Multicenter Prospective Validation of Prehospital Clinical Spinal Clearance Criteria

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Background: **Spine immobilization is one of the most frequently performed prehospital procedures. If trauma patients without significant risk for spine injury complications can be identified, spine immobilization could be selectively performed. The purpose of this study was to evaluate five prehospital clinical criteria—altered mental status, neurologic deficit, spine pain or tenderness, evidence of intoxication, or suspected extremity fracture—the absence of which identify prehospital trauma patients without a significant spine injury.**

Methods: **Prospectively collected emergency medical services data items included the above-listed criteria. Outcome data include spine fracture or cord injury, and also the level and management of injuries.**

Results: **A total of 295 patients with spine injuries were present in 8,975 (3.3%) cases. Spine injury was identified by the prehospital criteria in 280 of 295 (94.9%) injured patients. The criteria missed 15 patients. Thirteen of 15 had stable injuries, the majority of which were stable compression or vertebral process injuries. The remaining two would have been captured by more accurate prehospital evaluation.**

Conclusion: **Absence of the study criteria may form the basis of a prehospital protocol that could be used to identify trauma patients who may safely have rigid spine immobilization withheld. Evaluation of such a protocol in practice should be performed.**

Key Words: **Prehospital, Spinal, Clearance.**

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Spine immobilization for trauma patients is one of the most frequently performed prehospital procedures, with an estimated 1.9 to 2.4 million immobilizations performed yearly.[1] The decision to perform immobilization historically has been made largely on the basis of the mechanism of injury. Immobilizations are performed under the supposition that this procedure will prevent or avoid exacerbation of spinal cord injury during the handling and transportation of field trauma patients.

There is a large body of literature supporting the use of specific criteria to clear the spine clinically, without a radiograph, in the emergency department.[2–15] Most recently, the large NEXUS trial by Hoffman et al. has validated the use of clinical spinal clearance criteria in the emergency department (ED).[16]

In a retrospective study of multiple prehospital clinical indicators of spine injury, we demonstrated that 100% of patients with cervical injuries, 99% with thoracic injuries, and 97% with lumbar injuries had at least one of the following criteria documented on the prehospital record: an alteration in mental status, evidence of intoxication, spine pain or tenderness, neurologic deficit, and a significant distracting painful injury (DPI),[17] similar to those of the group reported by Hoffman et al. The cases in which DPI was the only clinical finding present all had prehospital suspected extremity fracture proximal to the hand or foot. This study provided the five prehospital clinical criteria for the current prospective study. The objective of this study was to prospectively validate that the absence of specific criteria (alteration in mental status, evidence of intoxication, spine pain or tenderness, neurologic deficit, or suspected extremity fracture) can be used to identify prehospital trauma patients without a spine injury and who do not require prehospital rigid immobilization.

PATIENTS AND METHODS

Study Design

This study was a multicenter, prospective, observational study of trauma patients who underwent full spine immobilization in the prehospital setting.

Study Setting

Seventeen hospitals and 23 transporting ambulance services in seven mixed urban/suburban/rural counties in south-

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ern Michigan participated in the study. A mixture of basic, advanced, and air ambulance services participated in the study. Hospitals involved varied from rural community hospitals to community teaching hospitals and American College of Surgeons–verified trauma centers.

Study Population

Patients of all ages with traumatic injury and spine immobilization performed in the prehospital setting using a backboard or other spine immobilization device were eligible for inclusion in the study. The decision to perform spine immobilization of trauma patients in the study areas was not altered for the study and was made on the basis of local emergency medical services (EMS) system protocols. All prehospital spine immobilization protocols in place at the time of the study were largely standardized and approved by the State of Michigan EMS Division. Mechanism of injury sufficient to cause a potential spine injury required immobilization in these protocols. Blunt trauma, either motor vehicle crashes or falls, accounted for the vast majority of patients.[18]

Patients transported by a participating air or ground prehospital provider to a participating hospital were eligible for inclusion in the study. Patients obtaining initial medical attention for a traumatic injury on a delayed basis at one of the participating hospitals who were immobilized and transported by ambulance from home or other out-of-hospital settings were also included. Patients transported from a site other than a prehospital scene, such as a hospital, ambulatory care center, or physician's office, or for whom outcome information could not be obtained or patients who died before hospital spine evaluation were excluded.

