# Prospective Performance Assessment of an Out-of-Hospital Protocol for Selective Spine Immobilization Using Clinical Spine Clearance Criteria

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**Study objective:** We determine whether the use of an emergency medical services (EMS) protocol for selective spine immobilization would result in appropriate immobilization without spinal cord injury associated with nonimmobilization.

**Methods:** A 4-year prospective study examined EMS and hospital records for patients after the implementation of an EMS protocol for selective spine immobilization. EMS personnel were trained to perform and document a spine injury assessment for out-of-hospital trauma patients with a mechanism of injury judged sufficient to cause a spine injury. The assessment included these clinical criteria: altered mental status, evidence of intoxication, neurologic deficit, suspected extremity fracture, and spine pain or tenderness. The protocol required immobilization for patients with a positive assessment on any of those criteria. Outcome characteristics included the presence or absence of spine injury and spine injury management.

**Results:** The study collected data on 13,483 patients; 126 of the patients were subsequently excluded from the study because of incomplete data, leaving a study sample of 13,357 patients with complete data. Spine injuries were confirmed in the hospital records for 3% (n=415) of patients, including 50 patients with cord injuries and 128 patients with cervical injuries. Sensitivity of the EMS protocol was 92% (95% confidence interval [CI] 89.4 to 94.6%) resulting in nonimmobilization of 8% of the patients with spine injuries (33 of 415). None of the nonimmobilized patients sustained cord injuries. The specificity was 40% (95% CI 38.9 to 40.5%).

**Conclusion:** The use of our selective immobilization protocol resulted in spine immobilization for most patients with spine injury without causing harm in cases in which spine immobilization was withheld. [Ann Emerg Med. 2005;46:123-131.]

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## INTRODUCTION

### Background

Spine immobilization as a precaution to prevent worsening of an unstable spine fracture or spinal cord injury has been the standard emergency medical services (EMS) treatment of trauma patients for more than 20 years.[1] Historically, the decision to perform spine immobilization has been based on the potential for spine injury as determined by the mechanism of injury.[2]

Although there is no proven benefit of spine immobilization, there is significant evidence of morbidity caused by the procedure itself. Immobilization has been demonstrated to cause back and head pain, resulting in an increased number of radiographs required to clear the spine in the emergency department (ED).[3-5] Rigid spine immobilization can also cause pressure-related tissue breakdown, restrict respirations, and, if used aggressively, actually cause spinal cord injury.[6,7]

### Importance

ED studies have confirmed the ability of clinical criteria to reliably determine the need for spine radiographs, although the majority of these have addressed only the cervical spine.[8-22] Hoffman et al[22] reported that only a small number of patients with cervical spine injury escaped capture using clinical clearance criteria in the ED.[22] Although the ED use of clinical spine clearance protocols has been reported,[23] the validity of using a similar protocol in the EMS setting has not been fully addressed. Relying on the results of studies from our institution,

**Editor's Capsule Summary**

*What is already known on the topic:*

Cervical traumatic injuries with or at risk for neurologic harm occur infrequently. To prevent this small risk, out-of-hospital care providers traditionally immobilized virtually all patients with trauma (suspected or real), which may have detrimental effects.

*What question this study addressed*

Can EMS providers in two counties in Michigan safely use a protocol to more selectively immobilize traumatized patients.

*What the study adds to our knowledge*

Despite educational attempts, 15% of trauma patients transported had no spine assessment documented in spite of potential need. When assessed, EMS providers immobilized 12% of patients not required by the protocol, and failed to immobilize 7% where that action was required. Thirty-three patients with spine column injury were not immobilized (either protocol failure or adherence failure); none had cord injuries detected. An estimated 39% of patients had immobilization withheld due to the protocol.

*How this might change practice*

This affirms the rare nature of cervical cord injury, and the barriers in performing EMS chart review-based research. It also confirms that changing providers' behavior - especially when a rare outcome is involved - is difficult.

Michigan's Washtenaw/Livingston Medical Control Authority develop an EMS protocol for selective immobilization.[24-26]

### Goal of This Investigation

This study investigated whether the use of an EMS protocol for selective immobilization resulted in appropriate immobilization without spinal cord injury associated with nonimmobilization.

## MATERIALS AND METHODS

### Study Design

This study prospectively examined outcome data on consecutive trauma patients who were evaluated using the southeastern Michigan EMS spine injury assessment protocol.

