Critical Review Form

Diagnostic Test

Association between a positive ED FAST examination and therapeutic laparotomy in normotensive blunt trauma patients, *J Emerg Med*, 2007; 33: 265-271

Objectives: "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 as 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." (p. 266)

Methods: This was a retrospective review of two university hospitals' (Oregon Health and Science University and University of Missouri-Kansas City) ED ultrasound quality assurance programs and trauma registry between February 1, 2002 and December 31, 2003. The trained chart abstractors used standardized data collection forms and a predefined "code book" for each variable. In addition, the chart abstractors met with investigators on a regular basis to review performance and resolve any disputes or questions.

Eligible patients were age 16-years or older with blunt injury mechanism and normotensive (systolic blood pressure ≥ 100 mm Hg) at the time of ED arrival. If no FAST images were available for review, patients were excluded. FAST examinations used a Sonosite 180 Plus with a 4.2 MHz transducer, a Sonosite 180 ultrasound with a 3.5 MHz transducer, or a Ultramark 4 Plus with a 3.5 MHz transducer. FAST exams were performed by the EM attending physician or senior resident, but "the treating attending emergency physician was ultimately responsible for making the final interpretation of the FAST examination." (p. 266) All FAST examinations were labeled either positive or negative at the time of examination. As part of the ED ultrasound quality assurance (QA) programs at both institutions, FAST results were confirmed "by review of the ultrasound images by one attending emergency physician specializing in emergency ultrasound or compared with dictated CT scan interpretations, operative findings, and clinical follow-up". (p. 266) For all analyses, the QA over-read FAST interpretation was used to define "true positives" for intraperitoneal fluid to reduce inter-operator variability.

The primary outcome was therapeutic laparotomy within two-days of ED presentation. A therapeutic laparotomy was defined as "an intra-abdominal therapeutic intervention performed during the operation." (p 267) The authors computed unadjusted and adjusted odds ratios between positive ED FAST and therapeutic laparotomy. Based upon an expected sample size of 1600 patients, a two-sided alpha 0.05, and 80% power (β = 0.20), the authors defined an unadjusted odds

ratio ≥ 6 with 95% confidence intervals that crossed 1 as no association, whereas a smaller odds ratio would reflect an inadequately powered sample size.

The authors planned a multivariable logistic regression model using generalized estimating equations to adjust for the potential confounding variables (including pre-hospital hypotension, tachycardia, intubation, Glasgow Coma Scale, age, and injury identified on abdominal-pelvic CT), as well as clustering within hospitals, between positive ED FAST and therapeutic laparotomy. They considered colinearity between predictor variables and assessed model fit using the Hosmer-Lemeshow goodness-of-fit test. Missing values for confounding variables were imputed using multiple imputations.

I.	Are the results valid?	
A.	**Did clinicians face diagnostic uncertainty?**	Presumably yes. The FAST exams were performed during the secondary survey before the CT results or operative findings were known, although this is not clearly stated. However, the authors used the QA over-read to define "true-positives" and the QA reviewers likely had all of the diagnostic and therapeutic data at hand when they reviewed the ultrasound images so *incorporation bias* is a potential source of bias. Incorporation bias will falsely increase research estimates of sensitivity & specificity.
B.	**Was there a blind comparison with an independent gold standard applied similarly to the treatment group and to the control group? (Incorporation Bias)**	No. FAST exams were verified by an US trained attending after the fact. Interpretations may have been biased by subsequent CT, OR reports and patient outcomes.
C.	**Did the results of the test being evaluated influence the decision to perform the gold standard? (Verification & Spectrum Bias)**	Yes. The results of the FAST may have influenced the decision to perform a CT or laparotomy. There was no effort to prevent this in the study. However, only 2 non-therapeutic laparotomies were performed and there were 40 patients with positive FAST that did not go to the OR at all. *Verification bias* will increase research estimates of sensitivity and decrease specificity, while *spectrum bias* will skew estimates of sensitivity and specificity upwards when the "sickest of the sick" are more likely to be enrolled.
II.	**What are the results?**	

<table>
<tr>
<td>A.</td>
<td>What likelihood ratios were associated with the range of possible test results?

