceptions increased for the critical need to enact changes in each of these areas at their own facilities.

DISCUSSION

We describe the development and initial testing of a computer-based simulation for training in key decision making for a hypothetical pandemic influenza outbreak. We conducted the simulation was conducted using a networked, computer-based system, and developed it based on the premise that instructional facilitators would be able to: (1) administer the same pandemic influenza exercise at many institutions; (2) use the simulation over an extended period of time; and (3) experience different simulation outcomes based on the decisions participants made in their respective training days. Emergency physicians may find use of such training to be valuable in order to ensure uniformity of training, capture the attention of staff and administrative personnel on a challenging topic where community engagement is required for success, and provide a leadership opportunity for facilitators to improve public health preparedness. Individual participants reported real-life feelings of performance pressure and other emotional responses as a result of the realistic visual and auditory inputs.

We contracted with Crisis Simulations International (Portland, Oregon USA) to design and develop a computer-

Table 6. Examples of key decisions made by hospital chief executive officer (CEO).

	Example 1	Example 2
Message	From: State Hospital Managing Director: The hospital has notified our clinic that they have cases of an aggressive influenza, and are in communications with the CDC regarding the situation.	From: State Hospitals Managing.
Question	From: Chief financial officer of State Hospitals: Our small clinic isn't really able to effectively isolate patients with possible aggressive influenza, are they? How will we avoid infection of other patients and staff? I'm worried about liability and think we need to move on this.	Some suspect influenza cases have been transported here from the Local Community Hospital. Infection Control is monitoring closely, and stocking up on N95 masks. We might want to consider our inventories system-wide, anticipating dispensing masks to patients and families of patients.
Decision 1	Get status update from clinic general manager	From: State Hospitals CEO Administrative Assistant.
Decision 2	Refer all suspect cases to our state hospital	I received a call from Purchasing. Per your standing requests, they are notifying us that our hospitals are dramatically requesting an increase in stocks of N95 masks, exam gloves, and other controls for airborne infection. Purchasing can't understand why. This is more than a little bump. What do you want me to do?
Decision 3	Have physician assistant call all patients and refer as needed	Restrict purchases to standard inventory levels
Decision 4	Close clinic	Allow purchases to proceed
Decision 5	Refer to MH Chief Med Officer	Ask for more information from purchasing

CDC, Centers for Disease Control and Prevention; *MH*, medical hospital

based simulation using their proprietary DXMA™ architecture. In computer-based simulation training, 2 core principles of simulation design differentiate it from others. Just as in real life, decisions do not happen in isolation. Within the simulation, a trainee may be faced with a decision that is triggered by an event occurring in the scenario or by decisions made by other roles/trainees earlier in simulation time. This is referred to as interdependency between roles. A decision made by role 1 leads to downstream effects that then triggers a decision to be made by role 2. This 2-decision series is called a cascading decision, which is used throughout the pandemic influenza simulation.

Based on a response system organized along the National Incident Management System (NIMS) footprint, we incorporated specified 2007 federal planning assumptions relating to highly pathogenic avian influenza into the computer program. Two educational consultants transformed the design document constructed by the SMEs into an educational assessment tool. Personalized facilitation provided with the exercise was designed by educational specialists, using knowledge gained from SMEs in the fields of emergency medicine, emergency preparedness, emergency medical service, hospital administration and infectious disease. This facilitator discussed key points and topics before, during and after this simulation to help mediate discussion and learning objectives.

To increase accuracy of the simulation experience, the SMEs determined 7 critical success factors: (1) Have clear policies and procedures for working with external organizations; (2) have clear internal policies and procedures for operation; (3) maintain adequate and dependable resources and supplies and outside services; (4) have dependable voice and data communication both within and across organizations; (5) support healthcare staff physically and psychologically; and (6) have policies and procedures for keeping the public informed.

Leadership positions that would be involved in such a crisis were designated. The positions were a hospital chief executive officer (CEO), an emergency medical service representative, an emergency management agency worker, an employee of the state health department, a hospital incident commander, and a hospital operations chief. Throughout the simulation duration, each leadership position participant was presented with messages, questions and decision options that would be expected in a real-life response scenario. Table 6 exhibits 2 decisions served up to the CEO.

The simulation provided decisions in a time-based sequence that simulated the first 8 weeks of the influenza outbreak within one community. The DXMA™ architecture that was used was unique in that it was designed to used the interdependent and cascading decisions made by participants in a collapsed timeframe. Thus, consequences of choices made by each leadership role affected the leader themselves, the overall outcome of the exercise, and fellow participants. These consequences were not necessarily linear; second- and third-order consequences resulted from decisions as well.

Audiovisual news reports were displayed as "live" video feeds triggered by participant decisions. The video streams added a sense of realism to the simulation and were broadcast at regular intervals. After the 1-hour simulation session, a

community influenza infection monitor, a case mortality estimate, and an infection percentage estimate provided participants further insight into the effects of their decisions. The data for these estimates was taken from 2 influenza surge programs created by the Centers for Disease Control and Prevention (CDC)—FluAid 2.0 and FluSurge 2.0. as determined by the SMEs. These federal flu preparedness models aim to provide hospital administrators and public health officials an estimate of the surge in demand for hospital-based services during a hypothetical influenza pandemic. They take into account the population of a respective location, as well as the number of emergency departments and intensive care unit (ICU) beds. Based on this data input, the number of infected patients requiring hospitalization is estimated, as is the associated mortality estimate.[10] As part of the "realistic features" of the simulator, it presents environmental disturbances systematically. During the central point of the simulation, participants received messages, questions, "live" video feeds and infection monitor updates at a pre-determined rate. This added to the fidelity and interactive nature of the simulation.

This simulation was intended to model a complex system, give participants the understanding of the inter-relationship repercussions of decisions undertaken, and give participants perspective to analyze their own facilitiess' preparedness. This simulation exercise found that the various types of responses needed to effectively manage a pandemic influenza outbreak were made evident to participants. This simulation workshop session revealed specific observations related to disaster preparedness medicine, such as, participants were less prepared than they originally thought prior to participating in the simulation. Foremost, however, is the fact that all 7 key success factors showed a significant increase in their importance ratings, leading to the conclusion that this simulation increased awareness of these issues. Further work is needed to translate knowledge into action, however, if sustainable changes in pandemic influenza readiness are to be realized. Subsequent to completing the simulation training, participants will presumably illustrate an improved comprehension of the means necessary to prepare for a pandemic influenza outbreak, yet this was not the main outcome. A useful training environment would provide the ability for personal growth and understanding to anticipate further organization and practice to decrease the effects of a potentially devastating viral illness. These include many key factors mentioned in the corresponding survey, such as increasing communications between public and crisis management, implementing/modifying triage protocols, and other modalities encountered within the simulation.

The purpose of the simulation workshop experience was to expose hospital personnel to an interactive platform that stimulated critical decision making and increased awareness to the vast amount of responsibilities personnel need, in preparation for, and in response to a pandemic influenza outbreak. Objectives were not to evaluate participant decisions as right or wrong, but rather to discuss the options, and observe how each decision has its own significant outcome on the final result of the surge. In the same respect, this was not a session in which participants were educated, or trained on mass casualty incident response.

LIMITATIONS

We rated each of the 7 factors at baseline and at the completion of the simulation, but no long-term follow-up data has been collected to evaluate sustainability. A secondary contact is needed to address this next step. The participation in a real event is the best way to achieve the greatest amount of experience when compiling information on any educational assessment. As with any other training method, time frames of the educational exposure are reduced to have a realistic and obtainable educational experience. This simulation breaks down an influenza outbreak from weeks to hours; this of course is not ideal, but an accepted practical approach to the time constraints of personnel. Another major limitation in this study stems from the fact that participants' occupations were not taken into account (whether they were nurses, physicians, unit managers, or administrators) when "playing" each role during the simulation. In future simulations, each participant should perhaps play a function that reflects their respective emergency response position. However, several trainees commented on the positive value of assuming other roles than they would ordinarily occupy, as it contributed to their overall knowledge of mass casualty management. Additionally, although the results of the death toll and surge capacity created were discussed in the facilitation portion of the training day, there is no mathematical model to provide participants scientifically valid feedback as to the consequences accrued from their decisions. While a test of regional personnel may be unsatisfactory in some respects, beta versions of this simulation were played with SMEs, including those outside the development group. We have found that educational translation is perceived by many as better when the SME is asked to play a role within the simulation outside their normal domain. Many have indicated it provided them insight into what others are/may be doing which could be in conflict with decisions they are making during an incident.

CONCLUSION

Development and testing of a computer-based, high-fidelity simulation trainer for a pandemic influenza outbreak can provide a platform for improved perceptions, importance, and recommendations for progress. Reproducibility and the inter-connectedness of decisions can be highlighted within the simulation training, which produces a full-scale weeks-long incident in a few hours. For emergency providers and trainers, this simulation is highly reproducible and can be facilitated to small and larger audiences.

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Ten Years of Frequent Users in an Urban Emergency Department

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Introduction: The purpose of this study was to determine if differences could be detected in the presentation patterns and admission rates among frequent emergency department users (FEDU) of an urban emergency department over a 10-year period.

Methods: This was an institutional review board approved, retrospective review of all patients who presented to the ED 5 or more times for 3 distinct time periods: "year 0" 11/98-10/99, "year 5" 11/03–10/04, and "year 10" 11/08–10/9. FEDU were grouped into those with 5–9, 10–14, 15–19, and ≥ 20 visits per year. Variables analyzed included number of visits, disposition, and insurance status. We performed comparisons using Kolmogorov-Smirnov and chi-square tests. A $p<0.05$ was considered significant.

Results: We found a a 66% increase in FEDU patients over the decade studied, with a significant increase in both the number of FEDU in each visit frequency category over the 3 time periods ($p<0.001$), as well as the total number of visits by each group of FEDU ($p<0.001$). The proportion of FEDU visits for the 5–9 group resulting in admission increased from 25.9% to 29% from year 0 to year 10 ($p<0.001$), but not for the other visit groups. In comparing admission rates between FEDU groups, the admission rate for the 5–9 group was significantly higher than the ≥ 20 group for the year 5 time period ($p<0.001$) and the year 10 time period ($p<0.001$) and showed a similar trend, but not significant, at year 0 ($p=0.052$). The overall hospital admission rate for emergency patients over the same time span remained stable at 22-24%. The overall proportion of uninsured FEDU was stable over the decade studied, while the uninsured rate for the overall ED population for the same time periods increased.

Conclusion: The results demonstrate the FEDU population is not a homogeneous group of patients. Increased attention to differences among FEDU groups is necessary in order to plan more effective interventions. [West J Emerg Med. 2013;14(3):243–246.]

INTRODUCTION

From 1998 to 2008 the number of emergency department (ED) visits increased by 30% from 94.8 million to 123 million, while the total national number of hospital-based EDs declined by 3.3% according to the American Hospital Association.[1] The Centers for Disease Control and Prevention (CDC) has reported that in 2007, approximately 1 in 5 persons in the United States (U.S.) population had 1 or more ED visits in a 12-month period.[2] Frequent ED Users (FEDU) are a diverse group of patients responsible for a disproportionate number of ED visits.[3-6] It is not well understood how FEDU have contributed to the overall increases in ED volumes, or in hospital admissions. Previous studies have described a variety of FEDU demographic characteristics but these studies have not described subgroups of FEDU relative to their presentation and admission patterns over extended periods of time.[3-10]

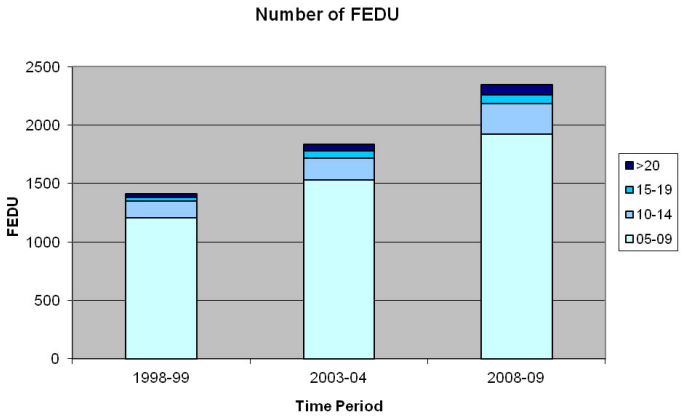

Figure 1. Number of patients in each frequent emergency department users (FEDU) group in years 0, 5, & 10.

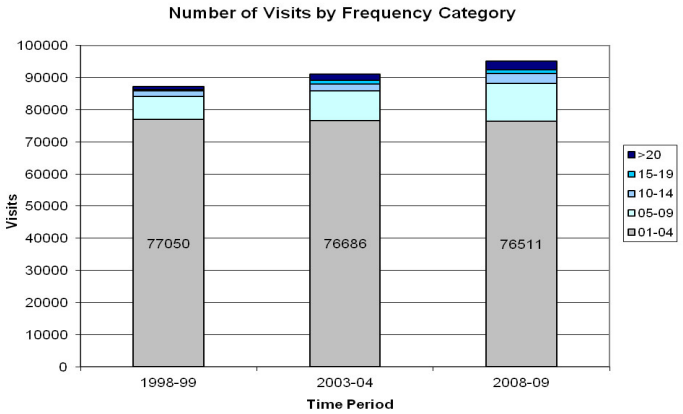

Figure 2. Number of emergency department visits by each frequent emergency department users group in years 0,5, & 10.

LaCalle and Rabin[3] noted in their systematic literature review of FEDU, "…although subgroups of the frequent user population exist, the results of existing studies fall short of characterizing the discrete groups, at least in ways that are useful in developing public policy".

Several large studies have analyzed the impact of FEDU on ED volumes. Two used statewide databases to examine FEDU. Cook et al[4] reviewed 3 years of ED presentations in Utah and defined FEDU as > 4 visits. In this study, FEDU accounted for 5% of ED patients but represented more than 21% of ED visits. Fuda and Immekus[5] reported all ED presentations of Massachusetts residents in 2003 and found 1% had ≥5 ED visits. This group of FEDU accounted for 3.8% of ED patients but represented 17% of ED visits. These patients had a higher rate of hospitalization. Mandelberg et al[6] reported 5 years of FEDU (≥ 5 visits/year) at San Francisco General Hospital. This group of FEDU accounted for 3.9% of ED patients and 20.8% of ED visits. None of these studies further stratified FEDU with respect to their visit frequency.

When FEDU have been stratified into groups according to visit frequency, differences have been detected. For example, Ruger et al[7] reported patients with 3–20 visits were more likely to be admitted to a hospital, while patients with > 20 visits were less likely to be admitted and were more likely to be triaged at a lower severity. Similar studies by Moore et al[8] and Blank et al[9] created distinct visit categories for FEDU, and then identified differences in such areas as triage acuity, insurance coverage, and admission rate.

The cited studies have documented the impact of FEDU on healthcare resource utilization as well as the heterogeneity of this population. The purpose of this investigation was to further characterize the FEDU population by stratifying visit frequency over time. Our hypotheses were that FEDU visits would increase over a 10-year period and there would be discrete differences seen over time within the FEDU categories.

METHODS

We conducted this institutional review board approved retrospective review at an urban, inner city hospital ED with > 95,000 annual visits using an electronic ED information system (EmSTAT, AllScripts, Cary NC). We grouped FEDU according to number of annual visits: 5–9, 10–14, 15–19, and ≥ 20 and studied over 3 time periods: November, 1998–October 1999 (year 0), November 2003–October 2004, (year 5), November 2008–October, 2009 (year 10). Variables analyzed included number of visits, number of FEDUs, disposition, and insurance status. Patients were considered to have no insurance if they were registered as "self-pay," "charity care," or "Medicaid pending." We chose the most frequently documented insurance status for analysis for each patient in each time period.

To assess differences in the distributions of the number of visits and number of FEDUs over the 3 time periods, we performed 1 sample Kolmogorov-Smirnov (K-S) test for each outcome. This method tests whether the numbers are evenly distributed across the 3 time points. For example, using the total number of visits from all 3 periods as the denominator, K-S would test whether the percentage of visits for 98–99, 03–04 and 08–09 are all equal to 33.3% (100/3). We performed this test instead of the typical analysis of variance (ANOVA) method because we only have 1 number for each time period and hence no measure of variability needed for ANOVA. Chi-square tests were done to assess differences in admission and insurance rates over time and within FEDU groups. We set the overall testing level at 0.05, and we used Bonferroni adjustments when assessing pair-wise comparisons of FEDU groups within a time point ($p<0.05/10$) and time points within a FEDU group ($p<0.05/6$).

RESULTS

We found a 68% increase in FEDU patients over the decade studied, which was significant as compared to the overall ED census increase ($p<0.001$) during the same time period. The increase in overall ED census was 9% from 87,230 (year 0) to 95,170 (year 10), while the increase in visits by the FEDU population increased by 83% from 10,180

Table 1. Summary of frequent emergency department user (FEDU) patient and visit data for all groups and time periods.

	Year 0			Year 5			Year 10		
FEDU groups	# patients	# visits	% of ED visits	# patients	# visits	% of ED visits	# patients	# visits	% of ED visits
5–9 visit group	1203	7156	8.2%	1530	9303	10.2%	1918	11734	12.3%
10–14 visit group	146	1651	1.9%	186	2132	2.3%	267	3084	3.2%
15–19 visit group	29	481	0.6%	60	993	1.1%	75	1247	1.3%
> 20 visit group	33	892	1.0%	58	1951	2.1%	84	2594	2.7%
Total	1411	10180	11.7%	1834	14379	15.8%	2344	18659	19.6%
ED visit total		87230			91065			95170	

Table 2. Admission rates for frequent emergency department user groups in years 0, 5, & 10.

Visits/year	Year 0	Year 5	Year 10	*P* value
5–9	25.9%	26.3%	29.0%	0.0089
10–14	23.9%	27.6%	27.2%	0.462
15–19	24.1%	18.2%	27.0%	0.208
> 20	14.8%	13.6%	12.5%	0.877
Total	22.9%	21.7%	23.2%	0.568

(year 0) to 18,659 (year 10) (Table 1). The percentage of visits accounted for by FEDU was 11.5% in year 0, 15.8% in year 5, and 19.6% in year 10. There was a significant increase in the number of patients in each visit frequency group over time (Figure 1) ($p<0.001$). The total number of visits by each FEDU group also increased ($p<0.001$) as shown in Figure 2.

Patients in the 5–9 group were the largest FEDU grouping across all time periods and had the greatest impact on ED volume. In years 0, 5, and 10, the 5–9 group accounted for 8.2%, 10.2%, and 12.3% of total ED visits, respectively.

The proportion of FEDU visits for the 5–9 group resulting in admission increased from 25.9% to 29% from year 0 to year 10 ($p<0.001$). Admission rates within the other groups did not change significantly (Table 2). In comparing admission rates between FEDU groups, the admission rate for the 5-9 group was significantly higher than the ≥ 20 group for the year 5 time period (26.3% vs. 13.6%, $p<0.001$) and the year 10 time period (29% vs. 12.5%, $p<0.001$). At year 0, the difference showed a similar trend but was not significant (25.9% vs. 14.8%, $p=0.052$). The overall hospital admission rate for emergency patients over the same time span remained stable at 22–24%.

The overall proportion of uninsured FEDU was relatively stable over the decade studied (4.0% in year 0, 1.8% in year 5, 5.6% in year 10). While this proportion remained relatively low for FEDU, the uninsured rate for the overall ED population for the same time intervals increased (12.6%, 17.9%, and 21.8% for years 0, 5, and 10, respectively).

DISCUSSION

The number of visits to this inner city ED has increased by 9% over the past decade. This is less than the 30% increase in total ED visits in the U.S. over this same time period. However, from 1998 to 2008, our ED had an 83% increase in FEDU visits as well as a 66% increase in FEDU patients. It is not known what proportion of the nationwide increase in ED visits is related to FEDU since this has not been reported. ED use per capita has increased from 34.1 visits/100 persons in 1996 to 40.5 visits/100 in 2006.[11] Our study suggests the reported increase in ED use per capita and overall ED use is related to increased FEDU visits. Our increases have occurred despite relatively stable insurance coverage for most of these patients, which is consistent with past FEDU studies.[3-7, 9-10] We postulate that the increase in FEDU visits is due to a lack of both primary and specialty care access in this inner city community.

Our results highlight the impact FEDU with 5–9 visits/year have on total ED volume. Distinct from the other FEDU groups, the 5–9 group had the most patients and visits as compared to all other groups over all 3 time periods. This group also had more visits than all the other FEDU groups combined. LaCalle and Rabin's[3] review article determined patients with ≥ 4 visits accounted for 21%–28% of ED visits. Our stratification of FEDU subgroups reported that this 5–9 group accounts for the most noteworthy volume percentages (8.2%, 10.2%, and 12.3% respectively for the years examined).

When broadly categorizing the FEDU population, admission rates were stable. However, when subdividing FEDU into groups, the 5–9 group was a generally sicker population as they had significantly higher hospital admission rates. Lower admission rates for the ≥ 20 group are consistent with the findings of past research focusing on "high" FEDU.[3,7] Although the ≥ 20 group of FEDU may be more visible, the 5-9 group is the driving force behind volume increases. While we did not specifically study the clinical conditions associated in our patients, previous experience with the > 20 group has shown a higher incidence of substance abuse, psychiatric complaints, and social challenges, particularly with housing and transportation.[12] We believe this important difference should be considered when planning FEDU interventions.

Previous impact studies have treated the FEDU population as a large homogeneous group for all patients with 5 or more

visits.[4-5] By purposefully stratifying into distinct groups, we were able to further characterize the heterogeneity of our FEDU population. We believe that any interventions targeting FEDU must consider the differences among the groups of FEDU and be tailored to their needs. LaCalle and Rabin's[3] review found "…no study has shown a threshold number at which striking differences in resources, demographics, or clinical import are observed." Our study demonstrated that the 5–9 group accounts for the greatest impact on ED volume and hospital admissions (i.e., healthcare resource utilization), fulfilling the threshold criteria LaCalle seeks. We believe the 5th visit is the trigger to implement specific planned interventions to address the healthcare needs of the FEDU population.

Interventions to address FEDU may be more effective if targeted to specific subgroups. For example, a program to address hospital readmission may be more effective if directed at the 5–9 group. A separate program for the ≥ 20 FEDU group may prove more beneficial to the ED.

LIMITATIONS

We did not examine use over the entire 10 years reported but instead used 3 1–year "snap shots" to characterize FEDU patterns. This is a single site study. FEDU are well known to frequent multiple EDs. This fact may underestimate the ED visits of some FEDU. Another limitation specific to this single site is that it is located in an economically challenged city with a declining population. The changes observed in this study may not completely reflect changes elsewhere. The data regarding insurance status were of variable accuracy due to changes in individual insurance status over time. A final limitation is that we did not study the clinical conditions associated with the visits.

CONCLUSION

The ED census has increased over the past 10 years. The increase at this inner city hospital is disproportionately due to an increase in FEDU. The 5–9 group had the greatest increase in visits with the highest admission rate. Stratification of the FEDU population by visit frequency over time yields new insights into this heterogeneous population and may aid in planning interventions to address the healthcare needs of these patients.

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Prescription History of Emergency Department Patients Prescribed Opioids

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Introduction: To use Colorado's prescription drug monitoring program (PDMP) to describe the recent opioid prescription history of patients discharged from our emergency department (ED) with a prescription for opioid pain medications.

Methods: Retrospective cohort study of 300 adult ED patients who received an opioid prescription. We abstracted prescription histories for the six months prior to the ED visit from the PDMP, and abstracted clinical and demographic variables from the chart.

Results: There were 5,379 ED visits during the study month, 3,732 of which were discharged. Providers wrote 1,165 prescriptions for opioid analgesics to 1,124/3,732 (30%) of the patients. Median age was 36 years. Thirty-nine percent were male. Patients were 46% Caucasian, 26% African American, 22% Hispanic, 2% Asian and 4% other. These were similar to our overall ED population. There was substantial variability in the number of prescriptions, prescribers and total number of pills. A majority (205/296) of patients had zero or one prescription. The 90th percentile for number of prescriptions was seven, while the 10th percentile was zero. Patients in the highest decile tended to be older, with a higher proportion of Caucasians and females. Patients in the lowest decile resembled the general ED population. The most common diagnoses associated with opioid prescriptions were abdominal pain (11.5%), cold/flu symptoms (9.5%), back pain (5.4%), flank pain (5.0%) and motor vehicle crash (4.7%).

Conclusion: Substantial variability exists in the opioid prescription histories of ED patients, but a majority received zero or one prescription in the preceding six months. The top decile of patients averaged more than two prescriptions per month over the six months prior to ED visit, written by more than 6 different prescribers. There was a trend toward these patients being older, Caucasian and female. [West J Emerg Med. 2013;14(3):247–252.]

INTRODUCTION

Prescription drug abuse is an increasing public health problem in the United States (U.S.).[1] Opioids are commonly prescribed for the relief of acute and chronic pain from multiple ambulatory settings, including pain clinics, office practices, dental practices and the emergency department (ED). However, access to these medications for the purposes of abuse is not uncommon; an estimated 10% of Americans report prescription drugs as their drug of choice for abuse;[2] and among patients of chronic pain clinics, opioid abuse has been reported in up to 24% of individuals.[3] An estimated 4.7 million people in the U.S. have taken opioids for nonmedical uses in the past month.[4] Given the increased use and abuse of these medications prescription opioids have become the number 1 cause of poisoning deaths in the U.S., surpassing cocaine and heroin as causes of drug-associated death.[5] The total number of prescription opioid related-deaths in the U.S. more than tripled from 1999-2006.[6] The most recent estimate is that prescription opioids are responsible for 73.8%

(14,800/20,044) of the prescription drug overdose deaths per year.[7]

Emergency medicine providers care for patients with pain from many different etiologies. The treatment of pain is frequently initiated without the benefit of an established doctor-patient relationship and often in an environment of limited time and resources. Patients and physicians may have different expectations for pain control. This may lead to frustrated or unsatisfied patients as reflected by the recent Institute of Medicine report suggesting that pain is undertreated in the ED.[8] Opioids are an important component of acute and chronic analgesia. However, physicians must balance the need for adequate pain relief with the risk for misuse, abuse and diversion.

The National Institute on Drug Abuse has suggested that a large number of prescriptions from multiple providers is a marker of prescription drug abuse, but it has been difficult to accurately asses the number of prescriptions until recently.[9] The National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 was established to support a controlled substance monitoring program in each state for the purpose of giving physicians a tool to aid in both prescribing controlled substances and identification of illicit fraud and abuse.[10] Prescription drug monitoring programs (PDMP) seek to provide a balanced approach to protect public safety and public health while supporting legitimate medical practice. Colorado obtained funding for a PMDP in 2006 to monitor Schedule II, III, IV, and V prescriptions. Data collection began in July 2007 and went live to providers in February 2008, providing prescription profiles for providers and pharmacists.

The purpose of this study was to characterize the recent opioid prescription history of patients discharged from the ED with a prescription for opioid pain medications. As a secondary aim we described 2 subpopulations, the top decile and the bottom decile in terms of number of prescriptions, to explore potential markers that could characterize subjects who may be at increased risk of seeking opioid prescriptions for abuse and diversion or poorly controlled chronic pain.

