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Point of care ultrasound on ground ambulances: an investigation of mortality outcomes

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SCHOOL OF MEDICINE

Thesis

**POINT OF CARE ULTRASOUND ON GROUND AMBULANCES: AN
INVESTIGATION OF MORTALITY OUTCOMES**

by

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ABSTRACT

Traumatic injury is a major burden in global healthcare systems, ranking among the leading causes of morbidity and mortality worldwide.¹ Patients are first encountered at the pre-hospital scene by providers of varying levels of expertise, such as emergency medical technicians (EMTs) and paramedics, who provide temporizing measures while patients are transported to receiving hospitals to receive definitive care.² Ultrasound is an ever-improving medical imaging modality which is increasingly portable, low cost, and provides diagnostic imaging rapidly without the harmful effects of radiation. The objective of this study is to determine whether introduction of prehospital ultrasound (PHUS) for use on ground ambulances by prehospital providers in order to improve choice of destination hospital and aid in needle thoracostomy for tension pneumothorax will have a positive impact on mortality rate of trauma patients in an urban EMS environment.

In the proposed study, trauma patients in the city of Boston, Massachusetts receiving care from Boston Emergency Medical Services (EMS) prehospital providers will be recruited over a 12-month period with a minimum goal of 2,500 patients in total. Emergency responses coded as trauma by EMS dispatch will be randomized at a 1:1 ratio to either utilize PHUS or to refrain from utilizing PHUS. A z-test will be used to analyze primary outcome of 30-day mortality rate in patients who receive PHUS care as needed

compared with patients who do not receive PHUS care. Study data will be collected directly from Boston EMS Electronic Medical Record (EMR).

This study will be the first of its kind to randomize at the patient level, and the first to investigate a major clinical outcome of ultrasound in prehospital medical care: 30-day mortality. Point-of-care Ultrasound is an intriguing diagnostic modality that is becoming increasingly feasible in the prehospital environment, and may improve outcomes in trauma patients. Current studies provide convincing evidence for the diagnostic accuracy of these devices, especially in evaluating hemoperitoneum and pneumothorax. If an improvement in mortality rate of patients treated with prehospital ultrasound (PHUS) is demonstrated, this will be convincing evidence for the implementation of PHUS in ground ambulances and air medical services across the United States and worldwide.

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LIST OF ABBREVIATIONS

ALS	Advanced life support
BLS	Basic life support
CNS	Central nervous system
CT	Computed Tomography
DPL	Diagnostic peritoneal lavage
EMR	Electronic medical record
EMS	Emergency medical services
EMT	Emergency medical technician
FAST	Focused assessment with sonography in trauma
HEMS	Helicopter emergency medical service
NPV	Negative predictive value
PHUS	Prehospital ultrasound
POCUS	Point-of-care ultrasound
PPV	Positive predictive value
PTX	Pneumothorax
eFAST	Extended focused assessment with sonography in trauma

INTRODUCTION

Background

Severe trauma is one of the major health care issues faced by modern medical systems, accounting for more than 5 million deaths worldwide per year, and permanent disability of millions more.¹ This number was expected to rise to as many as 8 million by 2020.¹ Young people are the most affected subset of the population, and in the United States, traumatic injury is the leading cause of death in individuals under 45 years old.³ In the United States, the major cause of blunt abdominal and thoracic trauma is motor vehicle accidents.⁴ Mortality rates range from 2-10% and vary depending on severity of the injuries sustained and presence of multiple organ trauma.⁴

Prehospital care by responding ambulances and their paramedic crews is essential for ensuring the survival of these patients. Since definitive care for severe trauma is possible only at a capable hospital staffed by a surgical trauma team, these patients are traditionally assessed and transported rapidly, with stabilizing care provided as needed.² However, the literature shows that even with rapid extrication, minimal on-scene care, and emergent transport to the nearest trauma-capable facility, it takes an average of 128 minutes to achieve definitive hemostasis from the time of injury to intervention in the operating room, resulting in up to 50,000 potentially avoidable traumatic deaths per year in the United States alone.⁴

Statement of the problem

Until recent years, the tools available at the disposal of prehospital providers for assessing and providing care to a trauma patient have been woefully limited. The trauma

physical exam, in particular, has been shown to be inaccurate at locating truncal and abdominal injury that may lead to potentially fatal complications such as pneumothorax or hemoperitoneum.⁵ But what if care *during* the transport of the patient could be improved?

Recently, the development of increasingly compact, affordable, and advanced portable ultrasound probes has made it reasonable to consider adding this imaging modality to the prehospital provider's toolkit for treatment of trauma patients.⁶

Ultrasound has long been used in the hospital and clinic setting, serving an array of diagnostic and clinical functions. Among its strengths are portability, ease of use, relatively cheap cost, and lack of radiation burden. When used at the bedside, the modality is referred to as "Point-of-care Ultrasound" or POCUS.

Many early investigations into PHUS exist, with more being added to the literature each year. These studies have shown promising data regarding the accuracy, speed, and feasibility of this modality. Prehospital POCUS has been investigated in multiple countries, including the USA and in Europe, and in the setting of both flight medicine and ground ambulance transport.⁷

However, a major gap in the literature remains, which is referenced frequently in these early studies. As of yet, there is no large-scale investigation of patient outcomes of prehospital POCUS.⁷ In particular, no study has investigated the 30-day mortality rate of trauma patients treated with prehospital POCUS. This parameter must be investigated in order to demonstrate a true benefit in the use of prehospital POCUS. Therefore, it is an

important and necessary next step to design a study capable of evaluating the effect of prehospital POCUS on 30-day mortality in victims of severe trauma.

