RESEARCH PROTOCOL:

PREHOSPITAL eFAST PERFORMANCE

A RETROSPECTIVE REVIEW.

Full study title.
Prehospital eFAST performance: a retrospective review of prospectively collected data

Short title.
Prehospital eFAST review.

Lay description of the project.
The purpose of the proposed study is to estimate the accuracy of point of care ultrasound in the prehospital setting. Specifically, the proposed study will assess the utility of extended-Focussed Assessment with Sonography in Trauma (eFAST) performed by prehospital physicians. Pre-hospital ultrasound findings will be compared to hospital-based imaging (either computed tomography (CT) scans, eFAST scans or surgical findings) for adult trauma victims presenting to major trauma centres in Sydney, Australia.

Study investigators.

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Background

The Focussed Assessment with Sonography for Trauma (FAST) scan is an established point of care ultrasound (POCUS) technique in the in-hospital setting. POCUS has been shown to improve outcomes in the Emergency Department, in particular by expediting the patient journey to definitive surgical intervention by aiding with early decision making. In the haemodynamically unstable trauma patient, the FAST scan has high sensitivity (70-95%) and specificity (98-100%) for detecting intra-abdominal haemorrhage.[1-5] In the setting of patients presenting with penetrating trauma and haemodynamically stable blunt trauma the reported accuracy diminishes significantly.[6 7].

In addition, ultrasound based assessment for pneumothorax (known as the extended-FAST or eFAST exam) is commonly added to the standard FAST scan. eFAST is consistently reported in the literature as a rapid and reliable test (Sn 86-98%, Sp 97-100%).[8-10] The skills to perform eFAST ultrasound can be rapidly acquired through focussed teaching.[11]

In terms of prehospital and retrieval medicine, portable ultrasound has been used widely in the Australian setting for more than a decade.[12] In the setting of trauma, eFAST in the prehospital setting is a potentially useful and reproducible technique for early patient assessment. eFAST has the potential to reliably detect intra-abdominal haemorrhage, pneumothorax and haemopericardium with greater accuracy than physical examination.[13] Ultrasound in this setting can be performed serially during patient transport with the findings relayed to the receiving hospital to aid with early decision making. In the prehospital environment, ultrasound is reported to have an accuracy that mirrors in-hospital scanning as well as the potential to alter patient management and destination.[14-17] However, there are some reported challenges to prehospital ultrasound which frequently result in incomplete scans. These include patient body habitus, time constraints, competing priorities and limited patient access.[18]

The Greater Sydney Area Helicopter Emergency Medical Service (GSA-HEMS) is a prehospital and retrieval medicine service treating critically ill and injured patients in New South Wales, Australia.

Over the past 5 years GSA-HEMS has reported an increased utilisation of POCUS during their trauma missions. During the 2014 calendar year, 480 patients underwent ultrasound scan with interpretation reports later recorded in the ultrasound database. Of these scans, 343 (71.5%) were performed in the prehospital arena, mostly eFAST studies.

Despite the gradual increase in the use of prehospital ultrasound by GSA-HEMS, there is little data surrounding the actual performance of this imaging modality. At present, there is a paucity of evidence presented in the peer reviewed literature with regard to diagnostic accuracy and its subsequent influence on patient management.

The primary aim of the proposed study is to examine the accuracy of prehospital eFAST scans performed by this service. The secondary aims are to describe the influence of prehospital eFAST scans on physician judgement and patient care and to identify areas for continuing education and training.

Aims of study

<u>Primary aim.</u>
To investigate the accuracy of prehospital eFAST ultrasound interpretation when performed by GSA-HEMS physicians.

<u>Secondary aims.</u>
- To describe patterns of eFAST abnormalities.
- To describe the influence of prehospital eFAST scans on physician judgement and patient care.

Hypothesis Statement

<u>Primary hypotheses.</u>
Prehospital eFAST scans are equally as accurate in identifying intraperitoneal free fluid (IPFF) as compared to a hospital-based gold-standard of CT scan or intraoperative findings.

Prehospital eFAST scans are equally as accurate in identifying pneumothorax (PTx) as compared to a hospital-based gold-standard of CT scan or intraoperative findings.

<u>Secondary hypotheses.</u>
- Prehospital eFAST interpretation is equally as accurate as in-hospital eFAST scan by a trauma team member in identifying IPFF and PTx.
- Prehospital lung ultrasound accurately identifies pneumothoraces requiring pleural decompression prior to hospital arrival
- Prehospital eFAST is equally as accurate in identifying haemothorax and pericardial fluid when compared to hospital eFAST, CT imaging or operative findings.
- There is no significant difference between the accuracy of prehospital eFAST interpretations when performed by GSA-HEMS consultants or registrars.

