Critical Review Form
Clinical Prediction or Decision Rule

Inaba K, Nosanov L, Menaker J, et al; AAST TL-Spine Multicenter Study Group. Prospective derivation of a clinical decision rule for thoracolumbar spine evaluation after blunt trauma: An American Association for the Surgery of Trauma Multi-Institutional Trials Group Study. J Trauma Acute Care Surg. 2015 Mar;78(3):459-65; discussion 465-7.

Objectives: "to examine this clinical problem in a large multicenter blunt trauma patient cohort and to develop a clinical decision rule with sufficient sensitivity and acceptable specificity for the detection of all clinically significant TL-spine fractures." (p. 460)

Methods: This multicenter, prospective, observational study was conducted at 13 Level I and II trauma centers in the US between January 2012 and January 2014. Patients aged 15 years or older suffering blunt trauma were eligible for enrollment. Exclusion criteria included Glasgow Coma Scale score of less than 15, intoxication, presence of a painful distracting injury, existing paraplegia or tetraplegia, concurrent cervical spine injury causing a neurologic deficit, and initial assessment greater than 24 hours after the injury. Patients who did not undergo any imaging of the TL spine were also excluded.

Data were recorded on a case report form by the resident or attending surgeon, including presence or absence of pain, midline tenderness, bony deformities, and neurologic deficits. All imaging decisions were made by the treating physicians and radiologic images were interpreted by an attending radiologist who was blinded to the study case report form contents. The primary outcome was the presence of a clinically significant fracture of the thoracic or lumbar spine, defined as any injury requiring surgery or a TL-spine orthosis (TLSO). This did not include isolated transverse process or spinous process fractures. The authors planned, *a priori*, to use the clinical examination and injury mechanism as components of the clinical decision rule. Univariate analysis was performed to determine which other predictors to use in the rule.

A total of 12479 patients were screened over the 2-year study period, of whom 3863 met inclusion criteria. Of these, 3056 (79.3%) underwent diagnostic imaging and were included in the derivation cohort. A clinically significant TL spine fracture was found in 264 patients, of whom 77 required surgical stabilization and 187 were treated with a TLSO brace. The mean age was 43.5 years and 66.3% were male.

	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).	No validation was performed. This study only conducted a derivation of the clinical decision rule, making this a level IV rule.
II.	**Has the instrument been validated? (Level II or III). If so, consider the following:**	
1a	Were all important predictors included in the derivation process?	Yes. The authors considered a wide range of clinical predictors, including mechanism of injury, presence or absence of midline spinal tenderness, presence or absence of neurologic deficits, patient demographics (including age), and vitals signs.
1b	Were all important predictors present in significant proportion of the study population?	No. While those predictors that were included in the final decision rule were present in a significant proportion of the population, potentially important predictors such as hypotension were not.
1c	Does the rule make clinical sense?	Yes. The final rule includes factors that clinically suggest a higher possibility of a significant thoracic or lumbar vertebral fracture.
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)?	N/A. This decision rule has not been validated.
3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	Mostly yes. In this study, the decision to perform thoracic and/or lumbar spine imaging was at clinician discretion, and patients that did not undergo imaging were excluded from the study. This low risk population represented ~20% of all eligible patients. Similarly, some higher risk patients were excluded as well, including those with a depressed GCS. Overall, this study still likely included a wide range of patients with a variety of injury mechanisms represented. It is important to note that low-risk patients were excluded and hence this rule would not apply to such patients (spectrum bias).

3b	Was there a blinded assessment of the gold standard?	Yes. The gold standard in this study would be considered the results of imaging (CT in 93.3%, plain films in 6.3%, and MRI in 0.2%). The authors report that, "All radiologic images obtained were interpreted by an attending radiologist who was blinded to the study case report form contents." (p. 460)
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	Yes. The case report form was filled out (based on history and physical exam findings) prior to the imaging studies being completed.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Possibly. The study included only those patients who underwent imaging of the thoracic and lumbar spine. Patients felt to be low risk based on history and physical exam findings, including those included in the rule, may not have undergone imaging and hence been excluded from the analysis (verification bias). The exclusion of these patients would likely falsely inflate the specificity of the rule.
4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	The final clinical decision rule consisted of the following criteria: 1. High-risk mechanism 2. Findings of pain, tenderness to palpation, deformity, or neurologic deficit 3. Age ≥ 60 If any of these were positive, the rule was considered positive. This rule had a sensitivity of 98.9%, specificity of 29.0%, positive predictive value of 11.6%, and negative predictive value of 99.6%. This corresponds to a positive likelihood ratio of 1.39 and a negative likelihood ratio of 0.04.
III.	**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:**	
1	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)?	Poorly. The exclusion of patients who did not undergo any imaging would lead to selection bias and spectrum bias. Since information regarding these patients was not available, it is not possible to know why imaging was foregone in these

		patients.
2	What was the impact on clinician behavior and patient-important outcomes?	Uncertain. No impact analysis has been performed using the rule.

Limitations:

1. **The investigators enrolled a <u>convenience sample</u> and provide no information regarding those patients who were eligible for the study but not enrolled due to timing.**

2. **The authors chose as their outcome defined as any injury requiring surgery or a TL-spine orthosis (TLSO). A multicenter study conducted in Canada found no benefit to TLSO bracing among patients with thoracolumbar burst fractures (<u>Bailey 2014</u>), suggesting this may be an inappropriate outcome measure.**

3. **Patients who did not undergo any TL spine imaging were excluded, representing 20% of eligible patients (<u>selection bias</u>, <u>spectrum bias</u>).**

4. **The authors did not provide <u>95% confidence intervals</u> for the reported test characteristics, and unfortunately there was insufficient information to calculate these.**

5. **This was a <u>derivation</u> study only (level IV CDR). This clinical decision rule will require validation, preferably in a variety of settings, and ideally would undergo impact analysis to determine its effect on test ordering and clinical outcomes.**

Bottom Line:

In this prospective, multicenter study involving cohort of patients who underwent thoracic and lumbar spine imaging following trauma, a clinical decision rule was derived with the following components: High-risk mechanism; findings of pain, tenderness to palpation, deformity, or neurologic deficit; and age ≥ 60. This CDR had a negative likelihood ratio of 0.04, suggesting a significant decrease in the probability of a clinically significant fracture if the CRD was negative. This CDR will need validation in a variety of settings, and ideally should undergo impact analysis to determine whether it will have any significant effect on clinical practice or patient-centered outcomes.