Hypothesis

Introduction of point-of-care ultrasound on ground ambulances for use by trained paramedics in a trauma protocol will reduce the mortality rate of trauma patients.

Objective

Based on the lack of current accurate diagnostic tools available to prehospital providers for evaluation of the traumatic patient, the objective of this study is to determine whether adding POCUS to the paramedic's diagnostic toolkit can improve the mortality of trauma patients. Specific aims are as follows:

Aims

- To determine whether use of prehospital ultrasound by paramedics on ground ambulances to choose destination hospital and aid in needle thoracostomy for tension pneumothorax improves mortality rate in patients with traumatic injury.
- To investigate whether prolonged transport time or severity of injury result in increased mortality benefit with implementation of PHUS.
- To characterize the importance of ultrasound as an effective diagnostic tool in the care of a prehospital trauma patient.

REVIEW OF THE LITERATURE

Overview

Prehospital care is essential in the prevention of morbidity and mortality in trauma patients.⁸ In the United States, the first crews to the scene are often ground ambulances, manned by paramedics and EMT's.⁹ These prehospital providers must make rapid assessments, provide early care, and decide on an appropriate destination hospital for the injured patient.

Traditionally, rapid assessment and transport of trauma patients ("load and go") has been considered the cornerstone of prehospital trauma care, based on optimizing transport time to fit the idea of the "golden hour".² The term is attributed to R. Adams Cowley, who founded the Shock Trauma Institute in Baltimore. In an article written in 1975, Cowley suggested that the first hour following an injury was the most crucial period of time in determining a critically-injured person's chance of survival.¹⁰ Subsequent studies over the years have provided evidence both supporting and refuting the idea of the golden hour, and though the term remains controversial, there certainly is an aspect of trauma care that is highly time dependent.¹¹ Specifically, an analysis of a 2009 military mandate to reduce time between combat injury and definitive care to less than 60 minutes demonstrated an improvement in patient outcomes and support for prehospital transport time as an important factor for traumatic injury survival.¹² However, treatment within the golden hour may be an exercise in futility, as definitive operative care can often take far longer than 60 minutes to initiate. In multicenter studies, prehospital transport times ranged from 37 to 76 minutes, and upon reaching the ED, time

to OR was an average of approximately 24 minutes or potentially even longer for anesthesia.² During this time, patients may die for any number of reasons, including uncontrolled hemorrhage, hemothorax, or pneumothorax. Therefore, though controversial, care during the "golden hour" itself is a target area for study and improvement in trauma management.

Traumatic hemorrhage is the second-leading cause of trauma-related mortality etiologies at 40%, trailing only CNS injury at 42%.¹³⁻¹⁵ It is also the major cause of mortality within the first hour of hospital admission following injury. Intraabdominal bleeding occurs in up to 12% of blunt traumatic injuries.¹⁶ This subset of traumatic hemorrhages are difficult to diagnose in the prehospital setting. Traditionally, these were diagnosed with an invasive procedure called diagnostic peritoneal lavage (DPL). DPL involves the insertion of a catheter into the abdominal cavity and aspiration of fluid in order to detect gastrointestinal contents such as red blood cells that are indicative of intraabdominal bleeding.¹⁷ DPL has a high diagnostic accuracy, but comes with a complication rate of approximately 1%.¹⁶ Alternatively, CT is able to visualize as little as 100 cc of intraabdominal fluid, but it is time consuming and only accessible in the emergency department.

Pneumothorax, a condition where gas enters the pleural space, is also a major cause of traumatic morbidity and mortality.¹⁸ It is most often caused by trauma, occurring in approximately 20% of victims of blunt traumatic injury.¹³ Pneumothorax can present significant risk to a patient, escalating with size. A large pneumothorax can build enough pressure within the mediastinum to interfere with venous return, leading to hypotension,

tachycardia, and severe dyspnea.¹⁹ This is termed a tension pneumothorax, and it is a life-threatening situation that requires immediate intervention. Even small and medium sized pneumothoraxes may result in progression of respiratory or hemodynamic compromise in unstable patients.¹³ Early intervention is crucial in these patients.

Improving diagnosis is the first step to effective prehospital trauma care. It remains particularly challenging to identify traumatic injuries to the abdomen and thorax. In a recent study, Helicopter EMS (HEMS) physicians missed truncal and abdominal trauma in 31% and 54% of cases respectively when they used physical exam alone.⁵ Point-of care ultrasonography is an emerging modality in prehospital care that could be utilized to address this issue and improve patient outcomes in blunt traumatic injury.

Ultrasonography is safe, and in the hands of a trained operator, can be performed quickly and efficiently to acquire high quality images for the purposes of diagnostics and intervention.⁶ Over the past two decades, ultrasound equipment has become more compact, portable, and affordable to purchase. Techniques for optimal visualization have continued to improve. Notably, the American Institute of Ultrasound in Medicine stated that the idea of the "ultrasound stethoscope" is moving closer to reality. Since its inception in the early 1990's, the technology has now become sufficiently small and portable to as a "point-of-care" modality.

Point-of-care ultrasonography (POCUS) refers to the use of ultrasonography at the patient's bedside to acquire dynamic images for diagnostics and procedural applications.⁶ The real-time images allow direct correlation of findings to the patient's presentation, and offer an array of potential applications in the field. POCUS can be

performed either in the hospital or prehospital environment, so long as operators are appropriately trained.

