Title
Prehospital Assessment with Ultrasound in Emergencies - PAUSE II - Implementation in the Field

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Prehospital Assessment with Ultrasound in Emergencies – PAUSE II – Implementation in the Field

THESIS

submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in Biomedical and Translational Science

by

Kevin Patrick Rooney

Thesis Committee:
Professor John Christian Fox, Chair
Professor Sheldon Greenfield
Doctor Kenneth Miller

2014
DEDICATION

To

Sarah

For her support and understanding of my extracurricular projects.

And, to my father

Whose example influenced me to pursue medicine.
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I would like to thank my committee chair, Chris Fox, for his guidance, support and understanding throughout this process. His vision for this study and encouragement helped motivate me to finish this challenging study. I will always be grateful to him for his advice on all aspects of my career.

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Finally, I would like to thank Ken Miller for his assistance in implementing this study. He facilitated our interactions with the Orange County Fire Authority paramedics. Without him, there would have been no study. His knowledge and experience will be essential to future iterations of this project.
ABSTRACT OF THE THESIS
Prehospital Assessment with Ultrasound in Emergencies – PAUSE II – Implementation in the Field
By
Kevin Patrick Rooney
Masters of Science in Biomedical and Translational Science
University of California, Irvine, 2014
Professor John Christian Fox, Chair

Background: Point-of-care ultrasound is an ideal imaging modality in the emergency department. Its study in the prehospital setting is limited. We previously published on paramedics’ ability to perform basic scans and recognize pneumothorax, pericardial effusion and cardiac standstill under classroom conditions. In this study, we trained paramedics to use cardiac ultrasound in the field.

Objectives: To determine whether paramedics are capable of obtaining cardiac ultrasound scans at a level adequate for decision-making. The primary outcome was a percentage of paramedic scans judged as adequate for clinical decision-making.

Methods: This was a prospective educational intervention using a convenience sample of professional paramedics with no prior US experience. Paramedics participated in a 3-hour training session then used US during dispatch calls. They saved scans for complaints of:
chest pain, dyspnea, loss of consciousness, trauma, cardiac arrest. The scans were later evaluated by two ultrasound-trained emergency physicians.

**Results:** Overall, four paramedics obtained adequate scans 89% of the time. In total, 17/19 unique patient studies were adequate for clinical decision-making. Two studies were of inadequate diagnostic quality. Two cardiac arrest studies were logged and paramedics correctly identified these cases as cardiac standstill.

**Conclusion:** Implementing ultrasound in the prehospital setting is challenging. Many unforeseen variables interfered with the study. We did not achieve statistical significance, so the study must be interpreted as a hypothesis-generating study. Areas to improve in future studies include continuity of enrollment and data collection. Focus should be on improving outcomes in survival, quality and resource allocation.
INTRODUCTION

This study was conducted over a roughly two-year timeframe. We had a budget of zero. It was the commitment of our study team that allowed us to complete the project and obtain our data. This study will hopefully be an important initial step in the evaluation of prehospital point-of-care ultrasound.
Chapter 1: Prehospital Point-of-Care Ultrasound

The overall purpose of this study is to determine if paramedics can be trained to utilize a portable ultrasound machine in the field. The hypothesis is that paramedics are capable, as judged by UC Irvine emergency ultrasound-trained physicians, of obtaining ultrasound images that are suitable for clinical decision-making in a mobile environment during an emergent call. Specifically, we will test the ability of paramedics to learn (in a classroom setting) and then use (in the field) a novel ultrasound protocol to observe two main views of the heart 1) left parasternal long axis and 2) subxiphoid four-chamber. We will also evaluate whether they can detect pathology, specifically cardiac standstill, using these two heart views. Another rationale for this study is that there is no widely recognized ultrasound protocol which specifically addresses only the immediate needs of the prehospital provider. This acquired data will also provide information about the feasibility and barriers of a mobile ultrasound system.

Point-of-care or bedside ultrasound is the method of study to which we are referring. We specify this because point-of-care ultrasonography is not meant to be a comprehensive radiologic study performed over an extended time period by a credentialed sonographer. It is meant to expeditiously answer a specific clinical question, usually in less than five minutes.1

Our hypothesis is that paramedics can acquire ultrasound video clips that are suitable for clinical decision-making, specified as adequate studies, in the back of an ambulance.
Chapter 2: Literature Review

Proven Utility of Bedside Ultrasound in the Emergency Department

In the past 20 years, bedside, or, alternatively, point-of-care ultrasound has proven its utility in the emergency department. Arguably, it has become the imaging modality of choice throughout academic emergency departments. This is a result of several factors of ultrasonography that relate to logistics and efficiency:

1. It is portable
2. It is accessible
3. It does not expose patients to radiation
4. It is a dynamic imaging modality
5. It can provide quick answers to clinical questions
6. It can immediately influence treatment
7. It increases the limited interaction time clinicians have with patients
8. It is relatively easy to learn

Because ultrasound is currently used as a first line diagnostic tool as an extension of the physical exam, it can be valuable in the emergent clinical setting.

