# LETTERS TO THE EDITOR

## Prospective Validation of Out-of-hospital Spinal Clearance Criteria: A Preliminary Report

*To the Editor:*—Spinal cord injury is one of the most devastating potential outcomes of trauma. The annual incidence of spinal cord injuries in the United States is estimated to be between 8,000 and 10,000 new cases.[1,2] Out-of-hospital spinal immobilization is performed to prevent new or worsened spinal cord injury during transportation in patients with unstable spinal fractures. There are currently no widely accepted clinical criteria in use to determine which patients require spinal immobilization and which ones can be transported to the hospital for evaluation without immobilization. This decision is currently made primarily based on the mechanism of injury.

While the literature supports using criteria to clear the spine clinically in the ED,[3] the out-of-hospital use of these criteria by paramedical personnel has not been validated. There may be factors such as variability of provider skill, scene distractions, or time proximity of injury to patient contact making an assessment at the scene unreliable.

Our retrospective analysis of out-of-hospital documentation of clinical indicators of spinal fracture demonstrated that essentially all patients with significant spinal fractures had an alteration in mental status (AMS), evidence of intoxication (EOI), spinal pain or tenderness (SP&T), neurologic deficit (ND), or a significant distracting painful injury (DPI) documented on the out-of-hospital record.[4] The cases in which DPI was the only clinical finding present all had a suspected extremity fracture proximal to the hand or foot, which was later confirmed in the ED.

The objective of this study is to prospectively assess whether the absence of all of the above retrospectively identified criteria can be used to identify out-of-hospital trauma patients without a significant spinal fracture. This report serves as an interim evaluation of an ongoing prospective test performance validation study.

### Methods

*Study Design:* We performed a multicenter, prospective, out-of-hospital, observational study to estimate the test performance of key historical and physical findings for prediction of spinal fractures. The current out-of-hospital treatment of the study population was not changed for the purpose of this study. The decision to perform spinal immobilization was based on mechanism of injury. By local EMS system protocol, any patient with a mechanism of injury that could potentially cause a spinal fracture or cord injury was immobilized. The study was approved by the St. Joseph Mercy Hospital Clinical Research Committee, the Washtenaw-Livingston County Medical Control Board, and the University of Michigan Medical Center Institutional Review Board (IRB). Similar IRB approval was obtained at other participating centers. No consent was necessary given the observational design.

*Study Population:* Patients of any age with atraumatic injury, who had spinal immobilization performed in the out-of-hospital setting using a backboard or other spinal immobilization device, were eligible for inclusion in the study. Only patients transported by participating air or ground out-of-hospital personnel to a participating hospital were included in the study. Patients who sought initial medical attention on a delayed basis and who were immobilized and brought by ambulance from home or other out-of-hospital settings also were included. Potential spinal fractures at all levels were included.

Patients found to have nontraumatic pathologic fractures or nontraumatic pathologic spinal cord injuries (e.g., due to neoplasm) were excluded. Also patients determined from the hospital chart outcome review to have been transported from a site other than a out-of-hospital scene, such as another hospital, ambulatory care center, or physician's office, were excluded. Patients for whom outcome information was not obtained also were excluded.

Study data were collected by 6 ambulance services transporting to 7 hospitals in 3 counties in southeastern Michigan. Three of the hospitals treat major trauma patients, including spinal cord injury patients. The other 4 hospitals transfer spinal injury patients to 2 of the trauma centers included in this study. All study sites service a mix of urban and rural populations. A mixture of basic, advanced, and air ambulance transporting services participated in the study.

Data collection began April 1, 1994. This preliminary report describes the first 2,102 completed cases, entered between April 1 and December 21, 1994. We estimate that 10,000 cases will be needed to capture our target of 100 cervical fractures.

*Measurements:* Out-of-hospital transporting ambulance personnel completed a standardized data questionnaire for all patients who met the study inclusion criteria (i.e., sustained an injury warranting standard spinal immobilization). Data items included mechanism of injury and the study variables (AMS, EOI, SP&T, ND, and DPI). The presence or absence of each data point was noted on a checkoff data sheet as determined by the out-of-hospital personnel examining the patient. Response options were yes, no, and unknown. Narrative descriptions of any DPIs also were noted.