Images captured by POCUS continue to improve in quality. Point-of-care ultrasound images nearly match the quality of those produced by large, stationary machines.⁶ Further, ultrasound devices now exist that are small enough to be carried in the pocket of a physician's lab coat, or a paramedic's jump bag.²⁰ These hand-held ultrasound devices show a high level of agreement with high-end, stationary sonography machines for abdominal fluid and pulmonary evaluation.

In 1996, the term FAST was introduced to describe a rapid, goal-directed ultrasound to investigate free intra-abdominal fluid in trauma patients. Through the FAST exam, ultrasonography is used to diagnose intra-abdominal and thoracic hemorrhage. The FAST exam involves scanning of four target views: the pericardial view, right upper quadrant (RUQ) view, left upper quadrant view (LUQ), and the pelvic view.²¹ Sonography can detect small amounts of fluid — as little as 20 cc — that may be abnormally present in these areas.¹⁶

Building on the FAST exam, a pulmonary portion was added. This more comprehensive exam was labeled the extended-FAST (eFAST). The eFAST adds two views of the left and right anterior hemithorax, looking for the opposing movement of the parietal and visceral pleura during lung expansion.¹⁶ This movement is termed lung "sliding" and its absence is indicative of air between the serosal membranes consistent with a pneumothorax.¹⁶ Multiple lung views may be acquired, but studies show that a

single view bilaterally is sufficient, while multiple views are time consuming and have not been shown to significantly improve sensitivity.²²

The full eFAST exam can be completed in less than 5 minutes with improved sensitivity and specificity over chest radiograph, which also takes much longer to acquire. In particular, Zhang et. al reported a time required of 2.3 ± 2.9 minutes to perform the eFAST.²³ Another more recent study reported that a single-view e-FAST was completed in a median time of 0.95 minutes.²²

The diagnostic accuracy of eFAST is 90-98% overall for intraabdominal injury.⁶ In evaluation of pneumothorax, sensitivity varies from 68-95% in studies.^{6,22-24} It is twice as sensitive as chest radiography for occult pneumothorax (PTX seen only on CT), and specificity is excellent at 98%.⁶ Though the eFAST exam is not as accurate as CT or diagnostic peritoneal lavage (DPT), it is faster and can be performed at a fraction of the cost of these other studies.²⁵ Importantly, ultrasound is also non-invasive and poses little risk of harm to the patient.

Today, early diagnostic imaging using ultrasound is a class-one recommendation for in-hospital assessment of the trauma patient.¹ Further, there is decreased time to surgery with this modality, as well as reduced length of hospital stay.⁵ Importantly, in-hospital ultrasound in select patients may even reduce mortality.

The logical next step for increasingly portable and accurate ultrasound technology is its introduction into the prehospital environment of air medical services and ground ambulances. To this end, the feasibility, efficacy, and accuracy of pre-hospital ultrasound has been investigated in various studies. In order to incorporate the technology,

prehospital providers must be trained and able to utilize it effectively, therefore, training programs and protocols have also been investigated.

Existing research

Ongoing investigations have provided positive evidence for several parameters of prehospital ultrasound use. One study, by Ketelaars et. al in 2013, was among the first to show that pre-hospital chest ultrasound in trauma patients could alter and improve treatment decisions for patients.²⁶ The study was an observational study, analyzing a total of 2,572 patients treated by a Dutch Helicopter Emergency Service (HEMS) over the course of four years, 326 of which received ultrasound during transport. The study found the plan of treatment changed in 21% of these patients.

The study is somewhat limited because it was from a fairly homogenous population (only patients within the Netherlands), and there was no control group or blinding performed.²⁶ Instead, a specific set of data were collected from the database of all helicopter "scrambles," including patient demographics, ultrasound exam characteristics, quality of image, and impact of the exam on treatment decisions. Furthermore, ultrasound image quality was rated "good" in only 55% of US examinations.

Sensitivity for pneumothorax was somewhat disappointing, at only 38%, but specificity was impressive at 97%.²⁶ PPV and NPV were 90% and 69%, respectively. Though the study was not a high-quality RCT or prospective cohort study, its results suggested that further investigation was warranted regarding the utility of ultrasound as a

pre-hospital diagnostic modality. Specifically, the results provided evidence that diagnostic information given by US is useful in decision-making.

In 2014, a study by Press et. al sought to evaluate the accuracy of eFAST performed by helicopter emergency medical services (HEMS) as a modality to discern the etiology of undifferentiated hypotension in trauma patients, especially related to pneumothorax (PTX). PTX is frequently misdiagnosed, leading to a high rate of needle decompressions in the field. In fact, as often as 26% of the time, needle decompressions are performed unnecessarily.²⁷ These unnecessary needle decompressions come with risk of complications, including iatrogenic pneumothorax, infection, or major vascular injury.²⁸ It is likely these unnecessary decompressions contribute to increased morbidity and mortality in the patients who receive them.

This was the first study of its kind carried out in the United States. Smaller studies had looked sparingly at the use of FAST in ground ambulances or during aeromedical transport to varying degrees of success. This study implemented a large-scale HEMS program, introducing ultrasound as a primary modality to assess the accuracy of prehospital providers in evaluating various aspects of the trauma exam, including abdominal, cardiac, and lung portions of eFAST.²⁷

The study's limitations included its volunteer recruitment of a small group of providers to learn ultrasound for the study (16 paramedics and 17 nurses) and relatively non-generalizable study population.²⁷ The air medical transport service that served as a basis for the study operates within a 150-mile radius and serves a large, urban academic Level I trauma center, but some difficulty remains in generalizing these results to a

broader population, where patient demographics, funding, and prehospital provider experience and training may differ. The study may also have been subject to bias, as ultrasound was dictated by protocol to only be performed after stabilization of patients, which introduced some degree of selection bias. Patients with significant injury that needed a greater degree of stabilization were less likely to be imaged. Importantly, the observational design of the study prevents data being drawn to illustrate the value of prehospital ultrasound pertaining to clinical outcomes. The authors emphasize that a large, multicenter trial could further explore effects on clinical outcomes as they were not able to do so here.²⁷

Providers in this study performed eFAST exams after stabilization was performed and were instructed to not change their care based on the result, which further limited the usefulness of this study.²⁷ However, there was high-quality data generated on the accuracy of the exams, as the eFAST findings were compared later to "gold-standard" testing subsequently performed at the hospital such as CT and laparotomy. Only 11% of ultrasound studies were rated as "indeterminate."