In 1999, Bode and colleagues demonstrated, in nearly 1700 trauma patients, that ultrasound was excellent for detecting intra-abdominal organ injuries or free intraperitoneal fluid, which, in a setting of trauma is indicative of a likely injury. Around
the same time, trauma surgeons and emergency providers from around the world convened to codify an ultrasound protocol that would become a cornerstone of Advanced Trauma Life Support (ATLS). The FAST exam, or Focused Assessment with Sonography for Trauma, is an important adjunct to the primary survey in trauma patients presenting to the emergency department. It involves evaluation of 3 abdominal compartments and the heart to assess for pathology.³

Cardiopulmonary Ultrasound

These initial studies jump started interest in emergency medicine for further exploration of ultrasound capabilities. Cardiopulmonary ultrasound was an important next step in the process. Dulchavsky was interested in adding lung ultrasound to the initial FAST protocol, as it was shown that ultrasound was useful in identifying pneumothorax.⁴ The extended FAST exam including lung windows was thus created and has since been shown as more sensitive than chest radiographs in detecting pneumothorax. Although technically included as part of the FAST exam, bedside echocardiography had not been explored thoroughly as an independent science in the emergency department. This began to change around 2001 when a group studied cardiac ultrasound in patients at high risk for pericardial effusion. In a screening study of 515 high risk patients, it was found that cardiac ultrasound performed by emergency physicians in the emergency department had a 96% sensitivity and 98% specificity for detecting pericardial effusion.⁵ More comprehensively, bedside ultrasound is excellent for evaluating left-ventricular contractility, and, more recently, it has been studied as a hemodynamic marker. Its application in measuring hemodynamics remains controversial, as accuracy is operator and clinical circumstance dependent.⁶–⁸
Advanced Cardiovascular Life Support

Point-of-care ultrasound is especially useful in the setting of the patient in cardiopulmonary arrest. Traditionally, in the ACLS protocol, a clinician is directed to review the “Hs and Ts” to search for an etiology for the arrest:

H: Hypovolemia, Hypoxia, Hydrogen ion, Hyper- or hypokalemia, Hypothermia
T: Toxins, Tamponade, Tension pneumothorax, Thrombosis

Often, this is challenging and in many cases, therapeutic management is chosen with the plan to re-evaluate a patient’s status in response to a chosen therapy. With ultrasound, a clinician can see into a patient and tangibly evaluate the etiology of a cardiopulmonary arrest in real time.9–12

We know now that early defibrillation and high quality resuscitation are significant impact factors on outcomes.13 It is useful to consider the place of ultrasound in this management. Several groups have advocated a placeholder for simple bedside ultrasound exams in the ACLS protocol.14,15 One interesting study proposed an integrated ACLS protocol for patients in pulseless electrical activity and also performed a prospective validation. Patients evaluated with ultrasound and found to be hypovolemic were volume resuscitated. Outcomes of return of spontaneous circulation and death were not significantly different in this population, however.16
As mentioned earlier, we know that early, sound adherence to the ACLS guidelines results in improved outcomes. The protocols are the most important medical service provided by prehospital care providers. However, ACLS is a resource consuming process. Therefore, another area of exploration is how ultrasound can be used as a decision tool to terminate resuscitative efforts.

Cardiac Standstill

Bedside ultrasound can be used to evaluate a most basic cardiac mechanism, whether a coding patient has any cardiac motion. No cardiac motion is associated with high mortality and this could be a guide in stopping resuscitative efforts. In a prospective observational study, Blaivas and Fox found that 136/136 patients without motion, known as cardiac standstill, on initial ultrasound died before leaving the emergency department.17 Tayal and Kline presented a case series of 20 medical patients with hemodynamic collapse who were examined by ultrasound. In this series, 8 patients had cardiac standstill and none had return of spontaneous circulation. Another 8 patients were found to have pericardial effusions and 7/8 of these patients survived to hospital discharge.18 In another prospective observation study of resuscitation patients with PEA and asystole, 36/36 patients without cardiac activity on initial ultrasound died without achieving return of spontaneous circulation.19 More recently, a systematic review examined these and other smaller studies and found that 2.4% of patients with cardiac standstill on bedside ultrasound during resuscitation had return of spontaneous circulation. The clinical outcomes survival to discharge and neurologic recovery were not available in this group of studies.20 However, based on this data, it has not been recommended by the American Heart Association to use
echocardiography independently as confirmation of expiration. It should, rather, be used to support or refute other evidence of patient status.

