Critical Review Form
Clinical Prediction or Decision Rule

The FAST is Positive, Now What? Derivation of a Clinical Decision Rule to Determine the Need for Therapeutic Laparotomy in Adults with Blunt Trauma and a Positive Trauma Ultrasound, *Journal of EM* 2004; 29:15-21

Objective: This study's objective was to derive a clinical decision rule for therapeutic laparotomy among adult blunt trauma patients who have a positive FAST exam as part of their initial evaluation. (p 15)
Methods: This was a retrospective review of a trauma registry at UC-Davis, a level I center over a 3 year period from 1996-1999. All patients over the age of 16 who presented as blunt abdominal traumas with a positive FAST scan defined as any presence of free intrabdominal fluid were eligible. Cases were identified through the institutional trauma and ultrasound databases, although no details are provided on what search terms were utilized, who conducted the search, how they were trained, whether they were blinded to the study objectives, or if standardized data abstraction forms were utilized. All FAST exams were performed by Registered Diagnostic Medical Sonographers (RDMS), not EM physicians. The primary outcome variable for this study was the need for therapeutic laparotomy which was defined a priori in conjunction with a Trauma Surgery co-investigator (see Table 2, p. 17). The authors analyzed 7 clinical and ultrasound variables: age > 60, episode of hypotension < 90, abdominal tenderness, chest injury, pelvic fracture, femur fracture, and presence of free fluid [FF] in the RUQ view of the FAST exam) to determine whether patients ultimately required a therapeutic laparotomy. A Kappa analysis was performed on subjective variables (abdominal tenderness, therapeutic laparotomy) based on 5% convenience sampling of the study population. The authors then analyzed which combination of the 7 factors would best predict the need for surgical management of blunt trauma patients utilizing binary recursive partitioning. The subsequent Clinical Decision Rule (CDR) was internally validated using 10-fold cross validation.

Guide		Comments
I.	***Is this a newly derived instrument* (Level IV)?**	
A.	Was validation restricted to the retrospective use of statistical techniques on the original database? (If so, this is a Level IV rule & is not ready for clinical application).	Yes, so the current study represents a Level IV (lowest level, not ready for widespread clinical application) CDR.
II.	**Has the instrument been validated? (Level II or III). No, but consider the following anyway:**	This clinical rule has not yet been externally validated. Without validating the CDR on a separate population, one cannot be certain of the results generalizability.

1a	Were all important predictors included in the derivation process?	Cannot answer this question because the prevalence of variables is not provided. The authors proposed 7 clinical and ultrasound variables which make intuitive sense, but it is unclear why these 7 were selected as opposed to something like H/H values, etc. This a priori selection also applies to the Table 2 which lists surgical interventions (ex lap) were considered therapeutic versus non-therapeutic. Some background information on the selection process in both situations would have been helpful.
1b	Were all important predictors present in significant proportion of the study population?	Again, I suspect that the presence of these predictors was in fact present in adequate amounts within the population studied, although this was not detailed in the paper. For example, a GCS < 13 was considered an major cut off since presence of abdominal tenderness (in a GCS > 13 patient) was considered one of the clinical predictor variables, but there is no mention of what proportion of patients had any change in their mental status.
1c	Does the rule make clinical sense?	Yes. Some might question the inclusion of subjective variables, but the authors demonstrated an impressive level of agreement above that expected by chance alone with abdominal pain & therapeutic laparotomy both 1.0 (perfect Kappa).
2	Did validation include prospective studies on several different populations from that used to derive it (II) or was it restricted to a single population (III)?	A derivation study, not yet been validated. This trial would have benefited from more patient demographics such as male versus female patient enrollment, the role of physiologic FF on FAST exam sensitivity. The authors used a cross validation and cost benefit analysis on the same patient population from which the CDR was derived.

3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	Uncertain. To answer this question one would need a reporting of Injury Severity Score or Apache II scores. The authors only report on mechanism of injury (Table 3, p. 18) and ED disposition, a loose surrogate of injury severity.
3b	Was there a blinded assessment of the gold standard?	In this study the gold standard was an laparotomy determined to be therapeutic based on the criteria from Table 2. The article makes no mention of whether there was blinding to the gold standard by the Ultrasonographers, Radiologists, Trauma Surgeons, or outcome assessors.
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	One would assume that the variables were recorded (and not later altered) prior to the laparotomy in the original medical record, in which case they would have been explicitly and presumably accurately interpreted without any way of knowing what the future laparotomy would demonstrate. There is little potential for bias here, since those recording the data real-time had no way of predicting a future study assessing the variables they were recording.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Almost certainly the constellation of variables assessed would have impacted the decision to proceed to the OR (or their absence to not go to the OR). Such flaws permit the possibility of *verification bias*.

<table>
<tr><td>4</td><td>How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?</td><td>Although the authors do not provide a 2x2 Table, they provide enough for you to construct one:
Therapeutic Laparotomy
<table><tr><th>RUQ Fluid</th><th>Yes</th><th>No</th><th>Totals</th></tr><tr><td>Present</td><td>105</td><td>39</td><td>144</td></tr><tr><td>Absent</td><td>30</td><td>56</td><td>86</td></tr></table>
Based upon this table the presence of RUQ fluid predicts therapeutic laparotomy with sensitivity 78%, specificity 59%, LR+ 1.9, and LR- 0.37. Thus the presence of RUQ fluid has weak discriminatory power to identify the need for laparotomy.

The authors also note that the presence of any of 5 variables (RUQ fluid, hypotension, femur fracture, abdominal tenderness, or age >60 predicted all 135 patients requiring therapeutic laparotomy (sensitivity 100%, specificity 13%, LR+ 1.15, LR- <0.01.</td></tr>
<tr><td>III.</td><td>Has an impact analysis demonstrated change in clinical behavior or patient outcomes as a result of using the instrument? (Level I). If so, consider the following:</td><td></td></tr>
<tr><td>1</td><td>How well did the study guard against bias in terms of differences at the start (concealed randomization, adjustment in analysis) or as the study proceeded (blinding, co-intervention, loss to follow-up)?</td><td>No impact analysis was performed.</td></tr>
<tr><td>2</td><td>What was the impact on clinician behavior and patient-important outcomes?</td><td>No impact analysis was performed.</td></tr>
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Limitations

1. **A Level IV derivation study which requires prospective validation on different patient populations before it can be applied to clinical practice.**
2. **The authors do not elaborate on how they selected the 7 clinical/US variables that would make up its decision rule tree and other variables might prove more efficacious.**
3. **A retrospective chart review with poorly defined methods (see methods commentary above).**

Bottom Line:

A derivation study demonstrating that blunt abdominal trauma patients who have RUQ FF are more likely than not to require operative repair with a positive LR of 1.9 (poorly predictive). The other 6 variables fared even less well in terms of their prediction potential. The addition of alternative variables may ultimately yield a more robust CDR. In short, this study needs validation and analysis of alternative variables. If validated, then Level II and III EP's may have a valuable tool by which to either call in the surgical team or set up for transfer to a trauma center more quickly. The current study probably has less application to academic and 24/7 Level I hospitals which have those services and more sensitive technologies (CT) much more readily available.