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ASSOCIATION BETWEEN A POSITIVE ED FAST EXAMINATION AND THERAPEUTIC LAPAROTOMY IN NORMOTENSIVE BLUNT TRAUMA PATIENTS

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□ **Abstract—Although a positive FAST (focused assessment with sonography for trauma) examination in hypotensive blunt trauma patients generally suggests the need for emergent laparotomy, this finding's significance in normotensive trauma patients is unclear. We tested the association between a positive FAST and the need for therapeutic laparotomy in normotensive blunt trauma patients. This was a retrospective cohort analysis of consecutive normotensive blunt trauma patients presenting to two trauma centers. The outcome was therapeutic laparotomy. The unadjusted association between a positive FAST and laparotomy was odds ratio (OR) 116 (95% confidence interval [CI] 49.5–273). This association persisted after adjusting for confounding variables (OR 44.6, 95% CI 1.77–1124). Thirty-seven percent of patients with a positive FAST required therapeutic laparotomy vs. 0.5% with a negative FAST. Among normotensive blunt trauma patients, there was a strong association between a positive FAST and the need for therapeutic laparotomy. Very few normotensive patients with a negative FAST required therapeutic laparotomy. © 2007 Elsevier Inc.**

□ **Keywords—ultrasound; focused laparotomy; blunt trauma; hypotension; mass casualty**

INTRODUCTION

The focused assessment with sonography for trauma (FAST) examination is increasingly being incorporated as an essential part of the initial emergency department (ED) evaluation of trauma patients. As a screening tool evaluating for evidence of intraperitoneal fluid, the FAST examination's underlying premise is that most clinically significant injuries are associated with the presence of free fluid accumulating in dependent intraperitoneal areas. Several studies have demonstrated the FAST examination to have similar diagnostic accuracy to diagnostic peritoneal lavage and computed tomography (CT) scan for demonstrating intraperitoneal fluid in blunt abdominal trauma patients (1–5). In addition, appropriately trained emergency physicians have been shown to be proficient in performing and interpreting FAST examinations in trauma patients (6,7). The American College of Emergency Physicians has classified the FAST ex-

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amination as one of the primary ultrasound applications for emergency physicians (8).

Despite the increasing availability, use, and accuracy of ED sonography for trauma patients, the implications of a positive FAST examination (i.e., demonstrating the presence of free intraperitoneal fluid) for patient management decisions remain unclear in the majority of trauma patients. Currently, at many trauma centers, clinical management after a positive FAST examination is dependent on the patient's hemodynamic status. Hemodynamically "unstable" patients, as evidenced by systolic blood pressure less than a pre-defined level (e.g., < 90 mm Hg or < 100 mm Hg), with a positive FAST examination will often undergo emergent laparotomy (2,9–16), whereas hemodynamically "stable" patients with a positive FAST examination will undergo CT scanning of the abdomen and pelvis to further define the precise intraabdominal injuries and to aid in further decision-making (2,10,12–14,17).

Although this strategy may be reasonable in large trauma centers, patients presenting to facilities without immediate CT capability [e.g., rural hospitals, military field setting, mass casualty situations (18)] or where timely risk stratification is critical pose more complicated management decisions. Assessing the need for emergent laparotomy in normotensive trauma patients with a positive FAST examination would assist in timely decision-making, particularly in situations where additional resources may need to be mobilized early to optimize patient care.

The primary objective of this study was to assess the association between a positive ED FAST examination and therapeutic laparotomy in normotensive blunt trauma patients. Secondary objectives included: testing whether such an association persisted after adjusting for several potential confounding clinical variables and assessing performance measures of the ED FAST examination when used as a diagnostic test for therapeutic laparotomy.

MATERIALS AND METHODS

Study Design and Setting

We analyzed a retrospective cohort of normotensive, blunt trauma patients presenting to two Level I trauma centers between February 1, 2002 and December 31, 2003. One of the medical centers is located on the West Coast and has an annual ED volume of 42,000 patients. The other medical center is located in the Midwest and has an annual ED volume of 57,000 patients. Both medical centers host emergency medicine residency programs. We defined "normotensive" as an initial ED systolic blood pressure ≥ 100 mm Hg. If the patient was hypotensive in the prehospital setting, but had a systolic blood pressure ≥ 100 mm Hg on the initial set of ED vitals, the patient was still included in the study. The dates were selected based on the implementation of formal quality assurance programs for ED ultrasound applications at both centers and the availability of trauma registry information that could be matched to ED ultrasound information. The Institutional Review Board at both medical centers approved the study.