Bedside Ultrasound as a Technician Level Skill

Obtaining point-of-care ultrasound video clips and interpreting them for patient management decisions is a highly advanced skill. The technical aspects of acquiring images, however, are not outside the skill boundaries of basic health care providers and the educated adults, given adequate training. This has been demonstrated by nurses who performed ultrasound of a limited spectrum with comparable accuracy and imaging as physicians. In addition, astronauts with no formalized health care training were able to obtain ultrasound FAST images in space weeks after undergoing basic sonography training. Medical schools across the country are implementing ultrasound curricula in the first year prior to students having had any formal clinical training. These medical students have proven successful at obtaining high quality ultrasound clips relevant to focused areas of a physical exam. At this stage of their training, students are similar to nurses or astronauts in the area of ultrasound – essentially untrained technicians. From these findings it is reasonable to expect that even non-medical personnel have the ability to learn technical skills of bedside ultrasound.

Bedside Ultrasound in Remote Environments

The prehospital setting is a relatively austere environment. Thus, it is relevant to review literature that deals with ultrasound in remote environments. Ultrasound is portable, accessible, transmissible and present throughout the world. Recent studies have examined
its use in locations across Africa, as an adjunct to Panamanian midwives’ healthcare in the setting of women’s health, and as a feasible diagnostic modality in space. More recently, its transmission across networks to expert over readers has been studied.

Prehospital Ultrasound

Paramedics are basic medical providers who utilize the ACLS protocol in their daily work. The study of point-of-care ultrasound in the prehospital setting is not nearly as feasible as in the emergency department, but several authors have pursued the use of ultrasound in this environment.

In Europe and Australia, emergency physicians ride along in the prehospital setting. Thus, initial studies examining the feasibility of ultrasound in the field have evaluated the ability of physicians to perform bedside ultrasound during transport to the receiving hospital. A French study involved 8 emergency physicians who were trained in ultrasound and then dispatched into the field to examine patients who met suspicion criteria for specific diagnoses. In total, 169 patients were scanned resulting in 302 exams. Positive findings were documented on 17% of these scans and ultrasound was found to have identified treatable pathology in 67% of these scans. The largest study to date was performed by Walcher and colleagues. They FAST-scanned 230 patients. Field bedside ultrasound performed by emergency physicians was found to be more accurate than physical exam alone at detecting pathology. Point-of-care ultrasound had sensitivity, specificity, and accuracy of 93, 99 and 99% when compared to hospital performed computed tomography or formal ultrasound. Physical exam findings were 93% sensitive but only 52% specific
with 57% accuracy. Most interesting about this study, however, was that in field ultrasound findings changed management in 30% of patients and changed triage hospital destination in 22% of patients.\textsuperscript{33}

Paramedics Performing Bedside Ultrasound

Paramedics have shown promise in learning to use bedside ultrasound. Using similar training sessions to those provided physicians and medical students, numerous simulation studies have tested the capabilities of paramedics to learn and retain ultrasound skills. In a study out of the UK, Brooke and colleagues demonstrated in a prospective observation cohort study that, after 10 hours of training, paramedics were able to achieve lung ultrasound technical skill at a adequacy threshold similar to expert physician sonographers. This study incorporated both formal scan identification testing and practical capabilities.\textsuperscript{34} In 2010, a study investigating 12 army intermediate paramedics trained in cardiac echocardiography was published. This was a prospective educational intervention in which subjects were taught two basic cardiac windows to obtain views of the heart. Paramedics were successful in practical application of skills learned during a didactic lecture and subsequent hands-on training. The most significant proposal from this study was a new measure for adequacy judgment of echocardiograms on a 6-point Cardiac Ultrasound Structural Assessment Scale (CUSAS).\textsuperscript{35} Chin and colleagues used the Backlund measure in a classroom study of their own. They trained 20 paramedics to recognize pneumothorax, cardiac tamponade and cardiac standstill on previously saved video clips. They also taught paramedics to obtain lung and cardiac ultrasound. Testing of the paramedics demonstrated that the paramedics were able to identify the specified
pathologies with an average score of 9.1/10 on a written video clip identification test. These paramedics were able to visualize lungs adequately to evaluate for pneumothorax 100% of the time. The CUSAS scores for 19/20 paramedics was greater than or equal to 4, which is higher than the suggested threshold for adequacy. Importantly, the authors found no association between image acquisition score and written test score. However, this is not surprising, and we mentioned earlier that while paramedics can learn the technical steps of point-of-care ultrasound, it is not expected that they have abilities to interpret scans.

