**Pediatric Prehospital Protocols Grant**

**Cervical Spine Immobilization**

**Evidence-Based Practice Summary**

Evidence-Based Practice Summary prepared by Elizabeth Crabtree, MPH, Research Specialist and Quinn Franklin, MS, CCLS, Research Specialist

**ASK THE QUESTION**

**Question 1:** For pediatric patients in the prehospital setting, what are the specific risk factors for cervical spine (c-spine) injury (CSI) that can be used to create a selective spinal immobilization protocol?

**Question 2:** For stable, alert, non-cooperative pediatric trauma patients in the prehospital setting, do the potential benefits of full spinal immobilization outweigh the potential harm of physiological and/or psychological injury secondary to forced immobilization?

**Question 3:** For pediatric patients with suspected cervical spine injury in the prehospital setting, what are the most age-appropriate methods of inline spinal immobilization to minimize harm?

**Question 4:** For pediatric trauma patients in the prehospital setting, can EMS providers accurately apply criteria for clearing cervical spines in the field?

**Search Strategy**

A comprehensive literature search was conducted to find relevant evidence to support the Prehospital Protocols – C-Spine Clearance. This search was conducted in May 2012 and included the following databases and websites: Cochrane Collaboration Database, Agency for Healthcare Research and Quality (AHRQ), National Guideline Clearinghouse, PubMed, Trip Database, American Academy of Pediatrics, Prehospital Emergency Care, Prehospital and Disaster Medicine, Annals of Emergency Medicine, The American Journal of Emergency Medicine, Academic Emergency Medicine, JEMS: A Journal of EMS, Pediatric Emergency Care, and the Canadian Journal of Emergency Medicine. Search terms included the following: spine OR spinal, selective AND/OR full spinal immobilization protocol, immobilization, spinal injury, forced immobilization, secondary injury, immobilization benefits, age-appropriate inline spinal immobilization, cervical spinal injury, cervical spine clearance, clearance criteria, pediatric, children, prehospital, out of hospital, and emergency care. Limits placed on the initial search terms were for literature published within the last 10 years, pediatric patients including 0-18 years of age, human patients and within the English language. Searches were expanded to include adults if pediatric data was lacking.
CRITICALLY ANALYZE THE EVIDENCE

Existing External Order Sets/Guidelines/Clinical Pathways

<table>
<thead>
<tr>
<th>External Guideline/Pathway/Order Set</th>
<th>Organization and Author</th>
<th>Last Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
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</table>

**Question 1:** For pediatric patients in the prehospital setting, what are the specific risk factors for cervical spine injury that can be used to create a selective spinal immobilization protocol?

**Recommendation:** When considering the development of a selective spinal immobilization protocol in pediatrics, patients with any of the following criteria should be immobilized: GCS < 15, focal neurologic findings, neck pain in children > 2 years, limited movement of the neck, substantial torso (clavicle, abdomen, flank, back, or pelvis) injury, diving injury, high-risk (head-on, rollover, ejection, death in vehicle, speed > 55 mph) motor vehicle collision, evidence of intoxication, or the presence of a painful distracting injury.

**Strength of Recommendation:** Strong

**Grade Criteria:** Moderate quality evidence

Eight observational studies were found that addressed the PICO question. Several large, multicenter trials conducted in adults assessed whether the absence of specific clinical criteria could be used by EMS practitioners to clear patients with c-spine injuries. In adults, the sensitivity of clinical criteria to identify patients with c-spine injuries ranged from 91-99% (Domeier 1997, Domeier 2005, Stroh 2011, Werman 2007). The criteria most commonly used in such protocols included: altered mental status, neurologic deficit, spinal pain or tenderness, evidence of intoxication, and suspected bone extremity fracture. A large, prospective trial of pediatric patients validated the following criteria to be predictors of c-spine injuries, based on criteria initially derived in adults: midline cervical tenderness, altered level of alertness, evidence of intoxication, neurologic abnormality, and the presence of a painful distracting injury (Viccellio 2001).