Study Population and Protocol

Patients were eligible for analysis if they were identified as trauma activation patients by standard regional trauma criteria, were 16 years or older with a blunt mechanism of injury, had an ED FAST examination recorded and confirmed, and were normotensive (i.e., systolic blood pressure ≥ 100 mm Hg) during the initial ED evaluation. Board-certified attending emergency physicians and upper-level emergency medicine residents (under the supervision of attending emergency physicians) performed the standard FAST examination on each study patient during the secondary survey using a Sonosite 180 Plus ultrasound machine with a 4.2-MHz transducer, a Sonosite 180 ultrasound machine with a 3.5-MHz transducer, or an Ultramark 4 Plus ultrasound machine with a 3.5-MHz transducer (all from Bothell, WA) (7). The treating attending emergency physician was ultimately responsible for making the final interpretation of the FAST examination. All ED FAST results were denoted as either positive or negative at the time of the examination and all FAST examinations represented the initial sonographic assessment of the patient after arrival to the ED (i.e., results from serial FAST examinations were unavailable for analysis). As part of ED ultrasound quality assurance programs at each site, FAST results were confirmed by review of the ultrasound images by one attending emergency physician specializing in emergency ultrasound (particularly if no further follow-up or imaging was available) or compared with dictated CT scan interpretations, operative findings, and clinical follow-up (e.g., admission for observation with discharge the following day). Through the review process, FAST results were confirmed as either positive or negative for free intraperitoneal fluid. Patients for whom FAST images were unavailable for review were excluded from the analysis ($n = 6$). For this analysis, a positive ED FAST examination was defined as a true positive (i.e., read as positive for free intraperitoneal fluid in the ED and confirmed as positive by formal review), which allowed

some reduction in the inter-operator variability in recognizing a positive FAST examination.

For the review of medical records and trauma registry information, reviewers at each study site abstracted data on standardized data collection forms. Each trauma registry had a predefined "code book" for each of the variables. The abstractors were formally trained in the data collection process and met with the investigators on a regular basis to review performance and resolve any disputes or questions. Data quality and reliability measures were performed as part of the standard trauma registry data processes. Information from the trauma registry at each hospital was matched with the ED FAST examination database using the date of presentation and hospital medical record number.

Variables

We considered several potential confounding variables, including: prehospital hypotension (systolic blood pressure $<$ 100 mm Hg), tachycardia (initial ED heart rate $>$ 120 beats/min), prehospital or ED endotracheal intubation, Glasgow Coma Scale (GCS) score, age, and injury identified on abdominal-pelvic CT scan. Because CT findings were not recorded in the trauma registries, we reviewed the final radiology reading for all abdominal-pelvic CT scans obtained for blunt trauma patients performed within 24 h of presentation using a standardized data collection form. The presence of any solid organ or intestinal injury evident on CT scan was considered an identifiable injury on CT; lack of such findings and cases where no CT scan was obtained were considered negative for identifiable injury. Age and GCS score were included in the model as continuous variables, and all other variables were coded as categorical terms.

Outcome

The primary outcome was therapeutic laparotomy within 2 days of presentation to the ED. A therapeutic laparotomy was considered any laparotomy where an intra-abdominal therapeutic intervention was performed during the operation (i.e., exploratory laparotomies or "quick look" laparotomies with no therapeutic intervention were not considered for the outcome group). We a priori included any therapeutic laparotomy within 2 days of the initial ED presentation to account for potential differences in operative decision-making among trauma surgeons and abdominal injuries missed on initial assessment. In this sample, more than 95% of laparotomies occurred within 2 days, and there were very few non-therapeutic laparotomies (n = 2).