Recently, Kim and Song have published two prospective observation simulation studies out of South Korea. One shows that paramedics are capable, with 61.3% sensitivity, of detecting free fluid on FAST scan of patients in an emergency department. With moderate or large amounts of fluid, they were 86.2% sensitive. A follow up study explored the possibility of transmitting ultrasound video clips wirelessly over a 3G network. Paramedics scanned a hemoperitoneum simulator and these scans were received and over read by emergency physicians. Qualitatively, the emergency physicians were able to accurately recognize hemoperitoneum on the transmitted images. These studies are important in taking the next step of paramedic ultrasound. Paramedics will not be able to change their management of patients by themselves if ultrasound becomes widespread in the prehospital setting. They will need technologic capabilities to efficiently and securely transmit these video clips to a receiving hospital.
The most robust and practical prehospital study to date was published in 2010 and involved paramedics using ultrasound in the field to perform FAST scans. Heegaard and colleagues performed a prospective educational intervention using a 6-hour initial training session with ongoing refresher sessions. They enrolled 104 patients: 20 abdominal aortic aneurysm screening exams and 84 FAST exams. The aorta exams were all read by the paramedics as adequate for interpretation and negative for pathology. The FAST exams included 70 negative scans, 6 scans positive for free fluid and 8 scans that were inadequate for interpretation. They reported a 100% proportion of agreement of paramedics with physician over readers who reviewed the scans. This study is most practical for exploring the feasibility of ultrasound in the field. However, our group reasoned that abdominal aortic aneurysm is a medical pathology that is too rare around which to design a prospective study.
Chapter 3: Methods

In this study, we initially trained paramedics to perform cardiac ultrasound examinations. We then tested them on their newly acquired skills. After that, we allowed the paramedics to take the ultrasound machine into the field during their daily calls. In the prehospital setting, four paramedics performed cardiac ultrasound on patients who reported the predetermined chief complaints noted earlier. The paramedics saved these video clips on the ultrasound machine for later review by the study team. The study team performed a review of these videos and graded them for adequacy based on a previous study.35 Throughout the study, paramedics were provided with refresher training courses every 6-8 weeks to help them maintain their scanning skills and answer any arising questions. The ultrasound video was recorded strictly for research purposes and did not become a part of any patients’ medical record.

Study population

This was a prospective, educational intervention study using an observational convenience sample of professional firefighter paramedics with the Orange County Fire Authority who voluntarily agreed to participate. They signed consent forms, underwent appropriate HIPAA and research procedural training in compliance with our institution’s Institutional Review Board. The Institutional Review Board approved all research activities prior to conducting the study. During the study, we trained and approved 20 paramedics to participate in the study. Study enrollment began in August, 2012 and was concluded in September, 2014.
Research Design

After completing all documentation and receiving approval to participate in the study, each paramedic participated in an approximately three-hour-long training session on point-of-care ultrasound. The training time was determined based on our previously reported PAUSE study and followed typical OCFA paramedic training time. No paramedic had any prior training in ultrasound. Instructors were study team members and instructor-to-paramedic ratios were 1:3 or better. The initial training session included a didactic module and a hands-on training module.

The didactic portion consisted of an outline of basic ultrasound and echocardiography principles and images. Specific areas of ultrasonography covered included basic theory, image acquisition, machine functionality and basic interpretation. Also, paramedics were provided a detailed explanation of the study goals and an overview of the PAUSE protocol to be used in the field. A brief question and answer session followed the didactic session to review any areas of confusion.
Ultrasound Basics
- Ultrasound imaging/ultrasonography: reflected sound waves used to image the body.
- Non-invasive and does not emit radiation like CT scans or X-rays.
- Sound passes through or reflects off various tissues at different speeds; it CANNOT go through bones.
- Sound beam comes out of the probe in a shape like a slice of pizza.
- Indicator on probe corresponds to screen indicator; helps to orient user.
- Sound beam depth can be adjusted to maximize size of relevant anatomy.
- F.A.R.T. (Fan, Angle, Rotate, Translocate) the probe to get the image you want.

Heart Anatomy Review and Scanning Windows

**Blood flow:**
From body --> R. atrium --> Tricuspid valve --> R. ventricle --> To lungs
From lungs --> L. atrium --> Mitral valve --> L. ventricle --> Aorta to body

**Parasternal long-axis:**
- Indicator to patient's left elbow-hip
- Easiest view to acquire on obese patients
- Best view to examine left heart function
- Good left ventricular contractility needed to pump blood to body

**Subxiphoid:**
- Indicator to patient's right side
- Aim probe to patient's left shoulder
- Imagine 2D slice sitting just behind sternum
- Both left and right heart chambers can be seen

Heart position in chest:
- Right side of heart is anterior
- Left side of heart lies behind and to the outer left

Figure 1: Paramedic Cheat Sheet.
Videos were also used as supplemental training during the didactic session. We provided prerecorded video clips on basic echocardiography taken from iTunes U lectures used to teach UC Irvine medical students. We also used brief SonoSite training videos on YouTube - http://www.youtube.com/watch?v=H_3V9xlDMA0 (Parasternal Long Axis) and http://www.youtube.com/watch?v=ew6uJvZDhmw (Subxiphoid).

Next, the paramedics participated in a one-hour hands-on training session. An emergency physician trained in bedside ultrasonography demonstrated the following views: a subxiphoid four-chamber cardiac view and a left parasternal long axis cardiac view. Healthy volunteers, either research study team members or paramedics, were used as human models for the hands-on session. The images obtained during this training session did not contain any model identifying information and was not used for any diagnostic purpose. Models verbally consented to being scanned with no diagnostic purpose. Research study team members (ultrasound-trained medical students and/or emergency physicians) were present during all training sessions.