Sensitivity was poor for hemoperitoneum, at 46% for hemoperitoneum alone and 64.7% for hemoperitoneum requiring operation. However, specificity was very high both for hemoperitoneum and hemoperitoneum requiring operation at 94.1% and 94% respectively. This finding supports the idea that U/S provides useful information that is unobtainable on physical exam alone, which can guide decisions regarding destination hospital and early mobilization of receiving hospital trauma surgery personnel. Similarly, in pneumothorax, provider sensitivity was poor at 18.7% for pneumothorax alone and

50% for pneumothorax requiring thoracostomy. These numbers are comparable to chest radiograph (23.3% sensitive), and reflect the ultrasound modality's limitations in catching small pneumothoraxes. Importantly, small pneumothoraxes (≤ 3 cm at lung apex or ≤ 2 cm at hilum) in hemodynamically stable patients are treated with observation only, as these generally are not clinically significant.²⁹ In patients who *are* hemodynamically unstable, the source of the instability is likely to be injury elsewhere, rather than the small pneumothorax. Therefore, this limitation of ultrasound is not likely to contribute negatively to patient care.

The specificity for pneumothorax and PTX that required thoracostomy, on the other hand, was nearly perfect.²⁷ Accurate positive interpretation rate approached 90% for pneumothoraxes requiring thoracostomy. It is crucial to note that in the context of the considerable difficulty of evaluating pneumothorax by auscultation in the field, this high degree of specificity holds promise. Ultimately, the authors stated that they felt there were numerous cases in which hemoperitoneum and pneumothorax were able to be diagnosed in the helicopter using ultrasound, with the potential to provide critical management to these patients that would not have been possible otherwise. They stated that the prospect of HEMS providers making early diagnosis with ultrasound in traumatic patients was "enticing."²⁷

Quick et. al sought to further investigate the utility of ultrasound for identification of pneumothorax. A 15-month prospective, observational study was conducted to assess the potential utility of prehospital ultrasound (PHUS) for diagnosis and treatment of pneumothorax.²⁴ Twenty-six flight nurses and paramedics were trained to perform and

interpret ultrasound through a series of lectures, along with ultrasound examinations of human volunteer and animal models. The crews performed standard ATLS care for patients, with the addition of eFAST exams which were then repeated by trauma surgeons upon arrival at the receiving hospital to compare sensitivity/specificity and accuracy. Flight crews were blinded to the trauma team interpretation of ultrasound findings and vice versa. 146 thoracic ultrasounds were performed in total. Overall, the prehospital ultrasounds had a sensitivity of 68% and specificity of 96%, versus ED trauma team ultrasound which had a sensitivity of 84% and specificity of 98%. Diagnostic accuracy of PHUS, defined as patients correctly diagnosed (with or without pneumothorax) among all study patients, was 91%.^{24,30} This figure compared well with 98% in-hospital diagnostic accuracy.

The study was limited overall by the small region where patients were drawn from (patients treated on University of Missouri's Staff for Life helicopters) as well as the small number of twenty-six trained flight crew members, who were highly experienced with a mean of 10.6 years in aeromedicine.²⁴ Additionally, clinical decision-making was not based on the results of in-flight ultrasound. As a result, it is again difficult to quantify clinical relevance in this study, especially with regards to patient outcomes, including morbidity and mortality.

The diagnostic accuracy results seem to confirm, however, that thoracic pathology can be readily identified with in-flight ultrasound. Aeromedical ultrasound was nearly as accurate as an in-hospital trauma surgeon at diagnosing pneumothoraxes (at 91% vs 98%).²⁴ Further, early intervention would appear to represent an opportunity to decrease

mortality rates. Needle decompression is indicated in tension pneumothorax, and ultrasound findings can be utilized to confirm adequate decompression. Considering these points, ultrasound has an obvious role in improving early management of tension pneumothorax. The study closes by again suggesting that a trial focused on patient outcomes such as morbidity and mortality is warranted.

More recently in 2017, Yates et. al provided evidence that in-flight crews could perform prehospital ultrasound with strong positive and negative predictive values for the identification of pneumothorax, hemothorax, and free abdominal fluid.³¹ PPV was 100% and NPV 98.3% for these parameters, which was equivalent to that of the trauma team's POCUS exam upon patient arrival to the trauma center.³¹ All blunt and penetrating trauma patients ages 18-99 requiring an air response based on regional protocols were included in the study population over an eighteen-month period.³¹

This study also placed a significant focus on appropriate training of prehospital providers.³¹ Crews were enrolled in a comprehensive curriculum which involved several steps. First, a didactic portion spanning 8 hours was completed. This was followed by supervised clinical practice on standardized patients, then an observed 1-hour exam where the learner had to navigate a clinical case. Finally, continuing education was required, where a minimum of 5 POCUS examinations were required per month with the supervision of an experienced provider.