Study design

A retrospective chart review of prospectively collected data on a convenience sample of adult trauma patients retrieved by GSA-HEMS.

Study setting/location(s)
GSA-HEMS is a prehospital and retrieval medicine service serving critically ill and injured patients in New South Wales, Australia. GSA-HEMS physicians work with paramedics and flight nurses on helicopters, fixed wing aircraft and road ambulances, and currently undertake around 1000 prehospital missions per year from bases in Sydney, Wollongong and Orange. Physicians rotate around all of these bases. This study will use data from prehospital incidents from all three bases where patients were transported to either Liverpool or Westmead Hospitals.

Study duration
It is expected that this project will take 12 months to complete.

Study population
Adult trauma patients retrieved by GSA-HEMS who underwent an eFAST ultrasound examination.

Recruitment process
Identification of participants
Participants will be identified from an AirMaestro database search. AirMaestro is the electronic, secure database kept by GSA-HEMS where by all treated patients have a clinical record created.

Inclusion criteria.
- Adults (aged ≥16 years) with a reported traumatic mechanism of injury.
- Prehospital contact with GSA-HEMS physician-paramedic team.
- Prehospital eFAST ultrasound recorded in AirMaestro database.
- Transported to Liverpool or Westmead Major Trauma Centres in NSW.
- CT scan or surgery within four hours of hospital arrival.
- ISS ≥12.

Exclusion criteria.
- Patients who died prior to arriving at the destination hospital
- Patients who did not undergo definitive imaging (eFAST, CT) or undergo surgery

Study outcomes

Primary outcome

The accuracy of the prehospital eFAST scan interpretation for intraperitoneal free fluid and pneumothorax against either CT imaging of chest/abdomen or intraoperative findings within four hours of hospital arrival as measured by McNemar's test.

		Hospital-based comparison (gold standard) to be compared against		
Component of eFAST	Prehospital eFAST	eFAST	CT	Operative findings
Intraperitoneal free fluid	Yes.	Yes.	Yes.	Yes.
Pneumothorax	No.	No.	Yes.	No.
Haemothorax	No.	No.	No.	No.
Pericardial effusion	No.	No.	No.	No.

Table 1. Example of Prehospital eFAST component results & comparison to 'gold standard' demonstrating a true positive scan for intraperitoneal free fluid and a false negative pneumothorax scan (prehospital and on arrival), consistent with an occult pneumothorax. The haemothorax and pericardial effusion components were true negatives.

Secondary outcome(s)

1. Accuracy of prehospital eFAST interpretation versus in-hospital arrival eFAST by a trauma team member, as measured by McNemar's test where a true positive is presence of the same finding on prehospital and arrival eFAST scan.
2. Accuracy of other prehospital eFAST findings (haemothorax and pericardial fluid) compared to hospital eFAST, CT imaging or operative findings, as measured by McNemar's test.
3. Accuracy of prehospital eFAST interpretations between GSA-HEMS consultants and registrars, as measured by Chi-Sq test.
4. Percent of prehospital interventions which are performed based on prior ultrasound findings (eg. thoracostomy for detected pneumothorax).

Study procedures

GSA-HEMS records all patient encounters in a clinical database called 'Airmaestro'. Details recorded include patient demographics, history, medications, interventions performed and clinical observations. In addition, the GSA-HEMS medical case-sheet is uploaded to this database. This case-sheet has a unique de-identified number. This database has a dedicated ultrasound registry allowing clinicians to record their findings, image interpretation, effect on scene time and influence on patient outcome. As a result, this study will assess the prehospital clinicians interpretation of the scans performed, not the scan itself.

This study will be a retrospective review of cases from January 1st 2013 to December 31st 2017. The study cohort will be identified as having undergone a POCUS scan from clinical records taken from the GSA-HEMS AirMaestro prehospital database (see Figure 1).