MATERIALS AND METHODS

Study Design and Setting

The local human subject research committee approved this retrospective cohort study and waived informed consent as the study used retrospective data. The study institution is an urban, university-affiliated ED with approximately 55,000 visits annually and an admission rate of approximately 25%. Our ED records are generated by an ED information system (EDIS; Pulsecheck, Picis Inc, Wakefield, Illinois), and all prescriptions are generated electronically and printed for the patient.

Colorado's prescription drug monitoring program tracks all dispensed prescriptions for controlled medications (excluding prescriptions dispensed at a Veterans Administration pharmacy), including opioids, in a database available to all providers with a Drug Enforcement Administration number. The database includes date filled, physician's name, drug, dose, quantity of pills prescribed, days supply, class of drug, type of insurance and pharmacy name and city. It does not identify if the prescriber is affiliated with a hospital, office or ED. The state board of pharmacy is in charge of program operation and oversight. Information is uploaded by pharmacies on a bimonthly basis. The longest possible delay between filling a prescription and the information being uploaded is 28 days. Once uploaded, the information is immediately available to users.

Selection of participants

Eligible participants were 18 year or older, had been discharged from the ED, and had received a prescription at discharge for a controlled opioid-containing medication between October 1, 2009 and November 1, 2009. Subjects were excluded if they only received a cough preparation containing hydrocodone or codeine. For subjects with more than 1 visit where an opioid was prescribed, only the first visit during the month was considered. Subjects were selected by entering all records for the month into a spreadsheet (Microsoft office excel 97-2003), assigning each subject a random number using the RAND function and sorting the records using the random number assigned to each record. We then selected the first 300 records as study subjects.

Data collection

The data from the ED and the prescription drug monitoring program were collected by 2 separate teams and assigned random patient identifiers to preserve the confidentiality of personal health information. We are able to use our EDIS to automatically populate our data collection spreadsheet (Microsoft Office Excel 97-2003) with fields collected on all patients (e.g. age, sex, ethnicity, etc). Background data for our ED in the month of October was abstracted electronically from the EDIS. Demographic data for our study population (age, gender, and race) was abstracted electronically from the EDIS. Two trained physician investigators manually abstracted ED charts to determine if the patient reported a preexisting medical condition expected to cause chronic pain, if the patient reported an opioid as a medication, and social history. A history of any of the following was considered a chronic pain condition: fibromyalgia, complex regional pain syndrome/ reflex sympathetic dystrophy, or any pain syndrome described by the patient as chronic and documented in the ED chart (e.g., chronic low back pain, chronic abdominal pain, chronic headaches, etc). Investigators were blinded to PDMP data but not to the study hypothesis. Ten percent of the data from the EDIS automated abstraction and 20% of the data from manual chart abstraction were randomly selected for double abstraction to assess inter-rater agreement. The 2 trained abstractors reconciled disagreements.

The information from the prescription database was separately abstracted by 2 pharmacists affiliated with and familiar with the program who were blinded to the clinical data and the study hypothesis. The Colorado PDMP was searched by entering the patient name and birth date. Patients were identified in the database when both the name and birth date matched. Subjects were considered to be the same person if names were very similar and birthdates matched (i.e. Jon Smith and John Smith), or if they were hyphenated and birthdates matched (i.e. Jane Smith and Jane Smith-Jones). The abstractors reviewed the prescription records for the 6 months preceding, but not including the incident ED visit. Data abstracted included: number of prescriptions, number of pills, number of providers writing a prescription, number of pharmacies where prescriptions were filled and number of different payer sources. All of the information was de-identified and entered into a spreadsheet by study number only. Finally we merged the 2 de-identified spreadsheets by study number.

Methods of measurement

Race was coded as African-American, Asian, Caucasian, Hispanic, or other/unknown. We defined an allergy to opioids as a self-report of allergy to any opioid but not to tramadol. An allergy to other analgesics was defined as a self-report of allergy to acetaminophen, aspirin, tramadol or as an allergy to non-steroidals (as a group or individual medications). Alcohol use, tobacco use and illicit drug use were determined by self-report. The variables obtained from the PDMP were abstracted as summary data (number of prescriptions, pills, and providers) for each patient rather than as individual data for each prescription. We did not record the specific medications a patient received.

We characterized patients in the top and bottom decile for number of opioid prescriptions in the 6 months preceding their ED visit. We selected number of prescriptions rather than total pills as our primary measure of use because we recognized that some chronic pain patients may require significant amounts of analgesic medications to treat their symptoms, but considered that optimal management for these cases would be fewer prescriptions for a larger total number of pills rather than many prescriptions for smaller numbers of pills.

Specific aims

Our primary aim was a characterization of the prescription history of patients who received opioid prescriptions in our ED. Our *a priori* secondary aim was a description of demographic and clinical characteristics of the top and bottom deciles in terms of number of prescriptions.

Analysis and Data Presentation

As we had no formal hypothesis for this exploratory study, we did not perform a power calculation and we used descriptive statistics. We used a sample size of 300 subjects as this provides a precision of plus/minus 6% for binomial variables with a frequency of 50%. Many of the variables were not normally distributed, so we used non-parametric statistics. For nominal data we determined proportions and for continuous data we used medians as a measure of central tendency and ranges and inter-quartile ranges as measures of variance.

RESULTS

In October 2009 our ED had 5,379 visits and 3,732 of those patients were discharged. The median age was 38 years with an interquartile range of 26 to 52 years. Forty-one percent were male. Patients were 46% Caucasian, 26% African American, 22% Hispanic, 2% Asian and 4% other or unknown. Providers wrote 1,165 prescriptions for opioid medications to 1,124/3,732 (30%) of the patients treated in the ED. The majority were for acetaminophen/hydrocodone (n=544), acetaminophen/oxycodone (n=347) or oxycodone alone (n=102). These 3 products accounted for 86% of all opioid prescriptions written that month.

The trained abstractors checked the electronic abstraction tool for accuracy. Ten percent of the charts were manually abstracted to verify the accuracy of the tool. Agreement between the abstraction tool and the abstractors for patient data (age, gender, chief complaint, prescription given, medications administer in the ED) was 99%. Each abstractor then reviewed 10% of the other abstractor's charts to verify the accuracy between the 2. Inter-investigator agreement was 100%. The tool was not built to abstract chronic pain, so after electronic abstraction the presence of these conditions was reviewed for each patient by the 2 abstractors. Five disagreements regarding whether a given patient did or did not have a chronic pain syndrome among 296 (1.7%) patients were reconciled by joint chart review.

We did not initially filter our 300 study records by subject age and therefore 4 subjects younger than 18 were excluded from the preliminary analysis. The remaining 296 subjects were of similar age (median 36 years, IQR 27 to 74 years), gender (39.5% male) and racial distribution (46% Caucasian, 26% African American, and 22% Hispanic) as our overall ED population. The most common chief complaints for patients who received opioid prescriptions in this study were abdominal pain (34, 11.5%), cold/flu symptoms (28, 9.5%), back pain (16, 5.4%), flank pain (15, 5.0%) and motor vehicle crash (14, 4.7%).

Overall, 205/296 (69%) patients who received a prescription for an opioid from our ED had 0 or 1 prescription for opioid-containing medications in the 6 months preceding their ED visit (Figure 1). There was substantial variation in the number of prescriptions, the total number of pills prescribed, the number of providers writing prescriptions and the number of pharmacies (Table 1). The 90th percentile for number of prescriptions in the 6 months preceding the ED visit was 7, while the 10th percentile was 0. As there were 122

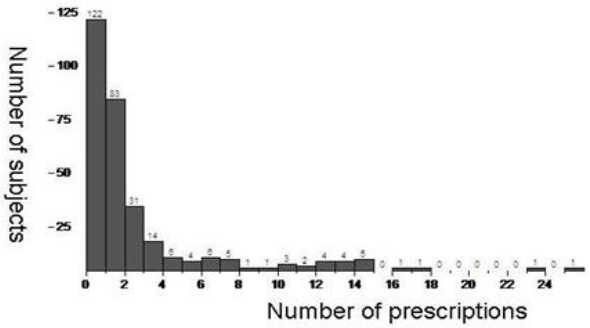

Figure. Number of subjects with corresponding number of prescriptions over the prior six months in a sample of patients (n=296) who were prescribed opioids and discharged from the emergency department

Table 1. Number of prescriptions, pills, providers writing prescriptions and pharmacies where prescriptions were filled for the prior six months in a sample of patients (n=296) who were prescribed opioids and discharged from the emergency department.

	Median	Interquartile range	Range
Number of prescriptions	1	0 to 2	0 to 26
Number of pills	15	0 to 45	0 to 3075
Number of providers	1	0 to 2	0 to 16
Number of pharmacies	1	0 to 1	0 to 10

patients with 0 prescriptions, we included all patients with 0 prescriptions in our description of the lowest decile.

The patients with 0 opioid prescriptions in the preceding 6 months resembled the general ED population in terms of age, gender and race. The patients in the highest decile appeared to be older, and had a higher proportion of Caucasians and females than our overall ED population (Table 2). More than 60% of patients in the highest decile did not report a chronic pain condition or opioids as a medication. For the highest decile, the median number of prescriptions per provider was 2, with a range from 1 to 6.5 and an interquartile range of 1.3 to 3.5.

LIMITATIONS

This study was performed at a single center with a small number of patients, which may not describe the population at large or apply to other settings. Physicians were not mandated to look up patients, and there is no way to track which patients

Table 2. Characteristics of patients with zero opioid prescription in the last 6 months, the highest decile (>7 Rx) for number of prescriptions in the 6 months preceding their ED visit and all other patients in the study group (1 to 7 Rx).

	No Rx Group	1 to 7 Rx	>7 Rx
Total number=296 n (%)	122 (41%)	149 (50%)	25 (9%)
Age median (IQR)	33 (25 to 49)	36 (27 to 49)	45 (29 to 54)
Male n (%)	62 (50.8%)	50 (33.6%)	5 (20%)
Race n (%)			
White	51 (42.1%)	67 (45.3%)	18 (72%)
Black	29 (23.9%)	42 (28.4%)	6 (24%)
Hispanic	32 (26.5%)	32 (21.6%)	1 (4%)
Other/missing	10 (8.2%)	2 (1.3%)	0 (0%)
Chronic pain n (%)	6 (5.0%)	11 (7.4%)	8 (32%)
Lists opioid as a medication n (%)	5 (4.1%)	16 (10.7%)	8 (32%)
Allergy to opioid n (%)	13 (10.7%)	11 (7.4%)	6 (24%)
Allergy to other analgesic n (%)	4 (3.2%)	7 (4.7%)	5 (20%)
History of ethanol use n (%)	36 (35.3%)	43 (32.1%)	5 (23%)
History of tobacco use n (%)	47 (43.9%)	60 (44.1%)	11 (48%)
History of illicit drug use n (%)	7 (7.5%)	8 (6.4%)	1 (5%)
Number of prescriptions median (range)	0	1 (1 to 7)	13 (8-26)
Number of pills median (range)	0	30 (8 to 1101)	542 (201-3075)
Number of providers median (range)	0	1 (1 to 7)	6 (2 to16)
Number of pharmacies median (range)	0	1 (1 to 6)	4 (1 to 10)

Rx, prescription; *IQR*, Interquartile range

were reviewed on the PDMP prior to receiving a prescription. This may have led to selection bias as a review of the PDMP by the individual provider may have affected the choice to prescribe opioids and prevented some frequent users from receiving a prescription and inclusion in our study. Our ascertainment of patient characteristics was limited by the retrospective data collection and manual provider data entry; it is possible that some information may have been incorrectly entered at the time of the ED visit.

Because our PDMP system relies on manual data entry to populate the databasethere is a potential for some inaccurate entries. We attempted to accommodate for this by including entries that were hyphenated or had similar spellings and the same birth date. It is also possible that drug-seeking individuals used several identities when acquiring prescription medications, which would result in several PDMP profiles and an underestimate of the amount of prescriptions identified in this study. The delay in pharmacies uploading data could potentially be as long as 28 days depending on when the prescription was filled. This was not an issue in this study as we chose a time period which would be outside the delay period. Methadone treatment programs and the Veteran Affairs Hospital are not required to participate in PDMP reporting in Colorado so it's possible some patients may have additional prescribed opioids not identified by our search. The PDMP lists providers by name but not affiliation or address. Therefore, it is possible that prescriptions may appear to have come from different providers when in fact they were from providers working together within the same office or clinic.

Finally, our conclusions are limited by the study design. While we believe that some of the prescription patterns in the months preceding the ED visit are suggestive of drug abuse or misuse, the appropriateness of the opioid prescription written in the ED during the incident visit cannot be determined using this study design.

DISCUSSION

The ED is a common destination for both patients seeking pain relief and those seeking to obtain prescription opioids for nonmedical use. To understand the breadth of the problem we need to first describe the population involved. Recent pharmacy data suggest that greater than 50% of outpatient opioid prescriptions were dispensed to patients who had already received an opioid prescription in the preceding month.[11] However, we found that a majority of patients discharged form the ED with an opioid prescription received ≤ 1 opioid prescription in the preceding 6 months. A small percentage received a large number of prescriptions.

We describe patients in the highest decile of number of prescriptions who averaged greater than 2 prescriptions per month and received prescriptions from an average of 6 providers over the study period. These patients received significantly higher amounts of opioid pain medications than a majority of our ED patients. Our study design does not allow us to determine if these patients were abusing or diverting opioids. It appears that this group was certainly at risk for these costly and dangerous behaviors. A large number of prescriptions from multiple providers has been suggested by the National Institute on Drug Abuse as a marker of prescription drug abuse.[9] If these patient were taking these pain medications as prescribed, they may have been at increased risk of death as recent data has described a strong association between the amount of opioids prescribed and risk of death.[11, 12]

This study should not be interpreted as a call to decrease the number of appropriate opioid prescriptions provided to patients treated in the ED or to be in conflict with recent evidence that ED providers should be more aggressive in their treatment of pain.[8, 13-18] Our ultimate goal is to determine if PDMPs can be used to decrease *inappropriate* prescriptions while maintaining appropriate prescriptions and adequate pain management. This study represents 1 of the initial steps in that process by describing populations involved, specifically the ED population.

Similar PDMP systems are now available in 40 states, while 8 additional states have enacted legislation but are not yet operational.[19] These programs provide objective information regarding a patient's prescription history. It has been recommended that they be used in appropriate pain management, but there is little research on how to interpret this information.[20] A number of states have begun using prescription monitoring program data as an epidemiologic tool. The present study is the first to combine this tool with clinical information to describe the recent prescription history and characteristics of patients receiving prescription opioids from the ED. Our study suggests there is substantial variability in the prescription histories of ED patients. Baehren et al. recently reported PDMP data among 179 ED patients, among which there was similar wide variability of number of recent prescriptions. In that study, clinician's review of PDMP data resulted in a change in prescribing behavior in 41% of cases, resulting in a reduction of or no opioids being prescribed 61% of the time, but an increase in the amount of opioids in 39% of the cases .[21]

While we recognize that prescription history must be considered within the context of other clinical information, we believe that developing a "high risk" prescription profile would help physicians identify patients who have received a large number of opioid prescriptions and who may be at risk for abuse or poor pain management. Patients identified using these methods could be further screened for drug abuse in the ED, undergo a brief intervention, be referred for substance abuse treatment or have their pain management plans modified to improve their quality of care. Furthermore, real-time methods of screening patients for potential drug abuse and diversion need to be explored, including potentially the automatic inclusion of a patient's PDMP data with his or her background medical data when seen for a clinic appointment or admission to the ED.

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Hunger and Food Insecurity among Patients in an Urban Emergency Department

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Introduction: To determine the prevalence of hunger and food insecurity among patients presenting to the emergency department (ED) over 3 consecutive years.

Methods: This was a cross-sectional study of patients presenting to the ED at Hennepin County Medical Center, and urban, Level I trauma center. We prospectively screened adult (age >18) patients presenting to the ED during randomized daily 8-hour periods between June 1 and August 31, 2007 and 2008, and randomized every-other-day periods between June 1 and August 31, 2009. We excluded patients with high acuity complaints, altered mental status, prisoners, those who did not speak Spanish or English, or those considered to be vulnerable. Consenting participants completed a brief demographic survey. The main outcome measures included age, gender, ethnicity, employment, housing status, insurance, access to food, and having to make choices between buying food and buying medicine. All responses were self reported.

Results: 26,211 patients presented during the study; 15,732 (60%) were eligible, 8,044 (51%) were enrolled, and 7,852 (98%) were included in the analysis. The rate of patients reporting hunger significantly increased over the 3-year period [20.3% in 2007, 27.8% in 2008, and 38.3% in 2009 ($p<0.001$)]. The rate of patients reporting ever having to choose between food and medicine also increased [20.0% in 2007, 18.5% in 2008, and 22.6% in 2009 ($p=0.006$)].

Conclusion: A significant proportion of our ED patients experience food insecurity and hunger. Hunger and food insecurity have become more prevalent among patients seen in this urban county ED over the past 3 years. Emergency physicians should be aware of the increasing number of patients who must choose between obtaining food and their prescribed medications, and should consider the contribution of hunger and food insecurity to the development of health conditions for which ED treatment is sought. [West J Emerg Med. 2013;14(3):253–262.]

INTRODUCTION

Over the last 2 decades, public policy and research have increasingly recognized the role of the emergency department (ED) in the care of socially disadvantaged populations.[1-6] As the current economic crisis in the United States (U.S.) threatens to increase the burdens of unemployment, housing instability, food insecurity and hunger among those populations, we may expect greater demands on the institutions that assist them, particularly the ED.[7] For healthcare providers, food insecurity and hunger are perhaps the most clinically significant of these patient experiences. Estimates from the U.S. Census Bureau and Department of Agriculture suggest that nearly 11.0% of all households and 12.1% of all individuals experience hunger and food insecurity annually.[8] More recent data suggest that, in 2008, hunger and food insecurity affected 14.6% of U.S. households overall, 21% of households with children, more than 25% of African Americans and Hispanic households, and 42% of households with incomes below the federal poverty level.[9] The cost of hunger and food insecurity in terms of direct health consequences and indirect social impacts (e.g. work days lost) has been estimated to be approximately $90 billion annually, compared to similar estimates of $79 billion

dollars for obesity, $138 billion for smoking, and $185 billion for alcohol abuse.[10-13]

Several studies from our institution have looked at the impact of hunger in the clinical environment. Nelson et al[14] examined the long-term consequences of hunger for patients with access to primary care. Interviewing both outpatients and hospitalized patients, the authors found that 13% had experienced a day without food in the prior month. Kersey et al[15] found the 1-year prevalence of food insecurity among adult ED patients at our county hospital to be 18%. Among those who felt forced to choose between food and medicine in that study, 14% had chosen food. A subsequent study by Biros et al[16] looked at similar questions among adult patients in our county institution, as well as among the parents of patients at a nearby children's hospital. In that study, 23.7% of enrollees reported hunger or food insecurity in the past year and 17.6% had chosen food over medicine. A significant proportion of those patients also felt that the latter choice had aggravated illness and led to ED visits and hospitalizations. This research has shown that, in addition to the issues of shelter, safety, and access to primary care that bring many patients to the ED, hunger and food insecurity are experienced by a relatively high percentage of patients, forcing many to choose between food and medicine, and likely leading to additional adverse health effects.

These studies suggest that the prevalence and impact of hunger and food insecurity in the acute care setting are clinically significant, and continue to be underestimated, particularly when these experiences are largely intermittent. Research in these areas has been limited primarily by relatively small to moderate sample sizes and non-randomized, convenience sampling methodology. The objective of our current study, therefore, was to reassess with greater accuracy the prevalence of hunger and food insecurity among ED patients. Following government definitions and prior studies, we understand the definition of "hunger" to be not having enough to eat, not eating for an entire day, or not eating because of lack of money to buy food. Similarly, we take "food insecurity" to be a frequent antecedent condition defined as the lack of nutritionally adequate food or the limited ability "to secure acceptable food in socially acceptable ways."[9,17] The goal of our investigation was to determine the rate of hunger among patients seeking care in our ED over 3 consecutive years. We have done so using a randomized sampling methodology that has been previously validated in the ED environment.[18,19] Within our ED population, we also examined housing, employment, and income, and reexamined choices between food and medicine.

METHODS

Study Design and Setting

This was a cross-sectional study conducted in the Hennepin County Medical Center (HCMC) emergency department (ED) in Minneapolis, Minesota. HCMC is an urban Level 1 Trauma Center with approximately 106,000 annual ED visits. HCMC The Human Subjects Research Committee approved the study prior to implementation. We prospectively screened patients presenting to the ED during randomized daily 8-hour data collection shifts between June 1 and August 31, 2007 and 2008, and randomized every-other-day 8-hour shifts between June 1 and August 31, 2009. In 2009 the study was conducted on alternate days from an unrelated survey study. Consenting participants completed a brief demographic survey.

Selection of Participants

All adult (age>18) patients in the ED were eligible for this study. We excluded patients with high acuity complaints per the treating clinician (including sexual assault), prisoners and those in police custody, speakers of languages other than English and Spanish, and patients presenting with altered mental status. Determination of what constituted altered mental status was determined by the treating emergency physician. Among those participants who were subsequently noted to have completed the study more than once, we excluded those whose presentations to the ED were separated by less than 2 weeks to coincide with frequency questions in the survey.

Interventions

A survey was administered to all eligible patients by trained research associates. In order to obtain a representative sample of ED patients, surveys were conducted during one daily randomly assigned 8-hour shift (7AM to 3PM, 3PM to 11PM, or 11PM to 7AM) each day of the study period in 2007 and 2008; in 2009 randomized shifts were included every other day. Patients were approached by trained and clearly identifiable research associates (RAs), who assessed patient eligibility and delivered the survey instrument in a standardized fashion. Administration of the survey occurred while patients were waiting to be seen by a clinician, or were waiting for test results; the survey never interrupted direct patient care. RAs were medical, public health and undergraduate students who were part of the volunteer Emergency Research Associate Program at HCMC. One hundred twenty-five RAs were trained in ascertaining study eligibility, consent processes, survey administration, as well as in answering and clarifying patient questions concerning survey questions. Training of RAs included several group orientation sessions, directed instruction in the completion of the survey, and instructional shifts for applied learning. Eight RAs were present during each study shift to conduct the surveys. After informed consent was obtained, each study participant was read a standard set of instructions, and any quesions about the survey content or process were answered. Participants then anonymously completed the brief survey. Participants had the option to decline to answer any individual question.

Methods of Measurement

Survey questions included age, gender, primary language, access to a primary care provider, self-reported health status, employment, housing status, insurance, access to food, and having to make choices between buying food and buying medicine. All responses were self reported; the anonymous nature of the survey did not allow independent verification of the information provided by participants. Respondents were asked to characterize their ethnic background as White, Asian, African American, Hispanic, Native American, or other. Housing was categorized as "property owner," "renting," "living with friends or relatives," "halfway house/transitional housing" and "homeless." Hunger from food scarcity was queried with the question "how often do you miss a meal or go hungry" and categorized as "never," "yearly," "monthly," "weekly," "2-3 times a week" or "daily.". The question "How often do you need to choose between buying food and buying medicine" was categorized as "never," "yearly," "monthly" and "weekly." Employment was categorized as "Currently employed, including part- time, " "Unemployed" or "Retired," The question of "How would you rate your overall health" was categorized as "Excellent," "Good," "Fair," and "Poor."

Data Collections and Processing

Patient enrollment was monitored centrally by a single RA who maintained an electronic log of all patients in the ED over that screening time period. One of the investigators entered data from completed paper surveys into a Microsoft Excel (Microsoft Corp., 2006) spreadsheet and maintained and electronically backed up on site.

Primary Data Analysis

We analyzed data using Stata 10.0 (Stata Corp., College Station, Texas). Descriptive statistics were used as appropriate. We compared ratios were compared using chi square tests. To compare unstable versus stable housing status and food scarcity versus food security, we performed multinomial logistic regression We included variables hypothesized to be associated with food and housing insecurity.[14-16] These included age, gender, primary language, ethnicity, access to a primary care provider, self-reported health, employment, housing, insurance, and chronic disease status. All results presented in the text are odds ratios with 95% confidence intervals.

In our regression analysis, we treated age as a continuous variable. For the purpose of analysis, we analyzed ethnicity as white (referent) and black and other as comparison groups. Health insurance status was treated as a categorical variable, including "private" (employment or individual, referent group) insurance, "Medicare, Medicaid, or Safety Net" coverage (including county and state programs), "no insurance," and "other" insurance. Housing was treated as a categorical variable, with "property owner" as the referent group and all other responses treated as comparison groups. Hunger from food scarcity was treated as a categorical variable, with "never" as the referent group. "Ever hungry" was defined as patients who reported food scarcity as "never" versus all other groups. We also treated "having to choose between buying food and buying medicine" as a categorical variable, with "never" as the referent group. Responses to "ever having to choose between food and medicine" were analyzed as all groups who reported choosing between buying food and buying medicine versus "never." We also treated employment as a categorical variable, with "currently employed" as the referent category. Self-reported health status was treated as an ordinal variable consisting with "excellent" as the referent

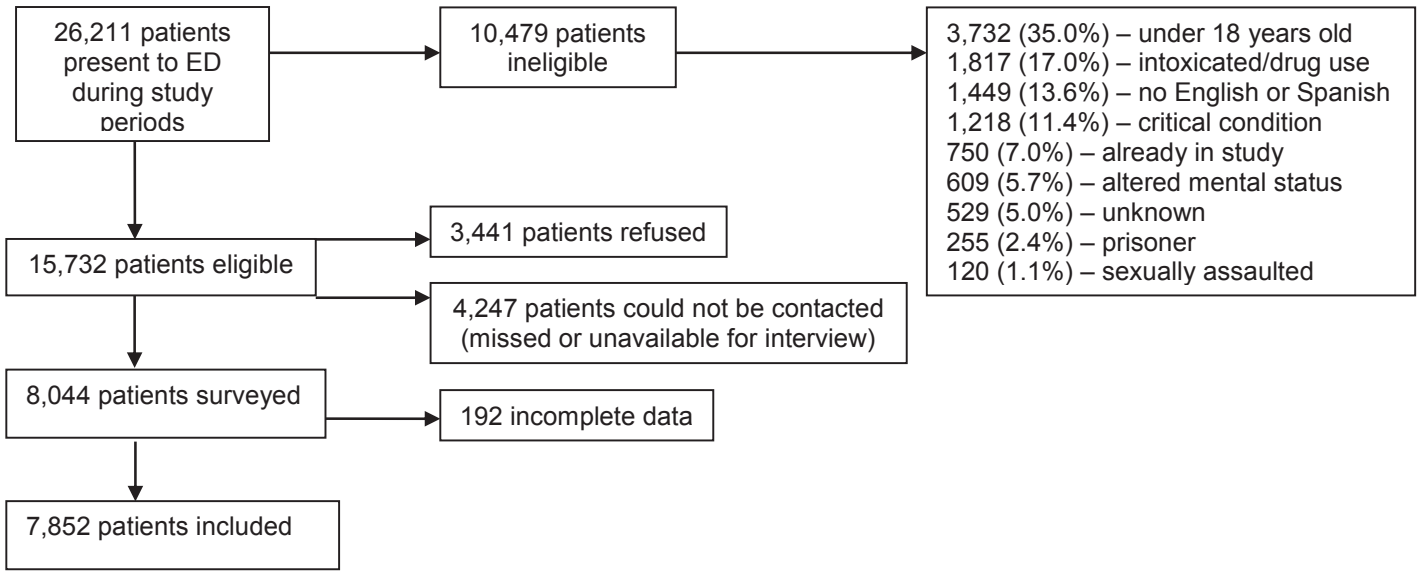

Figure. Emergency department patient flow.