A total of 190 complete eFAST exams were performed during the study period of June 2014 to December 2015.³¹ These were then compared with eFAST exams performed by the receiving trauma team, as well with CT scans or surgeon's notes as the

diagnostic gold standard. Twelve patients had positive findings identified by flight crews. Five of these cases were hemothorax/pneumothorax, six were hemoperitoneum, and one was in-flight cardiac arrest. Trauma team eFAST showed agreement in eleven of the twelve. The case without agreement underwent CT and was found to have a small hemoperitoneum. Thus, PPV and NPV of the flight crew for eFAST was ultimately 100% and 98.3% respectively, while these figures were 82.3% and 99.4% for the trauma team respectively.³¹ Using the Fisher exact test, there was no significant difference between the PPV and NPV of the flight crew and that of the trauma team crew on eFAST examinations ($P = 0.35$).³¹

The study was limited again by a small study population, as it involved one isolated flight company — the Nightengale Regional Air Ambulance flight company — contained to their 125-mile response zone surrounding Norfolk, Virginia. Additionally, though 190 eFAST exams were performed, only twelve of these had positive findings. As a result, the sample size was small and the statistical power of this study is low. Patients below 18 years of age were excluded, which also limits the generalizability beyond adult patients. Additionally, the study was a prospective observational study, and no results can be drawn regarding patient outcomes, including morbidity and mortality.

Systematic reviews are important recent additions to the literature, grouping together many of these smaller trials and drawing conclusions about the future direction of prehospital ultrasound. Though many small trials have explored prehospital ultrasound, they are prospective observational studies rather than randomized control trials. Specifically, there is a paucity of data on patient outcomes regarding morbidity and

mortality. The data is also heterogenous, with studies drawing from differing demographics and utilizing varied protocols and ultrasound equipment. These factors make it impossible to perform meta-analysis of the data.

Van der Weide et. al is the latest and most comprehensive of these systematic reviews. This 2019 study used a broad literature search that included databases PubMed, Embase, and Cochrane/Wiley Library, initially generating a pool of 3,343 records.⁷ After screening based on title and abstract, and reading to determine eligibility, nine studies were eventually selected for inclusion and analysis. Six of the studies were prospective and three were retrospective observational cohort studies. Three of the included studies have already been described above in this review of the literature: Ketelaars et. al (2013), Press et. al (2014), and Yates et. al (2017). These nine studies comprised a total of 2,889 patients, from differing populations in Europe, the USA, and China. Once reviewed, the results of these studies were grouped together into broad categories for analysis and discussion.

Three of the nine articles described a change in prehospital treatment of patients due to performing analysis.⁷ Specifically, as discussed above, Ketelaars et al. (2013) showed a change in decision regarding therapy in 19.2% of patients.²⁶ Both Ketelaars et al. and Walcher et al. demonstrated a change in prehospital treatment due to ultrasound findings, in 12.4% and 21% of patients respectively.^{26,32}

Three of nine articles demonstrated a change in the destination hospital due to use of PHUS. Notably, three of the articles were unable to investigate this parameter as they prohibited alteration of patient management due to PHUS findings.⁷ Ketelaars et al.

described a change in destination hospital in 4% of study patients, while Walcher et al. described a change in 22% of patients.^{26,32}

Three articles reported a change in receiving hospital response.⁷ Walcher et. al described a change in response as evidenced by operating room preparation and notification of an abdominal surgeon in 22% of cases.³² Ketelaars et al. described giving notification to the receiving hospital based on US findings in 8% of cases.²⁶

All nine included articles reported accuracy of pre-hospital ultrasound in some form, though the analysis was complicated by heterogeneity of endpoints in these various studies.⁷ Brun et al. showed a similar diagnostic accuracy of prehospital eFAST exams as compared to exams carried out in the ICU.³³ Heegaard et. al investigated the ability of paramedics to perform accurate eFAST exams in the prehospital setting, and determined that only 7.7% of the 84 eFAST exams performed were "inadequate," suggesting that paramedics were able to perform the exam appropriately in the field, even with minimal training.³⁴ Additionally, there was 100% agreement in interpretation of the exams between the paramedics and independent physicians.⁷ Ketelaars et al. showed a high sensitivity, specificity, PPV, and NPV for prehospital ultrasound (using PREP), using CT to determine diagnostic accuracy.²⁶ Press et al. evaluated accuracy of eFAST utilized by aeromedical transport, and found in particular low sensitivity for smaller pneumothoraxes not requiring thoracostomy, although specificity was high.²⁷ Ability of eFAST to detect hemoperitoneum was examined by Walcher et al., demonstrating that diagnostic accuracy was improved compared to physical exam alone.³² Yates et al. investigated the accuracy of eFAST performed by prehospital flight crews as compared to eFAST performed upon

landing in the emergency department, and found that the flight crews had a higher PPV but lower NPV than the ED teams that followed them.³¹

Van der Weide et. al concluded that prehospital ultrasound, performed by well-trained and capable prehospital providers, is capable of providing an adequate accuracy rate for multiple parameters in the eFAST exam and in particular is highly accurate in confirming and excluding hemoperitoneum in the prehospital setting.⁷

Multiple factors limiting a proper meta-analysis of the data are present in this study.⁷ Primarily, the nine articles included are highly heterogenous. The patient populations are from different countries, and involving particular regions. Sample sizes are somewhat small, limiting the power. Three of the studies are retrospective observational studies with a degree of recall bias. Endpoints varied, and notably, patient outcomes were not investigated in any of these studies. Training methods for the prehospital providers differed, ranging widely from a single three-hour session in Melanson et al. to the comprehensive curriculum implemented in Yates et al. that spanned multiple steps including an 8-hour didactic course and clinical practice, followed by continuing education. For these reasons, van der Weide et al. concludes by pointing out that while the preliminary data is promising for prehospital ultrasound, the meaning of the data is difficult to extrapolate, and gaps in the research remain.