All Patients
<table><tr><td></td><td>Therapeutic lap</td><td>Non-Therapeutic lap</td></tr><tr><td>FAST Free Fluid</td><td>25</td><td>42</td></tr><tr><td>FAST No Free Fluid</td><td>8</td><td>1561</td></tr></table></td>
<td>• 3350 eligible trauma patients, 49% of whom (n=1636) had an ED FAST exam matched to trauma records.
• At the two sites 6% and 8% were excluded due to pre-hospital hypotension.
• Excluded patients had higher in-hospital mortality (3.7% vs. 2.3%) and were older (41 vs. 37), but there were no differences in laparotomy rates, intubation rates, pre-hospital hypotension, Injury Severity Score, or pre-hospital/ED blood pressure.
• The unadjusted odds ratio for a positive FAST was 116 (95% CI 49.5-273) and the adjusted OR was 44.6 (95% CI 1.77-1124) which was well fit using the goodness-of-fit model (p>0.05).
• Based upon the 2x2 at left (re-constructed from data reported in the manuscript), the likelihood ratios of hemodynamically stable blunt abdominal trauma patients with a positive FAST result to predict the need for therapeutic laparotomy is:

LR+ 28.9 (95% CI 19.8-37.1)
LR- 0.25 (95% CI 0.12-0.43)

The wide confidence intervals indicate imprecision, most compelling for the negative likelihood ratio (upper range 0.43).</td>
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<td>III.</td>
<td>How can I apply the results to patient care?</td>
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<tr>
<td>A.</td>
<td>Will the reproducibility of the test result and its interpretation be satisfactory in my clinical setting?</td>
<td>These ultrasounds were conducted at two Level 1 trauma centers with ultrasound training programs, serving largely urban populations with similar characteristics to our patient population. There is little reason to suspect that these results would not be replicated at our institution, although a prospective analysis using the first sonographers-attending physician interpretation would be more pragmatic.</td>
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B.	**Are the results applicable to the patients in my practice?**	Yes. Hemodynamically stable blunt trauma patients have similar characteristics regardless of their location or mechanism. In addition, FAST was recorded by ED residents and interpreted in real time by ED attendings similar to our practice pattern.
C.	**Will the results change my management strategy?**	Not in isolation, but this adds to the growing body of literature supporting ED-performed/interpreted FAST as an accurate diagnostic test for diagnostic laparotomy when positive. While further prospective studies to assess FAST in the hands of less experienced learners are underway, it is now reasonable to use ED FAST exams to expedite CT imaging or operative exploration in hemodynamically stable blunt abdominal trauma patients when the FAST is abnormal. A "positive" FAST exam in these patients increases the pre-test probability for a therapeutic laparotomy of 2.0% to 37%. On the other hand, a normal FAST exam in hemodynamically stable patients does not sufficiently reduce the post-test probability (2.0% to 0.51%) to obviate the need for further work-up (serial exams, serial FAST, CT).
D.	**Will patients be better off as a result of the test?**	If this study is prospectively reproduced in heterogeneous settings (rural, non-academic, third world, etc.) it could be used at evidence to support more widespread use of FAST in blunt trauma as a screening tool to identify patients that require operative intervention or more invasive diagnostic evaluations.

Limitations

1) **Retrospective analysis, but excellent chart review methods minimize potential biases.**

2) **Various forms of diagnostic research bias are not addressed, including**

   a. **Spectrum bias which may inflate estimates of sensitivity & specificity, since this study recruited the "sickest of the sick".**
   b. **Verification bias may inflate estimates of sensitivity and decrease estimates of specificity.**

c. **Incorporation bias which may inflate estimates of sensitivity and specificity.**

Therefore, the reported estimates of sensitivity (at least) are likely skewed upwards.

3) **No assessment of reliability.**

4) **Failure to reference or use the STARD criteria.**

Bottom Line

The incidence of a therapeutic laparotomy is 2.0% and the FAST exam is an independent predictor of this need after adjusting for abdominal CT findings, injury severity, GCS, and pre-hospital hypotension. This study adds to the growing body of literature supporting ED-performed and interpreted FAST exams as an accurate diagnostic test for diagnostic laparotomy when positive. While further prospective studies to assess FAST in the hands of less experienced learners are underway, an ED FAST exam should be considered the Standard of Care to expedite CT imaging or operative exploration in hemodynamically stable blunt abdominal trauma patients when the FAST is abnormal. A "positive" FAST exam in these patients increases the pre-test probability for a therapeutic laparotomy of 2.0% to 37%. On the other hand, a normal FAST exam in hemodynamically stable patients does not sufficiently reduce the post-test probability (2.0% to 0.51%) to obviate the need for further work-up (serial exams, serial FAST, CT).