Can an Out-of-Hospital Cervical Spine Clearance Protocol Identify All Patients With Injuries? An Argument for Selective Immobilization

Study objective: We sought to determine the sensitivity of the Fresno/Kings/Madera emergency medical services (EMS) selective spine immobilization protocol in identifying patients with potential cervical injuries. We also sought to determine whether the protocol was safe in the out-of-hospital setting.

Methods: We conducted a retrospective chart review of all patients discharged from 5 trauma-receiving hospitals in Fresno County with the diagnosis of cervical spine injury between July 1, 1990, and June 30, 1996. All of these patients transported to the hospital by EMS personnel were selected for the study group. Medical records of those patients not immobilized were further investigated to identify protocol violations or deficiencies.

Results: There were 861 patients with significant cervical injuries during this time span. EMS personnel brought 504 patients to the hospital, of which 495 arrived in cervical spine immobilization. Of the remaining 9 patients, 2 refused immobilization, and 2 could not be immobilized; 3 injuries were missed by the protocol criteria, and 2 injuries were missed because of protocol violations. Of these last 5 patients, 1 patient had an adverse outcome, 2 injuries were considered unstable, 4 patients were older than 67 years, and one patient was 9 months old.

Conclusion: The Fresno/Kings/Madera EMS selective spine immobilization protocol is 99% (95% CI, 97.7% to 99.7%) sensitive in identifying patients with cervical injuries for immobilization. Those patients not identified were at extremes of age. These results suggest that selective immobilization may be safely applied in the out-of-hospital setting but should be used with caution at extremes of age.

INTRODUCTION

Because of the high morbidity, mortality, cost of treating cervical spine injuries, and litigation concerns, strict out-of-hospital immobilization protocols have been developed throughout the country.1-5 In an attempt to minimize further damage during extrication, transport, and transfer to hospital emergency departments, emergency medical services (EMS) providers are trained in a multitude of techniques to prevent spinal movement, typically including application of a cervical collar, rotational support, a spine board, and securing straps. This is time-consuming, expensive, uncomfortable, and potentially dangerous.6-13 The rationale for this aggressive immobilization protocol includes the following: occult injuries are missed at initial out-of-hospital evaluation and are better identified on hospital arrival, and spinal immobilization prevents neurologic deterioration with unstable injuries. Most of the literature on this topic involves the emergency physician assessment to determine who does and does not need radiography.2,14-26 The Fresno/Kings/Madera (FKM) EMS system implemented a selective spine immobilization clearance protocol in 1990 (Figure). Our study was designed to determine the sensitivity and consequent safety of this protocol in identifying the need for immobilization in patients at risk for potentially significant cervical injuries.

MATERIALS AND METHODS

All patients between July 1, 1990, and June 30, 1996, with the discharge diagnosis of cervical spine fracture, dislocation, or spinal cord injury without radiographic abnormality (SCIWORA) were identified by using International Classification of Diseases, ninth revision (ICD-9) codes at 5 trauma-receiving hospitals in Fresno County, including the only Level I trauma center. Patients discharged with ICD-9 codes 805.00-805.18, 806.00-806.8, 839.00-839.18, or 952-952.09 were included. Computer record searches were performed in a similar fashion at all of the study hospitals. Retrospective chart and trauma registry reviews (at the Level I trauma center) were then performed to identify patients brought to the hospital by FKM EMS providers. All charts were reviewed by the 2 authors to determine whether patients arrived in spinal immobilization. Documents reviewed included out-of-hospital care reports, ED charts, and nursing documentation. Patients not immobilized were considered to have potential “missed injuries.” These patients’ records were reviewed in detail by the authors simultaneously by using a standardized data collection form. It was then determined by consensus whether criteria for immobilization (Figure) were in fact present or absent. The authors also determined by consensus whether each missed injury was because of a misapplication of the protocol (“protocol violation”) or because of a deficiency in the protocol itself (“protocol miss”). The mode of arrival was determined by using the medical record, trauma registry, or out-of-hospital care reports. For the 11 patients whose mode of arrival could not be determined from these sources, an additional search of all FKM out-of-hospital care reports for their date of admission was performed. This produced 3 patients, all of whom were included in the study group. Patients not identified through this search were presumed to have arrived by means of private transport or with non-FKM EMS providers and were eliminated from the study.

