

Canadian C-Spine Rule study for alert and stable trauma patients: I. Background and rationale

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ABSTRACT

This paper is Part I of a 2-part series to describe the background and methodology for the Canadian C-Spine Rule study to develop a clinical decision rule for rational imaging in alert and stable trauma patients. Current use of radiography is inefficient and variable, in part because there has been a lack of evidence-based guidelines to assist emergency physicians. Clinical decision rules are research-based decision-making tools that incorporate 3 or more variables from the history, physical examination or simple tests. The Canadian CT Head and C-Spine (CCC) Study is a large collaborative effort to develop clinical decision rules for the use of CT head in minor head injury and for the use of cervical spine radiography in alert and stable trauma victims. Part I details the background and rationale for the development of the Canadian C-Spine Rule. Part II will describe in detail the objectives and methods of the Canadian C-Spine Rule study.

Key words: radiography, cervical spine injuries, decision rules

RÉSUMÉ

Il s'agit de la première partie d'un article en deux parties décrivant le contexte et la méthodologie de l'étude de la Règle canadienne concernant la colonne cervicale (Canadian C-Spine Rule study) visant à établir une règle de décision pour le recours rationnel à l'imagerie chez les victimes de traumatismes alertes et stables. Le recours actuel à la radiographie est inefficace et variable, en partie en raison d'un manque de lignes directrices fondées sur des données probantes pour guider les urgentologues. Les règles de décision clinique sont des outils de prise de décision fondés sur des recherches qui incorporent trois variables ou plus provenant des antécédents, de l'examen physique ou de simples tests. L'étude canadienne concernant les tomodensitogrammes de la tête et la colonne cervicale (Canadian CT Head and C-Spine Study) est un effort de collaboration sur une grande échelle visant à mettre sur pied des règles de décision clinique quant au recours au tomodensitogramme de la tête dans les cas de blessures mineures à la tête et à la radiographie de la colonne cervicale chez les victimes de traumatismes alertes et stables. La première partie décrit le contexte de la mise sur pied de la Règle canadienne concernant la colonne cervicale et sa justification. La deuxième partie décrira en détail les objectifs et méthodes de l'étude de cette Règle.

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Background

Cervical spine injuries

More than 1 million patients with neck injuries are seen annually in US emergency departments (EDs).^{1,2} Most have soft-tissue damage, but approximately 30 000 suffer cervical fractures or dislocations, and 10 000 suffer spinal cord injury.^{3–5} Canada has no readily available national ED data; however, based on extrapolation from US figures,^{1,2} we estimate that 410 000 motor vehicle collision (MVC) victims are seen annually in Canadian EDs. At the same time, Canadian emergency physicians see approximately 185 000 alert, stable adult trauma victims with potential neck injury.⁶ Of these, 0.9% have cervical spine (C-spine) fractures or dislocations.

Utilization of cervical spine radiography

Because of the potential for neurological injury, emergency care providers go to great lengths to protect the C-spine. Most trauma victims are transported to hospital with protective measures like a backboard, collar and sandbags — whether or not they have neck symptoms.^{5,7} Reports have suggested that clinical judgement is inadequate to predict significant injuries,^{8–10} and a recent survey found that 97% of 125 US trauma centres routinely ordered C-spine radiography for all trauma patients.¹¹ Canadian practice is more selective,⁶ but there is large variability among hospitals and physicians, and the use of C-spine radiography for alert, stable trauma patients remains inefficient. In Canada, about 110 000 alert stable trauma victims undergo C-spine radiography each year and in more than 98% of these examinations the findings are normal.⁶ There is a 2-fold variation in radiography rates among similar hospitals (37.0%–72.5%) and a 6-fold variation among emergency physicians (15.6%–91.5%). This variability persists even after controlling for differences in patient severity.

Less than 3% of trauma series have positive findings.^{7,9,12–22} Given the very low yield, many authors consider universal C-spine radiography inefficient.^{12–15,23–25} The huge number of normal radiographs adds to health care costs^{26,27} and to the burden of time and effort for ED staff. “Clearing the C-spine” often requires repeated imaging attempts, and this distracts physicians, nurses, orderlies and technicians from other responsibilities.²³

US EDs treat 4.1 million MVC victims annually¹ and charge from US\$90 to US\$230 for each patient having C-spine radiography. Total national ED charges for these studies are estimated at between US\$370 and US\$940 million. In Canada, more than \$30 million is spent annually

on outpatient C-spine radiography,²⁸ but it is unclear what proportion of this represents alert, stable trauma patients. What is clear is that the cumulative cost of high-volume procedures such as C-spine radiography is considerable and that these may contribute more to rising health care costs than expensive “high technology” tests.^{29,30} Guidelines that could lead to a modest reduction in the proportion of trauma patients undergoing C-spine radiography would produce a large savings in health care dollars.

