

The focused assessment with sonography in trauma (FAST) in hypotensive injured patients frequently fails to identify the need for laparotomy: a multi-institutional pragmatic study

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ABSTRACT

Background The ability of focused assessment with sonography for trauma (FAST) to detect clinically significant hemorrhage in hypotensive injured patients remains unclear. We sought to describe the sensitivity and specificity of FAST using findings at laparotomy as the confirmatory test.

Methods Patients from the Prospective Observational Multicenter Major Trauma Transfusion (PROMMTT) study that had a systolic blood pressure < 90mm Hg and underwent FAST were analysed. Results were compared with findings at laparotomy. A therapeutic laparotomy (T-LAP) was defined as an abdominal operation within 6 hours in which a definitive procedure was performed. The sensitivity and specificity of FAST were calculated.

Results The cohort included 317 patients that underwent FAST (108 positive, 209 negative). T-LAP was performed in 69% (n=75) of FAST(+) patients and 22% (n=48) of FAST(-) patients. FAST had a sensitivity of 62% and specificity of 83%.

Conclusions In our multicenter cohort, 22% of FAST(-) patients underwent T-LAP within 6 hours of admission. In hypotensive patients with a negative FAST, clinicians should still maintain a high index of suspicion for significant abdominal hemorrhage.

Level of evidence Level IV.

INTRODUCTION

The focused assessment with sonography for trauma (FAST) has become commonplace as a rapid diagnostic modality for the initial evaluation of patients with torso injuries in the USA.¹ An extensive body of literature on the use of FAST in trauma exists, and it has been recommended in the advanced trauma life support (ATLS) course.¹⁻³

In many trauma centers, a FAST (or a variant of FAST that includes additional views) is used as a screening examination for patients presenting with suspected torso injury.⁴⁻⁷ Although hemodynamically unstable patients with a positive FAST typically undergo immediate laparotomy without confirmatory imaging studies, those with a FAST that does not reveal free fluid often undergo additional diagnostic studies. This practice is in part based on previous data suggesting that patients with an indeterminate, often referred to as 'negative', FAST infrequently have injuries requiring

emergent surgical intervention.^{4,7} Clinically, it has been observed that the ability to accurately perform and interpret the FAST has been less precise.

As randomised trials evaluating the ability of FAST to identify the need for laparotomy have not been performed, the available evidence comes from observational and retrospective studies. The Prospective Observational Multicenter Major Trauma Transfusion (PROMMTT) study accrued injured patients in 2009-2010 that received one or more blood transfusions.^{8,9} Although the intended purpose of PROMMTT was to evaluate optimal blood product transfusion ratios, the extensive data collected has allowed for the study of other aspects of the acute management of injured patients, including FAST. In this study, we used the PROMMTT data set to evaluate the ability of FAST to identify hypotensive injured patients that received an emergent or urgent therapeutic laparotomy.

METHODS

Data were obtained from a database created by the Data Coordinating Center at the University of Texas Health Science Center at Houston for the PROMMTT study.¹ The study enrolled 1245 patients with injuries that received one or more units of red blood cells (RBC) within 6 hours of hospital admission and required the highest level activation at one of 10 level 1 trauma centers. Exclusion criteria included age <16, transfer from another hospital, pregnancy, >20% burn injury, inhalation injury, incarceration, cardiopulmonary resuscitation lasting more than 5 min prehospital or in the first 30 min after admission and death within 30 min of hospital admission. Data were collected in real time on a wide variety of patient characteristics, fluid and blood product infusions, diagnostic studies and surgical interventions.

For all patients, FAST was recorded as having been performed or not performed. When FAST was performed, it was recorded as 'positive' or 'negative'. Hypotension was defined as a systolic blood pressure <90 mm Hg either during transport or on arrival. Analyses were performed on all hypotensive patients that underwent FAST examination in the emergency department (ED). The specific views in which fluid was identified were not recorded, and no FAST scoring data were recorded. In most cases, the time the examination was performed was