In October 1997, the Washtenaw/Livingston Medical Control Authority implemented a spine injury assessment protocol for determining which trauma patients had indication for spine immobilization. All EMS personnel received training in the appropriate use of this protocol. The spine injury assessment consists of 5 clinical criteria: altered mental status, evidence of intoxication, neurologic deficit, suspected extremity fracture, and spine pain or tenderness.

Complete this section on all patients with a mechanism of injury suggestive of potential for spine injury.

| INDICATOR POSITIVE | YES | CANNOT ASSESS | NO |
|---|---|---|---|
| Altered Mental Status | | | |
| Evidence of Intoxication | | | |
| Neurological Deficit | | | |
| Suspect Extremity Fracture | | | |
| Cervical Pain | | | |
| Cervical Tenderness | | | |
| Thoraco/Lumbar Pain | | | |
| Thoraco/Lumbar Tenderness | | | |
| **Spine Immobilization (check)** | **YES** | | **NO** |

**Figure 1.** Spinal injury assessment documentation table.

The training instructed the EMS personnel to complete the assessment only on trauma patients with a mechanism of injury with potential for causing a spine injury and to omit the assessment for patients with insignificant mechanisms. This method for determining the need for the spine injury assessment was the same method previously used to determine the need for spine immobilization.

EMS personnel documented each assessment using a table preprinted on the EMS patient record (Figure 1). The protocol required immobilization for a positive assessment, defined as such if any of the criteria were positive or if an assessment of any of the criteria could not be completed for any reason. EMS personnel did not need to complete the entire assessment after finding a positive indicator, nor did they need to immobilize the patient if all indicators were negative.

### Setting

We examined data from a 2-county, mixed, suburban/rural, EMS system with 5 hospitals (including 2 trauma centers accredited by the American College of Surgeons), with 2 ground-transporting advanced life support (ALS) ambulance services, and 28 nontransporting first-response services. Emergency response is single-tiered ALS with first-response support when indicated. All levels of provider use the selective immobilization protocol.

We examined records for consecutive trauma patients transported by ALS services to hospitals within the 2-county EMS system from October 1997 through September 2001. Only trauma patients with a documented spine injury assessment on the EMS patient record were enrolled in the study.