All participating out-of-hospital personnel were trained on the study and data questionnaires. They were instructed to determine the presence or absence of each data point based on the initial patient evaluation. Definitions or instructions as to how to determine the presence or absence of each data point were limited to the following: AMS represented a patient who was not alert and oriented to person, place, and time; EOI was based on the smell of alcohol, history of intoxicant intake, or behavior consistent with intoxication; and other DPI was typically a long-bone fracture. As above, the per-

**TABLE 1** Frequency of Clinical Findings in Patients with and without Spinal Fractures

| Clinical Finding | Patients without Spinal Fracture (*n* = 2,034) | Patients with Spinal Fractures (*n* = 62) | Sensitivity | Specificity | PPV* | NPV* |
|---|---|---|---|---|---|---|
| Loss of consciousness | 256 (13%) | 15 (24%) | 27.3 | 86.1 | 5.5 | 97.5 |
| Altered mental status | 319 (16%) | 19 (31%) | 31.2 | 84.1 | 5.6 | 97.6 |
| Evidence of intoxication | 240 (12%) | 13 (21%) | 22.8 | 88.1 | 5.1 | 97.6 |
| Cervical spinal pain | 509 (25%) | 12 (20%) | 22.2 | 74.3 | 2.3 | 97.2 |
| Cervical spinal tenderness | 271 (13%) | 5 (8%) | 10.0 | 85.6 | 1.8 | 97.3 |
| Thoracic spinal pain | 247 (12%) | 20 (32%) | 37.7 | 87.5 | 7.5 | 98.1 |
| Thoracic spinal tenderness | 143 (7%) | 12 (19%) | 26.7 | 92.5 | 7.7 | 98.2 |
| Lumbar spinal pain | 322 (16%) | 20 (32%) | 37.7 | 83.1 | 5.9 | 98.1 |
| Lumbar spinal tenderness | 173 (9%) | 13 (21%) | 28.3 | 90.8 | 7.0 | 98.1 |
| Focal neurologic deficit | 103 (5%) | 7 (11%) | 12.5 | 94.8 | 6.4 | 97.5 |
| Long-bone extremity fracture | 103 (5%) | 11 (18%) | 18.0 | 95.0 | 9.6 | 97.5 |

*PPV = positive predictive value; NPV = negative predictive value.

sonnel were instructed to detail any potential DPI.

The completed data questionnaires were left in the ED of the receiving facility, or given to the ambulance supervisor for distribution and follow-up. Outcome data points were determined by medical record review. Outcome data elements included: presence or absence of spinal fracture or spinal cord injury, location of fracture when present, and treatment. This review was done by a physician or nurse designated by the study site coordinator. Patients with spinal fractures or spinal cord injuries were reviewed by the study site coordinator or the principal investigator. Admitted patients had their medical records reviewed at the completion of hospitalization to confirm that the patient met the inclusion criteria and to determine the presence or absence of spinal fracture or injury. The diagnosis of a spinal fracture required positive radiographic evidence. A significant spinal fracture was defined as any documented spinal fracture necessitating rigid stabilization or surgery. The presence of a spinal cord injury required documentation of this diagnosis by an appropriate specialist. Patients whose spines were cleared clinically in the ED were assumed to have no fracture.

*Data Analysis:* The principal investigator or trained designee reviewed and edited all data. The data were coded and entered into a Paradox for Windows V. 4.5 database (Borland International Inc., Scotts Valley, CA). Statistical evaluation was done using SAS for Windows V. 6.08 (SAS Institute Inc., Cary, NC).

Using the presence of ≥1 study criterion as a positive test and the presence of any spinal fracture (except sacral) or spinal cord injury as a positive outcome, the sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated for each of the out-of-hospital criteria examined individually. Out-of-hospital clinical data points listed as "unknown" were assumed to be positive during test performance analysis of fracture capture rates. However, when determining whether a specific spinal fracture patient had a single clinical finding, we excluded those cases where a finding was reported as "unknown."

The data were then reviewed to determine the group of criteria with the highest sensitivity and NPV for spinal fracture or injury and whether the absence of the proposed criteria could exclude the presence of a significant spinal fracture or injury. Ninety-five percent confidence intervals were calculated for the criteria groupings.

## Results

For this preliminary report, a total of 2,102 complete cases were reviewed. Six patients were excluded due to death prior to radiographic spinal assessment. All had AMS present. Of the remaining 2,096 patients, 859 (41%) were cleared clinically in the ED without obtaining any spinal radiographs. By spinal region: 967 (46%) did not have cervical radiographs, 1,809 (86%) did not have thoracic radiographs, and 1,721 (82%) did not have lumbar radiographs obtained, being cleared of spinal fracture or injury based on ED clinical assessment.