Data Analysis

We calculated unadjusted and adjusted odds ratios (OR) between a positive ED FAST examination and therapeutic laparotomy. Before the analysis, we estimated that approximately 1600 patients would be available for inclusion in the study. Using this projected sample size, estimated rates of positive ED FAST examinations and therapeutic laparotomy among normotensive trauma patients, two-sided alpha equal to 0.05, and beta equal to 0.20, we sought to estimate the minimum effect size (unadjusted OR) that could be demonstrated between a positive FAST and therapeutic laparotomy with this sample for the primary analysis ($=$ OR $\geq$ 6). We felt such a calculation to determine the minimum effect size measurable with this sample would assist in interpretation of the subsequent results (e.g., if the unadjusted OR was $>$ 6 with a 95% confidence interval [CI] that crossed 1, we would conclude there is not an association; a smaller OR with a 95% CI that crossed 1 could be secondary to inadequate power to detect a smaller effect size).

For the secondary analyses, we first used a multivariable logistic regression model adjusted for the potential confounding variables and clustering within hospitals to calculate the "adjusted" association between positive ED FAST and therapeutic laparotomy (19). Information on individual surgeons caring for each patient was not available, so the possibility of different surgical and clinical management strategies (i.e., correlated data) was accounted for at the hospital level using generalized estimating equations for the logistic regression model. We sought to include clinical variables available early in the ED course that were potentially associated with both positive FAST and laparotomy (i.e., confounders) and that may simulate important factors involved in surgical decision-making (in addition to FAST results.) Variables included in this analysis were: FAST, age, GCS score, identifiable injury on abdominal-pelvic CT scan, initial ED pulse $>$ 120 beats/min, EMS (emergency medical services) systolic blood pressure $<$ 100 mm Hg, and intubation. Although there were many more factors that could have been considered, the limited number of outcomes (i.e., therapeutic laparotomy) placed constraints on the number of predictor variables that could be included in the model. We also considered potential collinearity between predictor variables when selecting appropriate predictors. The Hosmer-Lemeshow goodness-of-fit test was used to assess model fit. Missing values for the confounding variables were imputed using multiple imputation (20–22).

To assess the FAST examination as a diagnostic test for therapeutic laparotomy among initially normotensive trauma patients in the ED, we calculated several measures of diagnostic accuracy, including sensitivity, specificity,

Table 1. Trauma Patient Demographics by the Presence or Absence of Intraperitoneal Fluid on ED FAST Examination

	Full Sample	Positive FAST	Negative FAST
	n = 1636	n = 67 (4%)	n = 1569 (96%)
Mean age (years) ± SEM	40.4 ± 0.52	34.4 ± 1.47	40.7 ± 0.38
Mean ISS ± SEM	9.7 ± 0.51	20 ± 0.61	9.3 ± 0.34
Mean EMS SBP (mm Hg) ± SEM	133.4 ± 2.94	121 ± 6.68	134 ± 2.62
Mean ED SBP (mm Hg) ± SEM	138.3 ± 0.8	131.8 ± 2.82	138.6 ± 0.17
EMS SBP < 100 mm Hg	113 (7%)	10 (15%)	103 (7%)
ED heart rate > 120 beats/min (%)	109 (7%)	9 (14%)	100 (6%)
ED GCS 13–15 (%)	1,497 (92%)	58 (86%)	1,439 (92%)
ED GCS 9–12 (%)	73 (4%)	5 (7%)	69 (4%)
ED GCS 3–8 (%)	66 (4%)	5 (7%)	61 (4%)
EMS or ED intubation (%)	183 (11%)	16 (24%)	167 (11%)
Injury on abdominal-pelvic CT (%)	98 (6%)	45 (67%)	53 (3%)
Laparotomy (%)	33 (2%)	25 (37%)	8 (0.5%)
In-hospital mortality (%)	38 (2%)	3 (4%)	35 (2%)

SEM = standard error of the mean; ISS = Injury Severity Score; EMS = emergency medical services; ED = emergency department; SBP = systolic blood pressure; GCS = Glasgow Coma Scale score; CT = computed tomography.

positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio.

To assess for the possibility of selection bias in the sample, we compared characteristics between patients included in the study to those trauma patients who were excluded but eligible (e.g., no ultrasound performed, ultrasound images unavailable, unable to match record, etc.).