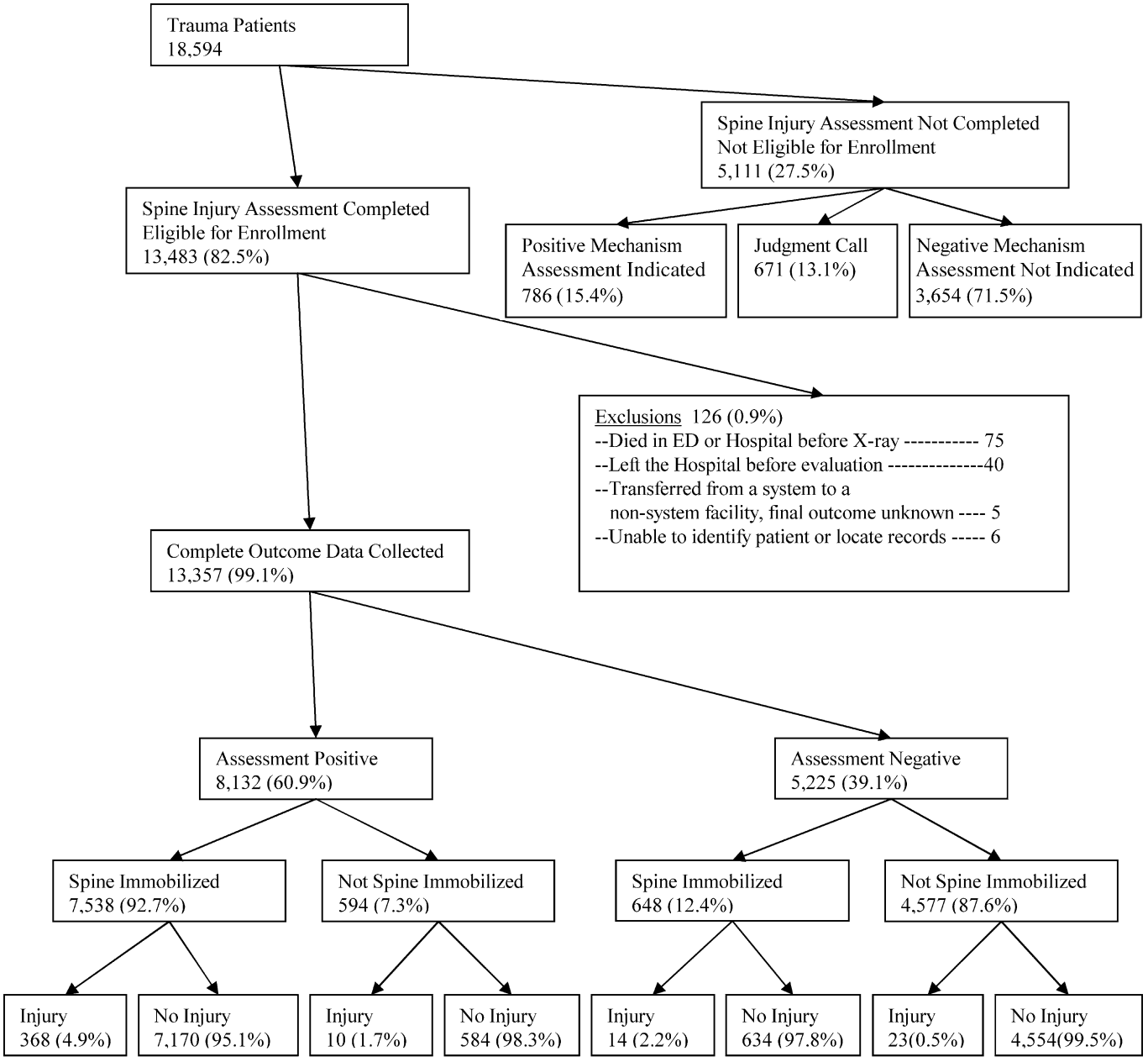



**Figure 2.** Compiled study results. Injury is defined as a spine fracture or spinal cord injury.

Trauma patients without a mechanism sufficient to trigger an assessment were not eligible for enrollment. Patients with incomplete outcome data and patients who died before hospital spine evaluation were excluded from the study.

EMS providers made the trauma-patient determination and included patients with any traumatic mechanism of injury. Many patients with this designation (for example, burns or isolated extremity trauma) had insignificant spine injury mechanisms.

**Data Collection and Processing**

The principal investigator reviewed all EMS patient records for the period of the study to enroll eligible patients. Outcomes were determined based on hospital records for enrolled patients. Data items abstracted from the EMS records included the patient's age, sex, and the mechanism of injury.

The spine injury assessment table completed by EMS personnel provided the evidence of spine injury assessment components, as well as the subsequent use (or nonuse) of spine immobilization. The study assumed the following based on the requirements of the assessment protocol:

- An assessment record with any indicator marked as positive or not able to be assessed was considered to be a positive spine injury assessment, even if other items in the assessment were missing.
- An assessment record with all indicators marked as negative was considered to be a negative spine injury assessment.