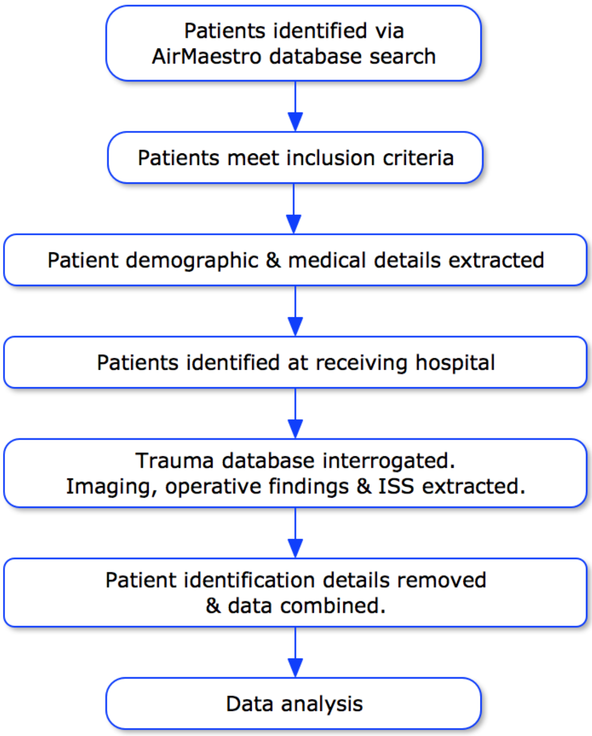

Figure 1. Intended data study process.

Data to be extracted are outlined in Tables 1 and 2. Data pertaining to prehospital eFAST interpretation will be gathered from both the AirMaestro database (Ultrasound registry and 'Case details' free-text field) and manual review of the hand-written casesheets. The casesheets and 'Case Details' field will be assessed by two consultant Prehospital and Retrieval Medicine Physicians with advanced qualifications in ultrasound (Certificate of Clinician Performed Ultrasound, Australasian Society for Ultrasound in Medicine). These assessments will involve a specific search for the following discrete terms; "eFAST", "FAST", "ultrasound", "US", "USS", "POCUS", "free fluid", "fluid", "FF", "pneumothorax", "PTX", "hiss", "lung down" and "air" including common misspellings. These assessments will be performed by both consultants simultaneously for best possible agreement of findings. If simultaneous casesheet review becomes too challenging, independent review will take place. At this stage, the level of accuracy and reliability with which the reviewers extract data will take place via an independent test of their data quality. This result will be reported as a kappa statistic.

Hospital-based data will be extracted as outlined in Table 3 including CT scan results and intraoperative findings within four hours of hospital arrival. Injury time is not routinely recorded by GSA-HEMS therefore "GSA-HEMS notification time" will be used as a surrogate representation for the time of injury. This data, as well as hospital-based eFAST results, ISS scores and length of stay will be sourced from the NSW Collector Trauma Registry at each facility.

The 'gold-standard' results with which the prehospital eFAST interpretation will be compared to is pathology found on either thoracoabdominal CT scanning or during emergency surgery, as long as either/or take place within four hours from hospital arrival. Prehospital eFAST interpretation will also be assessed for accuracy against an in-hospital eFAST examination performed on arrival to hospital, by a member of the local trauma team.

Study involvement by participants

<u>Recruitment and consent of participants</u>

A waiver of participant consent will be sought as this study is retrospective and non-invasive in that it uses demographic, physiological and patient treatment records which is measured routinely as part of clinical care, and analyses the predictive power of these data in relation to later outcomes. This data will not be changed or used in any other way than for the purpose of this study. No other data on the recruited patients will be collected in addition to that used in routine patient assessment and management. Identifiers will be used to collect data on demographics, prehospital and in-hospital investigations and outcomes; once these data are linked to the clinical data collected as part of routine assessment and management, the patients will be de-identified and data stored with patients allocated a unique study number. The ability to re-identify patients from these data will then not exist.

There is no risk to the rights, privacy or professional reputation of carers, health professionals and/or institutions as the study solely concerns the impact of a single clinical intervention which is used ubiquitously, and has no intent to identify individual clinicians or carers, nor to use the data as commentary on the institutions concerned.

<u>Safety considerations/participant safety</u>

There is no specific participation required by participants. With patient data being completely de-identified during the analysis there are no specific safety considerations to participants.

Data analysis plan

Variables to be collected.