The Viccellio study did not seek to find uniquely associated features in the pediatric population, yet a study by Leonard et al. did do this, In this case-control study (540 cases, 1060 controls) of pediatric patients younger than 16 years presenting to the hospital after blunt trauma, 8 factors were associated with c-spine injury: altered mental status, focal neurologic findings, neck pain, torticollis, substantial torso injury, diving, and high-risk motor vehicle crash. Another retrospective study of pediatric patients less than 3 years old found the following to be independent predictors of c-spine injuries: GCS >/= 14, involvement in a motor vehicle collision, GCS_EYE equal to 1, and age > 2 years (Pieretti-Vanmarcke 2009). Older age was also found to be a predictor for c-spine injury in a large retrospective review of pediatric patients admitted to the hospital following blunt trauma. The adjusted risk for CSI increased 2-fold in preadolescents, and 5-fold in adolescents (Mohseni 2011).

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If it is assumed that immobilization should occur only for those patients at risk for c-spine injuries, then consideration of the factors above should be made when deciding whether to immobilize a pediatric patient.

<table>
<thead>
<tr>
<th>Recommendation(s): Moderate Quality Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evident □ Yes □ No</td>
</tr>
<tr>
<td>Number of Studies: Total # 8 □ Systematic review □ RCT □ Observational</td>
</tr>
<tr>
<td>□ Case Reports □ Publication Bias</td>
</tr>
</tbody>
</table>

### Design Limitations

- None
- Insufficient sample size (Domeier 1997, Pieretti-Vanmarcke)
- Large losses to F/U
- Incorrect analysis of ITT
- Stopped early for benefit
- Selective reporting of measured outcomes (e.g., no effect outcome)

### Summary of Consistency

- No inconsistencies
- Wide variation of treatment effect across studies
- Populations varied (e.g., sicker older)
- Interventions varied (e.g., doses)
- Outcomes varied (e.g., diminishing effect over time)
- Head-to-head comparison in correct population
- Indirect comparisons (e.g., interventions to placebo but not each other)
- Different populations
- Different interventions
- Different outcomes measured
- Comparisons not applicable to question/outcome

### Indirectness of Comparison

- Total # of events is < 300 based on simulations & dependent on baseline risk & effect sizes (Domeier 1997, Pieretti-Vanmarcke)
- 95% CI includes negligible effect and appreciable benefit or harm
- Continuous outcomes
- 95% CI includes no effect and the upper or lower limit crosses the minimal important difference (MID), either for benefit or harm
- Upper or lower limit crosses an effect size of 0.5 in either direction (if MID is not known or differences in outcomes require the calculation of an effect size)

### Imprecision of Results

- Dichotomous outcomes
- Continuous outcomes

### Sample

| Domeier (1997): Multicenter, prospective observational study to assess whether absence of clinical criteria (altered mental status, neurologic deficit, spinal pain or tenderness, evidence of intoxication, and suspected bone extremity fracture) can identify EMS trauma patients without significant spinal injury. Study included data on 291 adult patients. |
| Domeier (2005): Prospective, observational study of 415 patients with spinal injuries. The study was meant to assess whether the absence of the following clinical criteria could be used for spinal clearance: evidence of intoxication, neurologic deficit, suspected extremity fracture and spine pain or tenderness. |
| Leonard (2011): Case-control study (540 cases, 1060 controls) of pediatric patients younger than 16 years presenting to the hospital after blunt trauma, and who received c-spine radiographs. The purpose of the study was to id risk factors associated with c-spine injury in children after blunt trauma. |
| Mohseni (2011): Retrospective review of 240.674 pediatric patients admitted to the hospital following blunt trauma. The objective of the study was to categorize the incidence and risk factors for CSI in different pediatric developmental ages. |

Domeier (1997):
- Spinal injury was identified by the presence of ≥ 1 criteria for 277 of 291 (95.2%) patients

Domeier (2005):
- Sensitivity of spine injury assessment was 91% (95% CI: 88.3-93.8%)
- 8% of patients with spine injuries were immobilized
- None of the nonimmobilized patients sustained cord injuries
- Specificity of the assessment was 40.1% (95% CI: 39.2-40.9%)