Study Period

Data were collected between April 1, 1994, and October 31, 1996. This study was conducted with the predetermined endpoint of entering sufficient patients to include a total of 100 cervical spine injuries.

Study Methods

Prehospital transporting ambulance providers were instructed to complete a standardized data questionnaire for all patients who met inclusion criteria. Data items including patient demographics, mechanism of injury, and presence or absence of the study clinical clearance criteria (altered mental status, focal neurologic deficit, evidence of intoxication, spine pain or tenderness, or suspected extremity fracture) were recorded on a check-off data sheet completed by the prehospital personnel examining the patient. Response options for each element were yes, no, and unknown. Mechanism of injury was entered using check-off boxes for common mechanisms and narrative entry for uncommon mechanisms.

All participating prehospital personnel were provided a brief didactic training session designed for orientation to the study and data collection sheet before enrolling patients. Participating ambulance service licensure varied from basic to air medical. Participants were to determine the presence or absence of each data point and complete the data sheet on the basis of the initial patient evaluation. Dislocations were included in the definition of suspected extremity fracture. Specific written definitions for each of the study criteria were not distributed.

Outcome data points were determined by medical record review. Outcome data elements included presence or absence of spine fracture or spinal cord injury, location of fracture if present, and inpatient or outpatient treatment. This review was performed by a physician or nurse designated by the study site coordinator. Patients with spine fracture or spinal cord injuries were reviewed by the study site coinvestigator or the principal investigator. All admitted patients had their medical record reviewed at the completion of hospitalization to confirm that the patient met the inclusion criteria and to confirm the presence or absence of spine injury.

Spine injury was defined as the presence of a cervical, thoracic, or lumbar spine fracture or spinal cord injury. Sacral fractures were not considered as spine injuries. The presence of a spine fracture was determined by positive radiographic evidence of an acute spine fracture on the basis of a radiologist's report. Presence of a spinal cord injury was determined by an appropriate specialist evaluation documented on the medical record. Patients without radiographic or specialist medical record documentation of a spine fracture or spinal cord injury were considered to have no spine injury. Patients with multiple levels of spine injury were classified according to the level of the most cephalad spine injury. Patients who were cleared clinically (without radiographs) in the ED were assumed to have no spine injury. Although not blinded to the prehospital evaluation, all chart reviews were conducted using the above criteria.

Surveillance to find patients who were cleared clinically and discharged from the ED but in fact may have had missed spine injuries was performed on study completion. Hospital medical record registries were searched for patients with spine injury that presented to participating spine injury treatment facilities during the study period. Our study database was searched for each of these patients to ensure no patient returned for treatment of a spine injury who was initially cleared clinically at a participating emergency department.

Statistical Analysis

The principal investigator or trained designee reviewed and edited all data. Abnormalities were investigated through the appropriate participating hospital or ambulance service. The data were coded and entered into a Paradox 4.5 database (Orem, UT) and analysis performed with SAS 6.08 (Cary, NC).

Using the presence of any of the study criteria as a positive test and the presence of any spine fracture or spinal cord injury as a positive outcome, the sensitivity, specificity, and positive and negative predictive values were calculated

for each of the prehospital criteria examined. Patients for whom the prehospital personnel were unable to assess a specific data point and for whom "unknown" was entered were assumed to have the finding present. Unknowns were treated in this fashion, thinking forward to an operational protocol in which patients who are unable to be assessed must be assumed to have positive findings to avoid missing spine injuries. Cases in which the prehospital evaluation of an individual criterion was listed as unknown were excluded from the individual criterion statistical evaluation. Sensitivity, specificity, positive and negative predictive values, and 95% confidence intervals of the study criteria as a whole to select patients with spine injury were calculated.