Table 1.				
Patient variables to be collected.				
Data variable number	**Data variable name**	**Type of data**	**Data variable categories or values**	**Definition of data variable**
1.	Study number	Ordinal	Text	Allocated study number/unique identifier
2.	Age	Continuous	YY/Unknown	Years rounded down
3.	Gender	Nominal	1= Male 2= Female 3= Unknown	Patient gender
4.	Weight	Continuous	Number/Unknown	Weight of patient in kg, as reported on case sheet.
5.	Mechanism	Nominal	1= Blunt trauma 2= Penetrating trauma 3= Unknown	Dominating mechanism of injury

Table 2.				
Mission variables to be collected.				
Data variable number	**Data variable name**	**Type of data**	**Data variable categories or values**	**Definition of data variable**
6.	Case sheet number	Nominal	Number	Patient's retrieval case sheet number
7.	GSA-HEMS notification time	Continuous	(hh:mm)	Actual time that retrieval team first notified, surrogate for 'time of injury'
8.	GSA-HEMS dispatched time	Continuous	(hh:mm)	Actual time that team dispatched
9.	Time at patient	Continuous	(hh:mm)	Actual time team arrives at patient
10.	Time departed scene	Continuous	(hh:mm)	Actual time retrieval team departs scene with patient
11.	Time at destination	Continuous	(hh:mm)	Actual time retrieval team arrives at receiving hospital

12.	Mode of transport	Nominal	1= Helicopter 2= Road ambulance 3= Fixed-wing	Primary mode of transport from scene to hospital
13.	eFAST images stored on database	Nominal	1= Yes 2= No	As recorded in AirMaestro Ultrasound registry
14.	Pneumothorax	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	As recorded in AirMaestro Ultrasound registry
15.	Intraperitoneal free fluid	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	As recorded in AirMaestro Ultrasound registry (FF in one region = Yes, No in all 3 regions = No, Indeterminate + No = Indeterminate)
16.	Region of free intraperitoneal fluid	Nominal	1= RUQ 2= LUQ 3= Pelvis	If IPFF reported, all areas reported as positive in AirMaestro.
17.	Haemothorax	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	As recorded in AirMaestro Ultrasound registry
18.	Pericardial fluid	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	As recorded in AirMaestro Ultrasound registry
19.	Prehospital clinical interventions	Nominal	1= Thoracostomy 2= Transfusion	Interventions performed by GSA-HEMS team
20.	Prehospital RSI	Nominal	1= Yes 2= No	Performed by GSA-HEMS team
21.	Prehospital intervention supported by ultrasound	Nominal	1= Yes 2= No	Intervention follows injury identification on eFAST (case sheet review) or “Procedural guidance” marked in AirMaestro.

Table 3.

In-hospital variables to be collected.

Data variable number	**Data variable name**	**Type of data**	**Data variable categories or values**	**Definition of data variable**
22.	Hospital eFAST (PTx) result	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	eFAST performed by clinician on arrival to hospital.

23.	Hospital eFAST (IPFF) result	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	eFAST performed by clinician on arrival to hospital. (FF in one region = Yes, No in all 3 regions = No, Indeterminate + No = Indeterminate)
24.	Hospital eFAST (haemothorax) result	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	eFAST performed by clinician on arrival to hospital.
25.	Hospital eFAST (pericardial effusion) result	Nominal	1= Yes 2= No 3= Indeterminate 4= Not recorded	eFAST performed by clinician on arrival to hospital.
26.	eFAST performed by 'credentialed' provider	Nominal	1= Yes 2= No 3= Not recorded	Either formal or in-house accreditation.
27.	Time of CT scan	Continuous	(hh:mm)	Actual time CT recorded in eMR.
28.	Hospital CT findings	Nominal	1= Negative 2= Positive (PTx) 3= Positive (FF) 4= Positive (HTx) 5= Positive (Pericardial eff)	Thoracoabdominal CT performed within 4 hours of hospital arrival
29a. 29b.	Organ specific CT findings Grade of injury	Nominal	1= Liver injury 2= Splenic injury 3= Mesenteric injury Number/Not recorded	Findings on thoracoabdominal CT performed within 4 hours of hospital arrival
30.	Time of OT arrival	Continuous	(hh:mm)	Actual time patient arrived in operating theatre.
31.	Operative findings	Nominal	1= Haemoperitoneum 2= No haemoperitoneum	Blood within peritoneal cavity at time of laparotomy/laparoscopy
32.	AIS Head	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code head injury
33.	AIS Face	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code face injury