Table 1. Emergency department patient characteristics.

Variable*	2007 n (%) [95% CI]	2008 n (%) [95% CI]	2009 n (%) [95% CI]	Total n (%) [95% CI]
Gender				
Male	1553 (51.8) [50.0, 53.6]	1877 (52.8) [51.1, 54.4]	675 (52.0) [49.2, 45.3]	4105 (52.3) [51.1, 53.4]
Female	1435 (47.9) [46.1, 49.7]	1674 (47.1) [45.4, 48.7]	624 (48.0) [45.3, 50.8]	3733 (47.5) [46.4, 48.6]
Unknown/ unreported	8 (0.3) [0.1, 0.5]	6 (0.2)[0.01, 0.3]	0 (0.0)	14 (0.2) [0.08, 0.03]
Age (median, range)	40 (18-98) [41, 42]	39 (18-93) [39, 40]	39 (18-89) [39-41]	39 (18-98) [40, 41]
Ethnicity				
Asian	48 (1.6) [1.1, 2.1]	36 (1.0) 0.1, 1.34]	20 (1.5) [0.9, 2.2]	104 (1.3) [1.1, 1.6]
Other	112 (3.7) [3.1, 4.4]	148 (4.2) [3.5, 4.8]	94 (7.2) [5.8, 8.6]	354 (4.5) [2.1, 4.7]
Hispanic	179 (6.0) [5.1, 6.8]	197 (5.5) [4.8, 6.3]	59 (4.5) [3.4, 5.7]	435 (5.5) [5.0, 6.0]
Native American	236 (7.9) [6.9, 8.8]	231 (6.5) [5.7, 7.3]	97 (7.5) [6.0, 8.9]	564 (7.1) [6.6, 7.8]
White	1200 (40.1) [38.3, 41.8]	1288 (36.2) [34.6, 37.8]	460 (35.4) [32.8, 38.0]	2948 (38.7) [38.6, 40.8]
African American	1206 (40.3) [38.5, 42.0]	1344 (37.8) [36.2, 39.4]	567 (43.6) [40.9, 46.3]	3117 (39.7) [37.2, 46.0]
Unknown/ unreported	15 (0.5) [0.2, 0.7]	313 (8.8) [7.9, 9.7]	2 (0.2) [-.06, 0.4]	330 (4.2) [3.8, 4.6]
Overall Health				
Poor	375 (12.5) [11.3, 13.7]	566 (15.9) [14.7, 17.1]	167 (12.9) [11.0, 14.7]	1108 (14.1) [13.3, 14.9]
Fair	856 (28.6) [27.0, 30.2]	1590 (44.7) [43.1, 46.3]	405 (31.2) [28.7, 33.7]	2851 (36.3) [35.2, 37.4]
Good	1357 (45.3) [43.5, 47.1]	1006 (28.3) [26.8, 29.8]	530 (40.8) [38.1, 43.5]	2893 (36.8) [35.8, 37.9]
Excellent	406 (13.6) [12.3, 14.8]	360 (10.1) [3.1, 11.1]	174 (13.4) [11.5, 15.2]	940 (12.0) [11.3, 12.7]
Unknown/ unreported	2 (0.1) [-0.03, 0.2]	35 (1.0) [0.06, 1.3]	23 (1.8) [1.1, 2.5]	60 (0.8) [0.6, 1.0]
Chronic Illness?				
Yes	1142 (38.1) [36.4, 39.9]	1497 (42.1) [40.5, 43.7]	532 (41.0) [38.3, 43.6]	3171 (40.4) [39.3, 41.5]
No	1845 (61.6) [59.8, 63.3]	2057 (57.8) [56.2, 59.5]	762 (58.7) [56.0, 61.3]	4664 (59.4) [58.3, 60.5]
Unknown/ unreported	9 (0.3) [0.1, 0.5]	3 (0.1) [-0.01, 0.2]	5 (0.4) [0.05, 0.7]	17 (0.2) [0.1, 0.3]
Employed**				
Yes	1334 (44.5) [42.7, 46.3]	1725 (48.5) [46.9, 50.1]	499 (38.4) [35.8, 41.1]	3558 (45.3) [44.2, 46.4]
No	1656 (55.3) [53.5, 57.1]	1827 (51.4) [49.7, 53.0]	798 (61.4) [58.8, 64.1]	4281 (54.5) [53.4, 55.6]
Unknown/ unreported	6 (0.2) [0.004, 0.4]	5 (0.1) [0.02, 0.3]	2 (0.2) [-0.06, 0.37]	13 (0.2) [0.008, 0.03]
Family Income				
< $5,000	546 (18.2) [16.8, 19.6]	553 (15.5) [14.4, 16.7]	262 (20.2) [18.0, 22.4]	1361 (17.3) [16.5, 18.2]
$5,000 - $24,999	865 (28.9) [27.2, 30.5]	1358 (38.2) [36.6, 39.8]	368 (28.3) [25.9, 30.8]	2591 (33.0) [32.0, 34.0]
$25,000 - $49,999	594 (19.8) [18.4, 21.3]	530 (14.9) [13.7, 16.1]	212 (16.3) [14.3, 18.3]	1336 (17.0) [16.2, 17.8]
$50,000 - $74,999	195 (6.5) [5.6, 7.4]	155 (4.4) [3.7, 5.0]	91 (7.0) [5.6, 8.4]	441 (5.6) [5.1, 6.1]
$75,000 - $99,999	765 (25.5) [24.1, 27.2]	229 (6.4) [5.6, 7.2]	22 (1.7) [1.0, 2.4]	1016 (12.9) [12.2, 13.7]
> $100,000	0 (0.0)	0 (0.0)	48 (3.7) [2.7, 4.7]	48 (0.6) [0.4, 0.8]
Unknown/ unreported	31 (1.0) [0.06, 1.3]	732 (20.6) [19.2, 21.9]	296 (22.8) [20.5, 25.1]	1059 (13.5) [12.7, 14.2]
Living Status				
Homeless	152 (5.1) [4.3, 5.9]	211 (5.9) [5.2, 6.7]	100 (7.7) [6.2, 9.1]	463 (5.9) [5.4, 6.4]
Halfway house***	149 (5.0) [4.2, 5.8]	142 (4.0) [3.3, 4.6]	57 (4.4) [3.3, 5.5]	348 (4.4) [4.0, 4.9]
Friends/ relatives	481 (16.1) [14.7, 17.4]	586 (16.5) [15.3, 17.7]	234 (18.0) [15.9, 20.1]	1301 (16.6) [15.7, 17.4]
Renting	1636 (54.6) [52.8, 56.4]	1879 (52.8) [51.1, 54.4]	722 (55.6) [52.9, 58.3]	4237 (54.0) [52.8, 55.0]
Property owner	511 (17.1) [15.7, 18.4]	535 (15.0) [13.9, 16.2]	147 (11.3) [9.6, 13.0]	1193 (15.2) [14.4, 16.0]
Unknown/ unreported	67 (2.2) [1.7, 2.8]	204 (5.7) [5.0, 6.6]	39 (3.0) [2.1, 3.9]	310 (3.9) [3.6, 4.4]
Insurance				
None	709 (23.7) [22.1, 25.2]	747 (21.0) [19.7, 22.3]	256 (19.7) [17.5, 21.0]	1712 (21.8) [20.9, 22.7]
Private	779 (26.0) [24.4, 27.6]	876 (24.6) [23.2, 26.0]	347 (26.7) [24.3, 29.1]	2002 (25.5) [24.5, 26.5]
Medicare/ Medicaid/ Safety	1211 (40.4) [38.7, 42.2]	1375 (38.7) [37.1, 40.3]	599 (46.1) [43.4, 48.8]	3185 (40.6) [39.5, 41.6]
Other	277 (9.2) [8.2, 10.3]	465 (13.1) [12.0, 14.2]	60 (4.6) [3.5, 5.8]	802 (10.2) [9.5, 10.9]
Unknown/ unreported	20 (0.7) [0.4, 1.0]	94 (2.6) [2.1, 3.2]	37 (2.8) [1.9, 3.8]	151 (1.9) [1.6, 2.2]
Primary clinical provider?				
Yes	1735 (57.9) [56.1, 59.7]	2096 (58.9) 57.3, 60.5]	756 (58.2) [55.5, 60.9]	4587 (58.4) [57.3, 59.5]
No	1244 (41.5) [39.8, 43.3]	1450 (40.8) [39.1, 42.4]	534 (41.1) [38.4, 43.8]	3228 (41.1) [40.0, 42.2]
Unknown/ unreported	17 (0.6) [0.3, 0.9]	11 (0.3) [0.1, 0.5]	9 (0.7) [0.2, 1.1]	37 (0.5) [0.3, 0.6]

CI, confidence interval
*all responses are self reported by study participants and not independently verified
**current employment includes any full or part time job
***includes transitional housing

Table 2. Food insecurity of patients in the emergency department.

		2007 n (%) [95% CI]	2008 n (%) [95% CI]	2009 n (%) [95% CI]	Overall n (%) [95% CI]
Total patients		2996 (38.2)	3557 (45.3)	1299 (16.5)	7852 (100)
Ever hungry		608 (20.4) [18.9, 21.8]	990 (28.8) [27.3, 30.0]	498 (39.2) [36.6, 41.9]	2096 (27.2) [26.2, 28.2]
Food scarcity	Daily	116 (3.9) [3.2, 4.6]	264 (7.4) [6.6, 8.3]	155 (11.9) [10.2, 13.7]	535 (6.8) [6.3, 7.4]
	2-3 times per week	130 (4.3) [3.6, 5.1]	255 (7.2) [6.3, 8.0]	138 (10.6) [8.9, 12.3]	523 (6.7) [6.1, 7.2]
	Weekly	90 (3.0) [2.4, 3.6]	153 (4.3) [3.6, 5.0]	82 (6.3) [5.0, 7.6]	325 (4.1) [3.7, 4.6]
	Monthly	135 (4.5) [3.8, 5.2]	161 (4.5) [3.8, 5.2]	63 (4.8) [3.7, 6.0]	359 (4.6) [4.1, 5.0]
	Yearly	137 (4.6) [3.8, 5.3]	157 (4.4) [3.7, 5.1]	60 (4.6) [3.5, 5.8]	354 (4.5) [4.0, 5.0]
	Never	2379 (79.4) [78.0, 80.9]	2449 (68.9) [67.3, 70.4]	771 (59.4) [56.7, 62.0]	5599 (71.3) [70.3, 72.3]
	Non-respondents	9 (0.3) [0.1, 0.5]	118 (3.3) [2.7, 3.9]	30 (2.3) [1.5, 3.1]	157 (2.0) [1.7, 2.3]
Ever had to choose between food and medicine		597 (20.0) [18.6, 21.4]	634 (18.4) [17.1, 19.7]	281 (22.6) [20.3, 24.9]	1512 (19.7) [18.8, 20.6]
Choose between buying food and buying medicine frequency	Weekly	158 (5.3) [4.5, 6.1]	166 (4.7) [4.0, 5.4]	87 (6.7) [5.3, 8.1]	411 (5.2) [4.7, 5.7]
	Monthly	202 (6.7) [5.8, 7.6]	199 (5.6) [4.8, 6.4]	92 (7.1) [5.7, 8.5]	493 (6.3) [5.7, 6.8]
	Yearly	237 (7.9) [6.9, 8.9]	269 (7.6) [6.7, 8.4]	102 (7.9) [6.4, 9.3]	608 (7.7) [7.2, 8.3]
	Never	2390 (79.8) [78.3, 81.2]	2805 (78.9) [7.8, 8.0]	988 (76.1) [73.7, 78.4]	6183 (78.7) [77.8, 79.6]
	Non-respondents	9 (0.3) [0.1, 0.5]	118 (3.3) [2.7, 3.9]	30 (2.3) [1.5, 3.1]	157 (2.0) [1.7, 2.3]

CI, confidence interval
*n (%)

Table 3. Housing status of patients in the emergency department.

		2007 n (%) [95% CI]	2008 n (%) [95% CI]	2009 n (%) [95% CI]	Overall n (%) [95% CI]
	Total patients	2996 (38.2)	3557 (45.3)	1299 (16.5)	7852 (100)
Living status	Homeless	152 (5.1) [4.3, 5.9]	211 (5.9) [5.2, 6.7]	100 (7.7) [6.2, 9.1]	463 (5.9) [5.4, 6.4]
	Halfway house/ Group home	149 (5.0) [4.2, 5.8]	142 (4.0) [3.3, 4.6]	57 (4.4) [3.3, 5.5]	348 (4.4) [4.0, 4.9]
	Living with friends/ Relatives	481 (16.1) [14.7, 17.4]	586 (16.5) [15.3, 17.7]	234 (18.0) [16.0, 20.1]	1301 (16.6) [15.7, 17.4]
	Renting	1636 (54.6) [52.8, 56.4]	1876 (52.7) [51.1, 54.4]	722 (55.6) [52.9, 58.3]	4234 (53.9) [52.8, 55.0]
	Property owner	511 (17.1) [15.7, 18.4]	535 (15.0) [13.9, 16.2]	147 (11.3) [9.6, 13.0]	1193 (15.2) [14.4, 16.0]
	Non-respondents	67 (2.2) [1.7, 2.8]	207 (5.8) [5.0, 6.6]	39 (3.0) [2.1, 3.9]	313 (4.0) [3.6, 4.4]
	Unstable living situation	633 (21.3) [19.8, 22.8]	797 (23.4) [22.0, 24.8]	334 (26.5) [24.0, 28.9]	1764 (23.1) [22.1, 24.0]

CI, confidence interval

group. We treated gender, non-English first language, living with chronic disease, and access to regular primary care were treated as binary variables. We used private insurance, home ownership and report of current employment as referent groups in our regression model. The covariance matrix derived from our regression model was used to determine intervariable correlation.

RESULTS

During the study 26,211 patients presented; 15,732 (60%) were eligible. We enrolled 8,044 (51%) and included 7,852 (98%) in the analysis (Figure). The characteristics of the study patients are presented in Table 1. The patient report of food scarcity and choosing between buying food and buying medicine are summarized in Table 2. The rate of patients reporting any hunger significantly increased over the 3-year period (20.3% in 2007, 27.8% in 2008, and 38.3% in 2009 [p<0.001]). The rate of patients reported ever having to chose between food and medicine also increased (20.0% in 2007, 18.5% in 2008, and 22.6% in 2009 [p=0.006]).

Table 3 summarizes living situations reported by study patients. The rate of patients reporting an unstable living situation significantly increased over the 3-year study period. (21.3% in 2007, 23.4% in 2008, and 26.5% in 2009 [p=0.001]). The characteristics of patients who described any hunger are compared to patients who did not describe hunger in Table 4. In addition to the socioeconomic status of the patient (i.e. employment, ethnicty, living situation), the

self-report of chronic illness also was related to the presence or absence of hunger. The characteristics of patients who had to choose between food and medicine are described in Table 5. In addition to socioeconomic characteristics that predicted the need to choose between food and medicine, those who had to choose were more often hungry. Odds ratios from the logistic regression model that predicts patient characteristics associated with hunger are described in Table 6.

LIMITATIONS

This study has several limitations. First, it was carried out in the ED of a single institution and describes the self-reported data of participating patients. Because our institution is a safety-net hospital, this study may overestimate the ED prevalence of socioeconomic stressors such as hunger and housing insecurity. Self-reporting may also limit our data, but would seem to be an inherent element of population research into food insecurity. It may also correlate with actual nutritional intake.[20-22] While this study benefitted from randomization, it was carried out during summer months, which in our state and climate may represent a low period of visits to the ED by socially disadvantaged patients, particularly those experiencing food or housing insecurity. The study was also conducted primarily in English, although participants could choose to participate regardless of primary language. Given that other studies have noted a higher prevalence of hunger among non-English speaking populations, our data may have underestimated that prevalence to some degree by excluding many non-English speakers, a not-insignificant subset of patients in our ED.[23] However, by including Spanish-speaking patients who desired to participate, we may have mitigated that effect, addressing a patient population previously shown to have the highest prevalence of food insecurity and hunger.[24,25] In addition, children were excluded from our sample population, although the effects of hunger on adults can be assumed to impact other family members as well. A significant number of patients who presented during the study were either missed or not available to be interviewed for the study. In addition, a large number of patients were critically ill and unable to provide consent or complete the survey. The study enrolled 30.7% of all patients who presented to the ED during the study periods, and we do not know the status of the patients who were not enrolled. Our goal was to study prevalence of hunger in the ED, but we have found the prevalence of hunger among patients presenting to the ED in stable condition and consenting to do a survey, which limits the generalizability of our findings. Furthermore, of interviewed subjects, there was a larger proportion of missing data from subjects in 2008 than in the other 2 years of the study. We do not know why there was more missing data in 2008, but the missing information may have changed the findings of our study. However, we do not believe that the higher proportion of missing data in 2008 greatly influenced the results of the study, as the results from 2008 are similar to those of the previous and latter years.

Table 4. Demographics by hunger status.

Variable	Ever hungry n (%)	Not ever hungry n(%)	p-value
Year			< 0.001
2007	608 (20.3)	2379 (79.7)	
2008	990 (28.8)	2449 (71.2)	
2009	498 (39.2)	771 (60.8)	
Gender			0.0002
Male	1169 (32.1)	2856 (67.9)	
Female	925 (25.5)	2731 (74.5)	
Unknown/ unreported	2 (14.3)	12 (85.7)	
Age, median (range)	40 (18-86)	39 (19-98)	0.0043
Ethnicity			< 0.001
White	683 (23.6)	2216 (76.4)	
African American	883 (29.0)	2163 (71.0)	
Other	450 (31.4)	983 (68.6)	
Unknown/ unreported	80 (25.2)	237 (74.8)	
Overall health			0.1582
Poor	312 (28.5)	781 (71.5)	
Fair	781 (27.9)	2014 (72.1)	
Good	728 (25.7)	2110 (74.3)	
Excellent	251 (27.3)	668 (72.7)	
Unknown/ unreported	24 (48.0)	26 (52.0)	
Chronic illness?			< 0.001
Yes	1006 (32.5)	2089 (67.5)	
No	1088 (23.7)	3498 (76.3)	
Unknown/ unreported	2 (14.3)	12 (85.7)	
Employed			< 0.001
Yes	715 (20.5)	2779 (79.5)	
No	1378 (32.9)	2813 (67.1)	
Unknown/ unreported	3 (30.0)	7 (70.0)	
Family income			< 0.001
< $5,000	496 (36.8)	853 (63.2)	
$5,000 - $24,999	803 (31.1)	1783 (68.9)	
$25,000 - $49,999	270 (20.3)	1063 (79.7)	
$50,000 - $74,999	60 (13.6)	380 (86.4)	
$75,000 - $99,999	177 (17.4)	842 (82.6)	
> $100,000	9 (18.8)	39 (81.3)	
Unknown/ unreported	281 (30.5)	639 (69.5)	
# of people in family (mean, SD)?	3.2 (3.2)	3.2 (3.7)	0.6779
Food/Medicine?			< 0.001
Yes	875 (58.3)	632 (41.7)	
No	1209 (19.7)	4936 (80.3)	
Unknown/ unreported	12 (27.9)	31 (72.1)	
Living status			< 0.001
Homeless	289 (62.6)	173 (37.4)	
Halfway house	115 (33.3)	230 (66.7)	
Friends/ relatives	389 (30.3)	896 (69.7)	
Renting	1064 (25.2)	3154 (74.8)	
Property owner	182 (15.3)	1006 (84.7)	
Unknown/ unreported	57 (28.9)	140 (71.1)	
Insurance			< 0.001
None	487 (28.9)	1195 (71.1)	
Private	381 (19.4)	1583 (80.6)	
Medicare/ Medicaid/ Safety	957 (30.7)	2165 (69.3)	
Other	236 (29.8)	556 (70.2)	
Unknown/ unreported	35 (25.9)	100 (74.1)	
Primary care provider?			0.0013
Yes	1167 (25.9)	3337 (74.1)	
No	926 (29.2)	2241 (70.8)	
Unknown/ unreported	3 (12.5)	21 (87.5)	

Table 5. Demographics by choosing between food and medicine status.

Variable	Had to choose between buying food and buying medicine, n (%)	Did not have to choose between buying food and buying medicine, n (%)	p-value
Year			0.0059
2007	597 (20.0)	2390 (80.0)	
2008	634 (18.4)	2805 (81.6)	
2009	281 (22.6)	962 (77.4)	
Gender			0.1330
Male	765 (19.1)	3243 (80.9)	
Female	746 (20.5)	2901 (79.5)	
Unknown/ unreported	1 (7.1)	13 (92.9)	
Age, median (range)	42 (18-83)	38 (18-98)	< 0.001
Ethnicity			< 0.001
White	433 (15.0)	2458 (85.0)	
African American	708 (23.3)	2326 (76.7)	
Other	319 (22.4)	1108 (77.6)	
Unknown/ unreported	52 (16.4)	265 (83.6)	
Overall health			0.1537
Poor	243 (22.3)	850 (77.7)	
Fair	533 (19.2)	2249 (80.8)	
Good	545 (19.3)	2282 (80.7)	
Excellent	181 (19.8)	735 (80.2)	
Unknown/ unreported	10 (19.6)	41 (80.4)	
Chronic illness?			< 0.001
Yes	882 (28.6)	2202 (71.4)	
No	627 (13.7)	3944 (86.3)	
Unknown/ unreported	3 (21.4)	11 (78.6)	
Employed			< 0.001
Yes	503 (14.4)	2981 (85.6)	
No	1007 (24.1)	3168 (75.9)	
Unknown/ unreported	2 (0.2)	8 (0.8)	
Family income			< 0.001
< $5,000	342 (25.5)	1001 (74.5)	
$5,000 - $24,999	609 (23.6)	1967 (76.4)	
$25,000 - $49,999	201 (15.2)	1124 (84.8)	
$50,000 - $74,999	45 (10.2)	395 (89.8)	
$75,000 - $99,999	138 (13.5)	881 (86.5)	
> $100,000	2 (4.3)	45 (95.7)	
Unknown/ unreported	175 (19.0)	744 (81.0)	
# of people in family (mean, SD)?	3.3 (4.2)	3.2 (3.4)	0.4526
Ever hungry?			< 0.001
Yes	875 (42.0)	1209 (58.0)	
No	632 (11.4)	4936 (88.6)	
Unknown/ unreported	5 (29.4)	12 (70.6)	
Living status			< 0.001
Homeless	171 (37.1)	289 (62.8)	
Halfway house	90 (26.1)	255 (73.9)	
Friends/ relatives	284 (22.2)	995 (77.8)	
Renting	828 (19.7)	3372 (80.3)	
Property owner	105 (8.8)	1084 (91.2)	
Unknown/ unreported	34 (17.3)	162 (82.7)	
Insurance			< 0.001
None	395 (23.6)	1277 (76.4)	
Private	231 (11.8)	1728 (88.2)	
Medicare/ Medicaid/ Safety	717 (23.0)	2396 (77.0)	
Other	145 (18.3)	647 (81.7)	
Unknown/ unreported	24 (18.0)	109 (82.0)	
Primary care provider?			0.1998
Yes	909 (20.2)	3588 (79.8)	
No	599 (19.0)	2549 (81.0)	
Unknown/ unreported	4 (16.7)	20 (83.3)	

SD, standard deviation

DISCUSSION

This study sought to assess the prevalence of hunger and food insecurity in the ED of a busy urban, public hospital. Using a more systematic and randomized sampling methodology, our results confirmed the high prevalence of hunger and food insecurity suggested by previous studies in our institution. We found an even higher prevalence of hunger than prior studies, one that exceeds the national average. In addition, collected over 3 years, the results suggest that the prevalence of hunger and food insecurity, as well as other indicators of socioeconomic disadvantage, may be increasing among our ED population. The increase in hunger and food insecurity was paralleled by an increasing prevalence of housing instability over the same time period. Similarly, there was no observed change in the proportion of patients who reported having medical insurance, having a primary care provider, and being employed.

Hunger was associated with employment status, family income, having to choose between food and medicine, and housing status in the current study. Hunger was not associated with having a primary care provider, number of people in a family, a patient's perception of his or her health, or ethnicity. These results have some construct validity and are not unexpected since tenuous employment status, for example, could be reasonably expected to impact hunger. It is concerning, however, that this study suggests a trend toward increasing hunger and food insecurity contextualized in a national economic downturn. The results suggest that this trend might be expected to continue to worsen, and thus that its burden on emergency providers and the patients they treat may increase. Of note, the percent change of unemployment in Hennepin County from 2007-2008 (19.5%) was higher than all but 14 of 87 Minnesota counties, and from 2008-2009, the percent change (55.1%) was higher than all but 12 Minnesota counties.[62] Only 11 of 87 Minnesota counties fared worse than Hennepin County with respect to the change in total collected sales and use tax revenues (-6.48%) from 2008 to 2009. Only 8 of 87 Minnesota counties fared worse than Hennepin County with respect to change in total taxable sales (-9.29%) over the same time period.[63]

Over the last decade, multiple studies have shown the adverse impact of hunger and food insecurity on physical and mental health outcomes. Among children, hunger and food insecurity are associated with increases in multiple nutritional deficiencies, anemia, viral syndromes, and ear infections.[26-36] In children and adults alike, hunger and food insecurity are associated with headaches, stomach aches, viral syndromes, and significant mental health problems including learning disabilities, anxiety, depression, suicidality, and psychosocial dysfunction.[37-45] Among adults, hunger and food insecurity are associated with increased adult obesity, hypertension, cardiovascular disease, diabetes, and higher mortality, lower viral suppression, lower antiviral therapy adherence and lower likelihood of receiving treatment among patients with human immunodeficiency virus or acquired immunodeficiency syndrome.[46-69] For adults

Table 6. Logistic model-characteristics associated with hunger.