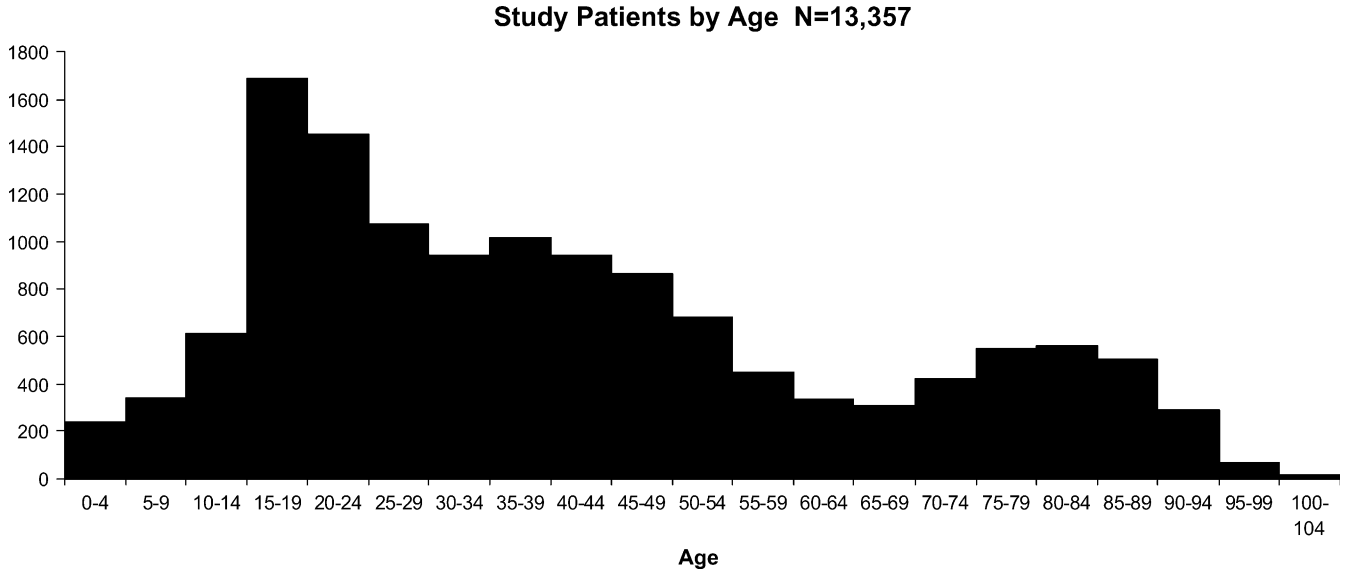



**Figure 3.** Distribution of study patients by age.

- If missing data precluded determining whether an assessment was positive or negative, the assessment was considered not to have been done.

The study relied on the patients' hospital records for evidence of the presence and location of spine fracture or spinal cord injury and, for patients with a spine injury, the data on the management of the injury.

Patients were assumed to be without injury if cleared clinically and discharged from the ED.

Spine injury was defined as the presence of a cervical, thoracic, or lumbar spine fracture or spinal cord injury. Sacral fractures were not considered spine injuries. A radiologist's report or specialist evaluation provided evidence of any diagnosis of spine fracture or spinal cord injury.

### Primary Data Analysis

We coded and entered the data into a Paradox 4.5 database (Orem, UT) and performed statistical analysis using SPSS 11.5 (Chicago, IL). The study considered a positive spine injury assessment as a positive test and the presence of a spine fracture or spinal cord injury as a positive outcome and calculated the sensitivity and specificity with 95% confidence intervals (CIs). As the study's primary outcome measure, the study considered spine immobilization as a positive test and the presence of a spine fracture or spinal cord injury as a positive outcome. We calculated sensitivity and specificity with 95% CIs.

To determine whether the omission of a spine injury assessment was appropriate, we completed a retrospective review of all EMS trauma patient records with no documented assessment. Based solely on whether we judged the mechanism of injury as having potential to cause a spine injury, we classified patients not given an assessment as (1) those with a significant mechanism of injury who should have received an assessment; (2) those with a negative mechanism for whom the assessment was withheld appropriately; (3) and those with a mechanism of injury for whom the need for assessment could be considered equivocal.

This study protocol was approved by the Washtenaw/Livingston Medical Control Authority, the Saint Joseph Mercy Hospital institutional review board and the University of Michigan institutional review board. The EMS selective spine immobilization protocol was approved by the Washtenaw/Livingston Medical Control Authority and the State of Michigan EMS Division.

## RESULTS

During the study period, 18,594 trauma patients were transported by our ALS services to hospitals within the EMS system. There were documented spine injury assessments for 13,483 of these trauma patients, making them eligible for enrollment in the study. Among this group, 126 patients were excluded from the study because of missing data, including 75 patients who died before radiographic evaluation, which left 13,357 patients with complete data (Figure 2).

Patients ranged in age from younger than 1 year to 104 years, with approximately 1,200 patients younger than 15 years and more than 2,700 patients 65 years and older (Figure 3). Spine injuries were present in 3% (415/13,357) of patients, with 12% of those patients (50/415) having a spinal cord injury. The cord injuries included 27% cervical (34 of 128), 10% thoracic (13 of 125), and 2.5% lumbar (4 of 162). Injuries at the T12, L1, or L2 levels accounted for more than 33% of all injuries. Injury distribution is presented in Figure 4 by the most cephalic spine level. Thirty-eight patients with spine fracture (9%) had a second, noncontiguous injury in a different area of the spine.

Positive assessments were documented for 61% (8,132/13,357) of patients, with immobilization not performed in 7% of these patients (594/8,132). Ten of these nonimmobilized