Leonard (2011):
- The authors identified 8 factors associated with c-spine injury: altered mental status, focal neurologic findings, neck pain, torticollis, substantial torso injury, diving, and high-risk motor vehicle crash
- Having 1 or more factors was 98% (95% CI: 96.99%) sensitive and 26% (95% CI: 23.29%) specific for c-spine injury

Mohseni (2011):
- 1.3% of patients (n = 3035) sustained a CSI
- The incidence of CSI in the stratified age groups was: 0.4% in infants/toddlers; 0.4% in preschool/young...
Pieretti-Vanmarcke (2009): Retrospective observational study of 83 patients ≤ 3 years with CSI. The objective of the study was to assess whether clinical criteria could be used to rule out CSI in patients younger than 3 years (Glasgow Coma Score <14, GCSEYE < 14, motor vehicle crash, and age 2 years or older).

Stroh (2001): Retrospective observational study of 861 adult and pediatric patients with cervical spinal injuries. The study was meant to assess whether the absence of the following clinical criteria could be used for spinal clearance: spinal pain or tenderness, significant multiple system trauma, severe head or facial trauma, numbness or weakness in any extremity after trauma, and altered mental status.

Viccellio (2001): Prospective, multicenter trial of 3065 pediatric patients to evaluate incidence of spinal injury in children. The presence or absence of the following criteria was noted: midline cervical tenderness, altered level of consciousness, evidence of intoxication, neurologic abnormality, and presence of painful distracting injury.

Werman (2007): Prospective observational study of 329 trauma patients ≥ 16 years who were transported via medical air lift to a hospital. Medical crews used the absence of the following criteria for spinal clearance: abnormal level of consciousness, evidence of intoxication, distracting painful injury, spinal tenderness or pain, or abnormal neurologic examination.

- children: 0.8% in preadolescents and 2.6% in adolescents
- The adjusted risk for CSI increased 2-fold in preadolescents and 5-fold in adolescents

Pieretti-Vanmarcke (2009):

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCS ≥14</td>
<td>12.5</td>
<td>5.0–31.6</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>MVC</td>
<td>5.1</td>
<td>2.8–9.0</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>GCSEYE = 1</td>
<td>6.9</td>
<td>3.4–14.2</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td>Age &gt;2 yr</td>
<td>2.2</td>
<td>1.2–4.0</td>
<td>&lt;0.00</td>
</tr>
</tbody>
</table>

Stroh (2001):
- Sensitivity of the spine immobilization protocol was 99% (95% CI: 97.7-99.7%)
- One 9 month old female with CSI was not identified by the protocol

Viccellio (2001):
- The decision rule correctly identified all pediatric CSI victims (sensitivity 100%; 95% CI: 87.8-100%), and correctly designated 603 patients as low risk for CSI (negative predictive value: 100%; 95% CI: 99.4-100%)

Werman (2007):
- The algorithm had a sensitivity of 90%, and a specificity of 16%

References:

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**Question 2:** For stable, alert, non-cooperative pediatric trauma patients in the prehospital setting, do the potential benefits of full spinal immobilization outweigh the potential harm of physiological and/or psychological injury secondary to forced immobilization?

**Recommendation:** Due to the risk of severe secondary injury or death, alternative means to minimize spinal movement during transport or no immobilization at all should be considered in situations when cervical collar placement has the potential to result in more neck movement than no immobilization at all.

**Strength of Recommendation:** Strong

**Grade Criteria:** Very low quality evidence

There were no relevant articles found directly addressing the PICO question. However, a number of studies conducted among adult patients found immobilization to be associated with a number of adverse effects.

One observational study among adult patients with blunt trauma found there was less neurologic disability among trauma patients who were not immobilized compared to those patients who were (Hauswald 1998), and a second retrospective review of adult patients with c-spine trauma found that c-spine immobilization was associated with an increased risk of death (Vanderlan 2009). Lastly, a systematic review of 17 RCTs found there to be adverse effects associated with immobilization (e.g., increased respiratory rate, skin ischemia, pain and discomfort) (Kwan 2005).