It is clear that more focused investigation of prehospital ultrasound is essential moving forward. In particular, a large trial with a generalizable patient population is needed. Prehospital providers taking part in this trial must be trained under a uniform and comprehensive curriculum, and investigation into homogenous endpoints, especially key

parameters involving patient outcomes such as mortality, must be evaluated. In following these guidelines, it will be possible to definitively assess the viability of ultrasound as a diagnostic and treatment-guiding modality in prehospital trauma care.

METHODS

Project design

This will be a randomized control trial of prehospital ultrasound use in trauma patients by ground ambulance versus traditional care i.e. no PHUS use. Randomization will occur at the patient level via EMS dispatch.

Study population and sampling

The source population used in this study will be trauma patients in the city of Boston who receive care from Boston EMS prehospital providers over a 24-month period. Emergency prehospital medicine is unique in its reliance on a dispatch team to answer 911 calls and code responses before scrambling ambulance units to the scene. This system will allow for randomization of care at the patient level in this study. Emergency responses encoded by Boston EMS dispatch that meet inclusion criteria (see Table 1 below) will be assigned at random to PHUS+ or PHUS-, indicating whether the responding medics will be allowed to or must refrain from using ultrasound in their clinical care of the patient *prior* to being dispatched to the scene. Medics will be informed of their status as PHUS+ or PHUS- when they are assigned to a call.

By designing the study in this way, many confounding variables are controlled for, especially in regards to differences in provider skill level, variation in medical decision-making style, etc.

Table 1: Inclusion and exclusion criteria for study population

Inclusion	Exclusion
- Boston EMS is responding to the scene.	- Outside company is responding.
- Incident coded as <i>Trauma, Motor Vehicle, or Fall</i> .	- Incident not coded as <i>Trauma, Motor Vehicle, or Fall</i> .
- Incident is Priority 1 or Priority 2.	- Incident is not Priority 1 or Priority 2.
- Responding unit is Advanced Life Support (ALS).	- Responding unit is Basic Life Support (BLS).

The sample size for this study will be approximately 2,500 emergency responses meeting inclusion criteria. This sample size calculation is obtained using the overall trauma mortality rate of 4.39%, drawn from the National Trauma Data Bank Annual Report by the American College of Surgeons, assuming a RR of 0.5 with application of ultrasound, and with power of 80% to reach $p = 0.05$.³⁵

According to data from the most recent publicly accessible version of Boston EMS's "Vital Statistics," approximately 7,500 responses to *Trauma, Fall, and Motor Vehicle Crash* occur per year.³⁶ Assuming a 24-month study design, it is reasonable to conclude that a sufficient quantity of response data will be able to be collected during this period.

Intervention

As shown in Figure 1 below, trauma responses which meet inclusion criteria will be randomized by the answering dispatcher by use of computer software installed on dispatch center desktops, which will assign PHUS+ or PHUS- to each response at a 1:1 ratio.

The Boston EMS ambulance unit will be notified of their PHUS status over radio communication and via text message concurrently with the address and details of the response, in order to achieve two-level, closed-loop communication between dispatch and prehospital providers.

If an ALS unit is assigned PHUS+, the prehospital providers will perform an eFAST exam for their patient. PHUS findings will then be utilized to guide choice of destination hospital. Findings will be communicated to the receiving hospital via Medical Control to allow assembling of receiving hospital trauma surgery team, as indicated. Furthermore, in the particular case of a tension pneumothorax, as per Massachusetts EMS protocols, EMT-Paramedics should proceed with needle thoracostomy.³⁷

PHUS- units are required to withhold use of ultrasound and not perform eFAST. Instead, these units will perform standard trauma care as delineated by Massachusetts EMS protocols and rely on clinical diagnosis to guide destination hospital decision-making and intervention in tension pneumothorax.³⁷

Therefore, the intervention group will always receive PHUS via eFAST exam, and the non-intervention group will never receive PHUS.