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Table 1 Baseline demographic, physiologic and biochemical data in patients with and without a FAST examination in the ED

| Variable* | FAST performed (n=327) | FAST not performed (n=118) | P value† |
|--|------------------------|----------------------------|----------|
| Age (years) | 39 (26–53) | 36 (25–52) | 0.43 |
| ISS | 27 (17–36) | 17.5 (9–29) | <0.001 |
| AIS head | 0 (0–3) | 0 (0–3) | 0.15 |
| AIS chest | 3 (0–3) | 1 (0–3) | <0.001 |
| AIS abdomen | 2 (0–3) | 1 (0–3) | 0.008 |
| AIS extremity | 2 (0–3) | 2 (0–3) | 0.10 |
| Sex (male) | 71.6% | 74.6% | 0.53 |
| Mechanism (blunt) | 75.7% | 43.2% | <0.001 |
| SBP in field (mm Hg) | 84 (71–100.5) | 80 (70–91) | 0.035 |
| SBP in ED (mm Hg) | 80 (70–88.5) | 80 (70–86) | 0.065 |
| Heart rate (beats per minute) | 105 (84–124) | 105 (83–120) | 0.063 |
| INR | 1.3 (1.2–1.5) | 1.2 (1.1–1.5) | 0.079 |
| Base deficit (mEq/L) | 8 (4–12) | 8 (4–12) | 0.041 |
| pH | 7.25 (7.14–7.34) | 7.26 (7.14–7.33) | 0.055 |
| Lactate (mEq/L) | 4.4 (3–6.3) | 5.4 (3–9.4) | 0.09 |
| Hemoglobin (g/dL) | 11.4 (10–12.9) | 10.8 (9–12.3) | 0.007 |
| Six-hour RBC requirement (units) | 4 (2–9) | 4.5 (2.5–10) | 0.86 |
| Twenty-four-hour RBC requirement (units) | 6 (3–12) | 5 (3–10) | 0.34 |

*Median values (IQR).

†Wilcoxon rank-sum test or χ^2 test.

AIS, abbreviated injury scale; ED, emergency department; FAST, focused assessment with sonography for trauma; INR, international normalized ratio; ISS, Injury Severity Score; RBC, red blood cells; SBP, systolic blood pressure.

recorded. Each center identified the type of practitioner that typically performed the FAST examination, but this information was not available on an individual case basis. Data on operative interventions in the first 6 hours were collected by body region (head, neck, chest, abdomen, pelvis, upper extremity, and lower extremity). Within each body region, the performance of specific operations as well as the time from admission to the operating room was recorded. Operative reports were not available.

FAST results were compared with the requirement for therapeutic laparotomy (T-LAP), which was defined as an abdominal operation within 6 hours of injury with a definitive procedure performed. Definitions for calculation of sensitivity and specificity were as follows: true positive=FAST(+), received a T-LAP; false positive=FAST(+), did not receive T-LAP; false negative=FAST(-), received a T-LAP; true negative=FAST(-), did not receive a T-LAP. Statistical analyses were performed with Stata V.12.1.

RESULTS

The PROMMTT database included 1245 patients, of which 445 were hypotensive either in the prehospital setting or on arrival to the ED. Among these, 327 (73.5%) patients underwent a FAST examination. Baseline demographic, physiologic and biochemical data for each group are given in [table 1](#). Patients that had FAST performed had a higher Injury Severity Score (ISS) and were more likely to have a blunt mechanism of injury. Among patients that did not have FAST performed, 28 (24%) underwent laparotomy within 1 hour of presentation. Of the 327 patients that underwent FAST examination, 10 patients did not have

Table 2 Requirement for T-LAP in injured patients with hypotension undergoing FAST

| | T-LAP (%) | No T-LAP (%) |
|------------------------------|-----------|--------------|
| Blunt mechanism (n=240) | | |
| FAST(+) (n=79) | 56 (71) | 23 (29) |
| FAST(-) (n=161) | 32 (20) | 129 (80) |
| Penetrating mechanism (n=77) | | |
| FAST(+) (n=29) | 19 (66) | 10 (34) |
| FAST(-) (n=48) | 15 (31) | 33 (69) |
| All patients (n=317) | | |
| FAST(+) (n=108) | 75 (69) | 33 (31) |
| FAST(-) (n=209) | 47 (22) | 162 (78) |

FAST, focused assessment with sonography for trauma; T-LAP, therapeutic laparotomy.

results recorded. The remaining 317 patients comprise the study cohort.

FAST was positive in 108 patients (34%) and negative in 209 patients (66%). The examination was initiated in a median time of 6 min after ED presentation (IQR 3–11 min). Examinations were conducted by ED physicians in six centers, surgeons in three centers, and radiologists in one center. Resident physicians conducted the majority of examinations, but detailed percentages were not available.