**Recommendation(s):** Very Low Quality Evidence

<table>
<thead>
<tr>
<th>Number of Studies</th>
<th>Total # 3</th>
<th>Systematic review</th>
<th>RCT</th>
<th>Observational</th>
<th>Case Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of Consistency</td>
<td>No inconsistencies</td>
<td>Wide variation of treatment effect across studies</td>
<td>Populations varied (e.g., sick, older) (Hauswald 1998, Vanderlan 2005)</td>
<td>Interventions varied (e.g., doses)</td>
<td>Outcomes varied (e.g., diminishing effect over time)</td>
</tr>
<tr>
<td>Imprecision of Results</td>
<td>Dichotomous outcomes</td>
<td>Sample size lower than calculated optimal information size</td>
<td>Total # of events is &lt; 300 based on simulations &amp; dependent on baseline risk &amp; effect sizes</td>
<td>95% CI includes negligible effect and appreciable benefit or harm</td>
<td>Continuous outcomes</td>
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Hauswald (1998): A 5-year retrospective chart review of 545 patients with blunt traumatic spinal or spinal cord injuries was conducted at 2 different university hospitals to examine the effect of emergency immobilization on neurologic outcomes of patients.


Vanderlan (2009): 199 charts of adult patients with penetrating cervical trauma at an urban charity hospital were retrospectively reviewed to determine if c-spine immobilization was related to patient mortality.

<table>
<thead>
<tr>
<th>Question 3: For pediatric patients with suspected cervical spine injury in the prehospital setting, what are the most age-appropriate methods of inline spinal immobilization to minimize harm?</th>
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<tbody>
<tr>
<td>There were few relevant articles found directly addressing the PICO question. However, two of the studies included in the systematic review specifically evaluated the techniques utilized on pediatric patients as well as the respiratory effects of spinal immobilization (Huerta 1987; Schafermeyer 1991). Huerta (1987) found that cervical spine stabilization is best achieved when using a rigid-type cervical collar in combination with supplemental devices such as a Kendrick Extrication Device® and half-spine board). Schafermeyer (1991) found that a child’s respiratory capacity was significantly reduced during spinal immobilization and there was not a preferred strapping technique to resulted in improved outcomes. In addition, Herzenberg, et al. (1989) found that in younger children (&lt; 7 years) extension was the proper position for reduction of injury which was further confirmed by Nypaver and Treloar (1994).</td>
</tr>
</tbody>
</table>

| Recommendation: Children younger than 8 years old should be transported with elevation of the back or an occipitally recessed backboard to optimize neutral positioning of the cervical spine. |

| Strength of Recommendation: Weak |
| Grade Criteria: Low quality evidence |

References:
### Recommendation(s): Low Quality Evidence

<table>
<thead>
<tr>
<th>Design Limitations</th>
<th>Summary of Consistency</th>
<th>Indirectness of Comparison</th>
<th>Imprecision of Results</th>
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<tr>
<td>None</td>
<td>No inconsistent</td>
<td>Head-to-head comparison in correct population</td>
<td>Sample size lower than calculated optimal information size</td>
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<tr>
<td>Insufficient sample size (Ahn 2011, Herzenberg 1989)</td>
<td>Wide variation of treatment effect across studies</td>
<td>Indirect comparisons (e.g., interventions to placebo but not each other)</td>
<td>Total # of events is &lt; 300 based on simulations &amp; dependent on baseline risk &amp; effect sizes</td>
</tr>
<tr>
<td>Lack of blinding (Ahn 2011, Herzenberg 1989)</td>
<td>Populations varied (e.g., sicker, older) (Ahn 2011, Herzenberg 1989, Nypaver 1994)</td>
<td>Different populations Anh 2011</td>
<td>95% CI includes negligible effect and appreciable benefit or harm</td>
</tr>
<tr>
<td>Large losses to F/U (Ahn 2011, Herzenberg 1989, Nypaver 1994)</td>
<td>Outcomes varied (e.g., diminishing effect over time)</td>
<td>Different outcomes measured</td>
<td>95% CI includes no effect and the upper or lower limit crosses the minimal important difference (MID), either for benefit or harm</td>
</tr>
<tr>
<td>Stopped early for benefit</td>
<td></td>
<td>Comparisons not applicable to question/outcome</td>
<td>Upper or lower limit crosses an effect size of 0.5 in either direction (if MID is not known or differences in outcomes require the calculation of an effect size)</td>
</tr>
<tr>
<td>Selective reporting of measured outcomes (e.g., no effect outcome)</td>
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</table>

### Sample

**Ahn (2011):** 25 studies included 2 of which were specific to pediatrics

Determined the current evidence available related to specific questions.