Table 1.

Hospital data.

<table>
<thead>
<tr>
<th>Trauma Center</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients (No.)</td>
<td>548</td>
<td>139</td>
<td>140</td>
<td>30</td>
<td>4</td>
<td>861</td>
</tr>
<tr>
<td>Patients arriving by means of EMS (No.)</td>
<td>372</td>
<td>73</td>
<td>40</td>
<td>15</td>
<td>4</td>
<td>504</td>
</tr>
<tr>
<td>Patients with cervical spine immobilization (No.)</td>
<td>371</td>
<td>89</td>
<td>37</td>
<td>15</td>
<td>3</td>
<td>495</td>
</tr>
<tr>
<td>Patients without cervical spine immobilization (No.)</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>9</td>
</tr>
</tbody>
</table>
Patients transferred from other hospitals were eliminated to avoid counting the same patient twice. Patients transferred between hospitals with known injuries were also eliminated because EMS personnel were not required to apply the protocol. No changes were made to this protocol during the study period.

Our system has an emergency medical technician (EMT)-basic paired with an EMT-paramedic, and the paramedic is responsible for all patient care. Paramedics are licensed by the state of California, and EMT-basic personnel are certified by the county. All new personnel undergo an orientation to our system by the EMS authority. A continuous quality-improvement process is in place to identify errors in judgment, policy and protocol violations, and potential areas for system improvement. Continuing education sessions also occur regularly, at which EMS personnel are provided guidelines to follow when faced with terms that require judgment. For example, we explain what is considered severe facial trauma and significant multiple system trauma.

The sensitivity was calculated for the application of the EMS protocol to patients who ultimately were found to have cervical spine injuries. Calculation of 95% confidence intervals (CIs) was done with a statistics program (Inter Cooled Stata 5.0; Stata Corp, College Station, TX) and reviewed by a statistician. This study was approved by the Medical Control Committee of the FKM EMS System and the Institutional Review Board of Community Medical Centers and accepted by all participating hospitals.

RESULTS

A total of 861 patients were discharged from the study hospitals with cervical spine injuries. Of these, 357 were eliminated from the study, the vast majority of whom were interfacility or non-FKM EMS transports; 504 (59%) patients were transported by local EMS agencies subject to our protocols, and 495 of these were immobilized. Table 1 summarizes the hospital data. Of the 9 patients not immobilized, 2 refused immobilization against medical advice, and 2 could not be immobilized despite attempts, 1 because of severe kyphosis and one because of extreme combativeness. These 4 patients were not counted as missed injuries because there was a documented intent to immobilize. The remaining 5 patients (Table 2) summarized below had missed injuries. In 2 (0.4%) patients, the criteria for immobilization were present, but immobilization was not attempted (protocol violation). In 3 (0.6%) patients, the criteria were absent (protocol miss). By using the most conservative approach and including all 5 of these patients, 499 patients identified out of 504 total patients translates to a sensitivity of 99% (95% CI, 97.7% to 99.7%) for immobilization of patients with confirmed cervical injury.

Patient 1 was a 73-year-old man noted on the out-of-hospital care report to have muscular neck tenderness and hand and knee lacerations after a motor vehicle crash (MVC). The ED record reported neither. The patient was discharged and returned the following day because of a stiff neck. He was given a diagnosis of stable minor anterior wedge fracture to the body of C6 and a questionable fracture to the right posterolateral arch. He was treated with a cervical collar and had no neurologic deficits.