Paramedics took turns practicing the subxiphoid four-chamber and left parasternal long axis views individually and in series. Instruction focused on image acquisition and identifying adequate views.

We taught paramedics to use two different types of ultrasound machines: a Mobisante (Redmond, WA) Mobius SP1 with a 3.5MHz phased array transducer and a GE (Fairfield, CT) Vscan with a 1.7-3.8MHz phased array transducer. Paramedics were instructed how to
save video clips for later review by the research study team. Step-by-step instruction sheets were attached to the ultrasound machines for reference between training sessions and while in the field. Paramedics performed the hands-on session until they were satisfied they could acquire adequate cardiac views.

Once the hands-on training was complete, each paramedic was immediately given two tests to assess the efficacy of the educational intervention. The first test was on video clip recognition. This exam was a series of 20 questions viewed on a laptop computer. Each question showed a de-identified video clip of a heart. Paramedics were instructed to identify the view (subxiphoid or parasternal long axis) in each video clip and select whether it was either beating or not beating. These answers were recorded on a test sheet for later grading. The second test was to acquire adequate left parasternal long axis and subxiphoid four chamber views of the heart without assistance. Paramedics held the probe in position and gave a signal when they felt an adequate view had been acquired.

On the written video clip recognition portion of the test, a question was considered correct if a paramedic identified both the orientation and the cardiac motion status correctly. The ultrasound window acquisition test was evaluated in real time. After the test, we reviewed the video clip recognition items with the paramedics and answered any final questions.

This teaching session was repeated every 4-6 weeks, simulating a normal paramedic training curriculum.
The field component of this study consisted of paramedic subjects acquiring cardiac video clips during daily dispatch calls. Paramedics obtained video clips of patients’ hearts while in the field, but if cardiac ultrasound interfered with ongoing treatment in any way, paramedics utilized their best judgment to terminate the imaging protocol.

Before arriving on scene, a paramedic prepared the ultrasound device by turning on the recorder and navigating to the scan mode. A unique study number identified each saved ultrasound video clip. These study numbers were generated at random by the ultrasound machine and had no association with patient identifying information. Paramedics were instructed to use their own judgment in selecting where to perform cardiac ultrasound. Paramedics performed cardiac ultrasound exams either 1) at the patient pick-up location while awaiting the ambulance or 2) during transport of a patient to the hospital. If one of these settings was deemed appropriate, a paramedic would begin scanning the patient using the parasternal long axis or subxiphoid sonographic window. The ultrasound video was recorded by the paramedic and identified only with the study number on the ultrasound screen. These scans were saved on a memory card in the device for later review.
Paramedics performed ultrasound exams on patients presenting with the following complaints: chest pain, dyspnea, loss of consciousness, trauma, cardiac arrest. During cardiac arrest resuscitation calls, cardiac standstill was assessed by paramedics. However,
ultrasound imaging was obtained only if the paramedics judged that it could be acquired without interfering with the standardized advanced cardiac life support protocol. Either during the re-assessment phase of the resuscitation or during chest compressions, one paramedic obtained ultrasound imaging while the other paramedic(s) performed the ACLS protocol on the patient. Additionally, ultrasound was performed only in cases where the paramedic performing the ultrasound was not needed for any of the ACLS protocol steps. The "reassessment phase of the resuscitation" occurs approximately every 2 minutes during the cardiac arrest protocol and is the period between cardiopulmonary resuscitation attempts. It is noted below as red diamond labeled "Check Rhythm" on the ACLS figure.
During the reassessment phase, the patient’s heart rhythm, pulse rate, airway and breathing are evaluated and a defibrillator is discharged, if appropriate. Because the reassessment phase occurs approximately every 2 minutes, paramedics had numerous opportunities during hospital transport to obtain cardiac ultrasound views in arrest patients. Paramedics also had the option to perform ultrasound imaging during chest compressions if it did not interfere with chest compressions. We emphasized to the
paramedics, most importantly, that they should not perform an ultrasound scan if they felt that it would interfere with or had the potential to interfere with standard patient management.

Informed Consent for Patients

We were granted a waiver of informed consent around patient selection for this study. The ultrasound protocol was designed to be observational with no impact on care. Introducing new technology into the prehospital setting is something that occurs commonly and continuously, so paramedics are experienced in adapting to such change. The paramedics have many years of experience running resuscitations and are able to make educated decisions about resource management. Furthermore, ultrasound video clips from the study were not tied to any patient’s medical record or identifying personal information. No protected patient health information was created. In addition, it was impractical to ask patient relatives for consent for the performance of ultrasound on patients with emergent complaints. Most often, there was neither time nor guaranteed presence of a representative. Ultimately, there was no other reasonable method to perform a study on the integration of ultrasound during a paramedic medical run than to waive informed consent of prehospital patients.