1. What is the optimal type and duration of prehospital spinal immobilization in patients with acute spinal cord injury

**Nypaver (1994):** N = 40 children < 8 years

Prospective

Determine the height of back elevation required to place the c-spine of children < 8 years in neutral position and whether agreement on the height required for neutral position could be reached by two independent observers

Utilized standard size padding with or without shims to raise the back off of the backboard.

**Herzenberg (1989):** N = 10 children < 7 years

Prospective

Investigate c-spine positioning through clinical, radiographic, and anthropometric studies.

**CI/RR**

### Ahn (2011):**

- Immobilization in the prehospital setting should include a cervical collar, head immobilization, and a spinal board.
- Patient should be transferred off of the board upon admission to a facility or if patients are awaiting a transfer.
- Padded boards or inflatable bean bag boards should be utilized to reduce pressure on the occiput and sacrum.

**NOTE:** Recommendations are intended for patients ≥ 12 years

**Nypaver (1994):**

- All children required elevation of the back for correct neutral position (mean height, 25.4 ± 6.7mm, 5 to 41 mm).
- Children < 4 years required more elevation (27 ± 7.2 versus 22 ± 4.2mm, P < 0.05).

**Herzenberg (1989):**

- All 10 children, extension was the proper position for reduction of the injury of the c-spine.

**NOTE:** Can be accomplished by a recess for the occiput to lower the head or a double mattress pad to raise the chest

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**Question 4:** For pediatric trauma patients in the prehospital setting, can EMS providers accurately apply criteria for clearing cervical spines in the field?

The Trauma Association of Canada Pediatric Subcommittee (2011) created a National Pediatric Cervical Spine Evaluation Pathway to evaluate the cervical spine in patients with a reliable clinical examination and in those with an unreliable examination. The committee found that it is possible to clinically clear the pediatric cervical spine in patients with a reliable clinical exam using a combination of the National Emergency X-Radiography Utilization Study (NEXUS) low-risk criteria and the Canadian C-Spine Rule (CCR) criteria. However, most of the research included adults with very few pediatric patients represented.

**Recommendation:** Implementation of pediatric selective spinal immobilization protocols that have prehospital providers apply previously established risk criteria for cervical spine injury should be considered.

**Strength of Recommendation:** Weak

**Grade Criteria:** Moderate quality evidence

<table>
<thead>
<tr>
<th>Recommendation(s): Moderate Quality Evidence</th>
<th>Design Limitations</th>
<th>Summary of Consistency</th>
<th>Indirectness of Comparison</th>
<th>Imprecision of Results</th>
</tr>
</thead>
</table>

**Number of Studies:** Total # Systematic review RCT Observational

**Publication Bias Evident:** Yes No

**Consistency**

- None
- Insufficient sample size
- Lack of blinding
- Lack of allocation concealment
- Large losses to F/U
- Incorrect analysis of ITT
- Stopped early for benefit
- Selective reporting of measured outcomes (e.g., no effect outcome)

**Indirectness of Comparison**

- None
- No inconsistencies
- Wide variation of treatment effect across studies
- Interventions varied (e.g., doses)
- Outcomes varied (e.g., diminishing effect over time)
- Head-to-head comparison in correct population (Pieretti- Vanmarcke 2009)
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- Comparisons not applicable to question/outcome

**Imprecision**

- None
- Sample size lower than calculated optimal information size
- Total # of events is < 300 based on simulations & dependent on baseline risk & effect sizes
- 95% CI includes negligible effect and appreciable benefit or harm

**Continuous outcomes**

- 95% CI includes no effect and the upper or lower limit crosses the minimal important difference (MID), either for benefit or harm
- Upper or lower limit crosses an effect size of 0.5 in either direction (if MID is not known or differences in outcomes require the calculation of an effect size)

**Design**

- Armstrong (2007): N = 103 adult Prospective, observational

  Determine whether the incidence of unnecessary c-spine immobilization by ambulance personnel could be safely reduced through the implementation of an evidence-based algorithm.

