

The Leeds Focussed Abdominal Sonography in Trauma in the Emergency Room (FASTER) study

Potential Benefits of the study:

The assessment of abdominal injuries in the trauma patient presents a diagnostic problem. Investigations available at present are either time consuming, necessitate a stable patient who can be transferred to the radiology department or carry a risk of harm.

Focussed abdominal sonography in trauma (FAST) is a rapid, limited ultrasound scan, which is performed during the resuscitation to detect the presence of free fluid. FAST has been shown in many studies to be as accurate as present investigations, but has not yet gained widespread acceptance in this country.

This study will assess the accuracy of ultrasound performed by emergency physicians in the assessment of the patient with blunt abdominal trauma compared to the currently available 'gold standard' investigations of DPL, CT, laparotomy and clinical observation.

A randomised, controlled trial is also planned to assess whether introducing the FAST protocol into trauma resuscitation results in faster management decisions, less use of existing investigations and better patient outcomes.

Summary:

- 1.1 At present the assessment of BAT in the emergency department present a diagnostic problem. Clinical examination of the abdomen can be unreliable especially in the severely injured or unconscious patient. Investigations most commonly employed include diagnostic peritoneal lavage (DPL) and CT scanning which both have disadvantages.
- 1.2 There is evidence from the United States and Europe that a focussed, abdominal ultrasound scan can reliably detect the presence of free intra-peritoneal fluid. In the context of trauma, this is assumed to be due to bleeding.
- 1.3 The advantages of ultrasound are that it is harmless, rapid, repeatable and can be performed during resuscitation. It does not prejudice other investigations.
- 1.4 Studies have shown that emergency physicians can perform accurate ultrasound assessment in trauma with limited training.

- 1.5 This study will assess the implementation of the FAST protocol by emergency physicians.

Background:

- 2.1 The identification of intra-abdominal injuries in the blunt trauma patient is essential but can at times be difficult. Prompt treatment of injuries contributes to better trauma outcomes, but there are still incidences of negative laparotomies performed for presumed intra-abdominal haemorrhage in the unstable patient.
- 2.2 DPL carries a small but significant risk of intra-abdominal injury and is time consuming. There is also some evidence that with the trend towards conservative management of intra-abdominal solid organ injury it may be too sensitive. As the technique of DPL involves introducing fluid into the abdomen it may make subsequent investigation more difficult to interpret.
- 2.3 CT scanning allows a detailed view of intra-abdominal pathology. However most scanners are located a distance from the emergency department and the patient must be stable before transfer. Use of a double contrast technique also necessitates a delay before scanning can commence of typically 40 minutes to 1 hour.
- 2.4 The FAST protocol has been developed in the United States. It utilises a limited four-view scan of the abdomen. These include the subcostal, Morison's pouch, LUQ and suprapubic views. Other protocols image the paracolic gutters but studies have not shown significant benefit from extending the scan to include these. The purpose of the scan is solely to document the presence of free fluid. A negative scan does not rule out intra-abdominal injury, but the presence of a sufficient amount of blood to be detectable on US would denote a severe injury that needs urgent attention.
- 2.5 This study will introduce FAST into the resuscitation process. The results will not be available to the members of the trauma team and will not contribute to patient management decisions.

Hypotheses:

The performance of a limited, rapid, ultrasound scan in the trauma patient is as accurate as present investigations.

Emergency physicians can perform limited abdominal ultrasound in the trauma patient after a short training period.

Personnel:

Emergency physicians who have undergone a standardised training programme will act as Emergency Physician Sonographers (EPS).
An Expert Sonographer (ExS) will oversee the training and review study scans.

Study co-ordinator

Steering group

Costs:

Ultrasound machine purchased by department.

Expert sonographer - 2-3 hours per week to review scans, more time during initial training period.

Study co-ordinator

Scanning protocol:

A focussed, limited examination designed to rule in the presence of free fluid. (Brief discussion of rule in / rule out philosophy.)

The scan should take no more than 5 minutes and will be performed at the end of the primary survey.

Resuscitation will not be disturbed.

The best view in each of the four probe sites will be recorded for later review and the whole examination will be video taped. The EPS will document the result of the scan as positive (definite free fluid), negative (no fluid seen) or indeterminate at the time of examination. The results will not be made known to the members of the trauma team and the patient will be investigated according to existing protocols (CT scan in the stable patient, DPL in the unstable, emergency laparotomy etc.).