Patient 2 was a 9-month-old girl with head and facial trauma consisting of a contusion above the left ear after an MVC. This was noted on both the out-of-hospital care report and the ED chart. She returned 3 days later, with her mother saying she would not turn her head, and was then noted to have spinal tenderness. She was diagnosed by magnetic resonance imaging with an odontoid fracture that was considered unstable. She was treated with a body cast. There were no neurologic deficits.
DISCUSSION

Spinal immobilization is taught to out-of-hospital personnel as a fundamental concept of paramount importance. However, this practice is based on little objective evidence and more out of concern for the severe morbidity and mortality of cervical injuries, potential worsening of unstable injuries during extrication and transport, and the fear of unrecognized occult fractures. No one can argue with the morbidity and mortality of these injuries, which are particularly tragic because of the young age at which they often occur. It is clearly in everyone’s best interest to first prevent these injuries and then minimize any secondary damage that may occur.

The idea of the occult cervical injury underscores much of the current widespread use of immobilization. This has led to extremely conservative out-of-hospital spinal immobilization protocols on the basis of mechanism of injury alone. Concern that undetectable unstable cervical injuries occur and that failure to immobilize will allow injury progression has precluded broad acceptance of selective cervical immobilization. By contrast, we do not advocate that all extremities be splinted on trauma patients but rely on assessment skills to make these decisions. It is interesting to note that there has never been a reliable case report of a truly occult cervical injury in the literature.

Hauswald et al41 questioned the entire concept of cervical immobilization. In a comparison of matched outcomes between patients in Malaysia, where no patients were immobilized, and New Mexico, where all patients were immobilized, the outcomes were actually slightly better in Malaysia. They propose that spinal cord injury occurs as a result of energy transfer and not motion itself. Although there is a greater energy transfer at the time of impact, motion of the spinal column without resistance within its normal range of motion transfers minimal energy to the cord. Thus, cord injury is primarily the result of the initial impact. Secondary damage is caused by swelling, free radical formation, and other chemical mediators but is not the result of unrestricted movement. This notion challenges our current thinking, and more research in this area is needed. Several other studies have questioned the wisdom of routine spinal immobilization because of its inherent risks and morbidity, ranging from pain and discomfort to respiratory compromise, increased intracranial pressure, and actual worsening of symptoms. However, despite these studies, immobilization remains the standard of care for known or suspected cervical injuries.

Much has been written on the appropriate evaluation of trauma patients once they arrive at EDs. Initially, the emphasis was on protocol-driven radiographs for most, if not all, patients with blunt trauma. More recently, the focus has shifted to selective use of radiographs after physician clinical evaluation. The recently completed National Emergency X-Radiography Utilization Study (NEXUS) study, a large multicenter project, has provided a stronger evidence-based approach to the evaluation and treatment of these patients. However, research involving physicians in the relatively controlled setting of the ED does not necessarily apply to EMTs and paramedics in the out-of-hospital setting.

Patient 3 was a 68-year-old woman with no history of trauma who complained that her joints felt “locked up,” was biting her tongue, had speech problems, and had right shoulder and neck pain. She had a significant past medical history, including hypothyroidism, hypertension, myocardial infarction with pacer placement, congestive heart failure, dialysis-dependent renal failure, and diabetes. Because of limited arm mobility, she underwent radiography and was found to have a stable subluxation of C4 on C5 with possible compression myelopathy. She was treated conservatively with a neck brace with extension and physical therapy and had partial resolution of her symptoms.

Patient 4 was an 83-year-old man who tripped and fell while walking with a walker. He presented with a left-eye hematoma and forehead laceration noted on the out-of-hospital care report and spinal pain and tenderness noted by the emergency physician but not by EMS providers. He was found to have a small stable chip fracture to the body of C2 and was treated with a cervical collar. He had no neurologic deficits.