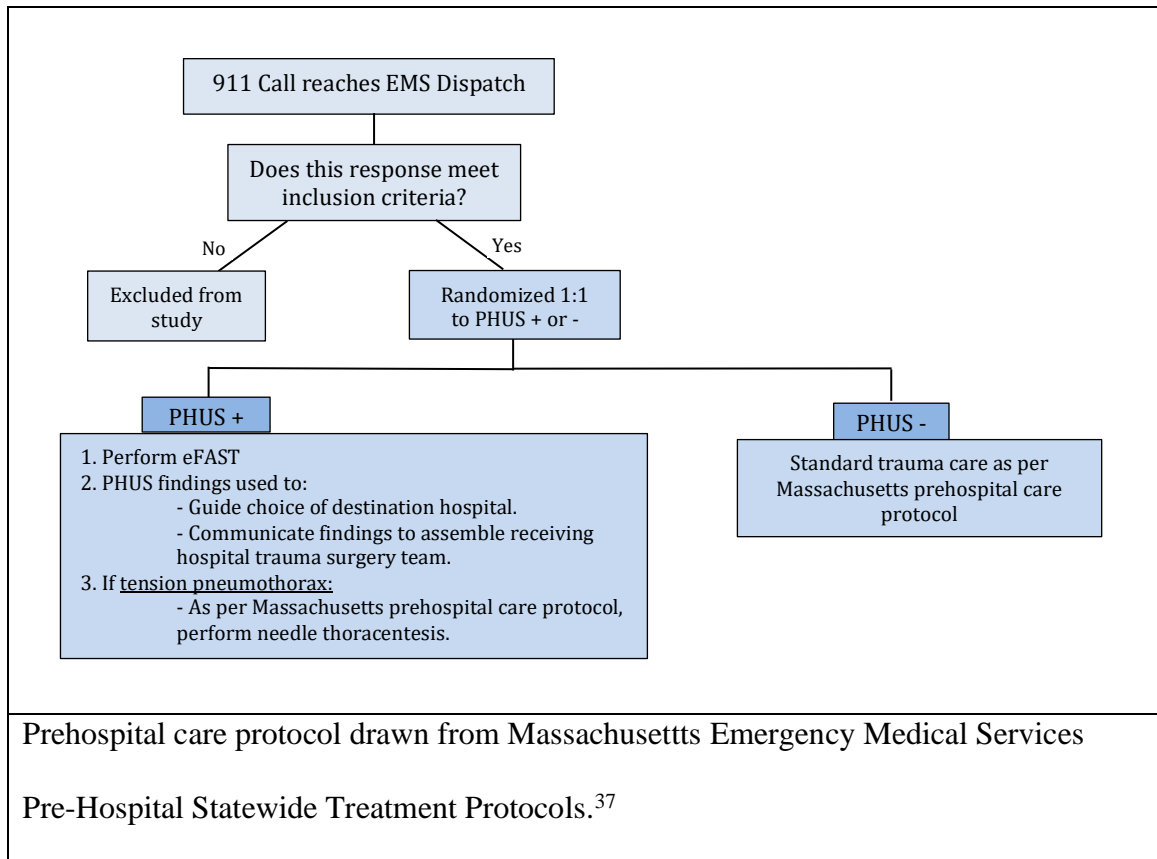


Figure 1: Study intervention flowchart

Project variables and measurement tools

The primary outcome variable for this study will be the 30-day mortality rate of trauma patients receiving care. Mortality will be defined as death from all causes prior to the 30th day following traumatic injury. In addition, two secondary variables will be collected from the EMR for use in stratified analysis: length of transport time and severity of traumatic injury. Finally, demographic information will be collected for each patient in order to determine generalizability of the study. The demographic data points will include age, biologic sex, race, and family income as a measure of socioeconomic status.

Recruitment

Participants will be recruited as stated above in the *Study Population and Sampling* section. Consent for enrollment will be implied if the patient is unresponsive or otherwise unable to make medical decisions. However, if the patient is conscious and oriented, or a legal representative is available at the scene, they must be informed of the risk/benefits of ultrasound in trauma care and be informed of their choice to opt out of the study, at which point they would receive Boston EMS standard care for trauma including PHUS as needed. This group of opt-out patients would not be included in the study.

Data collection

Data for this study will be collected from the electronic medical record (EMR) both of Boston EMS and of receiving hospitals. The relevant information for each patient, described above in *Project Variables*, will be transferred from the EMR to a Microsoft Excel spreadsheet in order to store and organize the information long-term. The spreadsheet will be password encrypted and stored on an external hard drive accessible only by the investigators and research assistant involved in the project to ensure safety and privacy of protected patient information.

Analysis

A z-test will be used to analyze the primary outcome: 30-day mortality rate in PHUS+ patients compared with PHUS- trauma patients. The z-test will be utilized as it is the most appropriate option to compare the difference in two proportions. The mean, standard deviation, and sample average will be calculated from the data in order to perform the z-test. Patient demographic information will be collected as categorical

variables, including age, sex, and race. An additional demographic variable, income, will be collected as a numerical variable. Stratified analysis of 30-day mortality rate will be performed. 30-day mortality rate will be stratified by time to hospital and by severity of injury, as shown in the tables 2 and 3 below. Time to hospital data will be acquired directly from the Boston EMS EMR. Severity of injury will be determined using the Injury Severity Score (ISS) to categorize each patient into mild, moderate, severe, or profound traumatic injury based on ISS score for stratified analysis.^{38,39}

Table 2: Stratified analysis by transport time (on-scene to hospital handoff)

	<15 minutes	15-30 minutes	>30 minutes
PHUS +			
PHUS -			

Table 3: Stratified analysis by severity of injury using ISS³⁹

	Mild (<9)	Moderate (9-15)	Severe (15-25)	Profound (>25)
PHUS +				
PHUS -				

Table 4: Timeline and resources

Summer 2021	<ul style="list-style-type: none"> - Submit for IRB approval - Begin partnership discussion with Boston EMS.
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Summer 2022	<ul style="list-style-type: none"> - Purchase ultrasound equipment in sufficient quantity to staff all Boston EMS ALS rigs per given shift. - Initiate ultrasound training protocols for Boston EMS paramedics as described in Yates et al.³¹ - Initiate dispatch training for delegation of PHUS status to responding units.
Fall 2022-Fall 2024	<ul style="list-style-type: none"> - Implement study protocol and data collection.
Winter 2024	<ul style="list-style-type: none"> - Data analysis.
Spring 2025	<ul style="list-style-type: none"> - Study completion. - Synthesize and submit manuscript for peer review.

Various resources will be required in the undertaking and completion of this study. In terms of personnel, a primary investigator will oversee the data collection and perform project oversight. The primary investigator will also serve as the key liaison between the research team and Boston EMS to address issues that may arise during the study. A research assistant will input data into the excel spreadsheet with the assistance of a co-investigator specializing in trauma care such patients are correctly categorized

using the Injury Severity Score (ISS). Lastly, a statistician will be required to analyze the data.