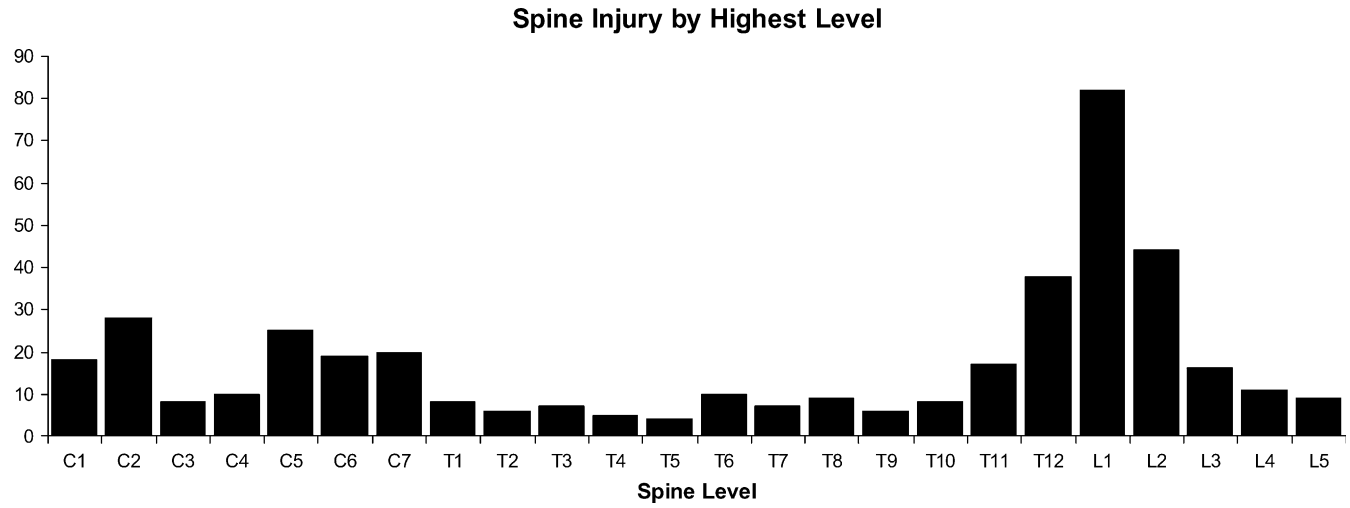



**Figure 4.** Spine injuries by level. Injury is defined as a spine fracture or spinal cord injury.

patients had a spine injury. All were treated conservatively, and none had a spinal cord injury (Figure 2).

Negative assessments were documented in 39% (5,225/13,357) of patients, with immobilization in 12% of these patients (648/5,225). Thirty-seven patients with negative assessments had spine injuries, and 14 of these patients had EMS spine immobilization. One patient with a negative assessment and immobilization was a young football player with a partial spinal cord injury. For this patient, "persistent stingers" were documented by EMS but misinterpreted as a negative finding on the assessment (Figure 4). Included among the 23 patients with negative assessments and withheld immobilization were 2 patients with high cervical fractures. These were C1 to C2 level injuries, without cord injury or morbidity, which were managed with halo immobilization. Both patients had minimal mechanisms of injury, and neither had other potential confounding injuries.

During the study period, there was no documented spine injury assessment for 27% of the trauma patients (5,111/18,594). A positive mechanism for spine injury occurred in 15% (786/5,111) of patients, and for these patients, an injury assessment should have been performed. A negative mechanism occurred in 72% (3,654/5,111) of patients, a group for whom an injury assessment was appropriately withheld. A mechanism of injury for 13% of the patients (671/5,111) was such that the need for assessment could be considered equivocal (Figure 2).

Spine immobilization was performed in 382 patients with a spine injury. Thirty-three patients were missed with application of the selective immobilization protocol (Figure 5). None of these missed patients were found to have a spinal cord injury. This group included the 2 patients with high cervical fractures, negative assessment results, and nonimmobilization. All other patients were treated conservatively for their injuries.

The spine injury assessment had a sensitivity of 91% (95% CI 88.3 to 93.8%) and a specificity of 40% (95% CI 39.2 to 40.9%). The primary endpoint, spine immobilization under the protocol, had a sensitivity of 92% (95% CI 89.4 to 94.6%) and a specificity of 40% (95% CI 38.9 to 40.5%). Immobilization was withheld from 39% of patients (5,171) based on the selective immobilization protocol (Table), which represents a nearly 39% reduction in spine immobilization in our EMS system compared with the previously used protocol.