34.	AIS Neck	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code neck injury
35.	AIS Thorax	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code thoracic injury
36.	AIS Abdomen	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code abdominal injury
37.	AIS Upper extremity	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code upper extremity injury
38.	AIS Lower extremity	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code lower extremity injury
39.	AIS External and other	Nominal	1= Minor 2= Moderate 3= Serious 4= Severe 5= Critical 6= Maximal 7= Nil	Highest code external or other injury
40.	ISS	Ordinal	1-75	Injury severity score - The sum of the squares of the highest AIS scores in three different body regions
41.	Principal diagnosis	Free text	Diagnosis/not recorded	ICD10AM Principal diagnosis code
42.	Hospital LOS	Ordinal	Number	Days (rounded up to nearest whole day)
43.	Discharge destination	Nominal	1= Deceased 2= Home 3= Rehabilitation 4= Other hospital	Destination at time of hospital discharge

Statistical tests to be conducted.
Demographics, ultrasound details, physiological observations, clinical interventions and in-hospital results will be reported as descriptive statistics. All analyses will be supervised by a senior biostatistician. Normally distributed outcomes will be reported as means (SD) and non-normal data will be reported as medians (IQR). Categorical data will be reported as count and proportions. As we will be conducting three hypothesis tests on the accuracy of E-FAST two-sided p-value of 0.05 will be considered statistically significant.

The accuracy of prehospital eFAST will be compared to its in-hospital gold standard using McNemar's test. Three comparisons will be performed, one for intraperitoneal free fluid, the other for pneumothorax, and finally for combined outcome of pericardial fluid or haemothorax. As we will be conducting three hypothesis tests on the accuracy of E-FAST, a bonferroni corrected two-sided p-value of 0.17 ((0.05 /3) will be considered statistically significant. If the sample size is not met, then a composite score will be created, combining true positives of intraperitoneal fluid, pneumothorax, haemothorax and pericardial free fluid to a single "E-FAST positive score" for prehospital FAST to the inhospital gold standard.

To compare the accuracy of prehospital FAST between consultants and registrars, the composite score of E-FAST positive outlined above will be used in a 2x2 table and analysed with Chi-Sq test.

Sample size and statistical power
From previous studies, the rate of prehospital positive FAST scans is 10-20%. To detect a difference on in-hospital imaging of 5% (15-25% positive FAST scan) we need 227 patients (at a power 0.8, sig level 0.05) if using McNemar's test.

Missing data plan
All variables will be examined for missing data. If the total is less than 10% then complete case analysis will be used. If the missing data is greater than 10%, consideration will be given to attempt multiple imputation using patient demographic details as the predictors in the regression equation. If the sample size is small (less than 100) and the missing data are > 10% then available case analysis will be used. All missing data methods will be presented in the final report.

Plan for dissemination of results
The results of the study will be presented at GSA-HEMs education and clinical governance days. A peer-reviewed publication is planned and if invited, a presentation or poster at local/international conferences.

Data security

Data will be stored in the Principal Investigator's office, in the Emergency Department, Liverpool Hospital. Once case and patient data are identified and linked, a unique linkage key will be generated for each set of linked data, and identifiers removed. Information will be stored in electronic form (REDCap database, Vanderbilt University). REDCap (Research Electronic Data Capture) is a secure, browser-based, metadata-driven, electronic data capture software designed by Vanderbilt University. The licensing for REDCap for this study is via the South Western Sydney Clinical School of the University of New South Wales, with data stored behind a firewall.

This database will be stored on the Principal Investigator's computer and will not be shared or distributed in any way, other than to the project investigators. As stated above, a unique linkage key will be generated for each set of linked data, each comprising records from the Emergency Department Information System, physiological and pathology data from ED and hospital records, and outcome data from inpatient clinical notes and Hospital Information System. Once linkage is achieved between the data, all identifying details will be removed.

From this point all analyses will be carried out on the de-identified dataset, and access to the prior identified data will only be available to the Principal Investigator for the purposes of security; i.e. if loss of de-identified data occurred due to computer malfunction, the database should be able to be rebuilt based on the original information. Once the de-identified database is complete, all identifiable data stored within the project database will be erased. This will, of course, not affect the original patient records and health information, which are stored in the standard fashion.

This information will be stored securely for a period of more than 10 years, in keeping with the NHMRC Australian Code for the Responsible Conduct of Research Practice (Section 2). Stored media files will be erased before being discarded, and all data will be removed from the drives to the new system. Simply deleting files does not remove data from a disc, therefore the most secure method to prevent the accidental disclosure of information will be used, by reformatting the hard disc.

Budget and resources

No specific finances will be required in order to complete the proposed project. There is no specific budget allocated to this project. Data extraction will be performed by the researcher during non-clinical/clinical-support time.

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