Purchasing ultrasound equipment will also be necessary. Boston EMS peak staffing is five ALS units in the city at a time, and each of these units must be equipped with handheld ultrasound probes.³⁶ Ten GE VScan Extend handheld ultrasound devices must be purchased in total, to allow for potentially damaged, lost, or stolen equipment during the course of the year-long study.⁴⁰

Institutional review board

This study will be submitted for Expedited BMC IRB review under Common Rule 4, which includes ultrasound as an example of data collected through noninvasive procedure.

CONCLUSION

Discussion

This study will bridge a gap in the literature regarding mortality rate of trauma patients using prehospital ultrasound.⁷ Previous studies have examined the accuracy, efficacy, and speed of prehospital ultrasound, but this will be the first of its kind to investigate 30-day mortality as a major clinical outcome of ultrasound as a prehospital diagnostic and treatment modality.

The study's design, which randomizes at the patient level, eliminates confounding variables that are notably present in other study types, including individual differences in provider skill level with ultrasound, years of clinical experience, and effectiveness of

communication and teamwork between prehospital team members on individual ambulance units.

Using an urban population will be beneficial in terms of the generalizability of this study. A diverse patient population is expected to be recruited throughout the course of data acquisition, owing to the fact that the trauma patients should be largely representative of the diverse population within the city of Boston. Demographic information will be diligently collected and laid out in the final product, in order to emphasize this area of study strength.

One anticipated obstacle is provider compliance with study protocol. It is possible prehospital providers may feel compelled to utilize ultrasound in emergent clinical circumstances that appear to warrant its use, even if they have been assigned PHUS-status by dispatch. It will be of utmost importance for the primary investigator to communicate thoroughly with Boston EMS and emphasize the long-term significance of providers adhering to study protocol.

Paradoxically, one drawback to this study is the aforementioned use of an urban population. A major strength of PHUS lies in its ability to provide diagnostic information which may result in change of destination hospital and adjustment of management decisions, two factors which are grow increasingly important with longer transport times. In an urban EMS setting, transport times are shorter than in a rural setting. In some cases, a responding ambulance may be on the doorstep of their receiving hospital, or merely blocks away. These close-range responses require only a fraction of time compared with a long-range transport from rural Massachusetts an outlying receiving hospital, which are

spread few and far between.³³ For this reason, we suspect that a more noticeable effect size may be seen if this study were carried out in similar fashion within a rural setting. Unfortunately, rural EMS call volume is drastically smaller than the urban volume of Boston. This study, if conducted in a rural setting, would likely require several years of data collection to reach an appropriate sample size. Furthermore, multiple EMS regions, and their respective EMS companies and dispatches, would need to be involved in study coordination and logistics. For these reasons, carrying out this research in a rural population is not practical or feasible at this stage of PHUS investigation.

Summary

Prehospital ultrasound (PHUS) is intriguing as a diagnostic and treatment modality that may improve outcomes in trauma patients. The development of the eFAST exam as a rapid and effective imaging protocol in trauma patients, as well as the increasing portability and decreasing cost of ultrasound devices, raise the possibility of adding this modality to the prehospital provider's toolkit. Handheld devices, small enough to fit in a paramedic's jump bag, are now widely available and accessible for purchase.

Current studies have continued to demonstrate the diagnostic accuracy of ultrasound, especially in detecting hemoperitoneum and ruling-out pneumothorax.^{7,27,31} Research has shown information gathered using prehospital ultrasound is able to alter treatment decisions in a significant proportion of trauma patients, and may lead to change in destination hospital for a more appropriate level of trauma care.⁷

This proposed study will evaluate the effect on 30-day mortality of using prehospital ultrasound in trauma patients. It will be the first investigation into a primary

clinical outcome of PHUS, and the results that are found will provide definitive evidence supporting or refuting the addition of this modality to the prehospital trauma care paradigm.

Clinical and/or public health significance

Traumatic injury is a major cause of morbidity and mortality in modern health care systems, with a particularly high burden among individuals less than 45 years old.^{1,3} A major component of the care for these patients takes place in the prehospital environment, where diagnostic methods are woefully lacking.⁵ Prehospital ultrasound (PHUS) is an emerging modality that offers a means of improvement in this arena.⁶ In this study, the 30-day mortality rate of patients treated with PHUS will be compared with the 30-day mortality rate of those treated with traditional methods alone. If an improvement in the 30-day mortality rate is found using ultrasound, this will be definitive evidence suggesting that lives of trauma patients can be saved by wide-scale incorporation of this modality on ground ambulances and air medical services across the United States and worldwide.

LIST OF JOURNAL ABBREVIATIONS

Acad Emerg Med	Academic emergency medicine: official journal of the Society for Academic Emergency Medicine
Air Med J	Air medical journal
Am Surg	The American surgeon
Br J Surg	The British journal of surgery
Crit Care	Critical Care
EJIFCC	Journal of the International Federation of Clinical Chemistry and Laboratory Medicine
Emerg Radiol	Emergency radiology
Int J Crit Illn Inj Sci	International journal of critical illness and injury science
J Am Coll Surg	Journal of the American College of Surgeons
J Emerg Med	The Journal of emergency medicine
J Surg Res	The Journal of surgical research
J Trauma	The Journal of trauma
J Trauma Acute Care Surg	The journal of trauma and acute care surgery
Md State Med J	Maryland State Medical Journal
N Engl J Med	New England journal of medicine
Open Access Emerg Med	Open access emergency medicine: OAEM

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CURRICULUM VITAE