Database management, multiple imputation, and statistical analyses were performed using SAS (SAS 8.1, SAS Institute, Cary, NC) and SAS-callable IVEware (Survey Methodology Program, Survey Research Center, Institute for Social Research, University of Michigan, Ann Arbor, MI).

RESULTS

Of the 3350 eligible trauma patients evaluated at both hospitals during this time period, 1636 patients had ED FAST results matched to trauma records and were available for analysis. The percentage of adult trauma patients excluded from the study due to ED hypotension at each study site was 6% and 8%, respectively. There were 1714 eligible trauma patients who did not have a recorded FAST examination or who were unable to be matched to a FAST record and were excluded. When comparing the group of normotensive trauma patients with an ED FAST examination who matched to a trauma record (n = 1636, 49% of all eligible patients) with eligible patients who were not captured in our sample (n = 1708), patients not captured had a higher in-hospital mortality rate (3.7% vs. 2.3%, respectively) and were older (median age 41 vs. 37); however, there were no differences in laparotomy rate, intubation rate, prehospital hypotension, Injury Severity Score, ED and EMS systolic blood pressure, and ED and EMS pulse rate. Of the 1636 patients, 67 (4%) had a positive ED FAST examination and 33 (2%) underwent therapeutic laparotomy. There were 15 additional FAST examinations initially read as positive for free intraperitoneal fluid, and later found to be negative after formal review (i.e., false positives). Patient demographics are listed in Table 1.

The unadjusted association between therapeutic laparotomy and a positive FAST examination was OR 116 (95% CI 49.5–273). After adjusting for potential confounders, the association between a positive FAST examination and therapeutic laparotomy persisted (OR 44.6, 95% CI 1.77–1,124). The multivariable logistic regression model used to generate the adjusted OR was well fit using the Hosmer-Lemeshow goodness-of-fit test ($p > 0.05$).

Of the 33 patients who underwent therapeutic laparotomy, 25 had a positive FAST examination (sensitivity 75.8%, 95% CI 57.7–88.9%). Of the 1603 patients who did not undergo a laparotomy, 1561 had a negative ED FAST examination (specificity 97.4, 95% CI 96.5–98.1%). Of those with a positive FAST examination, 37% (25/67) underwent laparotomy, whereas 0.5% (8/1569) of patients with a negative FAST examination had a therapeutic laparotomy. Summary measures for use of the ED FAST examination as a diagnostic test for therapeutic laparotomy are listed in Table 2.

DISCUSSION

The timely and accurate determination of which blunt abdominal trauma patients require acute operative intervention remains a clinical challenge. Physical examina-

Table 2. Summary Measures of the Use of Emergency Department FAST Examination as a Diagnostic Test for Therapeutic Laparotomy (n = 1636)

	Estimate	95% Confidence Interval
Sensitivity	75.8%	(57.7–88.9%)
Specificity	97.4%	(96.5–98.1%)
Positive predictive value	37.3%	(25.8–50.0%)
Negative predictive value	99.5%	(99.0–99.8%)
Positive likelihood ratio	29.2	(20.4–41.6)
Negative likelihood ratio	0.25	(0.14–0.45)

tion alone has been shown to be unreliable, especially in patients with distracting injuries or altered mental status (23). The FAST examination is increasingly being used as a screening tool for blunt abdominal trauma because it is accurate, rapid, non-invasive, repeatable, portable, and involves no contrast material or radiation exposure to the patient. Numerous studies have supported its ability to detect intraperitoneal fluid, but none have specifically evaluated its ability to predict the need for laparotomy among normotensive blunt trauma patients (2–5, 7,10,12–16,24–29). In this study, we demonstrate a strong association between the presence of intraperitoneal fluid evident on ED FAST examination and therapeutic laparotomy among normotensive blunt trauma patients. This association persisted after accounting for several clinical factors, abdominal-pelvic CT findings, and clustering among hospitals.