A total of 66 spinal fractures were present in 62 (3%) of the 2,096 patients. There were 19 cervical, 22 thoracic, and 25 lumbar fractures. There were 1,035 males and 1,061 females in the study population. Overall, the patients with spinal fracture were slightly older (mean age 41.8 vs 34.6 years; p = NS). In women, the spinal fracture patients were significantly older (51.8 vs 37.9 years; $p < 0.003$). Among the spinal fracture patients, the women were significantly older (51.8 vs 35.1 years, $p < 0.0005$). In these spinal fracture patients, the male:female ratio was 1.5:1.

Table 1 shows the individual test performance features of various clinical findings. Of the 62 patients with spinal fractures, only 10 had only 1 clinical finding present. There were 5 patients with either lumbar spine pain or tenderness, 2 with suspected long-bone extremity fracture, 1 with evidence of intoxication, and 2 with cervical or thoracic spine pain, respectively. The features of loss of consciousness, cervical tenderness, and thoracic tenderness were never present as the only clinical finding.

By retrospectively examining various groupings of the clinical findings, we were able to identify a maximum of 59 of the 62 (95%) patients with spinal fractures (Table 2). The combination of AMS, FND, EOI, SP&T, and DPI produced the highest sensitivity and NPV. Adding loss of consciousness did not improve sensitivity or the NPV and caused a decrease in the specificity of the criteria. No criteria were present for 768 (37%) of the patients, all but 3 without spinal fracture.

All 19 (100%) patients with cervical injury had ≥1 of the proposed out-of-hospital criteria present, as did 20 of 22 (90%) patients with thoracic injury and 24 of 25 (96%) patients with lumbar injuries. Of the 3 false-negative patients, 2 had stable thoracic compression injuries and 1 had a lumbar transverse process fracture. Two of the 3 were released from the ED. The third was admitted to the hospital for pain control and was discharged within 2 days.

### Discussion

The decision to perform out-of-hospital spinal immobilization has historically been based primarily on the mechanism of injury. Any patient with a mechanism of injury significant enough to potentially cause a spinal fracture is treated as if a spinal injury exists. Out-of-hospital personnel are instructed to assess neurologic function before and after spinal immobilization, but do not use clinical assessment to determine the need for immobilization.[5]

The state of Maine has implemented the use of a combination of mechanism of injury and clinical assessment to determine the need for out-of-hospital spinal immobilization.[6] Patients with a significant mechanism, such as a rollover motor vehicle crash, are immobilized as if they have a spinal fracture, while those without a significant mechanism, such as an ankle fracture without a fall, are not immobilized. Those patients with an indeterminate mechanism have a spinal injury assessment performed to determine the need for immobilization. Patients who have no spinal pain or tenderness, and who have a normal neurologic examination without conditions that would cause an unreliable examination, such as altered mental status, are treated as if they have no spinal fracture or injury. Patients who have positive findings on the clinical assessment are treated as if they have a spinal injury and have immobilization performed.

The Maine program was developed and implemented on a state level and has the benefit of providing liability protection to the out-of-hospital personnel performing an assessment under the state program. However, the Maine program was implemented without scientific out-of-hospital validation of the spinal clearance clinical criteria.

This study appears to be the first attempt to prospectively validate clinical criteria for determining the need for out-of-hospital spinal immobilization. To be useful, these criteria must capture all patients with unstable spinal fractures or those for whom movement, largely prevented by the use of spinal immobilization, could cause clinical deterioration by either initiating or exacerbating a spinal cord injury. Acceptable false negatives would be patients with stable fractures for whom immobilization is not necessary for treatment of the injury.

**TABLE 2** Sensitivity, Specificity, and Negative Predictive Value (NPV) with 95% Confidence Intervals for Combinations of Clinical Findings for Spinal Fracture

| Clinical Findings | Sensitivity | Specificity | NPV |
|---|---|---|---|
| Altered mental status or cervical, thoracic, or lumbar pain | 82.3% (72.8–91.8) | 48.2% (46.0–50.4) | 98.9% (98.3–99.5) |
| Any of the above or focal neurologic deficit | 83.9% (74.8–93.0) | 46.9% (44.7–49.1) | 99.0% (98.4–99.6) |
| Any of the above or suspected extremity fracture | 90.3% (82.9–97.7) | 42.9% (40.7–45.1) | 99.3% (98.7–99.9) |
| Any of the above or evidence or intoxication | 91.9% (85.1–98.7) | 38.6% (36.5–40.7) | 99.4% (98.9–99.9) |
| Any of the above or spinal tenderness (cervical, thoracic, or lumbar) | 95.2% (89.9–100.0) | 37.2% (35.1–39.3) | 99.6% (99.2–100.0) |
| Any of the above or loss of consciousness | 95.2% (89.9–100.0) | 32.7% (30.7–34.7) | 99.6% (99.2–100.0) |