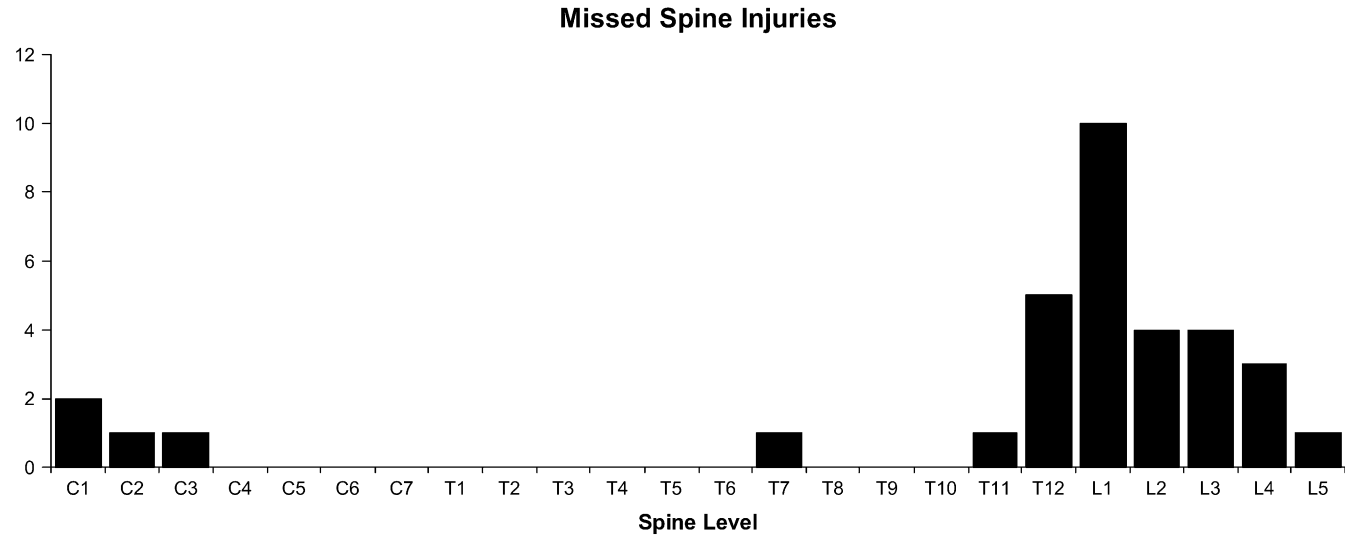
A sensitivity analysis was performed, adding the 786 patients with a positive mechanism and no assessment to our data set to assess their potential impact on the reported sensitivity of the protocol. The calculations were made assuming the same 3% fracture rate and 60% spine immobilization rate for these patients as reported for our data set. Using these assumptions, 24 additional injuries would be present. If none were captured by the protocol, the sensitivity would be 87% (95% CI 83.9 to 90.2%). If all were captured by the protocol, the sensitivity would be 92.5 (95% CI 90 to 95%).

## LIMITATIONS

There were 75 patients who were excluded from the study because of death before spine evaluation. No radiographs were obtained for these patients, and no autopsy reports were collected. All but 1 of these patients had EMS spine immobilization, making moot speculation that perhaps withheld immobilization and resultant spinal cord injury contributed to the deaths.

Not all spine injury assessments were recorded using the documentation table printed on the EMS patient record as instructed. An assessment should have been performed for 15.4% of patients who did not have it documented appropriately (Figure 2). Nearly all these patients were either immobilized or had immobilization withheld and justified based on an assessment documented in the narrative portion of the EMS patient record.

This study did not tabulate missing assessment data elements. After documenting a portion of the assessment as positive, indicating the need for immobilization, the EMS




| Age, y | Sex | Mechanism | Injury | Management |
|---|---|---|---|---|
| 58 | F | Fall: standing/sitting/supine | C1 ring, C2 odontoid | Halo |
| 86 | F | Fall: standing/sitting/supine | C1 ring, C2 odontoid | Halo |
| 91 | F | Fall: standing/sitting/supine | C2 lateral mass | Collar |
| 59 | M | Motorcycle | C3 body | Collar |
| 44 | M | Electrocution | T7 comp | TLSO |
| 74 | F | Fall: standing/sitting/supine | T11 comp | Pain control |
| 64 | M | MVA: unspecified | T12 burst, transv pro | TLSO |
| 59 | M | Pedestrian/MVA | T12 comp | TLSO: refused back board |
| 87 | F | Fall: standing/sitting/supine | T12 comp | Pain control |
| 68 | M | Fall: standing/sitting/supine | T12 comp | Pain control |
| 49 | F | Fall: height <10 feet | T12 comp | TLSO |
| 55 | M | Fall: height <10 feet | L1 body | TLSO |
| 45 | M | MVA front impact | L1 comp | TLSO |
| 70 | F | Fall: standing/sitting/supine | L1 comp | Unknown |
| 80 | F | Fall: stairs | L1 comp | Pain control |
| 84 | M | Fall: standing/sitting/supine | L1 comp | Pain control, physical therapy |
| 94 | F | Fall: standing/sitting/supine | L1 comp | LS corset |
| 99 | F | Fall: standing/sitting/supine | L1 comp | LS corset |
| 74 | F | Other known mechanism | L1, 2 comp | Pain control |
| 51 | M | Bicycle | L1, 2 transv pro | Pain control |
| 85 | F | Fall: standing/sitting/supine | L1, 3 comp | Pain control |
| 38 | M | Fall: height <10 feet | L2 burst | TLSO |
| 44 | M | Fall: height <10 feet | L2 comp | TLSO |
| 14 | M | Fall: height <10 feet | L2, 3 comp | TLSO |
| 52 | M | Fall: height 10–19 feet | L2, 3 trans pro | LS corset |
| 28 | M | Fall: height 10–19 feet | L3 body chip | Pain control |
| 72 | F | MVA, T-bone/side impact | L3 comp | TLSO |
| 79 | F | Fall: standing/sitting/supine | L3 comp | No treatment |
| 86 | F | Fall: standing/sitting/supine | L3 comp | Pain control |
| 72 | F | Fall: standing/sitting/supine | L4 comp | No treatment |
| 85 | F | Fall: standing/sitting/supine | L4 comp | Pain control |
| 88 | F | Fall: standing/sitting/supine | L4 comp | LS corset |
| 42 | M | Blunt personal injury | L5 ant/sup body | Pain control |

**Figure 5.** Missed spine injuries. *F,* Female; *LS,* lumbar support; *M,* male; *C,* cervical; *T,* thoracic; *comp,* compression; *transv pro,* transverse process; *l,* lumbar; *ant/sup,* anterior/superior; *TLSO,* thoraco-lumbar spinal orthosis; *MVA,* motor vehicle accident.

providers often marked the remainder of the assessment as not able to be assessed or left it blank. There were no negative assessments with missing data.

The reviewers were not blinded to the clinical findings and immobilization status before hospital record outcome review. By using strict definitions for spine fracture and spinal cord injury, we attempted to eliminate any potential bias introduced by this nonblinding. When an injury did not clearly meet the outcome definition, both investigators reviewed the case and reached agreement in all cases.

**Table.** Statistical analysis of selective immobilization protocol and spine injury assessment.

| Assessment | Injury | No Injury | Sensitivity | Specificity |
|---|---|---|---|---|
| Spine injury assessment | | | 91.0% (88.3–93.8%) | 40.1% (39.2–40.9%) |
| Spine injury assessment positive | 378 | 7754 | | |
| Spine injury assessment negative | 37 | 5188 | | |
| Immobilization protocol | | | 92.0% (89.4–94.6%) | 39.7% (38.9–40.5%) |
| Immobilization positive | 382 | 7804 | | |
| Immobilization negative | 33 | 5138 | | |

The retrospective review of EMS records without assessment served as a rough evaluation of one aspect of protocol compliance, the only criterion being our evaluation of the mechanism of injury. There were no objective criteria for this review, and there was no evaluation of interrater reliability. Furthermore, we did not review study patients for whom a spine injury assessment was performed to determine whether the assessment was in fact indicated based on the mechanism of injury.

Surveillance for patients who were cleared clinically in the ED and later returned with spine injury was not done for this patient population. We have previously reported on a surveillance of several thousand such patients with clinical or radiographic clearance. None of the patients returned with a missed injury after initial ED clearance.[25]

The calculated reduction in spine immobilization for our system was based on the assumption that the group undergoing assessment in this study was similar to those who had spine immobilization in our previous report.[25] Previously, EMS providers had been instructed to immobilize all patients with a mechanism that under the current study would require an injury assessment. Despite variations in protocol compliance and immobilization practice, the reported reduction in immobilization does agree with our predicted potential reduction of 39%.[25]

## DISCUSSION

Our selective immobilization protocol[27] asks EMS providers to evaluate patients for the presence of a mechanism of injury sufficient to cause spine injury and perform a spine injury assessment in these patients. The spine injury assessment consists of an evaluation of these 5 clinical criteria:

- altered mental status
- evidence of intoxication
- a suspected extremity fracture proximal to the wrist or ankle
- neurologic deficit
- spine pain or tenderness

The first 3 criteria establish that the patient is alert and can give a reliable examination. The last 2 are clinical signs of a spine or spinal cord injury. Patients with a sufficient mechanism of injury and who have positive results for any one of these 5 criteria should be immobilized. Those who have negative results for all criteria may have immobilization withheld.