Our findings are unique for several reasons. We excluded trauma patients with penetrating injury or hypotension during the initial ED evaluation, as these two high-risk groups often require laparotomy regardless of FAST results. We focused on normotensive blunt trauma patients, where the applicability of the FAST examination has been less clear. Some centers may forego performing a FAST examination on these patients, as the impact on clinical management has not been well defined and many of these patients will undergo subsequent CT imaging. We demonstrate that even after accounting for several confounding factors and CT findings, there was a strong, independent association between a positive ED FAST examination and therapeutic laparotomy. In addition, we analyzed therapeutic laparotomies that occurred within the first 2 days of patient presentation. We felt that such a window of time was needed to account for individual and institutional differences in surgical management, the possibility of missed injuries during the initial assessment, and delayed clinical manifestations of intra-abdominal pathology. We also combined patients from two institutions in different regions (West Coast and Midwest) of the United States to increase the generalizability of our findings.

Our results are similar to other studies that have attempted to associate FAST findings with the need for laparotomy. Although three studies demonstrated that the sensitivity for predicting the need for laparotomy increased with larger amounts of free fluid identified on FAST examination, two of them did not factor in the hemodynamic status of the patient (26,30,31). Huang et al. assessed the diagnostic ability of a positive FAST examination to predict the need for therapeutic laparotomy using an ultrasound scoring system based on the amount of free fluid in specific locations of the abdomen (a score of ≥ 3 was equivalent to at least 1000 mL of intraabdominal fluid) (26). Twenty-four of the 25 patients with a score ≥ 3 underwent a therapeutic laparotomy (96%), whereas only 9 of 24 patients (38%) with a score < 3 required laparotomy (26). Ma et al. evaluated whether the quantity of free intraperitoneal fluid evident on FAST examination, alone or in combination with unstable vitals signs, was sensitive for determining the need for laparotomy in blunt trauma patients (30). The results demonstrated that a large intraperitoneal fluid accumulation on FAST examination, especially in combination with unstable vital signs, was highly sensitive (100%) in determining the need for therapeutic laparotomy. The study, however, was limited by a small sample size (30). McKenney et al. demonstrated that patients with an ultrasound hemoperitoneum score ≥ 3 (based on measurement of intraperitoneal fluid quantity) had an 87% laparotomy rate compared to only 15% in those with a score < 3 (31). In the subset of patients who were initially normotensive in the ED with positive FAST examinations, 34 of 80 (42%) underwent laparotomy (31). Although our study did not correlate size of anechoic stripe on FAST to need for operative intervention, our study's adequate sample size enabled us to evaluate normotensive trauma patients, a subset whose clinical decision-making is often more challenging than those with unstable vital signs.

Several other investigators also have retrospectively analyzed the value of FAST for predicting need for laparotomy. Porter et al. reviewed 1631 trauma patients who underwent ultrasound as the primary screening test for abdominal injury to evaluate its role in determining the need for laparotomy (32). Of the 86 patients who required laparotomy, the FAST examination was positive in 80 (sensitivity of 93%, specificity 90%) (32). Bode et al. reviewed 338 patients with blunt abdominal trauma to evaluate the ability of the FAST examination to select patients needing immediate surgical laparotomy (28). Twenty-six of 28 patients requiring a therapeutic laparotomy had positive FAST results (93% sensitivity, 100% specificity) (28). Neither study, however, specified the hemodynamic status of their study populations. When limited to trauma patients who were hypotensive

(defined as systolic blood pressure ≤ 90 mm Hg) during the prehospital or ED evaluation, Holmes et al. noted the presence of intraabdominal fluid on ED FAST to be 83% sensitive for therapeutic laparotomy (9). Ng et al. evaluated a subset of 28 patients with free intraperitoneal fluid on the FAST examination but without evidence of solid organ injury on CT scan (33). Of the 21 patients who underwent therapeutic laparotomy, clinically significant visceral injuries were present in 16 patients (76%). The investigators recommended early laparotomy for all blunt abdominal trauma patients with more than a "trace amount" of free fluid on ultrasound, even in the absence of solid organ injury (33). Our study found similar results. Moreover, we accounted for potential confounding clinical variables, which previous studies did not account for in their methodology.