Sonographers:

Senior (consultant, SpR & ?staff grade) emergency physicians will act as sonographers having undergone a formal training and accreditation programme within the department.

Training of Sonographers:

All EPS will attend 5 hours of didactic teaching on US physics, abdominal anatomy and FAST technique. They will then have opportunity to practise the technique on 'normal' volunteers and simulated patients. The EPS will be expected to 'declare competence' prior to involvement in the study.

They will be required to record 10 scans for review with an expert sonographer who will oversee at least 3 scans.

It is envisaged that as numbers of trauma patients are unpredictable, regular refresher sessions will be needed to maintain skills – bimonthly 2 hour session using normal volunteers and simulated patients (CAPD patient volunteers).

Expert Sonographer

An expert sonographer will review a selection of the training scans of each emergency physician sonographer (EPS) and will oversee a proportion of these scans to monitor technique. All scans performed during the study will be reviewed later by the ExS and a decision made as to the adequacy of the images and appropriateness of the decision.

Trauma Team organisation

The management of trauma will continue along present guidelines. All resuscitations will be video taped for educational purposes and to allow accurate time documentation.

The team leader will be a senior emergency physician in all cases. Composition of the rest of the team will be decided upon an individual patient basis.

The time goals set for the period of the study are 30 minutes to a provisional management plan, 60 minutes from admission to leave resus. Issues of organisation of the trauma team will be addressed in preparation for the randomised, controlled trial.

Patient selection

All patients over 16 admitted to the resuscitation room as a result of blunt trauma will be eligible for the study. The study will enrol patients when there are two senior doctors in the department – one to lead the trauma team and the second to act as sonographer. This will usually be between 9am and Midnight.

Ethics committee approval

Ethics committee approval will be sought from the relevant bodies.

Consent

Conscious patients will be informed of the study and verbal consent will be sought. An information leaflet will be later available. Unconscious patients will be entered into the study without consent.

Outcomes

All scans will be reviewed by ExS

Each scan will be assessed for

- a) adequate / inadequate images
- b) positive / negative / indeterminate for free fluid

Improvement in (a) scan technique and (b) interpretation over the course of study will be documented. The learning curve of EPS will be assessed (previous studies have suggested as little as ten scans may be required).

Each EPS scan will be compared with outcome to document sensitivity, specificity etc. of US as a diagnostic test. The improvement in accuracy with increasing number of scans will be used to assess the learning curve.

Patient Outcomes:

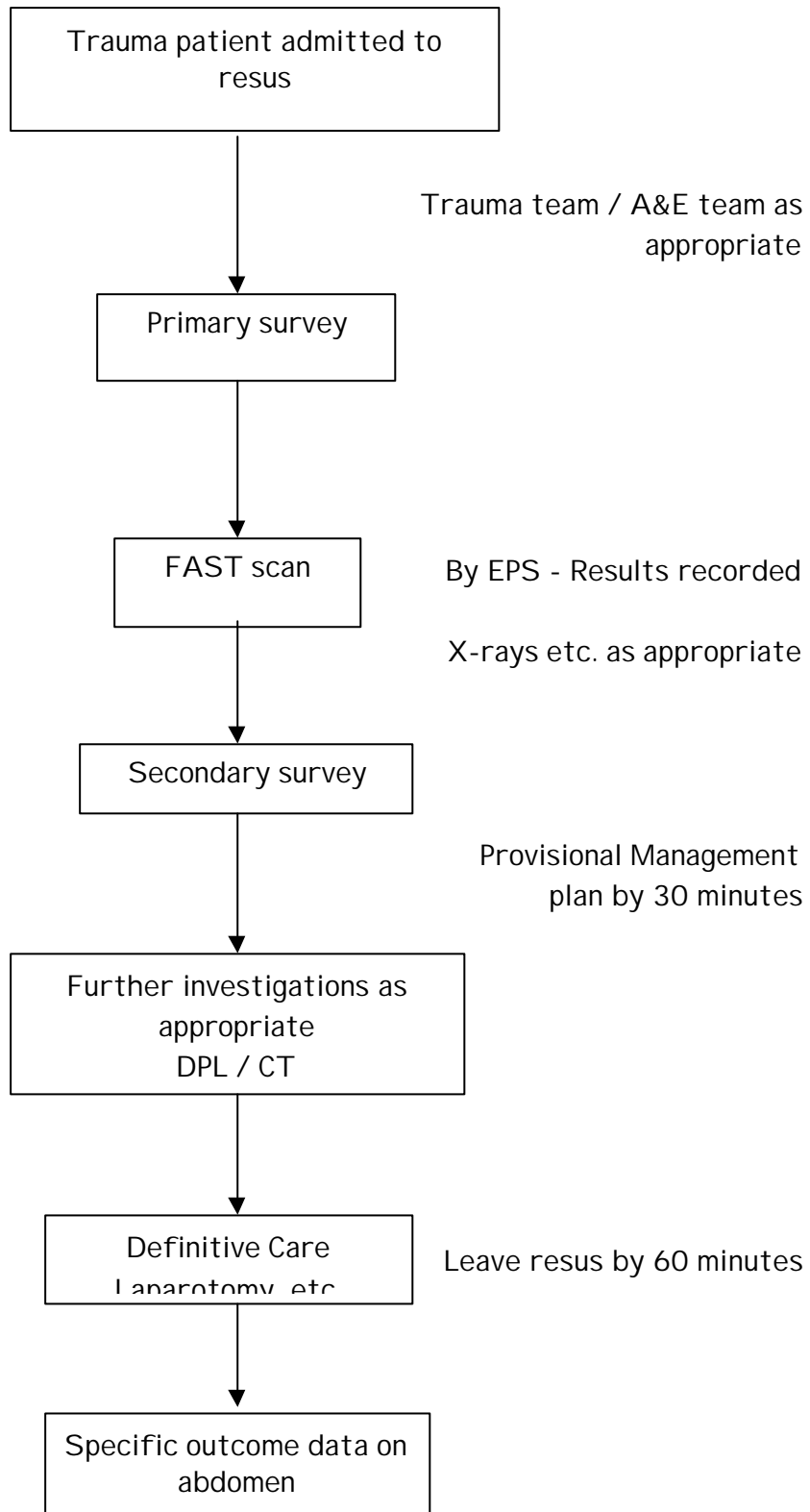
The outcome used will be definitive identification of intra-abdominal injury by CT scan / other investigations or laparotomy. Some patients have no further abdominal investigations after leaving resus. In these patients clinical in-hospital course will be examined to identify complications. Where patients are discharged within 14 days without formal abdominal imaging the GP will be contacted at one month post-discharge to identify adverse events related to intra-abdominal injury.

Data Collection:

A study proforma (EPS) will be filled in by the EPS on performing the scan. This will document patient details and scan findings.

A proforma (PD) will be enclosed with each trauma chart and patient demographics filled in to allow further data capture. If the patient is not entered into the study reason for this will be documented of this (PD) form.

Phase II : Study protocol



Study proforma (EPS):

Patient name:

Date:

A&E No:

Consent:

Date of Birth:

EPS Name:

Results:

Time started:

Time finished:

Scan quality:

(views obtained)

good

poor

Results:

Free fluid seen

No free fluid seen

Indeterminate

Adverse factors

Obesity

Abdominal scars

Other:

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GP attendances - related to intra-abdominal injury?
Referral to hospital
Death - PM results

Patient information sheet

You have been admitted to hospital following an accident. We need to make sure you have no injuries inside your abdomen. The standard methods for doing this are clinical examination, observation over a period of time or investigations. These include CT (computerised tomography) scanning (a body scan which involves X-rays) or diagnostic peritoneal lavage (a tube is inserted into the abdomen and fluid is put in and then emptied out to detect the presence of blood).

Thank you for agreeing to take part in this study. We appreciate your help.

We are investigating whether a brief ultrasound scan (the same type of scan that women have in pregnancy) can help us to pick up injuries earlier. The scan is limited and should take only about 5 minutes. It is performed by doctors from the accident and emergency department. It looks at a few specific areas within the abdomen to see if there is any blood, which would mean there has been an injury.

The scan is not the same as one performed in the X-ray department. That takes longer and looks at all the internal organs in the abdomen. Once we have performed this scan we cannot say that there is nothing abnormal inside the abdomen, we can only say that we cannot see any bleeding. If an incidental abnormality is seen we will inform you and write to your GP. This would probably need further investigation, which your GP can arrange.