The study has been approved or determined to be exempt from review 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 and all other participating centers. The study was determined to be exempt from review and informed consent because it was strictly observational and no practice change was made for the purposes of the study.

RESULTS

Participating prehospital providers completed a total of 9,170 patient data sheets. There were 195 cases excluded (Table 1), leaving 8,975 complete cases to serve as the study population. There were 295 (3.3%) patients with spine injuries, including 109 cervical, 86 thoracic, and 100 lumbar spine injuries. Table 2 lists the incidence of spinal cord injury by spine injury level.

The study population was evenly distributed by sex (50.5% female patients), with women being significantly older than men. Injured patients were more often older (mean age, 39.3 vs. 35.1 years; $p < 0.001$) and male (179 of 295 [60.7%]) (Table 3). Patients less than age 18 totaled 1,915. Thirty-five (1.8%) had spine injuries.

Table 4 lists the frequency of each clinical finding in patients with and without injury and shows the sensitivity, specificity, and positive and negative predictive values for each of the individual study criteria. Altered mental status and spinal pain were the most sensitive individual criteria.

Table 5 lists the number of spine injury patients in which only one clinical finding is present. Spine tenderness, evidence of intoxication, and focal neurologic deficit were least often present as a lone clinical finding in spine injury patients. Eight patients had a suspected extremity fracture proximal to the hand or foot as the only clinical criterion present. Thirty-five percent of the spine-immobilized patients had none of the study criteria.

Spine injury was identified by the presence of one or more criteria (altered mental status, evidence of intoxication, focal neurologic deficit, spine pain or tenderness, and suspected long bone extremity fracture) in 280 of 295 (94.9%) injured patients. The sensitivity, specificity, and positive and negative predictive values for the overall "study criterion" having at least one of the five prehospital clinical criteria present are listed in Table 6. Study criteria were not recorded as present in 15 patients with spine injury. These injuries are listed in Table 7. Two patients received more than basic immobilization or pain control for the treatment of their spine injuries. One patient had a cervical injury that required rigid immobilization. This patient would have been captured had a more thorough EMS history and examination been performed (see below). The second was a patient with multiple injuries including a hip fracture dislocation with an acetabular fracture. The patient's spine injury remained asymptomatic and was diagnosed on completing spine radiographs in the hospital.

Table 1 Exclusions

Reason for Exclusion	No. of Patients
Transported to nonparticipating hospital	76
Unable to identify patient from data sheet entries	51
Died in ED prior to spine evaluation	38
Unable to locate hospital records	11
Previous nonparticipating hospital evaluation	10
Patient refused transport or death on scene	5
AMA prior to ED evaluation	4

AMA, against medical advice.

Table 2 Spine Injury and Spinal Cord Injury Rates

	No. of Spine Injuries	Spinal Cord Injuries (%)
Cervical	109	41 (38)
Thoracic	86	10 (12)
Lumbar	100	6 (6)

Surveillance

Medical record registry searches were performed at the five spine injury treatment centers within the study area. These centers received 6,828 (74.5%) of the study patients initially and were the mostly likely centers to treat spine injuries that returned for treatment after initial clinical clearance. Four spine injuries were found on the medical record registry surveillance that were not identified during the initial medical records review. All were on admitted patients. They were missed on the initial medical record review but captured during the registry searches. There were no patients identified

Table 3 Comparison of Patients with and without Spine Injury by Mean Age and Sex

	No.	Without Spine Injury (yr)	No.	Spine Injury (yr)
All patients	8,680	35.1	295	39.3 ($p < 0.001$)
Male patients	4,447	32.8	179	37.7 ($p = 0.001$)
Female patients	4,528	37.2	116	41.8 ($p = 0.036$)

Table 4 Frequency of Clinical Findings in Patients with and without Spine Injury[a]