Patient 5 was a 76-year-old man who complained of back pain from the neck through the lumbar region several hours after chiropractic manipulation. He had a past history of a neck fracture 50 years previously. He reported progressive worsening of his pain over weeks, recently requiring the use of a walker. He had been ambulatory before his chiropractic visit that day, but shortly after returning home, he had increased pain and was no longer ambulatory. He was diagnosed with cervical cord dysfunction from a combination of cervical spondylosis, stenosis, degenerative disease, and displacement of an old nonfused unstable C2 fracture. He was treated with laminectomy, dens removal, and fusion from occiput to C4 and was discharged to a nursing home with residual quadriplegia.
There have only been a few clinical trials of cervical-immobilization practices in the out-of-hospital setting, all limited by the relatively small number of actual fractures. Domeier\(^43\) retrospectively studied clinical criteria that could identify patients with spinal injuries. They found that all 100 patients in their study with cervical injuries had either altered mental status, neurologic deficit, evidence of intoxication, spinal pain, or suspected extremity fracture. This was then prospectively studied, producing similar results, but with only 19 cervical fractures in the study population.\(^44,45\) The idea of EMS cervical spine clearance has also been studied by Brown et al.\(^46\) However, this study focused on the agreement between out-of-hospital EMS evaluation and the emergency physician evaluation and did not use radiography as a gold standard. Criteria used in the out-of-hospital setting for immobilization decisions have developed from a combination of expert opinion, advanced trauma life support guidelines, small EMS studies like those mentioned above, and extrapolation of ED research designed to identify those needing radiography.\(^2,14-26,47\)

Given the low incidence of cervical injuries and the even lower incidence of complications, a large number of fractures must be included to have sufficient clinical power to answer these questions definitively. Our study represents the largest study in the literature of out-of-hospital assessment of cervical injuries. We set out to answer the following questions: How sensitive are the FKM immobilization criteria in identifying patients with cervical injuries? Can out-of-hospital personnel accurately apply these criteria? Is implementation of a selective immobilization protocol safe?

The FKM spinal-immobilization protocol is notable in that it does not mandate immobilization by mechanism of injury alone, allows incorporation of spinal tenderness, and does not include a distracting injury criterion. Distracting injury would not have improved the sensitivity of our protocol unless the hand and knee lacerations and abrasions of patient 1 were considered distracting. However, Domeier et al.\(^48\) found 14 patients in their series in whom a distracting injury was the only indicator of a spinal injury. We recognize that inclusion of a distracting injury criterion is becoming accepted standard in out-of-hospital selective immobilization protocols.\(^49\) Although more research in this area is needed, we have in fact incorporated this criterion into the latest FKM immobilization protocol.

Fresno County has a mixed urban and rural population of approximately 1 million, with large Hispanic, Southeast Asian, and white groups, and serves the San Joaquin Valley with the only Level I trauma center between Sacramento and Los Angeles. Our 3-county EMS system transports approximately 75,000 patients per year, 27% of whom have trauma complaints. Of the 20,028 trauma patients transported between July 1995 and June 1996, the last year of our study, 7,077 had cervical immobilization, representing 35% of all trauma transports. On the basis of these estimates, our out-of-hospital clearance protocol was applied to approximately 42,000 patients during the study years. This results in immobilization of 85 patients for each one found to have a significant spinal injury. The vast majority of these patients were taken to the trauma-receiving hospitals included in the study and were available for review. For those patients with available demographics, 75% were male, 4% were less than 14 years old, and 7% were greater than 65 years old.

Of our 5 misses, 2 were attributed to a misapplication of the protocol by the paramedic and were considered protocol violations. Patient 1 was noted to have spinal tenderness yet was not immobilized because the cause of the tenderness was determined by the paramedic to be muscular. Nowhere in the protocol is there an allowance for EMS providers to diagnose the source of the tenderness. However, of note, this patient met no other criteria for immobilization, and the ED evaluation specifically documents no pain or tenderness. The distracting injury criterion, although not a part of our protocol during the study, would likely have missed this patient as well because his only other injuries were hand and knee lacerations and abrasions. Patient 5 presents a dilemma because he clearly complained of pain and neurologic dysfunction; however, the question remains whether chiropractic manipulation qualifies as trauma. If considered trauma, this remains a protocol violation. If not, this would become an injury missed by the protocol. We believe that the paramedic should have known to immobilize this patient because he documented an acute inability to ambulate after manipulation. This patient is also concerning because he represents the only patient who had an adverse outcome with residual quadriplegia. However, the extent of neurologic dysfunction did not change between the initial paramedic evaluation and the ED evaluation. Consequently, it seems unlikely that spinal immobilization would have changed the outcome in this situation.