Based on our results, we believe that a FAST examination should be an integral step in the diagnostic assessment of blunt trauma patients, including those who are normotensive. Our data suggest that FAST can assist in the risk stratification of such patients. Relying exclusively on a negative FAST examination may miss some patients who require a laparotomy; however, our results suggest that a negative FAST examination reduces the likelihood of requiring laparotomy in blunt abdominal trauma patients, particularly if the pretest probability of laparotomy is low. For example, consider the scenario of a low clinical pretest probability of laparotomy combined with modest negative likelihood ratio from a negative ED FAST examination; this combination may reduce the post-test likelihood of therapeutic laparotomy low enough to be clinically useful. Alternatively, a positive ED FAST examination in normotensive blunt trauma patients should be viewed as a strong predictor of the need for laparotomy. Such findings during the initial assessment may be particularly important in EDs that do not have CT capability readily available or with field use of ultrasound (e.g., military use or during search-and-rescue missions). Finally, although a negative FAST examination may be useful in reducing the likelihood of requiring a therapeutic laparotomy, it does not provide information on potential injuries in other anatomic regions (e.g., head, retroperitoneum, pelvis) and cannot be expected to replace a complete physical examination and clinical judgment in trauma patients with the potential for multiple injuries.

Limitations

Several potential limitations exist with our study. Because this study was based on a retrospective cohort of trauma patients, it is subject to all the limitations inherent to retrospective analyses. We used confirmed positive FAST examinations (i.e., true positives) for all analyses to reduce inter-operator variability in the interpretation of the FAST examination (i.e., different levels of ultrasound training and expertise in FAST interpretation). Therefore, these results integrate the assumption that FAST examinations are performed and interpreted by experienced personnel with a very low rate of false positives. There is a possibility that a false-positive FAST examination could result in an unnecessary operative procedure. Such a risk may be minimized by formal quality control and training programs for health providers intending to utilize FAST results for operative decision-making. Prospective assessment of the ability of the FAST examination to predict need for therapeutic laparotomy using real-time ED readings of a positive examination would assist in clarifying the true utility of this test in normotensive blunt trauma patients. In addition, we did not study the relationship between FAST results and other processes of care (e.g., blood transfusion, angiographic intervention, hospital length of stay).

We did not study the use of serial FAST examinations; repeat examinations may further increase the sensitivity of FAST for predicting the need for laparotomy, as several studies have suggested (1,2,12,15,27,28,32). When mandated by the mechanism of injury or an evolving physical examination, serial FAST examinations or an abdominal CT scan should be performed on the patient.

Because the surgeons who participated in the care of these trauma patients were aware of the ED FAST examination results, it is possible that these results may have factored into their determination of the need for laparotomy, thus potentially integrating work-up bias into the sample. However, we believe that the potential for this bias was minimal, as surgeons from the two institutions generally determined the need for laparotomy based on clinical and CT scan results in normotensive blunt trauma patients, rather than based on FAST results (there were only two non-therapeutic laparotomies identified in this sample). In addition, there may have been selection bias in generating this sample (i.e., only half of the eligible trauma patients had ultrasound images and readings recorded), however, the majority of clinical characteristics compared between patients included vs. excluded from the sample were similar. Despite these concerns, we believe our findings add important information regarding use of the FAST examination in a major subset of trauma patients (i.e., normotensive blunt trauma patients) where the utility of the FAST has been previously downplayed and under-investigated. These results provide a basis for further prospective investigation of the utility of the ED FAST examination in clinical management and health outcomes.

The confidence intervals around point estimates in our results are wide, especially for the adjusted association between FAST and therapeutic laparotomy. This lack of precision is explained in part by the uncommon presence of both the "exposure" variable (i.e., positive FAST examination) and the outcome (i.e., therapeutic laparotomy), the inclusion of several predictor variables, and potentially some collinearity between certain predictors. We believe that, although the confidence intervals are wide, the persistence of these results in an analysis that adjusts for important factors affecting clinical decision-making adds validity to our results.

CONCLUSION

An ED FAST examination demonstrating free intraperitoneal fluid is strongly associated with therapeutic laparotomy among normotensive blunt trauma patients, even after accounting for important clinical factors and abdominal-pelvic CT scan findings.

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