Critical Review Form Diagnostic Test

FAST scan: Is it worth doing in Hemodynamically stable blunt trauma patients? *Surgery* 2010; 148: 659-701

Objective: "To evaluate the results of the focused assessment with sonography for trauma (FAST) examination examination in the hemodynamically stable blunt trauma patients and to determine its role in the diagnostic evaluation of these patients." (p 696)

Methods: This was a (retrospective chart review) trauma registry study of all patients presenting to the Creighton University (which hospital) Level I trauma center ED between January 2002 and December 2008. As part of their secondary survey protocol all patients have a chest and pelvic x-ray and surgery resident-performed FAST exam. The Trauma Director, certified by Radiologists specializing in ultrasonography, credentialed all surgery residents. The FAST exam looked at four windows (pericardial, perihepatic, perisplenic, and pelvic) using a Zonare z.one Convertible Ultrasound system with a 2- to 5-MHz convex array transducer. The FAST exam is interpreted as positive if free intra-abdominal or pericardial fluid is visualized. Indeterminate FAST studies included inadequate organ visualization or any doubt about the study result.

The investigators defined true-positives as a positive FAST confirmed by the best available evidence with confirmatory tests including abdominal/pelvic CT, DPL, exploratory laparotomy, or observation. False positives represented positive FAST and lack of injury confirmation via the best available evidence. False negatives were a negative FAST when the best available evidence identified an injury. True negatives were a negative FAST and no injury using the best available evidence.

The authors do not describe any analytical plan, chart review methods, other diagnostic accuracy research methods, or power assumptions.

| Guide | | Comments |
|-----------|-----------------------------------------|--------------------------------------------------|
| I. | Are the results valid? | |
| A. | Did clinicians face diagnostic | Yes, is there a traumatic injury in abdominal |
| | uncertainty? | trauma patients? The investigators included |
| | | penetrating and blunt trauma patients in the |
| | | analysis. |
| В. | Was there a blind comparison with an | No. All of the trauma patients did not have a |
| | independent gold standard applied | FAST exam or legitimate gold standard testing |
| | similarly to the treatment group and to | (CT or laparotomy). Also, there was no |
| | the control group? | blinding of Radiologists interpreting the CT or |
| | | Surgeons evaluating the decision to perform or |
| | | interpreting the DPL/laparotomy. Incorporation |
| | | bias will falsely increase research estimates of |
| | (Incorporation Bias) | sensitivity & specificity. |

| С. | Did the results of the test being evaluated influence the decision to perform the gold standard? | Probably, since the ultrasound results were available while making a decision about further diagnostic testing or exploratory laparotomy. Whereas patients with a positive FAST exam all went to CT or exploratory laparotomy (87/88 = 99%) prior to the operating room, only 63% (1201/1894) of FAST negative patients had a CT ordered. In place of CT, 695 patients were observed but the investigators do not describe who observed them, using what protocol, or for how long. The diagnostic and therapeutic path for the 28.5% of patients who did not undergo a FAST exam is unclear. <u>Verification bias</u> will increase research estimates of sensitivity and decrease specificity. <u>Double-gold standard bias</u> will increase estimates of sensitivity for diseases that resolve spontaneously and decrease sensitivity for |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | (Verification and Double-Gold Standard | diseases that only become detectable during the |
| II. | Bias) What are the results? | follow-up period. |
| A. | What are the results: What likelihood ratios were associated with the range of possible test results? All Trauma Patients Abdominal No Abdominal No Abdominal Injury FAST + 88 5 FAST - 118 1896 Stable Blunt Trauma Abdominal No Injury Abdominal No FAST - 118 1896 Stable Blunt Trauma Abdominal No Injury FAST + 60 4 FAST - 87 1681 | 2,980 patients were evaluated by the trauma service, but 850 (28.5%) did not have a FAST exam, 18 (0.8%) had an inconclusive FAST exam, and 7 (0.3%) were dead on arrival leaving 2,105 patients (70% of total) available for analysis. 86.9% (1832/2107) of patients were hemodynamically stable blunt trauma patients. Note that the authors' denominator in Table I and III add to 2107 not 2105! Based upon the 2x2 tables at left, we calculated the following LR's All trauma patients LR+ 162 (95% CI, 65-449) LR- 0.57 (95% CI, 558608) Penetrating trauma patients LR+ inf (95% CI, 16.1-inf) |
| | | LR- 7.9% (95% CI, 57.9-68.7%) Blunt trauma patients LR+ 147.7 (95% CI, 59.6-410.7) LR- 0.57 (95% CI, 0.55-0.61) Blunt trauma HD stable LR+ 171 (95% CI, 62-552) LR- 0.59 (95% CI, 0.57-0.63) Blunt trauma HD unstable LR+ 21.7 (95% CI, 3.5-444) LR- 0.44 (95% CI, 0.38-0.67) |