Three patients with cervical injuries met none of the protocol criteria for immobilization (patients 2, 3, and 4). Patient 2, the 9-month-old child, had only minimal head trauma consisting of a contusion and hematoma above the left ear. Our protocol specifies severe head or facial trauma, and we believed this injury would not qualify under these criteria. This patient is especially concerning...
because she had the only unstable fracture in the group of patients missed by the protocol. Patient 3 clearly had neurologic complaints but no history of trauma and consequently was missed by the protocol because all of our criteria refer to the setting of trauma. Patient 4 was found to have both pain and tenderness in the ED but had none of the protocol criteria on the out-of-hospital examination and was therefore considered a protocol miss. The fact that the 3 patients missed by our protocol were at extremes of age, 9 months and 68 and 83 years, and that the 2 protocol violations were also elderly, 73 and 76 years old, gives rise to the idea of criteria modification on the basis of age. Many disease entities are more difficult to diagnose in the very young or very old because of atypical presentation or difficulties with communication, and our results lend support to the idea that this is also true for cervical injuries.

The 4 patients we eliminated from the study included 2 who signed against medical advice and 2 who were eliminated for technical reasons: 1 was the victim of a gunshot wound and was severely agitated, refusing any treatment except transport, and the other was an elderly patient with severe kyphosis, for whom backboard and collar could not be applied. The concept of mandating immobilization of all patients by protocol must also be questioned because some patients undoubtedly undergo deleterious effects as a result of this practice. This issue has been discussed before by Podolsky et al regarding a patient with ankylosing spondylitis whose symptoms worsened with a cervical collar.

There are a number of limitations to our study. The most significant is that because of its retrospective nature and the fact that paramedics are not required to document the specific indication for immobilizing each patient, we are unable to determine whether the protocol was actually followed correctly. Some patients may have been immobilized, despite not having an indication to do so by protocol. The fact remains, however, that many patients in our system are not immobilized as a result of this protocol, and the study results support making some allowance for the judgment of EMS personnel. We did not include data from the children’s hospital in our area, which may have biased our sample. However, all major trauma, including pediatric trauma, is taken to the Level I trauma center, which was included. A separate analysis of pediatric patients, who represent 15% of our trauma transports, was not performed; however, the immobilization protocol is the same for all patients in our system. Consequently, we believe that our results also apply to the pediatric population. Criteria for predicting cervical spine injury in pediatric patients has been studied before by Rachesky et al and were found to be similar to the adult criteria used in our protocol. Also, the vast majority of enrolled patients were injured in MVCs, falls, and diving; therefore, the sensitivity of the protocol for other mechanisms of injury may be less, especially for minor trauma, such as chiropractic manipulation. There are also several small hospitals in our area that may have received patients not identified by our study. Finally, our retrospective review may have missed patients who left the ED before evaluation, refused treatment at the scene, or were discharged and later presented to another hospital. We have no specific numbers for these groups; however, our EMS continuous quality improvement process has no knowledge of any such patients in the past 10 years.

In summary, we found that the FKM EMS spinal-immobilization protocol is 99% sensitive in identifying patients with significant cervical injuries for immobilization. If appropriately applied by EMS providers, with the possible exception of extremes of age, this suggests that implementation of selective immobilization is safe. Prospective validation addressing some of the limitations identified above is needed.

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REFERENCES

CLEARANCE PROTOCOL AND SPINAL IMMOBILIZATION
Stroh & Braude