The study clinical criteria correctly identified all significant spinal fractures. Of the 62 patients with spinal fractures, 31 were considered stable. Thirty-one required rigid immobilization or surgery for stabilization prior to hospital discharge and were considered unstable injuries. Only 3 of the 62 patients with spinal fractures were missed by the out-of-hospital clinical criteria. None of these patients would have been harmed had they been transported to the ED without spinal immobilization. Two of the 3 were released from the ED after fracture identification; 1 was admitted for pain control.

Spinal immobilization is not without complications. Head and low back pain caused by spinal immobilization has been well documented.[7–9] These findings when present in the ED can alter the clinical appearance of the patient and result in unnecessary radiographs. In addition, potentially detrimental effects on pulmonary function have been demonstrated.[10] There also have been case reports of spinal injury with neurologic deficit caused by attempts at immobilizing elder patients. Pressure sores caused by prolonged immobilization on a rigid spine board are another recognized complication.[11]

### Limitations and Future Questions

The out-of-hospital personnel were asked to use their initial evaluation of the patient to complete the out-of-hospital data sheet. However, patient care considerations require that they complete the form once they reach the hospital and have finished patient care duties. If the criteria findings change from the initial evaluation to the time the patient is left at the hospital, documentation bias could result. We have attempted to minimize this complication through study training sessions.

Interrater reliability was not addressed. It is hypothesized that if an injury is identified by the presence of a single criterion, then the presence of this criterion will not be subtle. To adequately evaluate interrater reliability, ≥2 out-of-hospital providers would need to do independent concurrent patient evaluations in the out-of-hospital setting. Such a procedure is impractical for this study. We did not compare data sheets with the information on the ambulance run sheet. Documentation requested on the data sheet was more specific than is typically available on the run sheet.

We did not determine whether patients with significant spinal fractures or injuries were brought to the hospital without immobilization. Review of trauma run records for the ambulance services in the Washtenaw and Livingston County area found that 75–85% of all types of trauma patients underwent spinal immobilization. With this high percentage of immobilization, we anticipated that almost all significant injuries transported by ambulance were immobilized.

The training level of our out-of-hospital personnel was not uniform. The specific training level of personnel filling out each out-of-hospital data sheet was not determined. Services in the study areas are a mix of basic, advanced, and air ambulance services.

Patients were missed due to failure of the out-of-hospital personnel to complete data sheets. During the first 6 months of the study, 60% of immobilized trauma patients had out-of-hospital data sheets completed. We have reported study compliance to the personnel and emphasized the potential benefit of the study. This effort has increased compliance with data collection, but it has never been >75% for a month. The compliance was roughly the same for basic life support (BLS) and advanced life support (ALS) transports. BLS and ALS transports are defined by the ambulance service, based on interventions in the field, and serve as a rough measure of severity of injury. Other measures of selection bias could not be evaluated as systematic information about patients without data sheets completed could not be obtained, other than that described above.

Surveillance for patients with asymptomatic fractures who were clinically cleared and later returned to the ED was not performed for this preliminary report. A search of the trauma, spinal injury, or medical record registries will be done at the completion of the study, and will include the entire study period, thus ensuring that no patient who was cleared either clinically or radiographically returned to a participating hospital at a later date with a missed spinal fracture.

When determining whether a specific spinal fracture patient had a single clinical finding, we excluded those cases where a finding was reported as "unknown." However, out-of-hospital clinical data points listed as "unknown" were assumed to be positive during test performance analysis of fracture capture rates. If these criteria are validated with further study, any patient for whom the out-of-hospital providers cannot accurately determine the presence or absence of any criterion would be treated as if it were present and the patient would be immobilized.

Further prospective validation of these criteria with a larger sample is needed prior to general implementation. In addition, implementation of the criteria will require additional personnel training related to a systematic spinal injury examination.

## Conclusion

In this prospective series of 2,096 patients having out-of-hospital spinal immobilization performed, 59 of 62 patients with spinal fractures were identified by the presence of either altered mental status, focal neurologic deficit, evidence of intoxication, spinal pain or tenderness, or a suspected extremity fracture proximal to the hand or foot. No significant fractures were missed. Presuming validation with further study, using the absence of these clinical criteria to obviate the need for spinal immobilization would have reduced the indication for spinal immobilization by 37% in this population.

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