| III. | How can I apply the results to | |
|------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | patient care? | |
| A. | Will the reproducibility of the test result and its interpretation be satisfactory in my clinical setting? | Uncertain since we do not have any results on a significant proportion of the trauma patients (805 of 2,980 possible patients 27%) and we do not know if these are predominantly HD stable/unstable blunt/penetrating trauma patients. |
| В. | Are the results applicable to the patients in my practice? | No. This is a Level 1 trauma center, but the Trauma Surgeons performed the FAST exams. In our institution, EM physicians perform the FAST exam. These estimates of diagnostic accuracy to reduce the probability of intra-abdominal injury differ significantly from estimates noted in multiple ED- based studies where the EM physicians perform the FAST exam (see PGY I paper). The authors of this research do not note this discrepancy or reference any of the EM literature. |
| C. | Will the results change my management strategy? | No. We currently use EM physician performed FAST exam to assess intra-abdominal injury risk after blunt trauma, not Trauma Surgeon ultrasounds. The current Standard of Care is to use FAST to more quickly queue patients for CT in frequently overcrowded environments, not to replace CT or to diagnose all of the injuries. The negative likelihood ratios are insufficient to use FAST as a method of ruling out traumatic intra-abdominal injury in HD stable blunt trauma patients. |
| D. | Will patients be better off as a result of the test? | If reading this study in isolation, the very low sensitivity suggests that CT abdomen is the definitive test of choice in HD stable blunt trauma patients. The authors declare "Following every FAST with a CT would lead to using more resources and time. Thus, whenever an injury is suspected in a HSBT (hemodynamically stable blunt trauma) patient, it would be more prudent for these patients to undergo a CT rather than a FAST to avoid missing injuries." (p 699) However, the various potential forms of bias that are not addressed by the authors, in addition to the complete disregard for diagnostic accuracy estimates of EM physician US leave substantial room for debate about these conclusions. |

Limitations

- 1) Limited <u>external validity</u> since Trauma Surgery (not EM) performed and interpreted the FAST exams.
- 2) No chart review methods
- 3) Failure to reference or incorporate the **STARD criteria**.
- 4) No data analysis plan.
- 5) No a priori power calculation.
- 6) No patient demographics (age, illness severity scores) or patient-centric outcomes.
- 7) No details about the large subset of patients with observation as the gold standard. Who "observed" them, where were they observed, using what protocol, and for how long were they observed?
- 8) Multiple forms of <u>diagnostic research bias</u>, some of which skews estimates of sensitivity downwards, all of which is not addressed by the investigators. These forms of bias include
 - a. <u>Double-gold standard bias</u>, which will increase estimates of sensitivity for diseases that resolve spontaneously and decrease sensitivity for diseases that only become detectable during the follow-up period.
 - b. <u>Incorporation bias</u>, which may inflate estimates of sensitivity and specificity.
 - c. <u>Verification bias</u>, which will inflate estimates of sensitivity and decrease estimates of specificity.
 - d. <u>Spectrum bias</u>, which may inflate estimates of sensitivity & specificity, since this study recruited the "sickest of the sick".

Bottom Line

In isolation, the very low sensitivity suggests that FAST exams simply waste time and resources while awaiting the inevitable CT in hemodynamically stable blunt trauma patients. However, the various potential forms of bias that are not addressed by the authors, in addition to the complete disregard for diagnostic accuracy estimates of EM physician US leave substantial room for debate about these conclusions. Also, the authors fail to recognize the CT is not always readily available in today's crowded

ED's or in other parts of the world where healthcare systems limit the availability of this expensive technology.