T-LAP was performed in 75 (69%) of the 108 FAST(+) patients ([table 2](#)). In the subset of patients with blunt injury, 71% underwent T-LAP in a median time of 32 min (IQR 23–77 min). In the subset of patients with penetrating injury, 66% underwent T-LAP in a median time of 18 min (IQR 14–24 min). The operative procedures performed are listed in [table 3](#). In all FAST(+) patients that underwent T-LAP, 49 (65%) patients received a damage control procedure. Three patients had a cardiac repair performed, all of which were isolated, and two patients underwent a non-therapeutic laparotomy. The median 6 hour and 24 hours RBC transfusion requirement for patients undergoing T-LAP was seven units (IQR 4–21 units) and 10 units (IQR 5–26 units), respectively. Ten patients died (9%) within the first 24 hours, all from exsanguination.

FAST examination was negative in 209 patients, of which a T-LAP was performed in 47 (22%, [table 2](#)). In the subset of patients with blunt injury, 32 (20%) underwent T-LAP in a median time of 100 min (IQR 59–210 min). In the subset of patient with penetrating injury, 31% percent underwent T-LAP in a median time of 26 min (IQR 20–56 min). The operative procedures performed are listed in [table 3](#). In all FAST(-) patients that underwent T-LAP, 29 (62%) patients received a damage control procedure and 17 (35%) received intraperitoneal packing. Four patients required a cardiac repair, two of which were isolated. Five underwent non-therapeutic laparotomy. The median 6 hour and 24 hours RBC transfusion requirement in patients with a false negative FAST was 8.5 units (IQR 4–18 units) and 11 units (IQR 5–24 units), respectively. Seven patients (15%) died within the first 24 hours (six from exsanguination and one from head injury).

A diagnostic peritoneal lavage (DPL) was performed in 25 of the 317 hypotensive patients that underwent FAST examination, 23 of which were done in FAST(-) patients. Of those performed in FAST(-) patients, five were positive and 17 were negative. In the five patients with a positive DPL, all received a T-LAP.

Table 3 Abdominal and cardiac surgical procedures conducted in the first 6 hours on patients with hypotension

| Procedure | FAST(+) (n=75) | | FAST(-) (n=48) | |
|---------------------------------|----------------|--------------------|----------------|--------------------|
| | Blunt (n=56) | Penetrating (n=19) | Blunt (n=33) | Penetrating (n=15) |
| Splenectomy or splenorrhaphy | 28 | 3 | 18 | 2 |
| Temporary abdominal closure | 29 | 9 | 14 | 5 |
| Abdominal packing | 27 | 11 | 12 | 5 |
| Liver procedure | 19 | 11 | 4 | 4 |
| Hemostasis of liver laceration | 13 | 6 | 3 | 4 |
| Perihepatic packing | 8 | 7 | 2 | 3 |
| Ligation of hepatic artery/vein | 3 | 1 | 0 | 3 |
| Lobectomy or wedge resection | 2 | 0 | 0 | 1 |
| Gastrointestinal procedure | 17 | 12 | 9 | 6 |
| Small bowel resection | 12 | 4 | 4 | 0 |
| Small bowel repair | 6 | 6 | 2 | 2 |
| Colon resection | 5 | 6 | 2 | 0 |
| Colon repair | 6 | 0 | 2 | 2 |
| Creation of stoma | 0 | 0 | 1 | 1 |
| Gastric repair | 1 | 2 | 1 | 2 |
| Suture of artery or vein | 15 | 11 | 2 | 2 |
| Repair of diaphragm | 4 | 4 | 3 | 3 |
| Repair of cardiac laceration | 0 | 3 | 1 | 3 |
| Repair of bladder | 2 | 2 | 0 | 1 |
| Partial resection of pancreas | 2 | 2 | 1 | 0 |
| Cholecystectomy | 2 | 1 | 0 | 0 |
| Nephrectomy or repair of kidney | 1 | 3 | 1 | 1 |
| Vascular shunt placement | 0 | 0 | 0 | 1 |

Totals do not add up due to patients undergoing multiple procedures.
FAST, focused assessment with sonography for trauma.

Of the 17 patients with a negative DPL, there was one T-LAP performed.

Values for sensitivity, specificity, positive predictive value, negative predictive value (NPV) and accuracy for FAST using T-LAP as the reference standard are listed in table 4. Overall, FAST was 62% sensitive and 83% specific for predicting the need for T-LAP. Sensitivity and specificity of FAST were lower in patients with penetrating injury than those with blunt injury (table 4).

DISCUSSION

During the past 20 years, multiple studies have reported on the sensitivity and specificity of FAST for detecting intra-abdominal injury.^{1,2,10} The majority of these have been done in hemodynamically stable patients with blunt trauma and have reported a high specificity and lower sensitivity, indicating that a positive FAST

is highly predictive of the presence of an intra-abdominal injury, whereas a negative FAST does not exclude injury. However, many of these studies have included large numbers of minimally injured patients that are unlikely to require operation, potentially leading to a selection bias.