Clinical Finding	Patients without Spine Injury (n = 8,680) (%)	Patients with Spine Injury (n = 295) (%)	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
Altered mental status	1,462 (17)	109 (37)	37.2	82.8	6.9	97.5
Evidence of intoxication	963 (11)	52 (18)	18.4	88.7	5.1	97.0
Cervical spine pain	2,202 (25)	65 (22)	24.3	73.9	2.9	96.8
Cervical spine tenderness	1,088 (13)	42 (14)	17.1	86.4	3.7	97.1
Thoracic spine pain	1,037 (12)	84 (28)	31.9	87.7	7.5	97.6
Thoracic spine tenderness	607 (7)	55 (19)	23.1	92.5	8.3	97.6
Lumbar spine pain	1,345 (15)	113 (38)	43.0	84.0	7.8	97.9
Lumbar spine tenderness	727 (8)	78 (26)	33.2	91.0	9.7	97.9
Focal neurologic deficit	450 (5)	51 (17)	18.5	94.7	10.2	97.3
Long bone extremity fracture	719 (8)	68 (23)	23.1	91.7	8.6	97.2

[a] Patients in whom the prehospital clinical assessment listed a specific finding as unknown were excluded from that criterion analysis in this table.

who were clinically cleared in the ED and later returned to the hospital with a spine injury.

DISCUSSION

The earliest widespread standards for ambulance transport recommended spine immobilization for patients with symptoms suggestive of spine injury.[19] After reports of significant ED and hospital failure to recognize spine injuries were published, it was evident that clinical judgment alone was insufficient to determine which patients should have spine radiographs.[20] Clinical practice in the prehospital setting evolved toward universal immobilization when the mechanism of injury was sufficient to potentially cause spine injury. Generally, spine radiographs were obtained for all patients brought to the ED when prehospital spine immobilization had been performed.

There have subsequently been a number of ED studies that have confirmed the ability of clinical criteria to reliably determine the need for spine radiographs. The most recent of these from Hoffman et al. found only a small number of patients who escaped capture by the use of clinical clearance criteria in the ED.[16]

Many EMS systems are beginning to clear trauma patients from spinal immobilization on the basis of the established ED clinical criteria and a recently published National Association of EMS Physicians position statement.[21] Our group previously reported on a retrospective analysis of the prehospital records of patients diagnosed with spine injury that was used to derive the prehospital spinal clearance criteria tested in this study.[17] This report is the first large study to prospectively assess clinical criteria that determine the need for prehospital spine immobilization.

To be useful, these criteria must capture, with high sensitivity, patients with significant spine injuries. Although 15 spine injuries were missed by the study criteria, only 2 needed more than basic immobilization or pain control. Although many of these patients were discharged with braces, bracing in spine injury is often used for comfort and not because of instability. Using the requirement of more than basic immobilization or pain control for the treatment of a spine injury as the definition of an unstable injury, none of the other 13 injuries could be considered unstable.

Both of the injuries missed by the criteria were because of incomplete prehospital patient evaluations. The first patient had a C1-2 injury diagnosed in the ED. He was found to have three of the prehospital clinical criteria: evidence of intoxication, alteration in mental status documented on the prehospital record, and cervical pain documented on the hospital records. The second patient with a T6-7 subluxation sustained multiple trauma including a fracture dislocation of his hip with an accompanying acetabular fracture clearly meeting criteria for a suspected extremity fracture. Both of these patients would have been easily captured with a more accurate prehospital evaluation. No patient with a spinal cord injury as an outcome was missed by the study criteria.

DPI is commonly used as one of the ED clinical spine injury clearance criteria and is also used in the National Association of EMS Physicians spinal clearance criteria. Our study used suspected extremity fracture, including fractures or dislocation proximal to the wrist or ankle, as the definition of DPI on the basis of the results of our earlier retrospective study.[17] Of the 15 patients missed by our study criteria, no other type of distracting painful injury was present in num-

Table 5 Spine Injury Cases with Only One Clinical Finding Present

Clinical Finding	No. of Spine Injuries
Altered mental status	10
Lumbar spine pain	10
Suspected extremity fracture	8
Cervical spine pain	3
Thoracic spine pain	3
Lumbar spine tenderness	2
Evidence of intoxication	1
Cervical spine tenderness	1
Focal neurologic deficit	1
Thoracic spine tenderness	0

Table 6 Statistical Summary for the "Overall Study Criterion": Has at Least One of the Five Prehospital Clinical Criteria Used in Detecting Spine Injury

	%	(95% Confidence Interval)
Sensitivity	94.9	(91.7–97.1)
Specificity	35.0	(34.0–36.0)
Positive predictive value	4.7	(4.2–5.3)
Negative predictive value	99.5	(99.2–99.7)

bers or consistency suggesting importance in spine injury assessment. In a 2001 report on DPI, Ullrich reported only three ED patients with cervical fracture and DPI as the only criteria present. That study was unable to make any conclusions to clarify which types of potential DPIs might be important in the evaluation of spine injury.[22]

Prehospital clinical data points listed as unknown were assumed to be positive for statistical analysis of fracture capture rates. Any patient in which the prehospital providers cannot accurately determine the presence or absence of a criterion would be treated as if it were present and the patient would be immobilized.

For the assessment of the individual clinical findings, if a finding is listed as unknown, the patient was excluded from the assessment of the frequencies of the individual clinical finding (Table 4). In the individual clinical finding assessment, including unknowns as positive would skew the frequencies of these findings as positive. In a patient with altered mental status as the indication for immobilization, spinal pain and tenderness cannot be evaluated and would be indicated as unknown on the prehospital data sheet. Including these as positive in an assessment of spinal pain frequencies would give misleading results for these frequencies.

Spine immobilization is not without complications. Complaints of head and low back pain caused by spine immobilization are common and have been well documented.[23–25] These alter the clinical appearance of the patient and can result in unnecessary radiographs. In addition, detrimental effects of spine immobilization on pulmonary function have been demonstrated.[26] In the elderly, there have been case reports of spine injury with neurologic deficit resulting from immobilization. Skin breakdown and decubitus ulcers caused by prolonged immobilization on a rigid spine board are recognized complications and contribute to subsequent morbidity.[27]

The benefits of spine immobilization have been questioned. In a study of spinal cord injury rates in a system that did not use immobilization compared with a system that used standard immobilization protocols, there was a higher rate of cord injury in the system that used immobilization.[28] Mechanistic arguments suggest that a patient who does not have a spinal cord injury caused by the trauma, which was sufficient to fracture the spine, has essentially no chance of developing a spinal cord injury caused by routine handling and transport.[28] Although not without technical flaws, this study raised an intriguing question as to the true benefit of rigid spine immobilization. Further study will need to be performed to validate this bold and controversial hypothesis.

Paramedics involved in our study were trained in the use of the study instruments but were not given specific training in evaluation of the study clinical criteria. The patients with significant injuries missed by the study criteria were patients in which improved field evaluation might have ensured capture of the injury. Although no patient with a spinal cord injury as an outcome was missed by the criteria, 15 patients with spine fracture were missed by the study criteria. Before systems consider implementation, a determination of the ability of the local EMS providers and the consequences of missed injury should be made. In our study population of

Table 7 False-Negatives in Patients Based on Study Clinical Criteria[a]

Patient	Age/Sex	Mechanism	Injury	Management
1	71/M	Fall, unspecified	C1, 2, odontoid Fx	Halo, pain control
2	80/F	Fall, standing	C 2/3 subluxation, 3–4 mm	Philadelphia collar, outpatient Orthopedics follow-up
3	87/M	MVC, frontal	C3–5 spinous process, C6 laminar, C7 compression	Philadelphia collar
4	16/F	MVC, head-on	C6 anterior body fracture	Stiff neck collar
5	45/F	MVC, frontal	C6–7 facet Fx	Cervical thoracic orthotic brace
6	42/M	MVC, rollover	T3 compression Fx <25%	Cervical thoracolumbosacral orthotic brace
7	33/M	MVC, rear-end	T7 compression Fx	Pain control
8	47/M	MVC, head-on	T6/7 subluxation	Spine fusion
9	78/F	Fall, <10 ft	T11 compression Fx	Thoracolumbosacral orthotic brace
10	24/F	Fall, 10–19 ft	L1 transverse process Fx	Pain control
11	36/M	MVC, rollover	L1 anterior body Fx	Back brace
12	71/M	Fall, 10–19 ft	L1, 4 body Fx	Lumbosacral orthotic brace
13	88/M	Fall, unspecified	L2, 4, 5 compression Fx	Pain control
14	40/M	Fall, <10 ft	L2 pedicle Fx	Pain control
15	20/F	MVC, unspecified	L4 transverse process Fx	Pain control