Inclusion and Exclusion Criteria

Adult cardiac subjects were Emergency Medical Service patients being transported by an Orange County Fire Authority paramedic unit. These adult patients were of any age 18 years of age or older, or of either gender. Women identifying themselves in the obtained
history as being pregnant and prisoners were not included in this study. Children under the age of 18 were not recruited in the study. Pregnant women, prisoners and children were not included in the study to simplify the approval and consent process.

In patients suffering from cardiac arrest where a cardiac ultrasound would interfere with treatment (i.e. if all paramedics in the ambulance need to be performing resuscitation procedures) ultrasound was not performed. Patients with unstable injuries besides cardiac arrest where a cardiac ultrasound would interfere with treatment, or any other patients whose medical care would be compromised by the addition of an imaging procedure were excluded from the study.

Orange County Fire Authority Paramedics were recruited from their stations. As mentioned above, because we are not comparing scans within our sample group, a selective recruitment policy should have no effect on the validity of our data.

Outcome Measures

Primary outcomes:

For this study, we evaluated two primary outcomes depending on the patient’s presenting chief complaint: A) whether each scan was adequate for medical decision making and B) whether cardiac arrest or unconscious patient scans showed a beating or non-beating heart.
A) For all patients: a dichotomous variable (“adequate” OR “inadequate”) recorded by the paramedic in the ambulance after this paramedic has obtained heart imaging. This variable is the judgment call made by the paramedic on the readability of the scan he obtained himself in the ambulance. The paramedic will judge a scan as adequate if he feels he obtained EITHER: 1) an “adequate” left parasternal long axis view OR 2) an “adequate” subxiphoid four chamber view of the patient’s heart. If the paramedic believes that BOTH the parasternal long axis view and subxiphoid four chamber view are unreadable, he recorded the patient scan as inadequate.

B) For cardiac arrest and unconscious patients: dichotomous variable (“beating” OR “non-beating”) describing heart movement recorded by paramedic in the ambulance after this paramedic obtained heart imaging that he has judged to be adequate (as described above).

Data collection
During the study, paramedics performed ultrasound scans on patients presenting with the following chief complaints: chest pain, dyspnea, loss of consciousness, trauma, cardiac arrest.

Electronic study sheets were utilized for tracking of paramedic ultrasound scans. Paramedics entered information into these study sheets for each patient scanned. The study sheets included a space for the run/study number, chief complaint, cardiac window obtained, adequacy of video clip acquired, whether the heart was beating or not beating.
and a free text area for general notes. Patient names and unique identifying information was not captured anywhere on the PAUSE II study sheets.

<table>
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<td><strong>Chief complaint:</strong></td>
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<td><strong>View obtained:</strong></td>
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<td><strong>Adequate view?</strong></td>
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<tr>
<td><strong>Heart motion:</strong></td>
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<td><strong>Notes:</strong></td>
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</table>

Figure 4: PAUSE II Study Sheet.
Furthermore, these ultrasound video clips were recorded strictly for UCI research purposes and did not become part of the patients’ medical records. None of the information obtained for use in this study were correlated to clinical information or used for clinical purposes. The ultrasound video clips were not shared with receiving hospitals. In addition, the Orange County Fire Authority has its own privacy methods in place to keep patient data confidential and restricted to research.

After the video clips were recorded and saved on the ultrasound machine, UC Irvine researchers reviewed them. Two ultrasound trained emergency physicians reviewed the paramedic-acquired clips independently and scored the clips on a 6-point scale as follows:

1) No myocardium visualized
2) Myocardium visualized
3) Partial ventricle visualized
4) Multiple partial chambers visualized (including at least one ventricle)
5) Full ventricle visualized
6) Multiple full chambers visualized (including at least one ventricle)

Figure 5: Cardiac Ultrasound Structural Assessment Scale for Adequacy.  

If there was disagreement between the two reviewers, the clips were reviewed together and a consensus score was agreed upon. A score of 4 required partial ventricular visualization. This was used as the threshold for an “adequate” cardiac view.

The two reviewers used the same process to grade the video clips as “non-beating” or “beating” hearts.
Data Analysis

Given the smaller than anticipated sample size not meeting our power requirement, we entered all data into a spreadsheet to perform calculations and organize tables and graphs (Excel, Microsoft Corporation, Redmond, WA). We used a simple proportion expressed as a percentage to determine adequacy of scans and percentage of cardiac arrest studies showing standstill.
Chapter 4: Results

In total, 20 paramedics split between 2 fire stations in Orange County, California were initially trained to perform bedside ultrasound utilizing the PAUSE II protocol. During the 2-year period that paramedics scanned patients in the field, 4 paramedics contributed scans. Two paramedics from each station contributed.

Figure 6: Paramedic Participants.

The paramedics used point-of-care ultrasound to scan 19 unique patients in the field. However, 2 of the patients did not receive scans meeting criteria to be considered adequate.
for clinical decision-making. Thus, paramedics obtained scans adequate for clinical decision making in 17/19 (89%) patients.