- Domeier (2005): N = 13,357 adults/pediatric patients Prospective, observational

  Determine whether the use of an EMS protocol *for selective spine immobilization would result in:

  - Armstrong (2007):
    - 69 (67%) patients had their c-spines cleared at the scene with no adverse effects; 60 of these patients were discharged from the scene; 9 were taken the ED and all were discharged home
    - 34 (33%) patients could not have their c-spines cleared; 4 (12%) self-discharged at scene and 30 (88%) were transported to the ED
  - Domeier (2008):
    - 415 with injuries- 50 with SCI and 128 with cervical injuries

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<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Design</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domeier (2002)</td>
<td>N = 8975 adults</td>
<td>Prospective, observational</td>
<td>Evaluate 5 prehospital clinical criteria—AMS, neurologic deficit, spine pain or tenderness, evidence of intoxication, or suspected extremity fracture.</td>
</tr>
<tr>
<td>Meldon (1998)</td>
<td>N = 190 adults</td>
<td>Prospective, observational</td>
<td>Determine the level of agreement between EMTs and Emergency Medicine physicians.</td>
</tr>
<tr>
<td>Stroh (2001)</td>
<td>N = 504 adult/pediatric patients</td>
<td>Retrospective</td>
<td>Determine the sensitivity of the Fresno/Kings/Madera EMS selective spine immobilization protocol in identifying patients with potential cervical injuries.</td>
</tr>
<tr>
<td>Vaillancourt (2009)</td>
<td>N = 1949 adult patients</td>
<td>Prospective, observational</td>
<td>Evaluates the performance characteristics, reliability, and clinical sensitivity of the Canadian C-Spine Rule (CCR) when used by paramedics in the out-of-hospital setting.</td>
</tr>
<tr>
<td>Werman (2008)</td>
<td>N = 329 adults</td>
<td>Prospective, observational</td>
<td>Determine the feasibility of applying prehospital algorithms in the air medical transport environment.</td>
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</table>

**Appropriate immobilization without spinal cord injury associated with nonimmobilization.**

\[
\text{Eligible for spinal clearance based on the absence of all of the clinical findings:} \\
- AMS \\
- Evidence of intoxication \\
- Neurologic deficit \\
- Suspected extremity fracture \\
- Spine pair or tenderness
\]

<table>
<thead>
<tr>
<th>Study</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domeier (2002)</td>
<td>Spine injury was identified by the criteria in 280 out of 295 (94.9%).</td>
</tr>
<tr>
<td>Meldon (1998)</td>
<td>Overall disagreement between EMTs and Emergency Medicine physicians regarding out of hospital CSI clearance occurred in 44 patients (23%; ( \kappa = 0.29; 95% \text{ CI: 0.15 - 0.43; } P &lt; 0.01 )).</td>
</tr>
<tr>
<td>Stroh (2001)</td>
<td>495 arrived in C-spine immobilization; 2 refused immobilization, 2 could not be immobilized, 3 were missed by protocol criteria, 2 were missed due to protocol violations.</td>
</tr>
<tr>
<td>Vaillancourt (2009)</td>
<td>Paramedics classified 12 important injuries with sensitivity 100% (95% CI; 74-100%), specificity 37.7% (95% CI; 6-40%).</td>
</tr>
<tr>
<td>Werman (2008)</td>
<td>49 with SCI and 12 of those had injuries that were unstable.</td>
</tr>
</tbody>
</table>

Protocol had a sensitivity of 92% (95% CI; 89.4-94.6%), specificity 40% (95% CI; 38.9-40.5%).
- Distracting painful injury
- Spinal tenderness or pain
- Abnormal neurologic examination

### References:


