## Critical Review Form Diagnostic Test

Blunt Abdominal Injury in the Pregnant Patient: Detection with US, *Radiology* 2004; 233:463-470

**<u>Objective:</u>** To determine the accuracy of Ultrasonography (US) for the detection of blunt intra-abdominal injury in pregnant patients and to compare differences between pregnant and non-pregnant patients of child bearing age. (p 463)

<u>Methods:</u> This was a retrospective chart review during a 7 year period from 1995-2002 at UC-Davis, a level I trauma center. All consecutive female patients between the ages of 10-50 who were involved in blunt abdominal trauma (BAT) and underwent FAST scanning were eligible. (p 464) US reports were retrospectively reviewed by one of three authors who identified 328 pregnant patients sustaining BAT with 23 intra-abdominal injuries. (p 465) Pregnancy was confirmed by US <u>and</u> serum/urine B hCG. The study looked for absolute evidence of injury on FAST focusing on evidence of free fluid, location of free fluid, and presence of parenchymal injury while avoiding homodynamic parameters. FAST ultrasounds were classified as true-positive, false –positive, and false-negative, avoiding any quantitative descriptions of parenchymal injury, fluid presence, or fluid location. All patients underwent FAST scanning prior to any other imaging or therapeutic intervention and results were correlated with CT and/or lapratomy results.

Guide		Comments				
I.	Are the results valid?					
<b>A.</b>	Did clinicians face diagnostic	Yes. This was a retrospective evaluation of US application				
	uncertainty?	to females of child bearing age during an 8 year period				
		(1995-2002) at a level 1 trauma center. The researchers				
		were looking at essentially 2 endpoints. The first was to				
		determine the accuracy of US (FAST exam) pregnant				
		patients sustaining blunt abdominal trauma (BAT). The				
		second was to compare sensitivities of FAST in BAT				
		between pregnant and non-pregnant females. (p. 464)				
В.	Was there a blind comparison with	There were no treatment and control groups, but rather				
	an independent gold standard applied	BAT with intra-abdominal injury versus BAT without				
	similarly to the treatment group and	AND pregnant BAT versus non-pregnant BAT. The				
	to the control group?	authors do not discuss whether the trauma service was				
		blinded to the results of the FAST exam as it was being				
		done during the secondary survey. All positive FAST				
		scans were compared to either CT and/or laparotomy as the				
		gold standard reference. Negative scans were not				
		compared to any gold standard (since this was what was				
		being evaluated), nor were they well followed up. Such a				
		phenomenon is called verification bias and may have				
		skewed the researchers' numbers in favor of erroneously				
		higher specificities.				

C.	Did the results of the test being evaluated influence the decision to perform the gold standard?	The answer to this question was not specifically addressed, so the critical reviewer must assume that the answer is "Yes". Such issues represent but one of several potential biases within the study which the authors neglected to identify. First, this was a retrospective chart review without clearly stated methods ( <i>selection bias, recall bias</i> ). Second, not all patients who sustained BAT underwent US testing which was left to the discretion of the trauma attending ( <i>selection bias</i> ). Third, as already mentioned above, the fact that true negative						
		FAST scans were not really followed up on may have introduced an unintentional bias by making the specificity falsely high ( <i>ascertainment bias</i> ). Finally, the fact that multiple radiologists were reviewing the FAST "wet reads" and there was no mention of a kappa score to account for interobserver variability ( <i>kappa analysis</i> of agreement beyond that expected by chance alone).						
II.	What are the results?							
<b>A.</b>	What likelihood ratios were associated with the range of possible test results?	Trimester 1st 2 <sup>nd</sup> 3 <sup>rd</sup> Not pregnant	Sensitivit   y   90%   25%   44%   71%	Specificit   y   89%   98%   94%   97%	NP V 98% 98% 95% 97%	Accurac y 89% 95% 90% 98%	LR + 8.2 12.5 8.8 23.7	<b>LR-</b> 0.11 0.76 0.6 0.3
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?	Probably not for a number of reasons. First, this was a modified FAST exam (not used at BJH) excluding the subxiphoid cardiac view and including multiple liver parenchymal views and 2 paracolic gutter. In contrast, our FAST scan is limited to 4 views including the subxiphoid cardiac view. Second, this study used a dedicated FAST sonographer trained in sonography. Our institution has residents who are trained in sonography with varying degrees of skill with the ultrasound machine and the FAST exam. EM physicians were not the ones doing the FAST exam in the current study.						
В.	Are the results applicable to the patients in my practice?	Yes, there is no reason to suspect UC-Davis female patients differ from BJH female patients.						

С.	Will the results change my management strategy?	Yes and no. Since our institution already does FAST exams on all trauma patients as part of the secondary survey, it was satisfying to see sensitivity numbers which supported the high 80's for sensitivity and the mid-high 90's for specificity as evidenced by our institutions' numbers and those found in the literature. However, the dramatic reduction in sensitivities in the $2^{nd}$ and $3^{rd}$ trimester of pregnancy suggests that the FAST is not a good modality to rule in disease. Although the reported specificities were excellent, the researchers' lack of follow up weakens their conclusions limiting one's confidence in applying this information to patients. Finally, the study demonstrated that in later pregnancy (>20 weeks), the likelihood of placental abruption was equal to that of splenic injury. However, the ability of US to detect that particular injury was terrible (sen 14%). Such patients require non-stress fetal monitoring.
D.	Will patients be better off as a result of the test?	Potentially. The study needs to be done in a prospective manner with better follow up for true negative FASTs in pregnant patients. If follow up studies demonstrated that FAST is, in fact, an acceptable screen to rule out injury in pregnant patients, its application in expediting patient care would be very warranted.

## Limitations:

- 1. Retrospective study design without clearly stated methods.
  - a. How were cases identified (by physician recall, ICD-9 codes, or other)?
  - b. How was the data abstraction undertaken? Were reviewers blinded to the study hypothesis? How was abstractor reliability assessed?
  - c. How was missing or conflicting data managed?
- 2. No intra-observer or inter-observer reliability assessment (Kappa score) performed to identify variability amongst the multiple radiologists who interpreted the initial FAST scans.
- 3. Lack of follow-up for patients who underwent only US evaluation and subsequent discharge. Evaluators do not make reference to any type of physical follow up set or follow up phone interviews to ensure the that patients they discharged remained safe or if they developed complications and followed up in a different hospital /ED. By not following up all patients equally, the authors leave open the possibility of ascertainment bias and verification bias.
- 4. Limited applicability to institutions where FAST exam is done by EM physicians and not by dedicated sonographers.

## **Bottom Line**

Retrospective study with poorly detailed methods concluding that sensitivities and specificities of FAST exams in BAT of  $1^{st}$  trimester and non-pregnant women is roughly equal to that of the "general" population. However, this study also showed that FAST sensitivities dropped to unacceptably low levels in the  $2^{nd}$  trimester (25%) and 3rd trimester (44%) which decreased the overall sensitivity of FAST exam for all pregnant patients. The main reason for lower sensitivities was that the false positive rate in pregnant patients was 50% and in non-pregnant patients was 25%. Another weakness of this article was the lack of follow up in patients who received FAST scanning as the only screen which may have artificially elevated specificity numbers. Of note, this study does highlight the higher-than-expected incidence of placental abruption in later pregnancy which is notoriously difficult to diagnose even under the best of circumstances and one can infer that all pregnant patients > 20 weeks gestation sustaining BAT should have a period of fetal monitoring after the initial trauma stabilization.