Between these 19 patients, the paramedics recorded and saved 30 total files. In addition, there were 2 additional files found to be corrupted. Of the 30 files available for evaluation, 14 were recorded using the subxiphoid window and 11 were recorded using the parasternal long axis. Five studies were inadequate for interpretation. Two of the inadequate studies on one patient, however, were performed in addition to a successful parasternal long axis view. Thus, this patient was considered to have been scanned adequately.
Judgment of cardiac motion was feasible in all 19 patients. Paramedics recorded 2 cases of cardiac standstill. Thus, 17/19 patients had beating hearts.

Based on these findings, paramedics were 89% successful in obtaining point-of-care ultrasound cardiac scans in the field. They have been 100% (2/2) successful at interpreting cardiac standstill scans as not beating.
<table>
<thead>
<tr>
<th>Patient</th>
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<th>Quality</th>
<th>Motion</th>
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</thead>
<tbody>
<tr>
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Table 1: Unique Patient-specific Results.
Figure 8: Adequacy of Unique Patient Studies

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Table 2: Overall Scan-specific Results.

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Figure 9: Breakdown of Scan Orientation
Chapter 5: Discussion

During this two-year trial, we discovered that implementing ultrasound in the prehospital setting with paramedics as sonographers is quite challenging. Many unforeseen variables interfered with the study. Ultimately, we did not achieve a statistically relevant number of enrollments, so the study must be interpreted as a hypothesis-generating study. We cannot authoritatively apply these findings to predict future, similar results. The two areas where we struggled most included continuity of enrolling patients and the data collection process.

Continuity of Enrolling Patients

We were challenged from the outset of this study. Without much literature in this area, there was no proven study design. Logistical obstacles were numerous. We were unable to secure grant funding for this study, so without a budget, we met with several vendors to assess feasibility of obtaining a portable ultrasound machine. Ultimately, we were able to use a device belonging to a specific physician for the duration of the study. Our intention was to publish preliminary results that would promote the study and help secure funding to roll it out to several paramedic units simultaneously.

It was time consuming to train and re-train paramedics for the study. We developed a strong relationship with the local Emergency Medical Services provider. However, identifying a consistent base station for the study proved challenging. Research administrative issues delayed training on several occasions and staff turnover at the fire stations prevented the paramedics who were initially trained from participating. This
occurred with several groups of paramedics. Thus, we continually enrolled and trained paramedics who did not ultimately have an opportunity to use the ultrasound machine on their daily calls. Having only one ultrasound device contributed to this problem as well.

A prehospital study such as this one is only successful if you develop rapport with the providers who are the participants. With the extended period of time between training sessions and having the ability to scan in the field, paramedics became less interested in participating. They have a busy environment in the field and their workflows are very protocolized. Thus, it was challenging to incorporate an extra process in emergency calls.

Data Collection
The primary difficulty we had during the data collection process involved collecting the electronic study sheets. It was initially planned to match the ultrasound video clips to the run/study numbers recorded by the paramedics on the electronic study sheets. However, completed sheets for all relevant scans were not available to the study team. Paramedics did scan patients, but there was a failure in process flow in the transmission of relevant scan data to the study team.

Not having paramedic study sheets negatively influenced our ability to statistically analyze the data. For instance, we were forced to assume that paramedics judged all saved scans as adequate for interpretation. Without the study sheets, we were also unable to analyze patients broken down by chief complaint.
We did not incorporate it in our initial plan, but other groups have evaluated time taken for sonographers to perform specific ultrasound exams. Especially in the emergent setting of ACLS, knowing how long it takes paramedics to perform scans would be a valuable data point.

Taken together, however, all of these factors were valuable lessons. In future studies, we will be prepared to avoid these obstacles. Also, although the hard science and academic structure of this study could have been more robust, the practical implications of such a challenging study may be a more valuable experience when extrapolated to real-world problems in medicine and business.

Other notable items and changes in protocol implemented throughout the study included the following:

We initially designated “syncope” as a chief complaint. This was changed to “altered level of consciousness” patients because paramedics do not make diagnoses of syncope in the field.

We used a nonvalidated measure for judging adequacy. Backlund and colleagues created this measure and used a threshold of 3/6 for adequacy. We arbitrarily chose a threshold of 4/6 for minimum adequacy due to need for more specificity when proposing process change in ACLS algorithm.
We started with 2 ultrasound machines. Paramedics only used the GE Vscan for field scans for the first 6 months of the project so we discontinued use of the Mobisante device.

After performing this study, I am confident that paramedics are capable of performing ultrasound in the field, and I anticipate that this will be eventually shown under the right conditions. In a future study, I would not dramatically change the research methods. However, I would add the following to mitigate the challenges mentioned above:

Add a facilitator on paramedic runs. Having a study team member riding along with paramedics would help remind the paramedics to perform and record scans. It would enhance the day-to-day relationship between study team and paramedics. This would improve efficiency across all areas of the data collection process.

Procure multiple ultrasound machines. Having an additional 5-10 machines would allow the data collection process to proceed more quickly. An important inefficiency in this study was the constant training and retraining of paramedics, the majority of whom did not contribute scans to the study. In order to get enough patients with cardiac standstill in a reasonable study time frame, multiple paramedic units must be utilized and this would require more ultrasound machines.

Ultrasound machines must be able to record video clips that are multiple minutes long. The current study included 3-second clips, which could possibly misdiagnose standstill in patients that had severe bradycardia. In addition to improving accuracy of a cardiac
standstill diagnosis, having a video clip record from the moment of turning on the machine would eliminate the step that a paramedic must push a button each time he wants to capture a scan.

*Emphasize that field imaging will change protocol based on scan results.* To improve buy-in from the paramedics and EMS leadership, the study team should verbalize the importance of changing actionable outcomes. For instance, communicating that scan findings will affect specific EMS protocol workflows is important. Selecting hospital destination based on capabilities (i.e. cardiac cath lab, trauma center) or creating a resuscitation termination decision point would be useful to highlight to EMS groups on a frequent schedule, perhaps by study team facilitators mentioned above. Another way to communicate practicality would be to periodically have real-time interpretation of paramedic field scans by a physician overreader utilizing remote video conferencing via Google Glass or Apple FaceTime.

In summary, it is relevant for paramedics to learn to utilize ultrasound because point-of-care ultrasound technology is improving and is becoming more accessible. It has proven useful to an ever-increasing population of healthcare providers. With the emergency department as an example, outcomes and quality of care in the prehospital environment and in ACLS can likely be improved with bedside ultrasound.
References


Appendix: Initial Statistical Plan

Our initial statistical goal was to determine the proportion of success for paramedic scans deemed “adequate” (for primary outcome A) and the proportion of paramedic scans correctly identified as “beating” or “non-beating” (for primary outcome B) as described below. The statistical approach was planned to be a confidence interval estimate as described below.

Primary outcomes

A) All scans judged by the paramedic as “adequate” or “inadequate” were to be judged by the MD team. The percentage of paramedic scans judged by the MD team to be “adequate” was our determination of paramedic accuracy. We had planned to use a two-sided 99% confidence interval for a single proportion using the large sample normal approximation which would have extended 0.05 from the observed proportion for an expected proportion of 0.95.

B) All scans judged by the paramedic as “beating” or “non-beating” were to be judged by the MD team. The percentage of paramedic scans in which the MD team agreed with the paramedic judgment of “beating” or “non-beating” would have been our determination of paramedic accuracy. We had planned to use a two-sided 99% confidence interval for a single proportion using the large sample normal approximation which will extend 0.10 from the observed proportion for an expected proportion of 0.90.
Primary outcome A:

For all scans, when the sample size is 127, a two-sided 99% confidence interval for a single proportion using the large sample normal approximation will extend 0.05 from the observed proportion for an expected proportion of 0.95. The expected proportion is based on previous studies stating that paramedics obtain adequate scans 95% of the time.

Primary outcome B:

For cardiac arrest and unconscious patient scans, when the sample size is 60, a two-sided 99% confidence interval for a single proportion using the large sample normal approximation will extend 0.10 from the observed proportion for an expected proportion of 0.90. The expected proportion is lower and the confidence interval is wider for outcome B because we expect it to be more difficult than outcome A for paramedics to assess, and, thus, we expect less accuracy in paramedic judgment and more variation. The movement of a “beating” heart is generally used as the main landmark in obtaining cardiac imaging. If a patient’s heart is not beating, we anticipated that it will be more difficult for paramedics to evaluate an image correctly.

Over the course of this entire study, the maximum total patients to be recruited would have been 187. We planned to enroll patients until we had 127 patient scans judged by paramedics as “adequate”. We had planned to assume that 10% of total scans would have been judged by paramedics to be “inadequate”. Thus we needed 141 total patients to evaluate paramedic judgment of an “adequate” scan (primary outcome A).
We had planned to enroll cardiac arrest and unconscious patients until we had 60 “adequate” scans judged by paramedics as either “beating” or “non-beating”. Again, assuming that 10% of scans would have been judged by paramedics as “inadequate”, that means that we would have needed 67 total cardiac arrest and unconscious patient scans (primary outcome B). However, each “adequate” cardiac arrest and unconscious patient scan also would have counted toward the 127 total “adequate” scans.

Therefore, we did not anticipate needing to enroll 141 + 67 total patients. That would have only happened if we did not have any “adequate” cardiac arrest or unconscious patient scans before reaching the 127 “adequate” scan quota.

Our minimum target sample size=127 (which would have included 60 “adequate” cardiac arrest and unconscious patient scans judged as “beating” or “non-beating” + 67 other “adequate” scans).

Our maximum target sample size=187 (which would have included 60 “adequate” resuscitation scans + 127 “adequate” other scans)

With this initial statistical plan combined with an analysis of chief complaint quotas taken from OCFA run database we estimated a two-year study.