

Critical Review Form

Diagnostic Test

Inaba K, DuBose JJ, Barmparas G, Barbarino R, Reddy S, Talving P, Lam L, Demetriades D. Clinical examination is insufficient to rule out thoracolumbar spine injuries. J Trauma. 2011 Jan;70(1):174-9.

Objectives: "to determine the sensitivity and specificity of a protocolized, structured clinical examination for the evaluation of the TL spine in trauma patients injured after blunt trauma." (p. 174)

Methods: This prospective, observational study was conducted at the Los Angeles County/University of Southern California Medical Center over a six-month period ending September 2008. Patients aged 15 years or older suffering blunt trauma were screened for eligibility. Patients who were felt to be "unevaluable"—including those with a Glasgow Coma Scale score < 15, those who were intoxicated, and those with a distracting injury—were excluded.

The remaining patients underwent a standardized physical examination of the thoracic and lumbar spine using a checklist, as well as a complete neurologic examination. Patients with any clinical signs underwent CT evaluation of their spine. Patients were followed throughout their hospitalization, and the aggregate "gold standard" was the final diagnosis based on imaging, surgical procedures, and clinical follow-up.

Out of 884 patients screened, 666 (75.3%) were deemed evaluable. Demographic information for these included patients was not provided. Among these patients, 56 (8.3%) had a TL spine injury, of which 29 (51.8%) had a normal clinical examination. Among those patients with a normal clinical examination and a positive TL spine injury, only two patients (6.9%) had a "clinically significant" injury, with both requiring TLSO stabilization.

Guide		Comments
I.	Are the results valid?	
A.	Did clinicians face diagnostic uncertainty?	Yes. At the onset of the study, clinicians were not aware whether patients had a fracture of the thoracic or lumbar spine.
B.	Was there a blind comparison with an independent gold standard applied similarly to all patients? (Confirmation Bias)	No. CT scan was not performed in all patients, and there is no mention of blinding of radiologists reading CT scans to the clinical data and exam findings. Knowledge of this information may have guided CT reads to some extent (incorporation bias).

C.	Did the results of the test being evaluated influence the decision to perform the gold standard? (Ascertainment Bias)	Yes. The authors note that "not all patients enrolled had a CT," (p. 178) and report that physical examination findings were used in large part to determine who needed imaging performed. While imaging alone was not considered the "gold standard," it seems unlikely that additional fractures were diagnosed in the absence of imaging. It is quite possible that there were patients with negative exam findings who had missed fractures, but given the follow-up provided, it seems unlikely that any clinically significant fractures were missed (partial verification bias).
II.	What are the results?	
A.	What likelihood ratios were associated with the range of possible test results?	<ul style="list-style-type: none"> For all fractures, physical examination had a sensitivity of 48.2%, specificity of 84.9%, LR+ of 3.19, and LR- of 0.61. For "clinically significant" fractures, exam had a sensitivity of 78.6%, specificity of 83.4%, LR+ of 4.73, and LR- of 0.26. For fractures requiring surgical management, exam had a sensitivity of 100%, specificity of 82.9%, LR+ of 5.85, and LR- of 0.
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. The authors do not provide the checklist used in their standardized assessment of the TL spine. They also provide no evaluation of inter-rater reliability for this checklist. While a physical examination (including neurologic exam) is routinely performed when assessing blunt trauma patients in our institution, more knowledge of the components of this testing and its reliability are needed to assess its reproducibility.
B.	Are the results applicable to the patients in my practice?	Yes. This study was performed in a level 1 trauma center, much like ours. The reported breakdown of mechanism of injury seems similar to what we see, and it is likely that the patient population is quite similar as well.
C.	Will the results change my management strategy?	No. This study was severely limited by its observational nature. Not all patients enrolled underwent evaluation by CT scan, which is the primary component of the "gold standard." The overall likelihood ratios for "clinically significant" injury are moderately helpful; specifically, the negative LR was 0.26, suggesting a moderate decrease in probability of disease, which may be helpful in young patients

		suffering a low-risk injury mechanism. On the other hand, when considering only need for surgical intervention as the outcome, physical exam had a negative LR of 0, which is extremely helpful. Given that there is some evidence that TLSO bracing is not clinically useful (Bailey 2014), this finding may suggest no need for imaging in patients with a negative exam. Overall, additional research will need to identify low-risk patients in whom a negative physical exam precludes the need for imaging.
D.	Will patients be better off as a result of the test?	Uncertain. Given that the "test" is a physical exam, then yes, all patients benefit from being examined. As noted above, the authors used need for surgical intervention or TLSO bracing as their definition of a "clinically significant" injury. Given that there is some evidence that TLSO bracing is not clinically useful, future studies may need to revise this definition.

Limitations:

1. Only patients with any clinical signs underwent CT evaluation of their spine. Given that CT was the only imaging modality and hence the only way to identify a fracture, this represents [partial verification bias](#) which could falsely inflate sensitivity and decrease specificity.
2. Radiologists who interpreted CT images were not blinded to physical exam findings.
3. 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 ([Bailey 2014](#)), suggesting this may be an inappropriate outcome measure.
4. [Likelihood ratios](#)—which provide much more clinically meaningful data than sensitivity, specificity, and negative/positive predictive values—and [confidence intervals](#) were not calculated or provided by the authors.
5. The authors do not provide the checklist used in their standardized assessment of the TL spine. They also provide no evaluation of [inter-rater reliability](#) for this checklist.

Bottom Line:

This prospective, observation study concludes that physical exam findings alone are insufficient to rule out thoracolumbar spine injuries. Unfortunately, the study suffers from issues with its primary outcome ("clinically significant" injury) given that there is debate as to whether TLSO braces are beneficial in patients with burst fractures. When looking at need for surgical intervention alone, physical exam was 100% sensitive (LR- 0) making it more than adequate to rule-out such injuries. The study was rather small, suffered from lack of blinding of radiologists and partial verification bias, and did not take into account mechanism of injury as a risk factor for thoracolumbar fracture.