The published data on the sensitivity and specificity of FAST in the trauma literature are difficult to interpret.² One reason for this is the variability in the reference standard to which FAST is compared. Some studies have included only patients that had a CT, DPL or laparotomy as a confirmatory test,^{5, 11-14} although others also include patients followed by clinical observation.^{4, 6, 7, 15-22} Few use findings at laparotomy as the sole reference standard. Indications for performing a FAST also vary widely between centers, with some centers performing FAST on almost all injured patients and others performing it more selectively.¹ A number of studies include a large number of patients with a relatively low ISS,² whereas others include a higher proportion of more severely injured.^{3, 7} The institutional experience with FAST also varies widely among centers, and thus its clinical application remains heterogeneous.^{16, 17, 21, 23} One study used a high-end ultrasound device typically only available for formal ultrasound examinations, and multiple institutions have implemented a more extensive ultrasonographic examination than the standard four-component FAST.^{2, 4} Finally, the FAST examination in some centers is performed by radiologists^{4, 17} or experienced ultrasound technicians,^{6, 7, 19} whereas in others it is performed by emergency medicine physicians or surgeons.^{2, 13, 16, 23}

A number of authors have published studies in which patients with a negative FAST had a very low probability of requiring

Table 4 Binary classification parameters for the ability of FAST to predict the need for T-LAP in injured patients with hypotension

| | Blunt | Penetrating | All |
|-------------------------------|-------|-------------|-----|
| Sensitivity (%) | 64 | 56 | 62 |
| Specificity (%) | 85 | 77 | 83 |
| Positive predictive value (%) | 71 | 66 | 69 |
| Negative predictive value (%) | 80 | 69 | 77 |
| Accuracy (%) | 77 | 68 | 75 |

FAST, focused assessment with sonography for trauma; T-LAP, therapeutic laparotomy.



T-LAP. Sirlin and colleagues reported a series of 3679 FAST(-) patients with blunt trauma from a single institution in which only 14 patients (0.4%) received a T-LAP.^{24 25} Another large single institution study in patients with blunt trauma evaluated 2242 patients that were FAST(-) with only 10 receiving laparotomy.¹⁴ Another reported that only 4 of 856 FAST(-) patients underwent laparotomy.¹⁵ Other studies have described similar findings.^{18 22 26-28} The majority of these studies included large numbers of patients with normal hemodynamics who were at relatively lower risk of having significant intra-abdominal hemorrhage.

Fewer studies have examined the sensitivity and specificity of FAST in patients with hypotensive trauma.^{4 6 7 13} Farahmand *et al* performed a retrospective analysis of FAST in 129 hypotensive injured patients at a single center for a 9-year period and reported that ultrasonographic examination had a sensitivity of 85% for detecting any injury and 97% for detecting injuries requiring operation.⁴ At this center, ultrasound examinations were conducted by radiologists and included additional components not part of a standard FAST examination, including dedicated paracolic gutter views and parenchymal solid organ evaluations. In another study of injured patients with hypotension or acidosis, FAST was reported to have a NPV of 93% when T-LAP was used as a reference standard.¹⁷ In a study restricted to patients with an ISS \geq 25, a similar NPV (92%) for FAST for prediction of T-LAP was reported.¹⁴ In two studies in patients with hypotensive blunt trauma, FAST identified all patients that received T-LAP.^{13 23} The largest study of FAST in patients with hypotensive trauma was published by Holmes in 2004 and included 447 patients.⁷ The sensitivity, specificity and NPV for prediction of T-LAP in this study were 83%, 95% and 95%, respectively.

Although FAST was originally intended for use in patients with blunt trauma, our data show it to be frequently performed in patients with penetrating injuries as well. In our study, FAST had a lower sensitivity and specificity in patients with penetrating injury as compared with blunt injury (table 4). This has also been described in other studies.²⁹⁻³¹ Some authors have found the higher rate of false negative FAST examinations in penetrating trauma to be predominantly due to hollow viscus injuries.^{29 30} In our study, 9 of the 15 patients that had penetrating injuries and a false negative FAST underwent laparotomy with control of hemorrhage from solid organ injuries or temporary intra-abdominal packing. The remaining six patients (40%) had isolated gastrointestinal or diaphragm injuries.