Variable	Crude odds ratio (95% CI)	p-value	Adjusted odds ratio (95% CI)	p-value
Year (ref: 2007)				
2009	2.53 (2.19, 2.92)	< 0.001	2.75 (2.28, 3.32)	< 0.001
2008	1.58 (1.41, 1.78)	< 0.001	1.65 (1.43, 1.91)	< 0.001
Gender (ref: female)				
Male	1.21 (1.09, 1.34)	0.0002	1.26 (1.11, 1.44)	0.001
Age (continuous)	0.996 (0.992, 0.999)	0.0084	0.99 (0.99, 1.0)	0.001
Ethnicity (ref: White)				
Black	1.32 (1.18, 1.49)	< 0.001	0.99 (0.86, 1.15)	0.933
Other	1.41 (1.23, 1.61)	< 0.001	1.13 (0.95, 1.33)	0.177
Overall health (ref: excellent)				
Poor	1.06 (0.87, 1.29)	0.539	1.00 (0.78, 1.28)	0.990
Fair	1.03 (0.87, 1.22)	0.711	1.05 (0.85, 1.30)	0.666
Good	0.92 (0.78, 1.09)	0.319	0.97 (0.79, 1.20)	0.813
Chronic illness? (ref: no)				0.140
Yes	1.55 (1.40, 1.71)	< 0.001	1.11 (0.97, 1.27)	
Employed (ref: yes)				< 0.001
No	1.90 (1.72, 2.11)	< 0.001	1.38 (1.20, 1.60)	
Family income (ref: >$100,000)				
<$5,000	2.52 (1.21, 5.25)	0.013	1.71 (0.77, 3.75)	0.185
$5,000 - $24,999	1.95 (0.94, 4.05)	0.072	1.70 (0.78, 3.72)	0.184
$25,000 - $49,999	1.10 (0.53, 2.30)	0.799	1.22 (0.55, 2.67)	0.625
$50,000 - $74,999	0.684 (0.32, 1.48)	0.337	0.91 (0.40, 2.07)	0.825
$75,000 - $99,999	0.91 (0.43, 1.91)	0.806	1.23 (0.56, 2.74)	0.605
# of People in family (continuous)	1.003 (0.989, 1.017)	0.6958	0.99 (0.97, 1.01)	0.316
Food/ medicine? (ref: No)				
Yes	5.65 (5.01, 6.37)	< 0.001	5.36 (4.64, 6.19)	< 0.001
Living status (ref: property owner)				
Homeless	9.23 (7.22, 11.8)	< 0.001	4.50 (3.27, 6.19)	< 0.001
Halfway house	2.76 (2.10, 3.64)	< 0.001	1.40 (1.00, 1.97)	0.050
Friends/ relatives	2.40 (1.97, 2.92)	< 0.001	1.29 (1.00, 1.67)	0.047
Renting	1.87 (1.57, 2.22)	< 0.001	1.19 (0.96, 1.47)	0.115
Insurance (ref: yes)				
No	1.12 (0.99, 1.26)	0.0760	1.02 (0.88, 1.20)	0.732
Primary care provider (ref: yes)				
No	1.18 (1.07, 1.31)	0.0013	1.09 (0.95, 1.26)	0.200

CI, confidence interval

and particularly elders, the experience of food insecurity or hunger is also associated with more activity-limiting health impairments, more hospitalizations and longer inpatient stays, as well as poorer overall health status as both subjectively or objectively reported.[49,56-61] Data from our institution have shown that a significant number of those patients who report having chosen between food and medications indicate that this choice has led to ED visits or hospitalizations.[15,16]

In our study, a high percentage of patients reported having to choose between buying food or medicine over the 3 years of the study. The number of patients describing themselves as being in "poor health" also increased, as did the number of patients who reported a chronic illness. While the growing prevalence of hunger among our ED patients is alarming, of most concern is the patient population that needs medications to maintain their health but cannot afford both medication and the food they need to survive. Identification of this most vulnerable group among all who are hungry might allow social resources to be focused on preventing medical decline in those who are forced to choose between food and medicine.

The studies above demonstrate the clinical importance of socioeconomic stressors such as hunger and food insecurity, particularly among ED patient populations. They suggest that clinicians should consider the contribution of hunger and food insecurity to the development of health conditions for which ED treatment is sought. Because of these results and the increasing role of the ED in the care of socially disadvantaged populations, public health officials and policy makers should consider coordinating with or directing resources to EDs to maximize surveillance and intervention efforts regarding food insecurity. These results add further support for attendance to social as well as medical needs of ED patients.

CONCLUSION

In summary, a large number of our urban ED patients experience food insecurity and hunger among other factors of socioeconomic hardship. Unfortunately, hunger, food insecurity, and unstable housing have become more prevalent among patients seen in this urban county ED over the past 3 years. The data presented here represent a large study that supports previous, smaller studies suggesting that hunger and food insecurity are common in the ED. Emergency physicians should be aware of the increasing number of patients who must choose between obtaining food and their prescribed medications, and should consider the contribution of hunger and food insecurity to the development of health conditions for which ED treatment is sought.

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Evaluation of California's Alcohol and Drug Screening and Brief Intervention Project for Emergency Department Patients

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Introduction: Visits to settings such as emergency departments (EDs) may present a "teachable moment" in that a patient may be more open to feedback and suggestions regarding their risky alcohol and illicit drug-use behaviors. Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an 'opportunistic' public health approach that targets low-risk users, in addition to those already dependent on alcohol and/or drugs. SBIRT programs provide patients with comprehensive screening and assessments, and deliver interventions of appropriate intensity to reduce risks related to alcohol and drug use.

Methods: This study used a single group pre-post test design to assess the effect of the California SBIRT service program (i.e., CASBIRT) on 6 substance-use outcomes (past-month prevalence and number of days of binge drinking, illegal drug use, and marijuana use). Trained bilingual/bicultural Health Educators attempted to screen all adult patients in 12 EDs/trauma centers (regardless of the reason for the patient's visit) using a short instrument, and then delivered a brief motivational intervention matched to the patient's risk level. A total of 2,436 randomly selected patients who screened positive for alcohol and/or drug use consented to be in a 6-month telephone follow-up interview. Because of the high loss to follow-up rate, we used an intention-to-treat approach for the data analysis.

Results: Results of generalized linear mixed models showed modest reductions in all 6 drug- and alcohol-use outcomes. Men (versus women), those at relatively higher risk status (versus lower risk), and those with only one substance of misuse (versus both alcohol and illicit drug misuse) tended to show more positive change.

Conclusion: These results suggest that SBIRT services provided in acute care settings are associated with modest changes in self-reported recent alcohol and illicit drug use.
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INTRODUCTION

Alcohol and drug misuse in the United States are major public health problems that degrade the physical and psychological well-being of individuals, families, and communities.[1-2] In recent years, the need for improved alcohol and drug use behavioral risk reduction strategies has led to the rise in popularity of brief interventions (BI), time-limited, structured, goal-oriented interventions that typically last 30

minutes or less.[3] In 2003, the Center for Substance Abuse Treatment (CSAT), within the Substance Abuse and Mental Health Services Administration (SAMHSA), began federal funding of Screening, Brief Intervention, and Referral to Treatment (SBIRT) demonstration programs. Unlike primary prevention that targets non or low-risk users, or treatment services for people already dependent, SBIRT provides early intervention services targeted at individuals who misuse alcohol or illicit drugs, but who may have not yet developed dependence.[4]

Although individual program frameworks vary, all SBIRT programs share 2 key components: screening and intervention. Individuals who screen positive for alcohol or drug problems are provided with an appropriate educational or therapeutic service. Most of those screening "positive" are categorized as relatively low risk and receive a BI, consisting of a time-limited motivational interview done in the ED that focuses on increasing patient awareness of the risks of substance abuse, feedback on normative use and safe limits, and eliciting motivation to change.[3] Individuals at moderate to severe risk are provided brief intervention plus brief treatment (e.g., 6 face-to-face counseling sessions) or Referral to Specialty Treatment for more intensive support.[3]

Studies have suggested SBIRT's effectiveness in emergency department (ED) patients.[5-11] The ED visit may present a "teachable moment" in which a patient may be more open to feedback and suggestions regarding their risky health-related behaviors. Despite the proliferation of BIs in EDs, a recent meta-analysis suggested that benefits from such services are not necessarily due to the BI itself, and that the benefits may be short-lived.[12] Studies have also identified substantial challenges with methodology and feasibility in such settings.[13] Further research is needed to determine the true effectiveness of BI in acute medical care settings.

The purpose of this evaluation study was to examine substance use outcomes of Southern California's large SBIRT service program, known as CASBIRT, which was conducted with a large convenience sample of ED/trauma patients in 12 acute care settings. Although it was expected that CASBIRT would exhibit levels of effectiveness similar to other SBIRT programs (particularly with regard to alcohol use), we believed it possible that some outcomes would be unique due to the socio-demographic characteristics of the residents of San Diego County, which includes a large Latino population. In addition, because data were collected in a border region with relatively high drug trafficking activity, it was possible that results would differ from other regions in the United States.

METHODS

Screening and Intervention Procedures

The California SBIRT program, CASBIRT, provided services from June, 2007 through July, 2010, and screened close to 120,000 patients in 12 San Diego County hospital EDs and trauma centers as part of routine care. A private area, usually the room in which the patient was waiting to receive care, was used to conduct the screening interviews. Screenings were conducted by trained Health Educators (HEs) at various times during the patient visits, and were frequently interrupted for medical care and resumed later in the visit. HEs attempted to screen all adult patients (18 years of age and older), regardless of the reason for their ED visit, with the exception of patients with severe illness/injury, acutely intoxicated patients, and patients who were not competent or capable to give consent. Patient participation was voluntary and permission (but not informed consent) to be screened was obtained prior to screening. HEs explicitly stated to the patient that the questions were asked of all patients for purposes of providing the medical team with comprehensive information about patient health status in order to improve overall quality of care. Typically, the screening process took about 10 minutes, although for higher risk patients, the process could take up to 30 minutes.

HEs screened patients using the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST), a 9-item instrument designed for the World Health Organization (WHO) in 1997 as a valid and brief method of screening for substance use in medical care settings.[14] The severity, or risk level of the patient's alcohol use and illicit drug use was derived from ASSIST items assessing past 3-month use of alcohol and eight individual illicit drugs (i.e., cocaine, cannabis, opioids, hallucinogens, amphetamine type stimulants, sedatives, inhalants, and an option for an "other" drug). We applied cut points, based on those of the developers but modified for our local ED population, were applied to raw severity scores to categorize patients into 1 of 4 risk categories for alcohol and each illicit drug.[15] For alcohol use, patients were categorized as Low-risk (scores of 0–6), *At-risk* (scores of 7–19), High-risk (scores of 20–26), or Severe-risk (scores of 27 and over). For use of each of the eight illicit drugs, patients were categorized as Low-risk (scores of 0–1), *At-risk* (scores of 2–18), High-risk (scores of 19–26), or Severe-risk (scores of 27 and over). For each patient, the *highest* of the 8 ASSIST drug risk levels was used as an *overall* measure of drug use risk. Risk level cut points for alcohol were different than the cut points for illicit drugs because some alcohol use is considered within safe, while any use of illicit drugs is considered a problem.

Low-risk patients for both alcohol and drugs were congratulated for their status and encouraged to continue practicing healthy behaviors. Patients in the other risk categories were offered services that corresponded to the severity of their risk level: all patients received a minimum of a brief intervention (BI); high risk patients were offered an opportunity to participate in up to 6 sessions with a brief treatment counselor in person or over the phone; and severe risk patients were offered Referral to Specialty inpatient or outpatient Treatment. If a patient fell into different risk

categories for alcohol and drug use, the service delivered was tailored to the individual's highest level of risk. If a patient declined a more intensive level of intervention, he or she was offered a lower intensity level of service.

CASBIRT's Brief Intervention

Core elements of the BI included focus on increasing patient awareness of the risks of their misuse, feedback on normative use and safe limits, and eliciting motivation to change.[3] The HE began by positively reinforcing healthy behavior, such as drinking within recommended limits or abstaining from illicit drug use. Depending on the severity of their substance misuse, HEs encouraged patients to reduce to the recommended drinking limits and to abstain from drug use while also detailing risks associated with heavy alcohol and/or drug use (e.g., long and short term health risks, financial, social, and legal problems). These interventions utilized motivational interviewing, a communication method that determines a person's willingness to change and attempts to negotiate a commitment to reduce substance use.[16-17] Brochures with educational information and guidelines for reducing risks were used to supplement and direct the dialogue between the HE and patient.

Health Educators (HEs) Training

CASBIRT utilized bi-cultural/bi-lingual (English/Spanish) HEs who were able to meet the linguistic and cultural needs of San Diego County's large Latino population. Twenty-seven paraprofessional Health Educators (HEs) delivered SBIRT services after receiving 3 months of training, including two weeks of training in cognitive behavior therapy from a licensed psychotherapist, and motivational interviewing training provided by the author (MH).[16-17] The curriculum also included alcohol and drug education, intervention protocol adherence, videotaped role-playing sessions, and onsite shadowing with feedback.

About 85% of the HEs were female. The majority had interviewing experience and were students pursuing bachelor's degrees in health and human service-related fields. Two HEs had master's degrees, and 1 had previously worked as a dentist in Mexico. HEs were present in most ED/trauma centers 7 days a week, with coverage from 7AM to 11PM.

Follow-up Procedures

As part of its program evaluation activities, CASBIRT's goal was to recruit 10% of all those screened for a follow-up telephone survey. After screening and delivering an intervention, a subset of patients was targeted by the HE for the 6-month follow-up interview. Patients who fell within an elevated alcohol or drug risk level (*At risk* or above), and whose last 2 digits of their telephone number fell within a specified range were asked about their willingness to participate in a follow-up. The range of the last 2 digits of telephone numbers was used to introduce randomness to the selection of patients targeted for follow-up. If patients consented to participate in follow-up, they provided their own contact information as well as that for at least 1 friend or relative who could be contacted in an attempt to locate the patient. Cohort maintenance activities in the form of periodic telephone contact and a postcard were used to keep in contact with those identified for follow-up. Patients were also informed they would receive a $20 gift card by mail upon completion of the follow-up interview.

Bilingual Evaluation Assistants (EAs), separate from Health Educators, were trained in health surveying, cohort maintenance, and Telescript software (Telescript, Inc., Norwood, NJ) to track and conduct 6-month telephone follow-up interviews. EAs continued to call each participant until they completed the 6-month interview or until the participant fell outside of the follow-up window at 8-months post intake. Six-month follow-up interviews consisted of the same alcohol and drug use items asked at intake. Follow-up interviews typically took 15 to 20 minutes to complete.

Sampling

Figure 1 graphically presents the flow and number of patients receiving screening/intervention, recruited into follow-up, and participating in follow-up. HEs approached 150,979 patients presenting to ED and trauma departments. Approximately 22% of those approached (n=32,886) did not complete the screening assessment for various reasons. As shown in Table 1, most missed screening opportunities were due to patients having been previously screened by CASBIRT, being incapable (e.g., disoriented), or being ineligible by virtue of age and language barriers. Only 1% of patients refused to be screened. Approximately 20% of those patients screened (n=24,363) screened positive for alcohol or drugs (or both) with the ASSIST instrument. A total of 2,436 screened patients consented to be in the 6-month follow-up sample. Of those, 1,504 (69%) were lost to follow-up, leaving 672 patients who comprised the complete longitudinal sample. The 1,504 patients lost to follow-up were included in the analyses using an intent-to-treat (ITT) approach whereby their intake responses were carried over as follow-up values.

Design and Measures

This evaluation study utilized a single group pre-post test design. Prior to the analyses, approval for the study was obtained from San Diego State University Institutional Review Board.

Outcomes. The Government Performance and Results Act (GPRA) assessment tool was used to assess past 30-day binge drinking and use of illicit drugs, as well as socio-demographic information.[18-19] GPRA's alcohol and drug use measures are modified items from the widely-used Addiction Severity Index.[20] Six dependent variables were computed at baseline and at follow-up: (a) past 30 day prevalence of binge

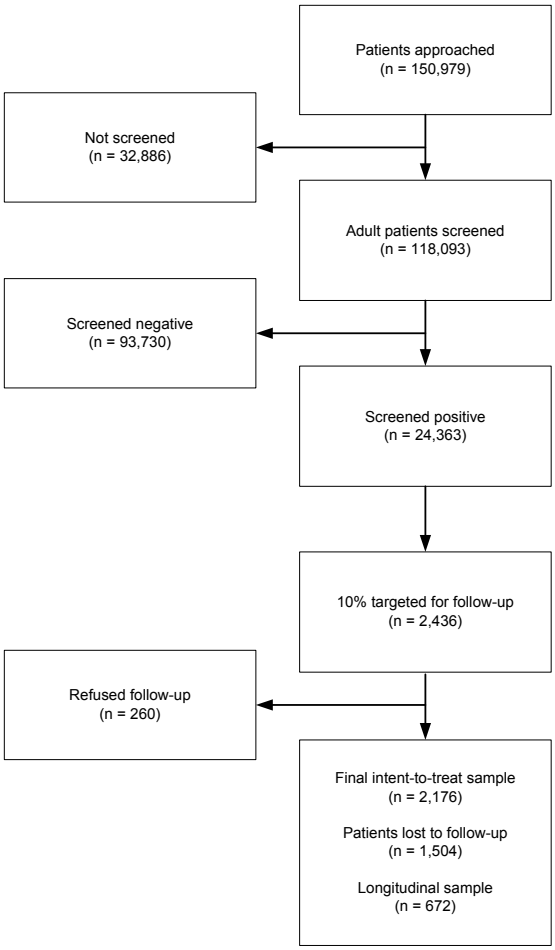


Figure 1. Chart showing formation of study sample.

drinking, i.e., 5 or more drinks per sitting (yes/no), (b) number of days of binge drinking in the past 30 days, (c) past 30 day prevalence (yes/no) of illicit drug use, (d) number of days of illicit or nonprescribed drug use in the past 30 days, (e) past 30 day prevalence of marijuana use (yes/no), and (f) number of days of marijuana use in the past 30 days.

Independent Variables. At intake, HEs asked the patient's gender, age, and race/ethnicity. Age was treated as a categorical variable, with groups defined as 18–24, 25–34, 35–44, 45–54, and 55 years and older. Race/ethnicity was determined using GPRA options and recoded into the following: Latino/Hispanic, Black, White non-Latino, and Other. Patient's ASSIST risk level for alcohol and drugs assessed at intake was categorized as low risk, *at risk*, high risk, or severe risk. Finally, a 'type of user' variable was computed with the 2 categories: (a) alcohol binger or drug misuser only, or (b) misuser of both alcohol and drugs.

Data Analysis

We used frequency distributions to describe the disposition of screening attempts and overall sample characteristics. We used Chi-square and t-test analyses to assess baseline differences in those followed and those lost to follow-up. Chi-square analysis was used to describe the sociodemographic characteristics of patients by type of user. To assess intake-to-follow-up change, we used a conservative ITT approach in which 6-month values for outcomes for those lost to follow-up were recoded with the last value carried forward (LVCF).[6,21] This approach meant replacing missing follow-up values with intake responses to avoid potential non-response bias. We then used generalized linear mixed models (GLMM) to assess changes in past 30 day prevalence of use (i.e., logistic GLMM) and days of use (i.e., linear GLMM) among those *At risk* and above for misuse, adjusting for clustering by ED/trauma site. We also used GLMM to assess subgroup differential change by separately testing interactions between time and gender, age, race/ethnicity, risk status, and type of user. In these interaction models, site and time main effects were included in the model. We conducted all analyses using SPSS Statistics release version 19 (IBM, Chicago, Illinois).

Table 1. Results of attempts to screen 150,979 patients for alcohol and illicit drug use.

Status	n (%)
Completed screening	118,093 (78.2)
Previously screened	8,267 (5.5)
Not capable (e.g., disoriented)	8,145 (5.4)
Ineligible	6,203 (4.1)
Not capable due to severe physical illness	2,835 (1.8)
Not complete (e.g., language barrier)	2,782 (1.8)
Not complete due to patient being discharged	2,670 (1.8)
Refused	1,613 (1.0)
Other	371(<1.0)

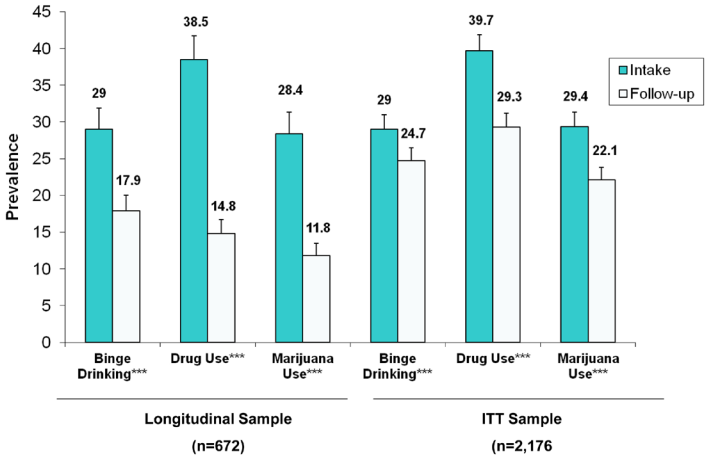
RESULTS

Adequacy of the Sample

Those lost to follow-up (n=1,504) and those successfully followed (n=672) were found to be similar with regard to sociodemographic characteristics and most baseline substance use measures, including: gender; age; race/ethnicity; status as an ED versus trauma patient; marijuana use risk level; prevalence of past 30 day alcohol binging, illicit drug use, and marijuana use; and the number of days in the past 30 days 1 used illicit drugs and marijuana. On the other hand, those lost to follow-up had a significantly higher alcohol risk level ($p<0.01$); a higher drug use risk level ($p<0.05$); and a higher number of days of binge drinking in the past 30 days ($p<0.001$) than those successfully followed.

Table 2. Demographic characteristics of alcohol only, drug only, and alcohol and drug misusers (intent-to-treat sample [ITT]).

Characteristic	Alcohol only % (n=538)	Drugs only % (n=1,171)	Alcohol and drugs % (n=462)	p-value
Gender				
Male	71	50.3	67.7	
Female	29	49.7	32.3	< 0.001
Age category				
18-20	2.2	9.7	8.2	
21-26	11.4	19.3	24.3	
27-34	16.4	17.9	20.2	
35-43	17.4	18.2	20.6	
44-51	24.3	17.4	15	
52+	28.4	17.5	11.7	< 0.001
Race/ethnicity				
Latino	45.1	34.5	39.6	
Black	10.3	15.5	14.5	
Other	5.7	6.6	5.8	
White	39	43.5	40.1	< 0.01
Type of site				
Emergency department	87.1	92.3	84.8	
Trauma center	12.9	7.7	15.2	< 0.001



**p<0.01
***p<0.001

Figure 2. Overall changes in prevalence of past 30 day binge drinking, illicit drug use, and marijuana use in the longitudinal sample and intent-to-treat sample (ITT).

Sample Characteristics

Fifty-nine percent of the ITT follow-up sample were men. The average age was 39 years of age (SD=13.9) with a range of 18 to 99 years. The follow-up sample was comprised of 42% non-Latino Whites, 38% Latinos, 14% Blacks, and 6% Other races/ethnicities. Roughly 40% of Latinos opted to have the intake interview in Spanish. Close to 90% of patients were screened in the ED while approximately 10% were screened in trauma units.

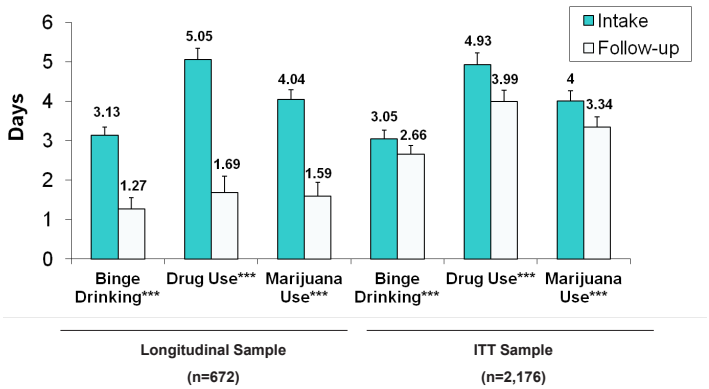
Of those screening positive for drug or alcohol abuse, 25% of the ITT sample misused alcohol exclusively, 54% misused illicit drugs only, and 21% misused both. As shown in Table 2, demographic characteristics differed significantly for those misuse groups. The alcohol-only group had a particularly high proportion of males, older patients, and Latinos. The drug use only group was almost equally comprised of males and females, was spread out fairly equally across age groups (with the exception of the 18–20 year olds), and was comprised of a large proportion of non-Latino Whites. Concurrent alcohol and drug misusers were predominately male, relatively young, and were typically non-Latino White or Latino. While trauma patients comprised a relatively small percent of patients overall, misusers of alcohol only and alcohol and drugs were more likely to be seen in trauma than were the drug only misusers.

Among those who were in the *At risk* or above categories for drug use, 48% had used marijuana in the last month, 14% methamphetamines, 7% cocaine, 5% heroin, 2% hallucinogens, 1.4% benzodiazepines, and 0.5% each morphine and oxycontin. About 2.5% reporting using another illegal drug in the past month; 3.5% reported injecting drugs in the past month. The mean number of different drugs used in the past month (excluding alcohol) was 0.7 (SD=0.78), with a range of 0–7 drugs. Among those using any illicit drug in the past month, the average number of drugs used was 1.2 (SD=0.62).

Changes in the Overall Sample

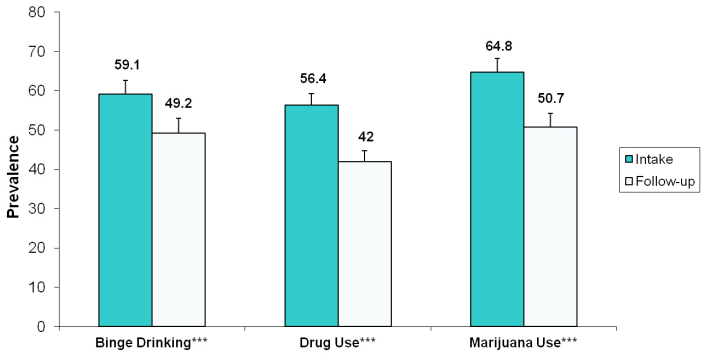
Figures 2 and 3 present changes in past 30 day prevalence and days of use, respectively, for alcohol binging, illicit drug use, and marijuana use for both the true longitudinal sample and the ITT sample. Differences in the magnitude of change in the two samples underscore the bias in estimates that can occur should data only from follow-up responders be used. ITT follow-up prevalence estimates were 1.4 higher (for binge drinking) to almost 2 times higher (for drug use and marijuana use) in the ITT sample than in the longitudinal sample (Figure 2). Regarding days of use, ITT sample estimates were over twice as high as those in the true longitudinal sample for all 3 substances.

All subsequent results will be based on ITT sample results. As shown in Figure 2 for the ITT sample, the past-month prevalence of binge drinking declined from intake to follow-up by a modest 4.3 percentage points; drug use prevalence reductions (10.4 percentage points) and marijuana use prevalence reductions (7.3 percentage points) were of



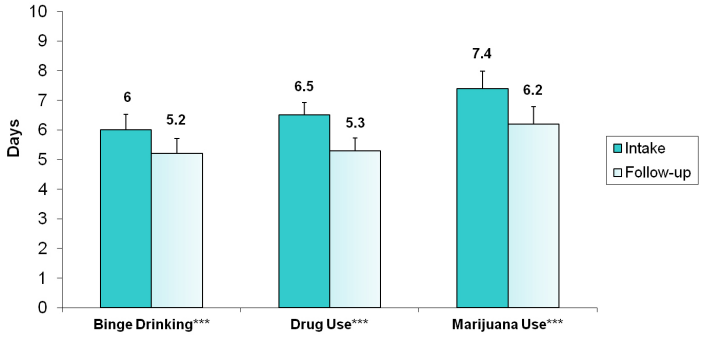
*** p<0.001

Figure 3. Overall changes in number of days in the past 30 that one binge drank, used illicit drugs, and used marijuana in the longitudinal and intent-to-treat sample (ITT).



*** p<0.001

Figure 4. Changes in past 30 day prevalence of binge drinking, illicit drug use, and marijuana use among those at risk.



***p<0.001

Figure 5. Changes in number of days in the past 30 that one binge drank, used illicit drugs, and used marijuana among those at risk.

greater magnitude than binge drinking prevalence changes. Days of binging for the ITT sample decreased by 0.39 days, illicit drug use decreased by almost 1 day, and marijuana use specifically decreased by 0.66 days (see Figure 3).

Changes in Those with Substance-specific Risk

Figure 4 presents changes in the past 30 day prevalence of binge drinking, drug use, and marijuana use for those in the categories *At risk or above* for the substance based on the ASSIST screener. GLMM analysis adjusting for site indicated statistically significant change in the past 30 day prevalence for all 3 substances, with binge drinking decreasing by 9.9 percentage points, and illicit drug use and marijuana use each decreasing by about 14 percentage points (Figure 4). As shown in Figure 5, reductions in days of use were also statistically significant: binge drinking decreased by 0.8 days, and both days of drug use and marijuana use decreased by 1.2 days.

Differential Change by Sociodemographic Characteristics and Risk at Intake

To examine whether change was similar by gender, age, race/ethnicity, risk category, or type of user (misuse of alcohol or drugs, versus misuse of both), interactions were tested for all 6 outcomes within GLMM, adjusting for site. For prevalence outcomes, a near consistent finding was seen in which males, those at high or severe risk for the substance, and misuse of one substance versus misuse of both showed greater past 30 day abstinence than did females, those at relatively lower risk, and those misusing both alcohol and drugs at intake (data not shown). Differential change in the past 30-day prevalence outcomes was not significant by age and race/ethnicity. Similarly, males and those at relatively higher risk at intake (high and severe risk) reported greater reductions in the number of days of use than did females and those at relatively lower risk at intake (data not shown). Age categories, racial/ethnic groups, and type of user did not vary greatly in days reduced, indicating reductions in days of use were fairly consistent among them.

DISCUSSION

This study examined patient alcohol and drug outcomes 6 months after participation in California SBIRT services which were routinely offered to patients at San Diego County EDs and trauma centers. The overall results were consistent with those of other studies which have demonstrated that screening and brief intervention programs are effective at reducing substance use.[4-5] Even after employing a conservative analysis approach that replaced missing follow-up data with intake values, there were statistically significant reductions in all 6 drug and alcohol use outcomes, although the clinical significance of these reductions is not known. Past-month abstinence from binge drinking, use of any illicit drugs, and use of marijuana specifically among those with risky levels

of misuse increased by about 10 to 14 percentage points (reductions in the range of 17% to 25%). Days of use in the past 30 days decreased as well, with binging days decreasing by almost a full day, and drug use and marijuana use specifically each decreasing by 1.2 days.

The InSight project in Houston Texas was a well-implemented and thoroughly evaluated SBIRT project that overlaps conceptually and methodological to some degree with the current study.[6] Therefore, we thought it useful to roughly compare our results to theirs. The reductions seen in the current study are considerably more modest that those reported by the InSight project, which reported an almost 50% reduction in the prevalence of heavy drinking, a 60% reduction in the prevalence of illicit drug use, and close to a 50% reduction in the number of days of heavy alcohol and drug use.[6] Geographical/demographic, methodological, and programmatic differences exist between the CASBIRT and InSight projects which make strict comparisons between the two projects' results difficult. For example, the projects used different screening instruments and definitions of risk/severity status. Screenings were conducted by professional health care workers in the InSight project, whereas CASBIRT employed paraprofessional health educators for both screening and intervention. InSight's follow-up rate of 66% was much higher than CASBIRT's; therefore, large-scale imputation of follow-up values was not necessary for InSight.

For the purposes of potentially informing future SBIRT service delivery, changes by baseline risk and sociodemographic subgroups were examined. The present study found a fairly consistent pattern of greater change among men (than women), among those at relatively higher risk status (versus lower risk), and among those with only one substance of misuse (versus both alcohol and illicit drug misuse). No differential effect was observed by race/ethnicity and age, indicating similar affect of CASBIRT services across age and ethnoracial groups. To some degree, these results parallel those of the InSight study, which reported greater decreases in alcohol outcomes among those at higher risk (although this was not observed in Insight's drug use outcomes).[6] This finding in both studies of greater change among those with the greatest problem severity is somewhat surprising, given SBIRT's primary focus on impacting the large number of non-dependent, relatively lower risk users.[3] It may be that, in both studies, those patients with higher risk or severity were more receptive and motivated to make changes than those at relatively lower risk levels. In addition, regression to the mean cannot be ruled out.

As with any research that requires follow-up with patients with risky drug and alcohol use behaviors, there was a concern that patients lost to follow-up were significantly different from those who were contacted at follow-up. Patients lost to follow-up reported higher mean days of binge drinking and higher alcohol and drug risk levels, but were not significantly different with respect to all other variables examined. Therefore, while some patients lost to follow-up may have had slightly more risky behavior patterns, the groups were otherwise quite similar, a surprising finding considering the low response rate.

LIMITATIONS AND STRENGTHS

Although the existing protocol for provision of Screening and Brief Intervention services in San Diego County included some data collection, its design as a service, rather than research program lends itself to several limitations. Since it was a real-world service provision project, randomization to treatment and control groups was not feasible. Without a control group, it is impossible to know if patients' substance use behaviors would have improved on their own, independent of services delivered. It is also possible that patients experienced test reactivity, whereby the measures themselves prompted the behavioral changes, rather than the interventions. Another potential explanation for decreased risky behaviors is the therapeutic effect of attention alone; that is, it may have simply been the time spent with a health educator that lead to behavioral changes, rather than how that time was spent. The baseline interview was conducted in-person, whereas the follow-up was a telephone interview. To the degree that these 2 methods differ with regard to veracity of reporting, a systematic bias could have been introduced. The large amount of missing follow-up data is a concern, and although imputation was conducted to reduce non-response bias, the use of last observation carried forward in analyses can introduce bias.[22] Finally, this study lacks biological confirmation of claims of abstinence or reduction. All data recorded at baseline and follow-up were collected exclusively through patient self-reports. Without biological confirmation, it is likely that some patients exaggerated or misreported their reductions in drug and alcohol use.

Despite the limitations, the present study has many strengths. Although not population-based, CASBIRT attempted universal screening and the convenience sample came from a large, ethnically-diverse patient population with a wide range of medical needs. Linguistically appropriate screening, intervention, and follow-up assessment was available for Spanish speaking Latinos. Interventionists (paraprofessional health educators) were well trained and supervised on an ongoing basis, working side by side with a supervisory Health Educator who provided feedback on an ongoing basis. CASBIRT services were integrated into the acute care setting, and were well received by ED/trauma staff and administrators. The analysis method based on intention to treat principles gives confidence in the results, insofar as non-response bias was reduced.

CONCLUSION

These results suggest that SBIRT services provided in acute care settings are associated with modest changes in recent alcohol and illicit drug use.

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Vital Signs
from the Centers of Disease Control and Prevention's MMWR

Fatalities and Binge Drinking Among High School Students: A Critical Issue to Emergency Departments and Trauma Centers

In conjunction with the Morbidity and Mortality Weekly Report published by the Centers for Disease Control and Prevention

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The Centers for Disease Control and Prevention (CDC) has published significant data and trends related to drinking and driving among United States (U.S.) high school students. National data from 1991-2011 shows an overall 54% relative decrease (from 22% to 10.3%) in drinking and driving among U.S. high school students aged ≥ 16 years. In 2011, this still represents approximately 950,000 high school students ages 16-19 years. The decrease in drinking and driving among teens is not fully understood, but is believed to be due to policy developments, enforcement of laws, graduated licenses, and economic impacts. Most significant to emergency physicians is that even with these restrictions, in 2010 approximately 2,700 teens (ages 16-19) were killed in the U.S. and about 282,000 were treated and released from emergency departments for injuries suffered in motor-vehicle accidents. In the same year, 1 in 5 drivers between the ages of 16-19 who were involved in fatal crashes had positive (>0.00%) blood alcohol concentration (BAC). We present findings from the CDC's Morbidity and Mortality Weekly Report with commentary on current recommendations and policies for reducing drinking and driving among adolescents. [West J Emerg Med. 2013;14(3):271–274.]

CDC MORBIDITY & MORTALITY WEEKLY REPORT FINDINGS

In the October 5, 2012, issue of Morbidity and Mortality Weekly Report (MMWR), the Centers for Disease Control and Prevention (CDC) reported data concerning drinking and driving among high school students aged ≥16 years. The report clearly illustrated that, even though there has been substantial progress in the last 2 decades to reduce drinking and driving among teens, 1 in 10 adolescents aged ≥ 16 years reported driving after consuming an alcoholic beverage, and most of them also reported binge drinking. According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) binge drinking is defined as a "pattern of drinking that brings a person's blood alcohol concentration (BAC) to 0.08 grams percent or above. This typically happens when men consume 5 or more drinks, and when women consume 4 or more drinks in about 2 hours."

To describe the trend in prevalence of drinking among United States (U.S.) high school students aged ≥ 16 years, data were gathered from the 1991-2011 national Youth Risk Behavior Surveys (YRBS), a component of the CDC's Youth Risk Behavior Surveillance System (YRBSS). Prevalence of drinking and driving was defined as driving 1 or more times when they had been drinking alcohol during the 30 days prior to the survey. The 2011 state YRBS data were used to describe drinking and driving prevalence in 41 states. For each national and 41 state surveys, students completed an anonymous and voluntary, self-administered questionnaire that contained identical questions about drinking and driving, current alcohol use, and binge drinking. The overall national response rate was 60% to 71% and overall state response rate was 60% to 84%.

The 1991-2011 national data shows an overall 54% relative linear decrease (from 22% to 10.3%) in the prevalence of drinking and driving among U.S. high school students aged ≥ 16 years. The decline in prevalence of drinking and driving is evident from 1997 – 2011. Prior to 1997, the prevalence in drinking and driving remained stable. The overall prevalence in drinking and driving in 2011 was 10.3%, which extrapolates to approximately 950,000 high school students ages 16-19 in

the U.S. and approximately 2.4 million episodes of drinking and driving during the past 30 days prior to the survey.

Furthermore, the national data illustrated significant differences in drinking and driving among gender, race, age, and patterns of binge drinking. Male students reported to be more likely than female students to drink and drive (11.7% and 8.8% respectively). Hispanics had the highest prevalence of drinking and driving (11.5%) compared to whites (10.6%) and blacks (6.6%). Data showed that drinking and driving increased with age, from 7.2% among 16 year olds, to 11.5% for 17 year olds and 14.5% aged ≥18 years. Drinking and driving was more than 3 times higher among students who reported binge drinking (32.1%) compared to those that reported alcohol use, but did not report binge drinking (9.7%). Overall, 26.4% of students reported binge drinking, yet among those reporting drinking and driving, 86.6% also reported binge drinking.

Additional state YRBS results reported in the MMWR showed that among the 41 states with available YRBS in 2011, the prevalence of drinking and driving per state varied threefold, from the lowest in Utah (4.6%) to the highest in North Dakota (14.5%). The prevalence of drinking and driving was higher than the national prevalence in 6 states: Iowa, Louisiana, Montana, North Dakota, Texas, and Wyoming; and lower in 9 states: Alaska, Indiana, Kentucky, Michigan, New York, North Carolina, Rhode Island, Utah, and Virginia. The remaining 26 states were not statistically different.

The CDC listed 6 limitations in their MMWR report. First, the YRBS does not measure whether a student has driven during the 30 days prior to the survey. Second, the YRBS defines binge drinking for teen males and females as ≥5 drinks within a couple hours, which is different from the nationally recommended definition. The MMWR report states that binge drinking in teen females would most likely be higher if reported using national definition of 4 drinks or more threshold. Third, data were not available to determine whether binge drinking occurred before driving. Fourth, the amount of over reporting or under reporting of behaviors in the YRBS cannot be determined. Fifth, data only apply to teens who are in school and thus is not representative of all persons in this age group. Finally, state-level prevalence estimates of drinking and driving were not available for 9 states: Washington, Oregon, California, Nevada, Hawaii, Maine, Minnesota, Missouri, and Pennsylvania.

COMMENTARY

"Get dressed. Ashley is in the hospital. We have to go there now." I hear my wife yelling at me as she hangs up the phone. I was confused and disorientated; I must been dreaming, was the first thought that ran through my head. It was midnight and our 17-year-old daughter was supposed to be spending the night at a friend's house after the prom festivities. She had to be okay, she was always very responsible. "Get up! We have to go now!" My wife repeated again. I could tell my wife was scared by the tone of her voice. Something must be very wrong with Ashley. I suddenly snapped awake and realize it was not a dream. "What happened to her?" I asked. She explained that Dr. Charles Smith, one of my colleagues, called to say that Ashley had been in a motor vehicle collision. She was stable but we needed to get to the hospital. As an emergency physician, many horrible scenarios played in my mind. I dressed quickly, and we raced to the hospital immediately. All I could think of was if she was okay. I recounted the earlier conversation with Ashley. I told her to be safe, not to drink, not to do anything irresponsible. What was she thinking? I parked the car and I rushed into the emergency department (ED) entrance; I could feel my heart beating faster and faster, not knowing what to expect. Over and over in my head, I am praying, "Dear God, please let my baby be OK." As I am about to walk into the trauma bay, Charles grabs me by the arm and says, "she not in there, we have her in a private room and she is stable but still a bit intoxicated. Ashley was involved in a drinking and driving collision, she was very lucky but unfortunately, the passenger, her friend Megan was not so lucky; she did not survive." As I walked into the room, Ashley began to cry and pleaded, "Oh, Daddy, I'm so sorry. Please don't be mad at me," she continued by promising never to drink again. I stood back for a moment, trying not to cry. I was not sure what to feel first. I was overcome by many emotions of relief, happiness and then anger and sadness. How could she have done this?

As emergency physicians, we deal with this kind of possible situation everyday, yet they never seem real until it hits home. Although Ashley should recover, Megan's family will never fully recover. The loss of a loved one is always hard, but it is even more difficult when you know that it could have been prevented.

It is striking to see that even though the MMWR reports a decrease in prevalence in drinking and driving since 1997, the leading cause of death among teens aged 16-19 years in the U.S. continues to be motor vehicle crashes[1].

To minimize the prevalence of alcohol-related injuries, the CDC has worked with EDs and trauma centers to implement alcohol screening and brief intervention (SBI) programs. Currently, the American College of Surgeons Committee on Trauma has required that all Level I trauma centers use SBI to screen all incoming patients for alcohol use, in efforts to identify risky drinking behaviors, and provide patients with a brief counseling or intervention session on-site.[8-11] Research on SBI has shown promising results. For each dollar invested in SBI, there was an approximate 4-fold return in reduced overall healthcare costs. In addition to lower healthcare costs, SBI results demonstrate promising effects by significantly decreasing drinks consumed per week and binge drinking episodes, and an overall 50% decrease in readmissions to trauma centers, EDs, and hospitals.[12] Current research demonstrates that alcohol SBI is a feasible and effective

method to detect significant differences in drinking patterns among gender, language, and age. It can be adapted to serve a spectrum of population demographics (such as teens, Latinos, etc.) and administered via modalities such as computerized or web-based delivery.[8, 13-17]

Despite research showing that a variety of interventions in ED and trauma centers show promise in reducing underage drinking and alcohol-related crash fatalities, the frequency of these behaviors still remains high in teens. The average age of drinking initiation has declined in the U.S.[3,18] In the MMWR report, the CDC addresses this issue by recommending that health professionals screen teens for the use of alcohol, drugs, and driving after alcohol or drug use. In addition, they recommend educating parents on how to identify at-risk behavior. The ED presents the opportunity for screening and education by initiating a "teachable moment." This creates a perfect window for intervention regarding alcohol abuse, yet, policies that support such measures have been "poorly followed or not implemented."[19-22] This is why more research, implementation of alcohol SBI, enforcement, and education is needed for adolescents

Many studies and SBI are focusing on patients ≥ 18-years-old and are missing younger teens who engage in alcohol use. It is important that future studies of alcohol SBI also address the developmental and demographic differences (ethnicity, race, and age) among populations.[13,20] For example, studies have shown important differences between black and white youths' motivation to consume alcohol.[21, 22] According to Cooper et al[21], coping motives (to reduce negative emotions) played a bigger role in black youth, and enhancement motives (to augment positive emotional states) were a greater role in white youth. Even though research is greatly lacking within the Latino and non-English speaking populations, some studies indicate significant differences in alcohol use among English- and Spanish-speaking patients.[8, 13,17]

Local law enforcement has devoted increased resources to address the problem by establishing special enforcement task forces against drinking and driving. There are random checkpoints, media campaigns, zero tolerance laws, graduated licenses and outreach events targeting adolescents. Yet even with all this work the CDC acknowledges that more needs to be done.[1] Furthermore, the National Highway Traffic Safety Administration reported that between 2000 – 2008 more than 23,000 drivers and 14, 000 passengers aged 16-19 years were killed.[5] Analysis of these motor vehicle collisions adjusting for miles driven showed younger teens with the highest rates, with fatal crash rates per mile driven for 16- and 17-year-olds at 150% and 90% greater, respectively, compared to older teens.[5] Therefore, as emergency physicians who witness these atrocities daily, we have the responsibility not to treat the aftermath, but also to prevent it. We need to serve as public health advocates, community organizers, and educators. Emergency medicine should encompass more than just diagnosing and treating acutely ill patients; we should act as leaders of our communities and encourage our colleagues, our residents and medical students to do the same.

In addition to working with local law enforcement agencies to encourage citizens to reduce underage access to alcohol, it is important that we take direct action in our communities. Emergency physicians could promote public health awareness and education by finding ways to help educate adolescents and parents on the facts of fatalities and binge drinking among high school students.

One example of how emergency physicians could promote public health awareness and education is working with medical students in the Emergency Medicine Interest Group (EMIG). EMIG students work closely with residents and faculty to increase involvement with local high schools and community leaders in DUI awareness campaigns such as Mothers Against Drunk Drivers (MADD). Events such as "More Than Just a Drink" are organized by high school students under EMIG and faculty leadership. In front of 800 of their peers, high school students reenact the consequences of a high-speed motor vehicle collision due to drinking and driving. Students watch as emergency services personnel (Fire, Police and ambulance services) approach the scene as if it was a real critical trauma, with real injuries and fatalities. Emergency medicine faculty, nursing and medical students take a major role in illustrating the dangers of drinking and driving by presenting real-life scenarios and photographs of driving under the influence (DUI) victims that have been treated in the ED. The students later broke out into small groups led by medical students where they discussed what they had witnessed and how they felt about it. By engaging high school students to not only witness, but also to participate in a live experience, EMIG hopes to create "a vivid emotional memory" that will deter them from drinking and driving in the future. This is just one of many ways in which we can make a local long-lasting impact on the community.[23]

In summary, the prevalence of drinking and driving has declined since the late 1990s, but alcohol-related fatalities and binge drinking among teens still remains high with 1 in 5 teen drivers involved in fatal crashes, and most (81%) with BACs higher than the legal limit for adults.[1] Because many of these alcohol-related injuries are first encountered in EDs and trauma centers, emergency physicians will be at the forefront of implementing appropriate research studies, educational tools and policies to further minimize drinking and driving among teens. Policy implementation and research are important, but it is equally vital to educate healthcare providers in the ED on SBI and prevention methods. Many EDs and trauma centers already have SBI programs in place for adults (≥18 years of age), and therefore, transitioning to a younger population would seem to be the next logical step.[8,11,13] As physicians we are not only healthcare providers and scientists, but also leaders and educators, with an important responsibility to help the Ashleys and Megans of this world grow up to fulfill their potential.

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Are Simulation Stethoscopes a Useful Adjunct for Emergency Residents' Training on High-fidelity Mannequins?

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Introduction: Emergency medicine residents use simulation training for many reasons, such as gaining experience with critically ill patients and becoming familiar with disease processes. Residents frequently criticize simulation training using current high-fidelity mannequins due to the poor quality of physical exam findings present, such as auscultatory findings, as it may lead them down an alternate diagnostic or therapeutic pathway. Recently wireless remote programmed stethoscopes (simulation stethoscopes) have been developed that allow wireless transmission of any sound to a stethoscope receiver, which improves the fidelity of a physical examination and the simulation case.

Methods: Following institutional review committee approval, 14 PGY1-3 emergency medicine residents were assessed during 2 simulation-based cases using pre-defined scoring anchors on multiple actions, such as communication skills and treatment decisions (Appendix 1). Each case involved a patient presenting with dyspnea requiring management based off physical examination findings. One case was a patient with exacerbation of heart failure, while the other was a patient with a tension pneumothorax. Each resident was randomized into a case associated with the simulation stethoscope. Following the cases residents were asked to fill out an evaluation questionnaire.

Results: Residents perceived the most realistic physical exam findings on those associated with the case using the simulation stethoscope (13/14, 93%). Residents also preferred the simulation stethoscope as an adjunct to the case (13/14, 93%), and they rated the simulation stethoscope case to have significantly more realistic auscultatory findings (4.4/5 vs. 3.0/5 difference of means 1.4, p=0.0007). Average scores of residents were significantly better in the simulation stethoscope-associated case (2.5/3 vs. 2.3/3 difference of means 0.2, p=0.04). There was no considerable difference in the total time taken per case.

Conclusion: A simulation stethoscope may be a useful adjunct to current emergency medicine simulation-based training. Residents both preferred the use of the simulation stethoscope and perceived physical exam findings to be more realistic, leading to improved fidelity. Potential sources of bias include the small population, narrow scoring range, and the lack of blinding. Further research, focusing on use for resident assessment and clinical significance with a larger population and blinding of graders, is needed. [West J Emerg Med. 2013;14(3):275–277.]

INTRODUCTION

A variety of medical simulation tools, such as task trainers, computer-based systems, virtual reality and haptic systems, as well as simulated patients and environments, exist as adjuncts to simulation-based medical education.[1-4] High-fidelity mannequins frequently serve as adjuncts in case-based simulation as they have the capability to simulate vital signs and physical exam findings while providing a patient to interact with. Anecdotally the quality of the physical examination findings present on these mannequins is frequently criticized. The auscultatory findings are criticized because of their importance in the role of diagnosis and treatment-related decisions. Criticisms are often directed at the mechanical background noise present, as well as the difficulty of interpreting findings due to the radiation of sounds (such as hearing diffuse crackles instead of basilar crackles on a respiratory examination).

Recently a simulation stethoscope has been developed to serve as an adjunct to simulation-based learning.[1] The simulation stethoscope consists of a receiver and a transmitter. The receiver appears similar to a stethoscope with the addition of a small black box on the tubing, while the transmitter is a handheld black box with 4 buttons and a switch. An SD card is used for storage of sounds and is capable of holding 12 unique sounds per card. This system allows for an individual to hear different findings based on the location auscultated over the course of a case without picking up background noise.

The objective of the study was to assess the utility of a simulation stethoscope as an adjunct in emergency medicine resident's simulation-based training using high-fidelity mannequins. Specifically, we wanted to determine its utility in perceived fidelity of physical examination findings, resident performance, and resident preference.

METHODS

Study design

This was a prospective, randomized, non-blinded, crossover observational study comparing 2 case-based scenarios with and without the use of a simulation stethoscope (Ventriloscope®, Lecat's Ventriloscope, Canton, OH). The study was approved by the local institutional review committee. The study subjects were PGY 1-3 emergency medicine residents who volunteered to participate in 2 simulation-based scenarios between June and July of 2011. Case-based scenarios were run using high-fidelity mannequins (MetiMan, CAE Healthcare, formerly METI of Sarasota, Fl.). Subjects were assigned a unique ID number that was kept confidential and used for data analysis only. Performance in the cases was not used for longitudinal assessment of subjects, and they were notified of this prior to participation. Randomization to a case associated with the simulation stethscope occurred by an even/odd rotating fashion based off of the order in which subjects signed up. Randomization of case order (simulation stethoscope-associated case first or second) was through an even/odd rotating fashion based off time slot assigned.

Statistics

Data were collected from the scoring sheets based off scoring anchors (Appendix 1) and from the evaluation questionnaire (Appendix 2) and entered into an Excel spreadsheet. Subjects were given 1 point for "Needs Improvement," 2 points for "Meets Expectations," and 3 points for "Above Expectations." If a point on the scoring anchor was not applicable it was left out when calculating the average score (i.e., if a patient did not deteriorate into pulseless electrical activity, then the recognition/management of that rhythm was not applicable).

We used data from scoring anchors to compare overall performance score and time taken per case. We averaged scores for each case and calculated a difference of means for the overall average score (average of subject's combined scores) between the cases in which a simulation stethoscope was used and those in which it was not. We used a 2-tailed paired student's T-test to compare subject's average scores. Total time taken per case was also compared with a difference of means as well as a 2-tailed paired student's T-test.

We used data from the evaluation questionnaire to compare subject's perceived realism of a case and associated physical exam findings, subject's preference for the use of a simulation stethoscope, as well as subject's confidence in diagnosis and treatment. Using the 5-point Likert scale, we used a 2-tailed paired student's T-test to evaluate the difference in how realistic subjects perceived the auscultatory findings. The percent of subjects who ranked the simulation stethoscope-associated case more realistic was calculated, as was the perecent of subjects who preferred the use of one. We used a 2-tailed paired student's T-test to compare results from the 5-point Likert scale assessing the subject's confidence in diagnosis and treatment of heart failure exacerbations and tension pneumothoraces.

Intervention

Subjects were randomized into two groups, with each group completing two cases. The first group used a simulation stethoscope for case #1 and the high-fidelity mannequin's natural auscultatory findings for case #2, while the second group experienced the reverse. We used pre-determined scoring anchors (Appendix 1) for the evaluation of their performance specific to each simulation-based case. The scoring anchors involved assessment on critical actions, time taken, and communication skills. Following the completion of both cases residents were given an evaluation questionnaire (Appendix 2) that was partially based off a previously validated questionnaire for physical exam.[5] A debriefing session followed the questionnaire regarding critical actions and instructional points involved in both cases. Prompting was given during each case at pre-determined intervals. The

first case was based on diagnosing a patient in decompensated heart failure from history, a pulmonary exam with bilateral basilar crackles, and corresponding vital signs. The second case was based on diagnosing a patient with a tension pneumothorax in extremis from history, a pulmonary exam with decreased breath sounds unilaterally, and corresponding vital signs. Each case required diagnosis from history and physical examination as subjects were unable to recieve test results (such as radiologic studies or blood work) until treatment was initiated.

RESULTS

Subjects average scores were significantly better on the case associated with the use of the simulation stethoscope, 2.5/3 compared to 2.3/3 (difference of means 0.2, p=0.04). Both groups, however, scored above "meets expectations." Taking into consideration the narrow score range (1–3), as well as a small sample, it was not possible to determine if this translates into clinical significance. The simulation stethoscope-associated case was found to have significantly more realistic auscultatory findings, 4.4/5 as compared to 3.0/5 without (difference of means 1.4, p=0.0007). Total case times did not differ considerably between the cases with or without the use of the simulation stethoscope, 28:49 with the simulation stethoscope and 30:02 without (difference of means 1:13, p=0.8). Subjects noted that the physical exam findings were most realistic in cases associated with the simulation stethoscope in 13/14 (93%) and that their preference was for the use of the simulation stethoscope as an adjunct to simulation in 13/14 (93%). There was no difference of either group's confidence in their diagnostic or treatment skills in heart failure exacerbations (p=0.24 and p=0.55 respectively) or tension pneumothoraces (p=1 and p=1 respectively).

DISCUSSION

The techniques and adjuncts of simulation-based medical education are broad and range from recorded sounds to standardized simulated patient encounters.[1-4] Simulation training has been studied in many fields, including anesthesia, surgery, obstetrics and gynecology, internal medicine, and emergency medicine, and is used to teach a variety of skills, including physical diagnosis, communication, and procedures.[2,3,6,7] Anecdotally there are numerous complaints with auscultatory findings present in current simulation-based training. In standardized patients, unless the patient has the finding present already, it has been impossible to have the actual examination correlate with the expected examination. Current high-fidelity mannequins are critiqued secondary to mechanical background noise when auscultating, and for the non-specific locations of auscultatory findings.

LIMITATIONS

Limitations in this study included the small population size, the lack of blinding, and the narrow score range. Specifically, the use of the narrow score range (subjects either received a 1, 2, or 3 for a score on each datapoint) makes it difficult to determine when clinical significance would be present. In addition, the authors were responsible for scoring each case and we attempted to prevent bias by using pre-determined and well-defined scoring anchors for each case. While a reference anchor was used throughout each scenario to ensure accuracy, there still exists a potential bias. The other primary potential bias is due to the inability to have either party blinded as the authors were responsible for controlling the simulation stethoscope, which has a black box on it differentiating it from a regular stethoscope.

CONCLUSION

We believe that a simulation stethoscope represents a useful adjunct in emergency medicine case-based simulation on high-fidelity mannequins. The simulation stethoscope was an easy device to learn and use, and did not significantly alter the amount of time required for each case. Subjects preferred use of the simulation stethoscope, and associated it with more realistic findings. Scores were significantly better with the use of the simulation stethoscope; however, the impact on clinical significance is yet to be determined.

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Rapid ^{13}C Urea Breath Test to Identify *Helicobacter pylori* Infection in Emergency Department Patients with Upper Abdominal Pain

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Introduction: In emergency department (ED) patients with upper abdominal pain, management includes ruling out serious diseases and providing symptomatic relief. One of the major causes of upper abdominal pain is an ulcer caused by *Helicobacter pylori* (*H. pylori*), which can be treated and cured with antibiotics. We sought to estimate the prevalence of *H. pylori* infection in symptomatic patients using a convenience sample at a single urban academic ED and demonstrate the feasibility of ED-based testing.

Methods: We prospectively enrolled patients with a chief complaint of pain or discomfort in the upper abdomen for 1 year from February 2011 until February 2012 at a single academic urban ED. Enrolled subjects were tested for *H. pylori* using a rapid point of care ^{13}C Urea Breath Test (UBT) [Exalenz Bioscience]. We compared patient characteristics between those who tested positive versus negative for the disease.

Results: A total of 205 patients with upper abdominal pain were tested over 12 months, and 24% (95% confidence interval: 19% to 30%) tested positive for *H. pylori*. Black subjects were more likely to test positive than white subjects (28% v. 6%, $P < 0.001$). Other factors, such as age and sex, were not different between the 2 groups.

Conclusion: In our ED, *H. pylori* infection was present in 1 in 4 patients with epigastric pain, and testing with a UBT was feasible. Further study is needed to determine the risk factors associated with infection, the prevalence of *H. pylori* in other EDs, the effect of the test on ED length of stay and the cost-effectiveness of an ED-based test-and-treat strategy. [West J Emerg Med. 2013;14(3):278–282.]

INTRODUCTION

Helicobacter pylori, *H. pylori*, is one of the most common worldwide human pathogens, estimated to infect the stomachs of approximately 60% of the world's adult population.[1] In the United States (U.S.), the current overall prevalence of *H. pylori* in adults is unknown but has been trending downward from approximately 32% in 1994.[2,3] People infected with *H. pylori* are more likely to develop duodenal and gastric ulcers, gastric lymphoma and gastric cancer. The eradication of *H. pylori* is associated with ulcer healing, gastrointestinal symptom improvement and a lower likelihood of ulcer recurrence and bleeding.

Estimating prevalence is important because, in an outpatient setting with high prevalence (>10%), current

gastroenterology specialty guidelines recommend a test-and-treat strategy for patients with uninvestigated dyspepsia who do not have any alarm features.[4] To our knowledge, no one has investigated the prevalence of active *H. pylori* infection among patients who present to the emergency department (ED) with abdominal pain. The purpose of this study was to describe the feasibility of using the point-of-care ^{13}C Urea Breath Test (UBT) to identify active *H. pylori* infection in patients who presented to a single, academic ED with a chief complaint of upper abdominal pain. In addition, we planned to estimate the prevalence of *H. pylori* as a basis for future studies and prior to implementation of a test-and-treat strategy.

METHODS

Study Design

Research assistants (RA) prospectively identified a convenience sample of adult patients with upper abdominal pain that was possibly caused by gastritis, dyspepsia or peptic ulcer disease. Eligible patients who agreed to participate signed a written consent form, answered a 1-page questionnaire and received a ^{13}C Urea Breath Test prior to ED discharge. Subjects who tested positive for *H. pylori* were prescribed a treatment regimen according to the American Gastroenterology Association guidelines; for those who tested negative, treatment was left to the discretion of the primary provider. This study was approved by the university's institutional review board.

Study Setting

The setting was a single-center, urban, academic ED with an annual volume of approximately 70,000 visits. The ED is associated with a mid-sized (371 inpatient beds) hospital with a Level 1 trauma center. The ED is staffed by board-certified emergency physicians (EP), midlevel providers and emergency medicine residents completing a 4-year residency program.

Study Population

To be eligible for the study, RAs identified patients aged 18 and older who presented to the study ED during a 1-year period beginning February 14, 2011 until February 7, 2012 with upper abdominal pain and received confirmation from the treating provider that the patient's abdominal pain could possibly be due to gastritis, dyspepsia or peptic ulcer disease. Patients were excluded from participation if they were pregnant, currently taking antibiotics, bismuth or proton pump inhibitors (PPIs), or they were unable to walk to the testing area. We excluded patients taking antibiotics, bismuth and PPIs because these medications decrease test sensitivity.

The RAs asked all eligible subjects to sign a written consent form. The RAs were trained in clinical research through structured seminars and supervised by a senior research study coordinator working in the ED. Generally, the RAs worked weekdays between the hours of 9AM - 5PM, but the coverage was not consistent throughout the study period. When a RA was working in the ED, they attempted to enroll consecutive patients.

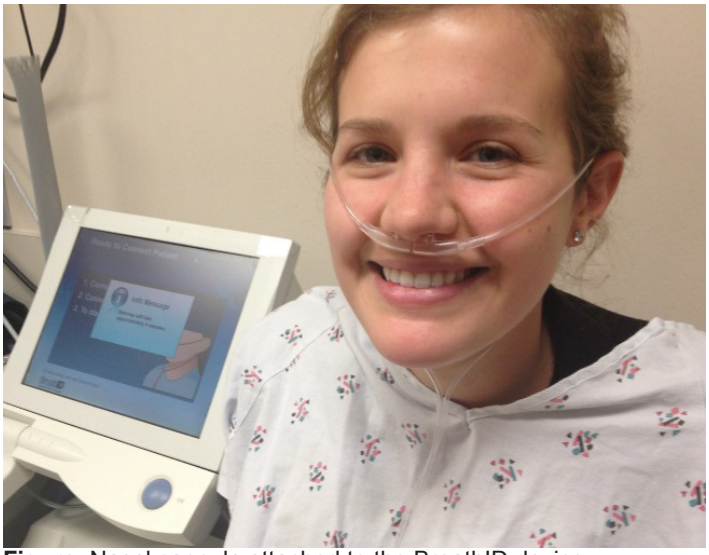

Figure. Nasal cannula attached to the BreathID device.

Study Protocol

RAs administered the ^{13}C UBT on all enrolled subjects. We used the ^{13}C-BreathID, which is a rapid UBT that has been approved by the Food and Drug Administration for the diagnosis of *H. pylori*. All patients had been nil per os (NPO) for 1 hour prior to test. To perform the test, subjects breathe normally through a nasal cannula attached to the BreathID device, a machine about the size of an EKG machine or small ultrasound machine (Figure). After establishing a baseline $^{13}CO_2/^{12}CO_2$ ratio, the system prompts the RA to administer a 75 mg ^{13}C-urea tablet (tablet form 99% ^{13}C enriched urea) and 4.5 g citric acid-based powder (4 g citric acid, 0.149 mg aspartate, orange aroma, and FD&C yellow acid (Tartrazine)) dissolved in approximately 200 mL tap water. On the basis of molecular correlation spectrometry, the BreathID continuously measures $^{13}CO_2$ and $^{12}CO_2$ concentrations from the patient's breath and establishes the $^{13}CO_2/^{12}CO_2$ ratio, which is displayed versus time on the screen.

High urease activity detected on exhalation is a marker of *H. pylori* infection with a sensitivity and specificity greater than 95%.[5] The cutoff point or threshold for the BreathID has been determined to be 5 [delta] over baseline. Thus, a test result is defined as positive if the final reading is greater 5. Test sensitivity is decreased by medications that reduce organism density or urease activity; so it is recommended that bismuth and antibiotics be withheld for at least 28 days and PPIs for 7-14 days prior to the UBT. Results were obtained within 10 to 15 minutes and printed automatically. Training was provided by a manufacturer representative and consisted of a 30-minute demonstration to the principal investigator (PI) and the study coordinator. The PI and coordinator then trained the RAs to properly administer the test.

Both the subjects and the treating EPs were informed of the results after the test was completed. Interpretation of the test was performed at the point of care. Assuming no allergies to penicillin, subjects who tested positive were prescribed triple-therapy (clarithromycin 500 mg po BID, amoxicillin 1000 mg BID and omeprazole 20 mg BID for 10 days, first-line treatment per American Gastroenterological Association [AGA]) and referred to outpatient gastroenterology for followup.[4] Subjects who tested negative were treated at discretion of the EP. The RAs recorded the UBT results and basic demographic information (age, gender, race, ethnicity and insurance status) using structured data collection sheets. These data were then entered into REDCap, an X electronic data capture tools.[6]

The primary outcome was rate of positivity for *H. pylori* among those enrolled. First, using chi-square test of homogeneity, we compared limited demographic and clinical characteristics of subjects with upper abdominal pain whom we enrolled in the study to all patients who presented to the study ED with a chief complaint of abdominal pain during hours when the RAs were working. Differences were considered statistically significant if the associated p-value ≤ 0.05. Second, we calculated the active *H. pylori* infection rate and 95% confidence interval (CI) by age, gender and race/ethnicity. Finally, we calculated the time to disposition from a query of the electronic medical record for all groups as an objective marker of feasibility. We conducted all analyses using Statistical Analysis Software (SAS) version 9.2, Cary, North Carolina.

Table 1. Percent distribution of all emergency department visits with abdominal pain compared to study sample by *H. pylori* status.

Characteristic	All abdominal pain n=1,039	Study sample n=205	*H. pylori* positive n=49	*H. pylori* negative n=156
Age				
18 – 34	46%	48%	45%	49%
35 – 54	33%	39%	37%	39%
≥ 55	20%	13%	18%	12%
Female	68%	64%	61%	65%
Race*				
White	28%	28%	7%	34%
Black	62%	58%	76%	53%
Other	10%	14%	17%	13%
Triage acuity				
1-2	13%	10%	10%	10%
3	79%	82%	84%	81%
4 – 5	8%	8%	6%	9%
Arrival time				
7AM – 11AM	25%	39%	45%	37%
11AM – 3PM	51%	44%	39%	46%
3PM – 7PM	24%	17%	16%	17%
Day of week				
Monday	21%	23%	33%	20%
Tuesday	21%	22%	22%	22%
Wednesday	20%	18%	10%	20%
Thursday	20%	22%	25%	22%
Friday	18%	15%	10%	16%
Time to disposition**				
< 2 hrs	22%	13%	4%	15%
2-4 hrs	23%	22%	20%	22%
4-6 hrs	35%	45%	43%	46%
> 6 hrs	20%	21%	33%	17%

* Race is missing in 16 participants.
**Significant difference between all abdominal pain patients and study sample's time to disposition, and significant difference between *H. pylori* positive and *H. pylori* negative patients' time to disposition.

RESULTS

There were no significant differences between the abdominal pain patients we screened for the study during the hours when the RAs were working versus hours when the RAs were not working by demographics (age, gender or race), triage acuity or time of day or day of week (Table 1). The average age of those enrolled and tested for *H. pylori* was 38 years. Almost two-thirds of study subjects were female (65 %) and the majority were black (53%). Three hundred seventy-onepatients were screened for eligibility, and the most common reasons for exclusion from the study were

Table 2. Prevalence of *H. pylori* Infection in study sample by demographic characteristics.

Characteristic	N	Prevalence (95% confidence interval)
Overall	205	24% (18%, 30%)
Age		
18 – 34	99	22% (14%, 30%)
35 – 54	79	23% (14%, 32%)
≥ 55	27	33% (15%, 51%)
Gender		
Male	74	26% (16%, 36%)
Female	131	23% (16%, 30%)
Race*		
White	53	6% (0%, 12%)
Black	110	28% (20%, 36%)
Other	26	27% (10%, 44%)

* Race is missing in 16 participants.

that the patient was currently on a PPI (n = 31), the patient was currently taking antibiotics (n = 24), the patient declined the test (n = 20), or, the patient had taken bismuth or pepto-bismol earlier that same day (n = 18.) The remaining subjects who were screened did not have upper abdominal pain when approached.

A total of 205 patients with upper abdominal pain were tested over 12 months, and 24% (95% CI: 19% to 30%) tested positive for *H. pylori*. *H. pylori* infection was significantly more prevalent among black subjects compared to whites (Table 2). Black subjects were significantly more likely to test positive than white subjects by chi-square test (28% v. 6%, $P < 0.001$). Other factors, such as age and sex, were not different between the 2 groups. The time to disposition appeared longer in the study group versus the general pool of abdominal pain patients. Past medical history was recorded for all enrolled subjects. Twenty-three (17.3 %) subjects reported a history of ulcer or gastritis or reflux; 4 (3%) subjects had diabetes mellitus; 7 (5.3%) had gallstones; 3 (2.3%) had liver disease; and, 4 (3%) had pancreatitis. In addition, 15 (11.3%) subjects were active smokers, 12 (9%) subjects were previous smokers and 4 (3%) reported drinking more than 5 drinks per day. Twenty-two (25.6%) subjects were currently taking PPI antacids and 22 (25.6%) reported to take NSAIDs on most days. A total of 42 (48.8%) subjects described pain that started more than 2 days prior to the ED visit. Twelve subjects received an ultrasound as part of ED evaluation, 14 received a computered tomography as part of ED evaluation, and 29 (19.3%) of subjects received intravenous narcotics as part of ED management.

DISCUSSION

This study demonstrated that approximately one-quarter of ED patients with upper abdominal pain had active *H. pylori* infections. Some patients infected by *H. pylori* may have had peptic ulcers or gastritis or non-ulcer dyspepsia, diseases in which clinical benefit has been demonstrated after eradication therapy. The test-and-treat strategy has been demonstrated to decrease morbidity and promote cost-effective care in prior studies in the outpatient setting with high prevalence.[7] If prevalence is high, a similar strategy applied in the ED could benefit patients and the overall healthcare system. In our experience, the UBT was a promising test to utilize in the ED because of the rapid result, the ease of test, the tolerability of test, and the ability to change management of a common complaint. There was a small but significant increase among the study population in the percent of patients who did not receive a disposition under 2 hours. Whether the test will be feasible in other EDs that lack resources similar to our ED is unknown.

Racial and socioeconomic disparity in *H. pylori* infection rates have been described previously.[8] If the racial disparities observed in our ED are also observed in other EDs and in follow-up studies designed to primarily explore this association, then conducting *H. pylori* testing in EDs that treat a predominance of non-white patients may be a useful strategy. In general, the prevalence rates that we found for whites and blacks are similar to the general population data.

We found the UBT to be easily administered by non-clinical staff and well-tolerated by ED patients. The test-and-treat strategy is recommended for outpatient settings and could be adopted in an ED with high local prevalence. Medicare reimbursement for the UBT averages $93.[9] Other forms of testing for *H. pylori* infection, such as serum antibody tests, stool antigen test and upper endoscopy, may be less feasible in the ED. The serum antibody test does not distinguish if infection is active or resolved. The need to obtain a stool sample may make the stool antigen test more difficult during an ED visit. Finally, the upper endoscopy requires a specialist and procedural sedation.

We are currently not aware of any other U.S. EDs that routinely perform *H. pylori* testing. Possible reasons why testing for *H. pylori* is not performed in the ED include the lack of availability of the test, the idea that dyspepsia is not an emergency diagnosis, or, the concern that a patient may not receive appropriate follow-up care.[10] To address follow-up access, we initially planned to follow all subjects for clinical data as outpatientsbut have not included that data due to incompleteness. In the future, we will follow patients who tested positive to determine symptom relief, *H. pylori* eradication rates and medication compliance.

There are potential clinical benefits to the test-and-treat strategy for ED patients with uninvestigated dyspepsia/ abdominal pain. First, eradication treatment with antibiotics can be started immediately after the initial visit in the ED.[7,11] Second, patients may be spared the cost and side effects of prolonged treatment with PPIs and an invasive procedure, such as an upper endoscopy. Third, for patients with limited access to primary care and specialty care, there may be an overall reduction in incidence of long-term *H. pylori*-related complications, such as ulcers, gastritis or neoplasm.[12] Future studies are required to address whether patients experienced symptomatic improvement after therapy and whether patients had identifiable gastrointestinal pathology such as neoplasm, gastritis or ulcer.

One potential negative result to the ED test-and–treat approach would be to provide false reassurance for a patient with pre-existing gastric cancer and to decrease likelihood that a patient would follow up with a GI specialist for diagnostic upper endoscopy. Another possible negative outcome would be to increase the risk of premature closure of diagnosis and influence a clinician to miss a different cause of the pain, such as pancreatitis.

LIMITATIONS

Our study of prevalence of *H. pylori* infection in the ED has 4 limitations. First, our estimate may reflect a healthier sample than the general ED population of upper abdominal

pain because subjects were asked to walk to the UBT machine and not all abdominal pain patients can walk across the ED to take a test. Second, our study used a convenience sample that may introduce selection bias. We attempted to limit that source of bias by approaching sequential patients and by comparing demographics of our study sample with the general ED population. Third, we may have underestimated the *H. pylori* prevalence by excluding patients with active treatment for gastritis, including bismuth and patients taking PPIs. Fourth, this study occurred at a single ED, and other EDs may find a meaningfully different rate of *H. pylori* prevalence depending on the patient population they serve.

CONCLUSION

We have shown approximately 25% prevalence of disease in symptomatic patients and demonstrated the feasibility of using the UBT in our ED. Based on current outpatient recommendations, the test-and-treat strategy to dyspepsia should be considered in environments that have greater than 10% prevalence. Finally, given the apparent association with non-white race, this infection may represent a health disparity that should be addressed as part of a larger public health campaign.

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Evaluation of a New Nonnvasive Device in Determining Hemoglobin Levels in Emergency Department Patients

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Introduction: The Masimo Radical-7 Pulse CO-Oximeter is a medical device recently approved by the US Food and Drug Administration that performs noninvasive oximetry and estimated venous or arterial hemoglobin measurements. A portable, noninvasive device that rapidly measures hemoglobin concentration could be useful in both austere and modern hospital settings. The objective of this study is to determine the degree of variation between the device's estimated hemoglobin measurement and the actual venous hemoglobin concentration in undifferentiated emergency department (ED) patients.

Methods: We conducted a prospective, observational, cross-sectional study of adult patients presenting to the ED. The subjects consisted of a convenience sample of adult ED patients who required a complete blood count as part of their care in the ED. A simultaneous probe hemoglobin was obtained and recorded.

Results: Bias between probe and laboratory hemoglobin measurements was −0.5 (95% confidence interval, −0.8 to −0.1) but this was not statistically significant from 0 ($t_{0.05,124} = 0.20$, $P > 0.5$). The limits of agreement were −4.7 and 3.8, beyond the clinically relevant standard of equivalency of ± 1 g/dL.

Conclusion: These data suggest that noninvasive hemoglobin determination is not sufficiently accurate for emergency department use. [West J Emerg Med. 2013;14(3):283–286.]

INTRODUCTION

In most medical settings, the only way a medical practitioner can determine hemoglobin (Hb) concentration is through a percutaneous blood draw. Many clinical scenarios, especially those involving critically ill or injured patients, rely on single or serial Hb measurement determinations for clinical decision making. Even with current point-of-care testing, blood draws are invasive, potentially painful, time-consuming, resource intensive, costly, and may expose healthcare providers to blood-borne pathogens.

A portable, noninvasive device that rapidly measures Hb concentration could be useful in both austere and modern hospital settings. Patients with suspected blood loss could have real-time Hb determinations that could impact aggressiveness of care. The Masimo Radical-7 (Masimo Corporation, Irvine, California) is a medical device recently approved by the US Food and Drug Administration that performs noninvasive oximetry and estimated Hb measurements. Using a fingertip probe similar to a standard pulse oximetry sensor, the device noninvasively determines a hemoglobin level within 1 to 2 minutes without requiring any other equipment.

Several small studies conducted on humans and animals have shown a correlation between this noninvasive technology and venous Hb levels in controlled settings.[1–4] Data collected by the manufacturer on a cohort of healthy volunteers, surgery patients, and adults undergoing a

hemodilution protocol reported a correlation coefficient of 0.9 between venous and noninvasive Hb levels.[5,6] Unfortunately, correlations are not appropriate for practical usage as they only describe a relationship without much useful clinical information.[7]

The purpose of our study is to further evaluate the accuracy of the Masimo Radical-7 technology by comparing its noninvasive venous hemoglobin measurements with actual venous hemoglobin levels in undifferentiated emergency department (ED) patients. This is the first study evaluating this technology in an ED population. Our main outcome is the determination of the degree of variation between these 2 methods.

METHODS

Study Design

We conducted a prospective, observational, cross-sectional study of adult patients presenting to our ED from February 2009 to January 2010. The ED is an urban Level II trauma center with an annual census of 70,000 to 75,000 visits and is the home of an emergency medicine residency that cares for a large population of young, generally healthy, active duty soldiers and their families, as well as many middle-aged and elderly military retirees. This study was approved by the hospital's institutional review board (IRB).

Selection of Participants

The subjects consisted of a convenience sample of 127 adult ED patients who required a complete blood count (CBC) as part of their care in the ED. Patients could be enrolled by any attending or resident physician working in the ED. Patients not requiring a CBC as part of their ED evaluation were ineligible. The decision to obtain a CBC was at the discretion of the attending emergency physician. Study participants provided verbal consent after receiving a handwritten information sheet about the device and study. We excluded subjects younger than 18 years, pregnant women, prisoners, and those who lacked the mental capacity to refuse or consent to participation as directed by our IRB. Only a single Masimo probe Hb measurement and single laboratory Hb measurement were taken per subject. To distinguish between the values measured by the Masimo probe and the target laboratory values, it was estimated that a minimum of 70 to 80 patients would be required, assuming a Hb range of 6 to 16 g/dL, a constant analytic standard deviation of 1 g/dL, a single measurement for each patient, type I error of 5%, and a statistical power of 90%.

Study Materials

The study device was the Masimo Radical-7 Pulse CO-Oximeter handheld unit (version 7.7720 with rev-D sensors) and RDS-2 docking station (version 5129). The device uses an infrared fingertip sensor to measure several physiologic parameters in addition to venous Hb, including heart rate, oxygen saturation, carboxyhemoglobin, and methemoglobin values. Venous Hb results are given in 0.5 g/dL increments and are generally obtained in less than 1 minute. The stated venous Hb measurement range of the device is 0 to 25 g/dL, with highest accuracy between 8 to 17 $\pm$ 1.0 g/dL.

A major factor known to influence the accuracy of the device is the perfusion index (PI), a numerical assessment of signal quality and pulsatile strength, as well as an indirect measure of peripheral perfusion relative to a particular monitoring site. A PI greater than 1.0 signifies a more accurate venous Hb value. Placing the patient's hand in a gravity-dependent position generally results in a higher PI and more accurate reading. Ambient factors such as decreased temperature or physiologic states that reduce blood flow to the fingertips may result in a lower PI and less accurate venous Hb readings. The presence of nail polish, dark skin color, and patient motion do not affect device performance. Ambient light can reduce device accuracy, and thus the manufacturer recommends and provides for the use of a dark plastic finger cover to reduce exposure.[5]

Data Collection and Processing

The noninvasive measurement device probe and dark plastic cover was applied to the patient's gravity-dependent clean index finger, and the Hb value was recorded either before or just after the CBC was performed and before the results were known. Peripheral venous phlebotomy was performed in standard fashion. A unique patient identifier was recorded on the initial table, so that the provider could accurately match the venous hemoglobin level to the noninvasive value. All data were handwritten in the study log binder. This information was later transferred to an electronic spreadsheet.

Statistical Analysis

Equivalence was assumed to be within 1 g/dL of Hb. This threshold was chosen by the authors as a reasonable difference that would be unlikely to affect clinical decision making. To assess agreement between measurements obtained by the 2 methods, we performed a Bland-Altman analysis.[8] This method allows quantification of the difference between the 2 techniques under consideration, and thus allows us to assess if the device has sufficient accuracy to allow acceptance of the device values in lieu of standard laboratory techniques. As articulated by Bland and Altman,[7,8] statistical methods such as Pearson correlation or *t* tests are not appropriate for method comparison studies, as they do not allow evaluation of either difference or accuracy between techniques. These data are summarized by the mean, the bias, and the 95% confidence range of the differences between techniques (limits of agreement). Bias is the difference between the proposed method and the standard technique, and therefore estimated as the mean difference between Hb readings from the Masimo and the laboratory blood draw (standard). The limits of agreement were calculated as (mean difference $\pm$ 2 standard deviation). We evaluated the possibility of systematic variation over the range of

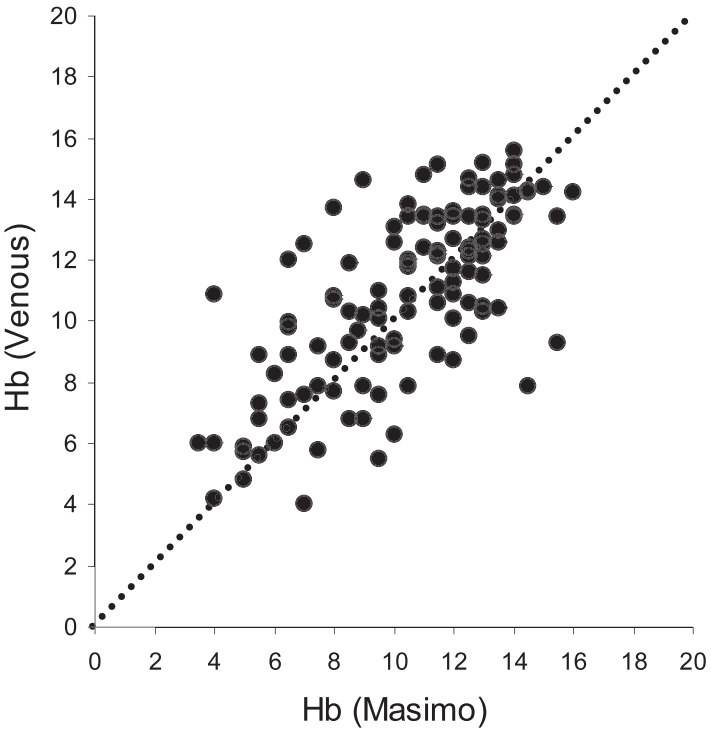

Figure 1. Scatter plot of Masimo hemoglobin (Hb) values versus laboratory hemoglobin values. Dotted line represents 1:1 line of equivalency.

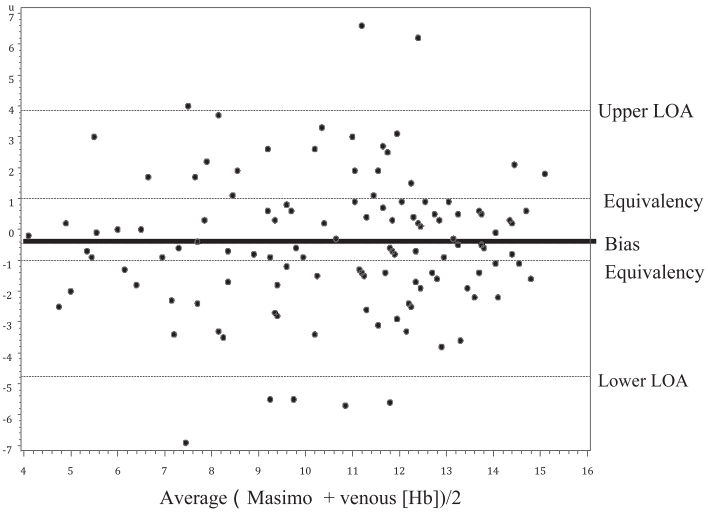

Figure 2. Bland-Altman plot of the difference between Masimo and venous hemoglobin (Hb) measurements. Dark line represents Masimo bias. Inner dashed line represents area of equivalency, which is ± 1 g/dL of Hb. Outer dashed line represents limits of agreement. *LOA*, limit of agreement.

measurement values (differences between the 2 techniques, changing as Hb measurements become more extreme) by calculating the rank correlation between the absolute differences and the average.[8,9] All calculations were performed in SAS version 9.1 (Cary, North Carolina).

RESULTS

During the 11-month study period, 127 measurements were obtained from individual patients with a wide array of both medical and traumatic presentations typical of any ED of this size, paired with completed laboratory Hb determinations. Figure 1 is a scatter plot of probe Hb values versus laboratory Hb values, with a 1:1 line of equivalency. Bias was the difference between Masimo probe readings and the laboratory blood draw. Bias between probe and laboratory Hb measurements was −0.5 (95% confidence interval, −0.8 to −0.1) but this was not statistically significant from 0 ($t_{0.05,\ 124} = 0.20$, $P > 0.5$). The limits of agreement were −4.7 and 3.8, beyond the clinically relevant standard of equivalency of ± 1 g/dL. There was no systematic difference over the various hemoglobin ranges ($r = 0.06$, $P = 0.52$). There were large outliers, 2 above and 5 below the limits of agreement lines. Additionally, 23/127 (18%) were above the upper clinical equivalence boundary and 44/127 (35%) were below (see Figure 2).

DISCUSSION

Our study on a convenience sample of patients evaluated by the Masimo Radical-7 clearly showed that the device is not ready for use in clinical decision making. The limits of agreement were −4.7 and 3.8, and were beyond the prespecified, clinically acceptable range of ± 1 g/dL. These differences resulted in both overestimation and underestimation of the laboratory Hb values. This phenomenon was seen equally across all Hb ranges.

There were 8 instances in which differences of greater than 4 g/dL between the probe and laboratory measurements were noted. These outliers, combined with the patients for whom readings could not be obtained, bring into question the utility of the device for obtaining rapid, accurate results for patients who require immediate intervention.

Since this trial was completed, another iteration of software for the device has been issued. To our knowledge, this new software has not been tested clinically and its effects on the accuracy and precision of the device are unknown.

LIMITATIONS

A single laboratory Hb concentration for each patient was used as the "gold standard" and was not repeated. These measurements represent a single time point and did not evaluate accuracy of serial measurements over time. Serial probe measurements may have been able to identify if large probe variances were consistently inaccurate or if there were occasional random probe errors among a collection of accurate readings. Some of the extreme outlying values could have been due to laboratory error or inadvertent dilution rather than probe inaccuracies. Given the sheer number and standardization of laboratory blood analysis, this is unlikely. Although not recorded in our analysis, there were many instances in which a venous Hb value was obtained with a PI less than 1.0. This too

could explain some of the extreme outlying values and overall performance of the device.

There was an occasional patient for whom the device did not give a reading. These patients were not included in the data analysis, nor were they tracked to determine the actual percentage of patients for whom this technology did not give any result.

Future areas of study include the evaluation of accuracy of the Masimo Radical-7 over time, using multiple measurements, as well as the impact of these measurements in clinical decision making.

CONCLUSION

In the first trial of noninvasive Hb testing done in the ED setting, the device, with the software package available to us, was not capable of providing clinically acceptable results. However, noninvasive technology is promising and should not be discounted. Further study on subsequent, planned iterations of the software and hardware should be studied for use in the ED.

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Predictors of Successful Telephone Contact After Emergency Department-based Recruitment into a Multicenter Smoking Cessation Cohort Study

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Introduction: Emergency department (ED) studies often require follow-up with subjects to assess outcomes and adverse events. Our objective was to identify baseline subject characteristics associated with successful contact at 3 time points after the index ED visit within a sample of cigarette smokers.

Methods: This study is a secondary analysis of a prospective cohort. We recruited current adult smokers at 10 U.S. EDs and collected baseline demographics, smoking profile, substance abuse, health conditions, and contact information. Site investigators attempted contact at 2 weeks, 3 months, and 6 months to assess smoking prevalence and quit attempts. Subjects were paid $20 for successful follow-up at each time point. We analyzed data using logistic and Poisson regressions.

Results: Of 375 recruited subjects, 270 (72%) were contacted at 2 weeks, 245 (65%) at 3 months, and 217 (58%) at 6 months. Overall, 175 (47%) were contacted at 3 of 3, 71 (19%) at 2 of 3, 62 (17%) at 1 of 3, and 66 (18%) at 0 of 3 time points. At 6 months, predictors of successful contact were: older age (adjusted odds ratio [AOR] 1.2 [95%CI, 0.99–1.5] per ↑10 years); female sex (AOR 1.7 [95%CI, 1.04–2.8]); non-Hispanic black (AOR 2.3 [95%CI, 1.2–4.5]) vs Hispanic; private insurance (AOR 2.0 [95%CI, 1.03–3.8]) and Medicare (AOR 5.7 [95%CI, 1.5–22]) vs no insurance; and no recreational drug use (AOR 3.2 [95%CI; 1.6–6.3]). The characteristics independently predictive of the total number of successful contacts were: age (incidence rate ratio [IRR] 1.06 [95%CI, 1.00–1.13] per ↑10 years); female sex (IRR 1.18 [95%CI, 1.01–1.40]); and no recreational drug use (IRR 1.37 [95%CI, 1.07–1.74]). Variables related to smoking cessation (e.g., cigarette packs-years, readiness to quit smoking) and amount of contact information provided were not associated with successful contact.

Conclusion: Successful contact 2 weeks after the ED visit was 72% but decreased to 58% by 6 months, despite modest financial incentives. Older, female, and non-drug abusing participants were the most likely to be contacted. Strategies to optimize longitudinal follow-up rates, with limited sacrifice of generalizability, remain an important challenge for ED-based research. This is particularly true for studies on substance abusers and other difficult-to-reach populations.
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INTRODUCTION

The ability to obtain successful telephone contact with patients after emergency department (ED) visits has important implications for clinical care and research. Telephone follow-up is used for a variety of clinical applications, which include monitoring changes in health status; ensuring compliance with discharge instructions; notifying patients of new results or follow-up appointments; and quality improvement and patient satisfaction surveys.[1-4] For observational and interventional studies, longitudinal follow-up after ED visits is vital to measure patient outcomes, including change in condition, responses to interventions, and adverse events. Although methods of analyzing missing or incomplete data have been established,[5,6] having study subjects that are lost to follow-up reduces sample size and precision, and often introduces bias because missing data are rarely random events.[7,8] Some investigators have even cautioned against telephone calls as the sole means of follow-up for ED patients, although the vast majority of longitudinal ED-based research uses this method.[9]

Several studies have analyzed predictors of successful follow-up after ED visits for clinical and research outcomes.[1,2,9-14] Recent ED-based public health initiatives have focused on screening, brief interventions, and referral for patients with substance abuse, including tobacco, alcohol, and recreational drugs.[15] Neuner et al[14] analyzed predictors of loss to follow-up in an ED-based intervention for problem alcohol use and found that tobacco use was the strongest predictor. Although cigarette smokers are often cited as a group that is difficult to contact after ED visits, no prior study has focused specifically on analysis of follow-up in a cohort of ED cigarette smokers.[2,14,16-18] This topic is particularly important because of the growing interest in developing effective ED-based smoking cessation interventions, as suggested by a consensus of emergency medicine organizations,[19] the Institute of Medicine,[20] and the US Preventive Service Task Force.[21]

Accordingly, the objective of this study was to identify baseline characteristics associated with successful contact at 3 time points after an index ED visit for a cohort of cigarette smokers. The results of this study have implications for other hard-to-study populations, including ED- based studies of disadvantaged populations and other substance abusers.

METHODS

Study Design, Setting, and Participants

This study is part of a prospective cohort study, conducted in 2008–2009, using subjects recruited from 10 EDs in 8 geographically diverse U.S states. During a 10-day enrollment period, trained research staff screened consecutive ED patients for tobacco use. Patients were recruited during peak volume hours (9:00AM to midnight). Each site enrolled a minimum of 36 subjects.

Eligible subjects were 18 years or older who currently smoked cigarettes and met the Centers for Disease Control and Prevention definition for being a smoker, based on response to the question: "Have you smoked at least 100 cigarettes (5 packs) in your life?" There was no minimum smoking rate, and we enrolled both daily and non-daily smokers, based on the response to the question: "Do you now smoke cigarettes every day, some days, or not at all?" Response choices were "currently smoke every day"; "currently smoke some days"; or "currently do not smoke". We excluded patients with illnesses that precluded conversation or adequate comprehension of the study's requirements, including those with altered mental status, acute intoxication, hostile or agitated behavior, an insurmountable language barrier, or severe illness (e.g., intubation, persistent vomiting). In addition, subjects with high risk of being lost to follow-up were excluded, including those who had no current residence, a transient residence (planned to move during the next 6 months), or no access to a telephone that is always in service. However, we did not exclude individuals based on their alcohol or drug use.

Data Collection

Subjects completed a self-administered, paper-and-pencil baseline assessment in the ED to collect data on smoking-related variables and predictors of cessation. Assessments were printed in both English and Spanish. To accommodate patients with poor eyesight or illiteracy, the assessment could be completed through research staff interview. To reduce demand bias, which could lead to under-reporting of tobacco use and over-reporting of interest in cessation, participants were re-assured that their responses would not be shared with their treating clinicians. The specific measures used for this paper, which represent a subset of the full battery, are described under the *Measures* section.

All subjects received treatment-as-usual by their medical providers for their tobacco use. The research staff did not provide any counseling; however, after baseline data collection was complete, subjects received an educational pamphlet on smoking cessation published by the U.S. Department of Health and Human Services (www.ahrq.gov/consumer/tobacco/helpsmokers.htm) and a list of tobacco cessation treatment options, which included a National Quitline telephone number (1-800-QUIT-NOW). Furthermore, subjects who screened positive for depression, alcohol, or drug use were given the respective educational pamphlet published by the Association for Behavioral and Cognitive Therapies (www.abct.org), as well as brochures with national mental health hotlines and state-based behavioral health referral services (findtreatment.samhsa.gov).

Contact information included primary and secondary phone numbers; phone number(s) for up to 2 alternate contact people; phone number type (daytime, nighttime, or cellular); and addresses for the subject and alternate contacts. Site research staff attempted telephone follow-up interviews 2 weeks, 3 months, and 6 months after the ED visit to assess their smoking behavior, including quit attempts and 7-day

abstinence. The *primary outcome* for this study was the number successful contacts for the 3 time points (range 0 = 3). A maximum call window of 7 days was used with at least 3 attempts to each valid phone number made before the contact attempt was deemed unsuccessful. Calls were spaced across times of day (morning, afternoon, evening), and occurred on at least 2 different days. To improve response rates, modest financial incentives were provided to participants ($20) and sites ($50) for each successful follow-up.

The study was coordinated by the Emergency Medicine Network (EMNet). Data collection forms were reviewed by EMNet staff and missing or inconsistent data were reconciled through communication with the sites. All data underwent double data entry. The institutional review boards at all 10 sites approved the study. Participants provided written informed consent.

Measures

Demographic data included age, sex, race/ethnicity, health insurance, educational level, and annual household income.

Smoking history was assessed using the average number of cigarettes smoked per day and cigarette pack-years. *Readiness to quit smoking* was indexed by, "How ready are you to quit smoking within the next month (0 = not at all; 10 = 100% ready)?"[22,23] A score of 1 through 5 was considered "low" readiness and 6 through 9 as "high" readiness.

Problem alcohol use was measured by the Rapid Alcohol Problem Scale (RAPS), a well-validated brief screener for alcohol-related problems.[24] The RAPS consists of 5 yes/no questions: "During the last year, have you had a feeling of guilt or regret after drinking?", "During the last year, has a friend or family member ever told you about things you said or did while you were drinking that you could not remember?", "During the last year, have you failed to do what was normally expected from you because of drinking?", "Do

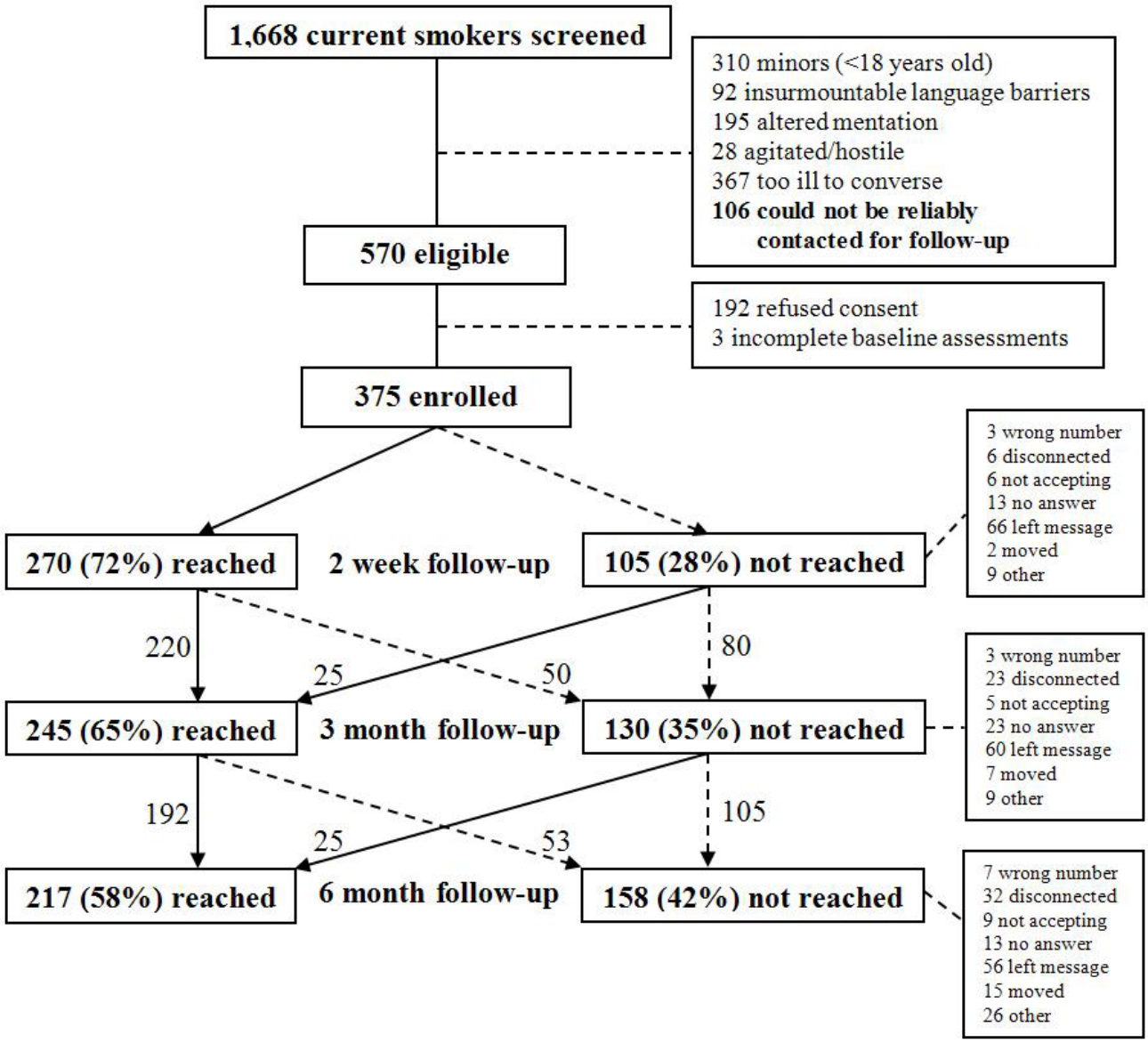

Figure 1. Eligibility and successful contact at 2 week, 3 month, and 6 month follow-up time points.

Table 1. Baseline characteristics of 375 enrolled participants.

Characteristics	n	%
Demographics		
Age, years		
18–29	96	26
30–44	128	34
45–59	128	34
≥ 60	22	6
Female sex	210	56
Race/ethnicity		
White, non-Hispanic	152	41
Black, non-Hispanic	137	37
Hispanic	73	20
Other/Multiracial	10	3
Health insurance		
Private	79	22
Medicare	22	6
Medicaid or other public	129	37
Uninsured	123	35
High school graduate	282	76
Annual household income, $		
< 20,000	148	39
21,000–40,000	91	24
≥ 41,000	57	15
Don't know/confidential	79	21
Smoking history		
Cigarettes per day		
1-10	198	54
11-20	118	32
≥ 21	54	15
Cigarette pack-years		
0-10	124	34
10.5–20	108	29
>20	136	37
Readiness to quit smoking		
Not at all	33	9
Low*	138	37
High*	97	26
Completely ready	107	29
Substance abuse		
Problem alcohol use		
None	134	36
RAPS screen negative	148	40
RAPS screen positive	89	24
Recreational drug use score		
None	261	71
Below RDPS cutoff	48	13
Above RDPS cutoff	59	16
Clinical information		
Self-reported smoking-related illnesses		
0	93	25
1–2	120	32
≥ 3	162	43
Depression	127	34
Triage acuity		
1–2	58	16
3	181	50
4–5	124	34
Emergency department disposition		
Admitted	91	24
Discharged	264	71
LWBS/LAMA	17	5
Location Information		
≥ 2 telephone numbers provided	141	38
Cell phone only provided	86	23
Alternate contact provided		
No	228	61
Yes, at same location	52	14
Yes, at different location	58	16
Yes, at unknown location	36	10

RAPS, Rapid Alcohol Problem Scale; *RDPS*, Rapid Drug Problem Scale; *LWBS*, left without being seen; *LAMA*, left against medical advice

* Score of 1 to 5 was considered "low" readiness and 6 to 9 considered "high" readiness

Table 1 continued →

Table 2. Association between baseline participant characteristics and successful contact at 6 months.

Characteristics	Successful contact n (%)	Adjusted odds ratio (95%CI)*
Total	217 (58%)	--
Demographics		
Age, years		1.2 (0.99-1.5)**
18–29	52 (54%)	--
30–44	66 (52%)	--
45–59	83 (65%)	--
≥ 60	15 (68%)	--
Female sex	134 (64%)	1.7 (1.04-2.8)***
Race/ethnicity		
White, non-Hispanic	92 (61%)	1.7 (0.9-3.2)
Black, non-Hispanic	86 (63%)	2.2 (1.2-4.5)***
Hispanic	35 (48%)	Referent
Other	4 (40%)	0.6 (0.1-2.6)
Health insurance		
Private	54 (68%)	2.0 (1.03-3.8)***
Medicare	18 (82%)	5.7 (1.5-22)***
Medicaid or other public	73 (57%)	1.2 (0.7-2.1)
Uninsured	61 (50%)	Referent
High school graduate	161 (57%)	--
Annual household income, $		
< 20,000	82 (55%)	--
21,000–40,000	53 (58%)	--
≥ 41,000	36 (63%)	--
Don't know/confidential	46 (58%)	--
Smoking history		
Cigarettes per day		
1-10	118 (60%)	--
11-20	66 (56%)	--
≥ 21	31 (57%)	--
Cigarette pack-years		
0-10	66 (53%)	--
10.5–20	64 (59%)	--
≥ 20.5	83 (61%)	--
Readiness to quit smoking		
Not at all ready	18 (55%)	--
Low	77 (56%)	--
High	57 (59%)	--
Completely ready	65 (61%)	--
Substance abuse		
Problem alcohol use		
None	73 (54%)	--
RAPS screen negative	93 (63%)	--
RAPS screen positive	49 (55%)	--
Recreational drug use score		
None	169 (65%)	3.2 (1.6-6.3)***
Below RDPS cutoff	25 (52%)	2.0 (0.8-4.7)
Above RDPS cutoff	20 (34%)	Referent
Clinical information		
Self-reported smoking-related illnesses		
0	45 (48%)	Referent
1–2	70 (58%)	1.6 (0.9-3.0)
≥ 3	102 (63%)	1.6 (0.8-2.9)
Depression	77 (61%)	--
Triage acuity		
1–2	36 (62%)	--
3	109 (60%)	--
4–5	67 (54%)	--
Emergency department disposition		
Admitted	56 (62%)	--
Discharged	152 (58%)	--
LWBS/LAMA	8 (47%)	--
Location Information		
≥ 2 telephone numbers provided	86 (61%)	--
Cell phone only provided	55 (64%)	1.4 (0.8-2.4)
Alternate contact provided		
No	133 (58%)	--
Yes, at same location	30 (58%)	--
Yes, at different location	32 (55%)	--
Yes, at unknown location	22 (61%)	--

RAPS, Rapid Alcohol Problem Scale; *RDPS*, Rapid Drug Problem Scale; *LWBS*, left without being seen; *LAMA*, left against medical advice

*Variables with $P < 0.20$ in unadjusted analysis included in the multivariable model

**per ↑10 years

***$P < 0.05$

Table 2 continued →

Table 3. Overall total number of successful follow-up contacts (range 0-3).

Number of time points with successful contact	n	%
3 of 3	175	47
2 of 3	71	19
1 of 3	62	17
0 of 3	66	18

you sometimes take a drink in the morning when you first get up?", and "During the past year, have you lost friends or a significant other because of your drinking?" A score greater than 0 is used as a threshold to warrant further assessment of alcohol abuse or dependence.

Problem drug use was measured by the Rapid Drug Problem Scale (RDPS),[25] which is identical to the first 4 items of the RAPS with the exception that recreational drugs replace drinking. A score greater than 0 is used as a threshold to warrant further assessment of recreational drug abuse or dependence.

Smoking-related illnesses were categorized based on whether they met criteria for a smoking-related disease as outlined by the US Surgeon General.[26] This is a commonly used strategy to classify smoking-related diseases and has been applied successfully to ED patients.[27,28]

The *Depression* screener consisted of the Patient Health Questionnaire-2,[29] a well-established, 2-item screener assessing sad mood and anhedonia over the past 2 weeks (0 = None/Little of the time, 1 = Some of the time, 2 = Most of the time, 3 = All of the time). A score greater than 0 on either item was considered a positive screen.

Additional clinical data included *triage acuity* (on a 5-point scale) and *ED disposition* (admit vs. discharge).

Data analysis

The primary goal of the data analyses was to measure the association between baseline participant characteristics and successful follow-up at 2 weeks, 3 months, and 6 months. We performed statistical analysis using Stata 10.1 (StataCorp, College Station, TX). Unadjusted associations between baseline characteristics and successful contact were analyzed using chi-square tests, or Fisher's exact test as appropriate. We included variables with unadjusted $p<0.20$ in the multivariable models to minimize risk of overfitting (no variables were forced into the models).

Using multivariable logistic regression, we adjusted for participant characteristics to measure the association with successful contact at 6 months. In addition, we used multivariable Poisson regression to measure the association between baseline characteristics and the number of successful follow-up contacts (range 0-3). Two-tailed p-values < 0.05 were considered statistically significant. The goodness-of-fit for the multivariable models was confirmed using the Hosmer-Lemeshow test.

Table 4. Multivariable Poisson regression for number of successful follow-up contacts (range 0-3).

Characteristics*	Incidence rate ratio	95%CI
Age per ↑10 years	1.06**	1.00-1.13**
Female Sex	1.19**	1.01-1.40**
Health insurance		
Private	1.13	0.92-1.39
Medicare	1.21	0.89-1.65
Medicaid or other public	0.99	0.82-1.20
Uninsured	Referent	
Recreational drug use score		
None	1.37**	1.07-1.74**
Below RDPS cutoff	1.34	0.99-1.82
Above RDPS cutoff	Referent	
Smoking-related self-reported illnesses		
0	Referent	
1–2	1.10	0.89-1.36
≥ 3	1.12	0.91-1.37
≥ 2 telephone numbers provided	1.11	0.95-1.29

CI, confidence interval; *RDPS*, Rapid Drug Problem Scale;
*Variables with $p<0.20$ in unadjusted analysis included in the multivariable model
**$p<0.05$

RESULTS

There were 8,241 patients who presented to the participant EDs during the 10-day enrollment period. Study staff screened 3,800 patients for potential enrollment, of which 2,132 (58%) were classified as non-smokers. For the remaining 1,668 current smokers, the numbers and reasons for exclusion are presented in Figure 1, and included 106 that did not have reliable contact information (non-stable residence, no telephone service). There were 378 patients enrolled into the study; 3 subjects were removed because of missing data, leaving 375 for this analysis.

The characteristics of study participants are shown in Table 1. Compared to patients who were not enrolled (i.e., not eligible, not approached, or refused), subjects were more likely to be younger, have Medicaid insurance, and be discharged (versus admitted) (all $p<0.05$; data not shown). There were no differences observed between those enrolled and those not enrolled by sex or race/ethnicity.