Distracting painful injury is commonly used as a criterion in spine-assessment algorithms.[28] Based on our previously published work, we have narrowed the definition of distracting painful injury to suspected extremity fracture.[24,25] We have not found other painful injuries that have been present as the only clinical finding in EMS patients with spine injury.

Although the EMS providers were instructed to perform spine immobilization based on the spine injury assessment, this did not universally occur. We evaluated protocol compliance using a comparison of assessment results with immobilization practice and, secondarily, based on a retrospective evaluation of trauma patients for whom the assessment was not documented. There were significant deviations between the treatment prescribed by assessment and that actually performed.

When evaluated as an isolated test, the assessment as documented missed a few more patients than did actual immobilization. One patient with a partial cord injury missed by the assessment was immobilized by EMS, but that patient's clinical findings were interpreted incorrectly by the EMS providers, who then completed a negative assessment based on that interpretation. Two significant cervical fractures were missed by the assessment, resulting in transport without immobilization. Although neither of these patients had an adverse outcome, these cases might raise questions about the general applicability of this protocol to all EMS systems. A study comprising a much larger number of patients would be needed to address that question; the possibility of an adverse event using this protocol cannot be totally excluded with this study.

There have been few evaluations of EMS selective spine immobilization reported by other groups. In a small evaluation of an out-of-hospital selective immobilization protocol, Muhr et al[29] reported a 33% reduction in immobilization compared to historic controls. This was a very small study and did not include an outcome evaluation. In a large retrospective analysis of a selective immobilization protocol, Stroh and Braude[30] reported 99% sensitivity for a protocol that included loss of consciousness and significant mechanisms of injury as additional criteria requiring immobilization.

Presumed benefits of out-of-hospital selective immobilization include reduction of unnecessary immobilization, with corresponding reduction in the patient discomfort and morbidity inherent to rigid immobilization using a backboard.[3] Considering the lack of proven benefit and the potential for significant injury from rigid immobilization, schemes to reduce EMS spine immobilization must be explored.

Our protocol for selective immobilization through the use of an EMS spine injury assessment performed well in a number of areas. The protocol enabled EMS providers to make logical

decisions about spine immobilization based on knowledge and patient clinical findings instead of caution and mechanism of injury alone. The selective immobilization protocol resulted in the omission of spine immobilization for 39% of the study patients. Although spine immobilization was not performed for some patients for whom it would have been appropriate, none of these patients had a spinal cord injury as an outcome.

This report, the largest prospective performance assessment of an EMS protocol for selective spine immobilization to date, is based on our previously developed and validated EMS spine injury clinical assessment criteria. The southeastern Michigan EMS spine injury assessment protocol allows for selective spine immobilization with a high degree of safety. The use of our selective immobilization protocol resulted in spine immobilization for most patients with spine injury and without causing harm because of withheld spine immobilization.

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*Author contributions:* RMD and SMF conceived and initiated the study. RMD performed all initial and injury medical record reviews and drafted the manuscript. SMF reviewed all EMS patient records and obtained all patient outcomes and reviewed the data, statistical information, and manuscript. KW was the statistical consultant for the study and reviewed the study design, performed the statistical analysis, and reviewed the manuscript. RMD takes responsibility for the paper as a whole.

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IMAGES IN EMERGENCY MEDICINE

*(continued from p. 114)*

**DIAGNOSIS:**

On presentation vital signs revealed temperature of 102° F. Physical exam revealed an otherwise healthy appearing female with erythematous pharynx and prominent tonsils without discharge. Uvula was midline. Limited cervical range of motion to the right and obvious tenderness to palpation anteriorly to the left neck were noted. Remaining exam was unremarkable. Blood work revealed WBC of 16.5 with left shift. Chemistry and coagulation panel were normal. A computed tomography (CT) scan with contrast of the neck was obtained (see Figure).

Contrast enhanced CT of the neck revealed a clot in the left internal jugular vein. The blood cultures grew *Fusobacterium varium*. The diagnosis of Lemierre syndrome was subsequently made.

Lemierre syndrome (septic thrombophlebitis of the internal jugular vein) results from complications of dental, pharyngeal or mastoid infections. Extension to the cavernous sinus is one of the feared complications. Etiology is due to anaerobic gram negative bacteria, primarily *Fusobacterium necrophorum*. In addition to routine blood work (CBC, chemistry and coagulation profile) radiographic evaluation may include contrast enhanced CT scan, MRI, or Doppler ultrasound of the affected vessel. Treatment includes prompt anticoagulation and antibiotics.