The most important observation in this study is the high rate of false negative FAST examinations. The overall 62% sensitivity of FAST in this study of hypotensive patients is among the lowest reported in the literature. Given that these data were obtained from 10 level 1 trauma centers in the USA, it is likely to be a valid representation of the use of FAST in many trauma centers across the country. Ideally, a test that is used to triage severely injured patients with hypotensive trauma would have a low likelihood of missing significant intra-abdominal hemorrhage. Yet, in this study, 22% of patients with a FAST deemed 'negative' received a T-LAP. The injuries found at laparotomy in this study were not insignificant in that 65% of these patients were considered to have undergone a damage control procedure by the attending surgeon, and 35% received intra-abdominal packing for hemorrhage control. The RBC transfusion requirement at 6 hours (median 8.5 units) was also significant in patients with a false negative FAST, indicating substantial blood loss. Of the seven patients with a false negative FAST that died within 24 hours of injury, six had exsanguination listed as a cause of death.

It is interesting to note that in FAST(-) patients in whom DPL was performed, DPL correctly identified the receipt of a T-LAP in 21 of 22 cases. Prior to widespread use of the FAST examination, DPL was regarded as a highly sensitive screening modality for intraabdominal injury.⁹ More recently, it has largely been replaced by FAST, in part due to the invasive nature of the procedure. In this study, DPL correctly identified the need for T-LAP in 95% of FAST(-) hypotensive patients. Although CT scan remains the most sensitive and specific test for identifying intra-abdominal injury, it can frequently take up to 30 min to perform and is less suitable for use in hemodynamically unstable patients. Based on these data, the use of DPL should be selectively considered as an important confirmatory test to screen FAST(-) patients who are considered to be at high risk for intra-abdominal hemorrhage. Others have also recommended that DPL be considered in this situation.³²⁻³⁴

Our results also show that not all injured patients with hypotension and a positive FAST require immediate laparotomy. In our cohort, 31% of FAST(+) patients did not require T-LAP in the first 6 hours. Most of these were managed non-operatively, with only two patients undergoing a non-therapeutic laparotomy. This study was not designed to allow for detailed analysis of this subset of patients, and we were unable to find objective criteria to identify which FAST(+) patients can safely be managed non-operatively. However, the low rate of non-therapeutic laparotomy suggests that clinicians are generally able to identify these patients.

Our study has a number of limitations. The PROMMTT study was designed primarily to evaluate the use of different blood product ratios in injured patients. Information was collected on diagnostic studies (including FAST), but this was not the main intent of the study. This was an unplanned secondary analysis of prospectively collected data, and thus the database lacks important details that could have been incorporated into a study in which FAST was the main focus. For example, specific CT findings were not recorded so we were unable to characterize patients that had non-operative management of solid organ injuries. Narrative data from individual patient resuscitations and operative reports were not collected; therefore, the details regarding the volume of hemoperitoneum or other potentially important findings were not available for analysis. We were unable to characterize patients with false negative FAST examinations in which a delay in operation led to meaningful clinical sequelae. In patients with multiple sources of bleeding, we were unable to analyze the relative degree of hemorrhage that occurred in each body cavity so it is possible that multiple sources of hemorrhage were responsible for the high rate of transfusion and mortality due to hemorrhage.^{35 36} This study had no information on institutional practice patterns such as the indications for FAST at each facility, the ultrasound-related training that practitioners had received or the types of examinations that were done (ie, a standard four-component FAST vs a more extended examination). Additionally, we were unable to analyze if there were instances in which FAST was done primarily for training purposes in patients that otherwise had clinical indications for emergent laparotomy.

An important caveat to this study is that all patients enrolled in PROMMTT received at least one unit of RBC within 6 hours of presentation to the ED. Therefore, this data set included a subset of patients with hypotensive trauma that was skewed toward the inclusion of patients with more severe injuries and hemorrhage. The calculated sensitivity and specificity for FAST may have been different if patients that did not require transfusion were included.

It is not surprising that the accuracy of FAST in this study was not as high as has been reported by others. The practitioners in this study were from multiple specialties, differing levels of training and experience performing FAST. The sensitivity and specificity reported in this study reflect pragmatic FAST performance in hypotensive trauma patients at 10 level 1 trauma centers in the USA.

CONCLUSIONS

In this study of severely injured patients with hypotensive trauma, 22% of patients with a negative FAST obtained on arrival to the ED underwent T-LAP within 6 hours of admission. In hypotensive injured patients with a negative FAST and no other obvious source of bleeding, either a confirmatory test such as diagnostic peritoneal lavage or immediate laparotomy should be considered.

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