The overall successful follow-up contacts declined with each successive time point (see Figure 1) —72% at 2 weeks,

65% at 3 months, and 58% at 6 months. However, there was cross-over between responders and non-responders at each time point, including 14 (18%) participants not contacted at 2 weeks or 3 months but who were successfully contacted at 6 months. At all time points, the most common reason for unsuccessful contact was a working phone number where voicemails were left and not returned; however wrong, changed, or disconnected telephone numbers were more common with later follow-up time points.

Unadjusted and adjusted associations between baseline characteristics and successful contact at 6 months are presented in Table 2. In unadjusted analysis, characteristics associated with higher rates of successful contact at 6 months included older age, female sex, non-Hispanic ethnicity, private or Medicare insurance, no recreational drug use, greater number of smoking related illnesses, and permanent residence. In the multivariable analysis, female sex, non-Hispanic black race, private insurance, Medicare, and no recreational drug use were associated with statistically significant higher odds of successful contact at 6 months.

The overall total number of successful follow-up contacts is displayed in Table 3. Most (82%) were successfully contacted at 1 or more time points, but only 47% were contacted at all 3 time points. The characteristics most predictive of the total number of successful contacts were older age, female sex, and no recreational drug use (Table 4).

DISCUSSION

In prior ED-based studies, current smokers have been cited as a group at risk for being lost to follow-up.[2,14] In the present study that exclusively recruited current smokers, successful follow-up was challenging, despite modest financial incentives and efforts to exclude potential participants with limited or transient contact information. Factors found to be associated with increased odds of successful follow-up included older age, female sex, and no drug use. The major strengths of this study were recruitment at 10 geographically diverse sites and multiple follow-up time points.

Successful follow-up for clinical care or research requires two basic elements: (1) the participant must be found, and (2) the participant must be willing to cooperate with the purpose of the call (e.g., receive clinical results or research data collection). We excluded potential participants with no current residence, a transient residence, or no access to a telephone that is always in service to reduce the risk of inability to find the participant over the 6-month follow-up period (10% of exclusions). Additionally, financial incentives for participants and site investigators were meant to incent motivation to be located and complete follow-up.[30] Compared to clinical care follow-up where patients are typically motivated by their health to receive results or instructions, research participant cooperation with the purpose of follow-up is more challenging, particularly in behavioral health research. For the present study, for which the objective of assessing smoking and smoking cessation rates over time was clear, participants may have had motivation to avoid follow-up calls from the guilt or embarrassment of continued smoking. This hypothesis requires further study.

Identifying baseline characteristics associated with successful contact may help to derive selection criteria that improve follow-up, particularly in study populations already at high risk for unsuccessful contact. However, the importance of high follow-up rates for internal validity must be weighed against the loss of generalizability (external validity) of study results. In this population of ED patients that currently smoke, problem recreational drug use was identified as the factor most likely associated with lower rates of successful contact at follow-up and potentially amenable to use as an exclusion criterion (compared to problem drug users, non drug users had an OR of 3.2 for successful follow-up at 6 months). This is consistent with prior studies of general ED patients.[12,31] Also consistent with prior ED-based studies,[2,13,14] younger age and male sex were also associated with lower contact rates (OR for successful follow-up at 6 months 1.2 per ↑10 years of age and 1.7 for female compared to male sex). However, restricted selection criteria on the basis of age or sex would severely limit generalizability of most ED-based studies. Additionally, younger men and substance abusers are typically at highest risk for risky health behaviors, and therefore, exclusion of these populations may be ethically and practically untenable. Acknowledging that lower follow-up rates may result, further research on different contact methods such as e-mail, web-based format, social networking, and text messaging should be considered.

Overall, these results suggest that the results of the primary study have reduced applicability to younger, male, and drug abusing populations, which are known to have higher smoking rates and are also most recalcitrant. The primary data analyses will likely need to impute smoking status for those lost to follow-up. Interestingly, variables related to the primary study purpose of smoking cessation, such as smoking rate and motivation to change were not associated with successful contact rates. Thus, concerns about missingness being meaningfully related to smoking behavior, and consequently introducing a critical bias in our interpretations about smoking patterns, are lessened. Additionally, amount of contact information (e.g., number and types of phone numbers, alternate contact people) were not associated with successful follow-up. Although significant effort is made to collect these data in longitudinal studies, their impact on follow-up rates may not be large. This finding merits further investigation.

The present study used multiple time points over 6 months, which allowed assessment of attrition over time. With this analysis, we found that 24% of participants that were not contacted at 2 weeks were successfully contacted at 3 months, and 21% that were not contacted at 3 months were successfully contacted at 6 months. These rates were comparable to those that crossed over from successful to

unsuccessful contact between the time points (19% and 22%, respectively). Also, nearly one in five participants that appeared lost to follow-up with unsuccessful contact at 2 weeks and 3 months were successfully contacted at 6 months. These results collectively suggest that serial follow-up is a dynamic process that involves more than just fixed participant baseline characteristics. They also suggest that two unsuccessful contacts are insufficient to establish futility, since future contact still appears possible.

LIMITATIONS

The data were collected only on current smokers in the ED for a research application. Consequently, the results should be generalized with caution for research in other ED patient populations and other medical settings. Additionally, these results in research study context should not be generalized to follow-up for clinical care, since the purposes of these contacts are very different. Additional work replicating our results across different patient populations and other settings is needed. Although recruitment at 10 geographically diverse EDs is a strength of this study, all sites were urban, academic centers and this limits the generalizability to community or rural EDs. Care should also be taken when comparing these results with studies using a different procedure for selecting patients with limited contact information, collecting contact information, and obtaining follow-up. These procedures may affect success rates and the characteristics associated with success.[32] Specifically, potential subjects were aware of the financial incentive to participate in the study at the time of consent, which may have created an enrollment bias. The sample size for this study was relatively modest which may have obscured actual differences (i.e., Type II error). However, the larger and clinically significant differences in successful follow-up contact rates were likely identified.

CONCLUSIONS

In our study of ED patients that currently smoke, successful contact 2 weeks after the ED visit was 72% and decreased by 6 months to 58%, despite modest financial incentives. This may reflect the difficulty in obtaining follow-up in ED-based studies on substance abuse. Variables related to smoking cessation (e.g., cigarette pack-years, readiness to quit) and amount of contact information provided were not associated with successful contact. Successful follow-up for research is challenging, but our models indicate that older, female, and non-drug abusing participants are the most likely to be contacted. Surprisingly, non-response at earlier timepoints did not necessarily infer long-term loss to follow-up. Strategies to optimize longitudinal follow-up rates, with limited sacrifice of generalizability, remain an important challenge for ED-based research, particularly for studies on substance abusers and other difficult-to-reach populations.

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Safety and Efficacy of Prehospital Diltiazem

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Introduction: Very few studies exist on the use of diltiazem in the prehospital setting. Some practitioners believe this medication is prone to causing hypotension in this setting. Our goals were to determine whether the prehospital administration of diltiazem induced hypotension and to evaluate the efficacy of the drug.

Methods: Our two-tiered system is located in a suburban region of New Jersey with advanced life support (ALS) care provided by fly-car units. The ALS units do not transport patients, and all of them are hospital based. The ALS providers are employed by the hospital system. In New Jersey, all ALS care requires online medical control, including the administration of diltiazem. We retrospectively reviewed patient care records for those who were believed to be in rapid atrial fibrillation and were given diltiazem in a suburban emergeny medical services system over a 22-month period. We examined the differences between heart rate (HR) and blood pressure (BP) on the initial evaluation and on arrival to the emergency department (ED). A hypotensive response was defined as a final systolic BP (SBP) less than 90 mmHg and a drop in SBP of at least 10 mmHg. Diltiazem was considered effective if the ED HR was $<$100 beats per minute (bpm) or if it decreased $\geq$20%.

Results: During the study period, 26,979 patients were transported. Of these patients, 2,488 had a documented rhythm of atrial fibrillation or atrial flutter. Of the 320 patients who received diltiazem, 42 patient encounters were excluded for incomplete data, yielding 278 patients for analysis. The average initial SBP was 139 mmHg and the average diastolic BP was 84 mmHg. The average diltiazem dosage was 16.7 mg. Two patients became hypotensive. The average initial HR was 154 bpm. On arrival to the ED, 33% of the patients had an HR $<$ 100 bpm and 69% had a drop in HR $\geq$ 20%. The overall efficacy of prehospital diltiazem was 73%.

Conclusion: In the prehospital setting, diltiazem is associated with a very low rate of hypotension and appears to be effective in decreasing HR adequately. Prospective studies are needed to confirm these findings. [West J Emerg Med. 2013;14(3):296–300.]

INTRODUCTION

Atrial fibrillation is a common dysrhythmia in the United States. Its prevalence has been reported from 2.3% in persons older than 40 years to 5.9% in persons older than 65 years.[1] Uncontrolled rapid atrial fibrillation with an accelerated ventricular response can lead to impaired diastolic filing, loss of atrial kick, decreased ventricular output, and decreased coronary perfusion. The primary treatment goal is to control the ventricular rate. However, there are various methods of treating uncontrolled atrial fibrillation. In an unstable patient, cardioversion is the first-line treatment. If the patient is stable, various pharmacologic agents can be used, including digitalis, beta-blockers, and calcium channel blockers. One such calcium channel blocker is diltiazem.

Diltiazem slows atrioventricular (AV) nodal conduction, thereby prolonging the AV nodal refractory period. This

medication is widely used in the emergency department (ED) setting. In the past, its use in the prehospital setting was limited because of various storage issues, particularly the need to store it at 2°C to 8°C. However, with the introduction of lyophilized diltiazem, it has been asserted that this medication can and should be used by prehospital providers in treating tachydysrhythmias.[2]

Many emergency medical services (EMS) systems have adopted the adult advanced cardiac life support guidelines recommending the use of intravenous (IV) diltiazem as a first-line pharmacotherapy to control the ventricular response in rapid atrial fibrillation.[3] However, previous studies have shown that IV administration of diltiazem can lead to a decrease in blood pressure because of its negative inotropic effect and its inhibition of intracellular calcium influx on vascular smooth muscle, leading to a decrease in total peripheral resistance. Several studies totaling more than 450 patients have described up to an 18% prevalence of reported diltiazem-induced hypotension (defined as systolic blood pressure [SBP] $<$ 90 mmHg) with a mean of 9.7%.[4]

Furthermore, the safety and efficacy of this medication when used in the prehospital setting has not been well studied.[5] A Medline review of the literature revealed only 1 prior study in which the safety of diltiazem in the prehospital setting was evaluated. This retrospective case-controlled study of 43 patients who were given diltiazem in the prehospital setting demonstrated good efficacy and no adverse effects.[1]

We sought to determine whether the use of diltiazem is safe in the prehospital setting by determining the prevalence of hypotension in patients who were administered diltiazem. Our secondary objective was to evaluate the efficacy of prehospital administration of diltiazem by determining the percent of patients whose heart rates were controlled after being treated with diltiazem.

METHODS

Setting/System

Our system is in a suburban region of New Jersey. Seven advanced life support (ALS) fly-car units in our system bring approximately 90% of their patients to 1 of 3 hospitals. Two of the hospitals in the system are community hospitals, and one is an academic tertiary care center with an emergency medicine residency. The system is two-tiered, and ALS units do not transport patients. All ALS units are hospital based, and ALS providers are employed by the hospital system. Every ALS unit consists of 2 ALS providers. In New Jersey, all ALS care requires online medical control. Thus, for every patient treated by ALS services, the provider must contact a physician by telephone to receive online medical control. The ALS providers can perform and transmit electrocardiograms (ECG) at their discretion, but they cannot administer diltiazem until instructed to do so by the physician as per our system's protocols. Accordingly, the administration of diltiazem requires online medical control from the base hospital and is not protocol driven. Similarly, ALS units carry lidocaine, amiodarone, and adenosine, which can also be given at the physician's discretion via medical command and are not standing orders in the protocols for our system.

Population

The ALS providers in our system cover 244 square miles, perform 26,000 dispatches per year, and treat approximately half of the calls to which they are dispatched.

Data/Analysis

Using our prehospital patient care record electronic database, emsCharts Inc (Pittsburgh, Pennsylvania), we retrospectively reviewed charts of all patients treated by our ALS providers over a 22-month period from February 2007 to November 2008. The review was conducted according to applicable criteria previously proposed by Worster et al.[6] The people abstracting the data were trained, inclusion and exclusion criteria were established, and variables were defined. The medical record database was also identified. Those patients with missing data were not included in the analysis as described in the Results section. However, sampling did not occur in this study because all patients treated with diltiazem were selected. Abstraction forms were not used because the data were evaluated and analyzed in an electronic database. In addition, the abstractors were aware of the hypothesis and study objectives; their performance was not monitored; and interrater reliability was not discussed, tested, or measured because the data analysis was based on objective data and not on the judgments or opinions of the people abstracting the data. This study was exempt from institutional review board approval.

After unique patient identifiers were removed, we selected those patients with a heart rate (HR) greater than 100 beats per minute (bpm) who were given diltiazem. We then examined the HR and blood pressure (BP) at the initial evaluation and on arrival to the ED. The differences in HR and BP between the initial evaluation and ED arrival were calculated. A priori, a hypotensive response after the administration of diltiazem was defined as a final SBP less than 90 mmHg and a drop in SBP of at least 10 mmHg from the initial reading. Diltiazem was considered effective if the HR on ED arrival was less than 100 bpm or if the HR had decreased at least 20%. The number of administrations of diltiazem and the milligram dose of each administration were also noted for each patient.

RESULTS

During the study period, 26,979 transports were conducted. The average time from arrival on the scene to arrival at the ED was 28 minutes (standard deviation [SD], 20 minutes), and the average transport time (time from leaving the scene to arriving at the ED) was 10 minutes (SD, 6 minutes). Of these patients, 2,488 had a documented rhythm of atrial fibrillation or atrial flutter. We reviewed the charts of 324 patients who were given diltiazem in the prehospital setting.

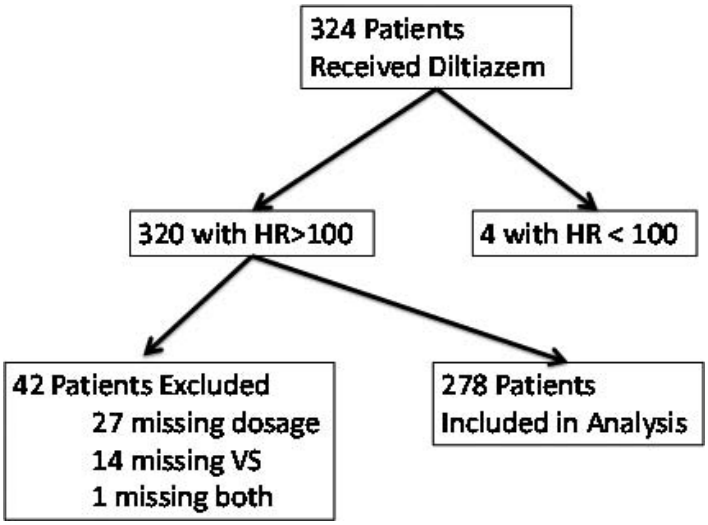

Figure 1. Study demographics. *HR*, heart rate.

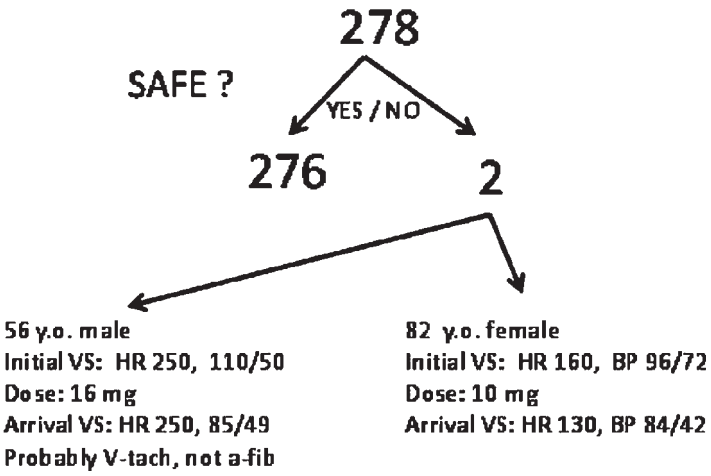

Figure 2. Safety of diltiazem. *HR*, heart rate; *BP*, blood pressure.

Their demographic and transport information can be found in the Appendix (online only). During the 22-month period, each paramedic in our system administered diltiazem to an average of 3.3 patients (SD, 2.8; 95% confidence interval [CI], 2.9–3.9). Of the 324 patients, 4 were given diltiazem for an HR less than 100 bpm. Of the remaining 320 patients, 27 were excluded because the dose of diltiazem was not recorded on the prehospital chart. An additional 14 patients were excluded because the HR and BP readings were not complete. One patient chart was excluded because it was missing both the diltiazem dose and complete vital signs (Figure 1).

Safety

Of the 278 patients included in the analysis, 2 patients became hypotensive after treatment with IV diltiazem. Thus, the prevalence of hypotension was 0.7% (95% CI, 0–2%; Figure 2).

Efficacy

Of the 278 patients in the analysis, 33% (95% CI, 27–38%) had an HR of <100 bpm on arrival at the ED. Sixty-nine percent (95% CI: 64–74%) of patients had a drop in HR ≥ 20%. Accordingly, 73% (95% CI, 68–78%) of patients overall had an effective response in which the HR was <100 bpm or the HR decreased by at least 20%. Neither of the 2 patients who became hypotensive had effective responses (Figure 3).

DISCUSSION

To our knowledge, this is the largest retrospective chart review of diltiazem use in the prehospital setting. Very few studies have evaluated the use of diltiazem in the prehospital setting. In 1999, Wang et al[1] conducted a retrospective, case-controlled study of 43 patients with HRs > 150 who were treated with diltiazem and compared these patients to 27 control subjects. The study found that none of the patients given diltiazem required treatment for hypotension, cardiac arrest, or intubation. Except for 1 patient with a low baseline SBP who received diltiazem, Wang et al[1] found no instances of SBP reduction below 90 mmHg after treatment with diltiazem. Furthermore, using a similar definition for successful treatment as in the current study, Wang et al[1] found that 35 of the 43 patients (81%) receiving diltiazem therapy had an overall therapeutic response.

Our study found only 2 patients who had a hypotensive response to diltiazem. One patient was an 82-year-old woman who had an initial HR of 160 bpm and was initially borderline hypotensive with a BP of 96/72 mmHg. After being treated with 10 mg of diltiazem, her HR decreased to 130 bpm and her BP dropped to 84/42 mmHg. The other patient was a 56-year-old man who presented with chest pain and dyspnea that started while he was jogging. He was treated with 16 mg of diltiazem for an initial rhythm that was interpreted as atrial flutter. His initial vital signs included a HR of 250 bpm and a BP of 110/50 mmHg. On arrival in the ED, his HR remained at 250 bpm, but his BP dropped to 85/49 mmHg. On further review of his chart,

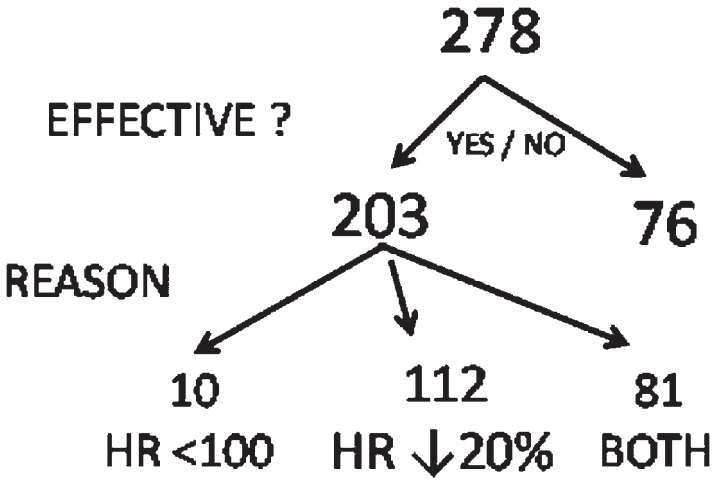

Figure 3. Efficacy of diltiazem. *HR*, heart rate.

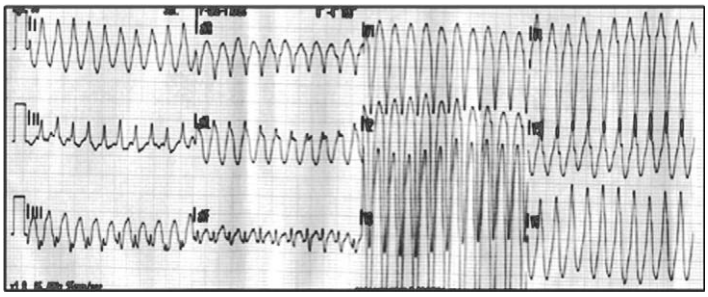

Figure 4. Electrocardiogram of a 56-year-old previously healthy man with chest pain and shortness of breath that started while he was jogging.

however, it was determined that his initial rhythm was probably ventricular tachycardia instead of atrial flutter/fibrillation (Figure 4).

In addition, the percentage of patients who experienced a hypotensive response to diltiazem slightly drops if the excluded patients are included in the analysis. Forty-two patients were excluded from the study for incomplete data. Of these patients, 27 were missing only the dose of diltiazem given, and 11 patients were missing only diastolic BPs. None of these patients became hypotensive after the administration of IV diltiazem. Thus, if these patients were included in the analysis, the rate of hypotension would be 0.6% (95% CI, 0–1.5%). In addition, 33 of the 38 patients excluded had an effective response to diltiazem. Accordingly, if these patients were included in the analysis, the efficacy of diltiazem would increase to 75% (95% CI, 70–79%).

Four of the excluded patients were missing HR or SBP measurements on initial presentation or on arrival at the ED. Even if it is assumed that all of these patients became hypotensive after receiving diltiazem, the prevalence of hypotension would only increase to 1.9% (95% CI, 0.4–3.4%). Furthermore, if these 4 patients had ineffective responses to diltiazem, the efficacy of diltiazem would drop only 1% to 74% (95% CI, 69–79%).

Nevertheless, the concern that diltiazem has adverse side effects is still prevalent. Vinson et al[7] reported a patient who developed tetany with sudden respiratory arrest after receiving a standard dosage of diltiazem (ie, 0.24 mg/kg IV) over 2 to 3 minutes for narrow complex atrial fibrillation with a rapid ventricular response. Vinson et al[7] reported that within 1 minute of receiving the diltiazem, the patient developed severe, generalized muscle spasm associated with rapidly decreasing oxygen saturation to below 60%. The patient ultimately became unconscious and was about to undergo rapid sequence intubation. Before the patient was intubated, he was given 10 mL of 10% calcium chloride, and his tetanic contractions immediately resolved. Vinson et al[7] reported that spontaneous chest excursions then returned, followed by a steady recovery in oxygenation and ventilatory function.

Hypotension is another major adverse effect of diltiazem, and it is believed that 2 main mechanisms of action are responsible for this adverse effect: (1) its effect on vascular smooth muscle as an inhibitor of intracellular calcium influx, thereby decreasing total peripheral resistance, and (2) its negative inotropic effect. Accordingly, it would be reasonable to believe that pretreatment with calcium chloride may prevent this hypotensive response. Oshida et al[8] studied the effects of calcium chloride on the cardiac effects of verapamil and diltiazem in rat hearts. The study found that calcium significantly counteracted the negative inotropic effects of diltiazem and verapamil but potentiated the negative chronotropic effects of these medications.

Kolkebeck et al[4] studied this issue in humans and performed a prospective, randomized, double-blinded, placebo-controlled study to determine if pretreatment with calcium chloride would blunt an SBP drop after the administration of IV diltiazem. Seventy-eight patients with atrial fibrillation/flutter and a ventricular rate of at least 120 bpm were enrolled. Half of these patients received IV calcium chloride as a pretreatment and the other received a placebo. All patients received IV diltiazem in a standard, weight-based dose, and the pretreatment solution was given again if a second dose of diltiazem was required. Kolkebeck et al[4] found no statistically significant blunting of a drop in SBP with calcium chloride pretreatment. Furthermore, both groups had an equal decrease in HR that was statistically significant. In addition, there were no adverse events in those patients that were pretreated with calcium chloride.

Given that the use of diltiazem in the prehospital setting is controversial, some have found that using IV diltiazem and electrical cardioversion for the treatment of rapid atrial fibrillation may be unnecessary. Abarbanell et al[3] retrospectively reviewed cases of rapid atrial fibrillation over a 12-month period from October 1998 through September 1999 in the low-volume urban EMS system of Evanston, Illinois. They found 33 persons who presented with rapid atrial fibrillation, representing 0.69% of their total prehospital volume, and none of them received IV diltiazem or electrical cardioversion. Nine patients received prehospital treatment consisting of nitroglycerin, furosemide, aspirin, morphine, or IV fluid bolus therapy. The remainder of the patients were treated only with symptomatic/supportive care consisting of observation. All of the patients reported symptomatic improvement after care was provided, regardless of the use of prehospital interventions. In addition, severe hemodynamic instability, cardiac dysrhythmias, iatrogenic complications, or conditions requiring endotracheal intubation were not noted in any of the patients. Accordingly, the authors found that prehospital rapid atrial fibrillation is infrequently encountered, predominantly hemodynamically stable, and readily treatable with symptomatic/supportive care and cautious observation. Consequently, the authors suggest that the use of IV diltiazem

and electrical cardioversion in the treatment of prehospital rapid atrial fibrillation may be unnecessary.

Given these various issues and the lack of clear guidance regarding the use of diltiazem in the prehospital setting, it remains a continual challenge to train paramedics on the proper use of the drug. As demonstrated in this study, diltiazem was inappropriately administered in 1 patient who was in ventricular tachycardia instead of atrial fibrillation. Although this instance was the first recorded time that the paramedic administered the drug, we cannot easily determine whether it was his very first administration of the drug because the electronic database was instituted only 1 month before the start date of this study. Nevertheless, this particular medic had been working for approximately 5 years at the time of this incident. Although this study shows that diltiazem is very safe and effective in the prehospital setting, this case of incorrect administration of diltiazem reinforces the need for continuing medical education on rhythm strips, ECGs, and appropriate use of the medication.

LIMITATIONS

The current study has several limitations. First, the ECGs and rhythm strips were not reviewed to ensure that patients treated with diltiazem were in atrial fibrillation. It is possible that some of the patients in the study were in sinus tachycardia, supraventricular tachycardia, or even ventricular tachycardia (as was the case with one of the patients who became hypotensive). Despite this limitation, the study shows how safe and efficacious diltiazem will be in real practice where similar mistakes could be made. Another limitation of the study is that the prehospital system in New Jersey is unique in that all patients treated by prehospital ALS providers need online medical control. Because physicians are directly involved in every decision to give diltiazem, it is possible diltiazem would be given to a different set of patients in other systems. Finally, this study has the same limitations of all retrospective studies, such as reporting errors.

CONCLUSION

Although the use of diltiazem for the treatment of rapid atrial fibrillation in the prehospital setting remains controversial, we found that diltiazem is associated with a very low rate of hypotension and appears to be effective in decreasing HR adequately. We strongly support and advocate for prospective studies to further examine this issue.

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Conflicts of Interest: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding, sources, and financial or management relationships that could be perceived as potential sources of bias. The authors disclosed none.

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