Fx, fracture; MVC, motor vehicle crash.

[a] Fifteen injuries were missed by the criteria. Only patients 1 and 8 required more treatment than basic immobilization or pain control.

immobilized patients, no patient with a missed injury had an adverse outcome.

Implementation of the criteria will require additional EMS training to perform a spine injury clinical assessment using the criteria, as they currently do not routinely perform a clinical examination for assessment of potential spine injury. In clinical practice, the use of these clinical criteria to determine the need for spine immobilization could reduce the application of spine immobilization by 35% in our patient population. The implications for time and cost savings in the delivery of emergency care as well as patient comfort and safety are likely considerable.

Limitations

The prehospital personnel were instructed, during their study orientation, to use the initial evaluation of the patient to complete the prehospital data sheet. However, patient care considerations allowed data form completion only once the patient was delivered to the hospital. If the clinical examination of the patient changes from initial evaluation to the time the patient is left at the hospital, this could affect the way the data sheet is completed and introduce bias. Because of the time required in the ED to make the diagnosis of spine fracture, the EMS providers were essentially blinded to the patient outcomes.

Interrater reliability was not addressed. To adequately evaluate prehospital interrater reliability, two or more prehospital providers would have had to perform independent concurrent patient evaluations in the prehospital setting, which was impractical for this study.

There was no attempt to determine whether patients with spine 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% to 85% of all types of trauma patients underwent spinal immobilization. With system protocols that require spine immobilization in all patients with a mechanism of injury having the potential to cause a spine injury, it was assumed that all significant injuries transported by ambulance would be immobilized.

Training level of prehospital personnel is not uniform. The specific training level of personnel filling out each prehospital data sheet was not determined. Services in the study areas were a mix of basic, advanced, and air ambulance services.

Many eligible patients were not entered into the study because of failure of the prehospital providers to complete study data sheets. During the first 6 months of the study, 60% of immobilized trauma patients had prehospital data sheets completed. The compliance was roughly the same for basic life support and advanced life support level transports. Basic life support and advanced life support transports are defined by the ambulance service, on the basis of interventions in the field, and serve as a rough measure of severity of injury. The degree to which selection bias was present could not be assessed, as outcomes of patients without data sheets completed were not determined.

Surveillance for asymptomatic spine injuries that were clinically cleared and later returned to the emergency department was not performed for each individual patient. However, the search of medical record registries covered nearly 75% of the patients in the study and included the centers in the study region most likely to be involved with the evaluation of a patient with an initially missed injury. To a high degree of certainty, it is clear that there were no patients who were clinically cleared and discharged from an ED who later returned with an initially undiagnosed spine injury.

CONCLUSION

In this prospective series of 8,975 patients with prehospital spine immobilization performed, 280 of 295 patients with spine injuries were identified by the presence of at least one of the five study criteria: altered mental status, focal neurologic deficit, evidence of intoxication, spine pain or tenderness, or a suspected extremity fracture. The two patients with significant missed injuries might have been captured with a more accurate prehospital evaluation. Additional EMS provider training will be necessary to ensure accurate performance of a prehospital spine injury assessment using these criteria. Quality assurance mechanisms should be developed to ensure appropriate application of prehospital clinical spine clearance protocols. Evaluation should be performed using these criteria in an operational setting to validate their performance in the field.

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