Previous guidelines for cervical spine radiography

There is considerable controversy among emergency physicians, neurosurgeons and trauma surgeons regarding the indications for C-spine radiography. Some insist that all trauma patients should undergo imaging,^{3,8,21,31–33} and the American College of Surgeons’ Advanced Trauma Life Support course recommends that “cervical spine films be obtained on all patients with injuries above the clavicle — especially head injuries.”³³ Many trauma experts believe that a selective approach is preferable but do not provide clear recommendations.^{10,11,13,16,22,34–37} Most authors feel that radiography is unnecessary in alert patients with no neck pain or tenderness,^{5,7,9,12,14,18,23–25,38–45} but only a few are willing to suggest that imaging might be withheld in alert patients with pain but no midline bony tenderness.^{15,17,19}

Emergency practice is characterized by high case volumes, brief physician–patient contact, uncertain follow-up and fear of medicolegal repercussions.^{46–48} In such circumstances, physicians often fall into the widely advocated and inefficient approach of ordering C-spine radiographs for most or all trauma patients. Perhaps the greatest uncertainty surrounds alert patients with minimal symptoms and normal physical findings,¹⁵ who represent the largest group of blunt trauma patients and a huge potential for improved efficiency. But Canadian and US emergency physicians have differing views on this topic,^{49,50} and the consensus is that more research is necessary before C-spine radiography guidelines for alert trauma patients can be implemented.^{7,9,11,14,16,17,19,20,24,34,37–40,44} Future studies should be rigorous, prospective and involve large numbers of patients.

Evidence-based guidelines have improved radiographic utilization in patients with ankle and knee injuries, and there is a clear need for such guidelines in alert trauma patients with potential neck injury. These guidelines or decision rules must be very sensitive for detecting C-spine injuries and must not compromise care of trauma patients. Our research has shown that the majority of Canadian and US emergency physicians would adopt a sensitive and reliable decision rule for C-spine radiography.⁵⁰

Critical appraisal of previous studies

During the last 10 years, emergency physicians,^{7,9,14–16,19,36–38,40,45,49} trauma surgeons,^{3,5,10,12,13,20–22,39,44,51,52} and radiologists^{18,32} have attempted to identify subgroups of trauma patients who need not undergo C-spine radiography. We identified these studies by performing a MEDLINE database search (1966 to 1998; MeSH terms “spinal injuries” and “radiography”), an online search for “related articles,” a review of article bibliographies and a review of the investigators’ personal reference libraries. Unfortunately, although many studies have been published, they are highly variable in design, and none meet accepted methodological criteria for clinical decision rules (Table 1), as we discuss in the following critical appraisal.

The outcome measure for most studies was the presence of any radiographic fracture or dislocation; but different studies used different radiographic protocols, ranging from a single lateral view¹³ to 3 views^{10,18,19,21,32,44} to 5 views,^{9,15,16,36,40} and many gave no specific number of views.^{5,12,14,17,20,22,37–39,45,52} In most studies, outcome assessment was done in a unblinded fashion by investigators who were aware of the predictor variables. Only a few studies gathered data prospectively using data collection forms,^{9,10,15,17,19,40,44,45,52} no study described training the physicians to collect data in a standardized fashion, and no study explicitly collected the predictors without knowledge of the outcome. Only 1 study measured interobserver agreement to assess reliability.⁵³

Eligibility criteria have often been unclear in previous studies, making it difficult for readers to interpret and apply the findings to their own patients. Most studies lacked a standardized patient definition, enrolling any trauma pa-

tient who had C-spine films ordered at the treating physician’s discretion.^{5,9,16,18–22,40,44,45} Many included only patients with head or facial injury,^{10,12–15,36,51,52,54} documented C-spine fractures,^{3,32,38,39} high-risk injury mechanism,⁷ or the presence of neck pain.¹⁷ Some excluded patients with a decreased level of alertness,^{7,12,17,39,52} others deliberately included such patients,^{5,9,13,15,19,36,37,40} and the rest failed to specify level of alertness.^{3,10,14,16,18,20–22,32,38} Only 2 studies specified that subjects should be adults;^{14,15} the rest did not report age restrictions. Approximately half of all studies considered only admitted patients;^{3,7,12,13,21,22,32,36–39} the rest included all patients seen in the ED. Some studies excluded patients with penetrating injuries,^{12,14,15,19,22,36,40} and a few studies explicitly excluded intoxicated patients,^{12,13,39} patients with unstable vital signs,³⁶ those presenting more than 24 hours after the injury,¹⁷ and those transferred from other locations.⁴⁰ Most studies had fewer than 30 patients with abnormal radiographs^{7,9,10,12–19,36,40,52} and some studies had none.^{3,32,38,39} The statistical techniques used were generally rudimentary, and only 1 study performed a multivariate analysis.¹⁰ Few studies derived simple, clinically sensible guidelines. Only 3 assessed the accuracy of their recommendations by calculating sensitivity and specificity,^{10,19,40} only 1 attempted to prospectively validate their guidelines,⁴⁵ and none implemented their guidelines to determine their true impact on patient care.

The NEXUS criteria

Of particular note are the US-based NEXUS (National Emergency X-Radiography Utilization Study) criteria, which have received much attention after the publication of an impressive validation study incorporating more than

Table 1. Methodological standards for clinical decision rules

1. The **outcome** or diagnosis to be predicted must be clearly defined, and assessment should be made in a blinded fashion.
2. The clinical findings to be used as **predictors** must be clearly defined and standardized, and their assessment must be done without knowledge of the outcome.
3. The **reliability** or reproducibility of the predictor findings must be demonstrated.
4. The **study subjects** should be selected without bias and should represent a wide spectrum of characteristics to increase generalizability.
5. The **mathematical techniques** for deriving the rules must be identified.
6. Decision rules should be **clinically sensible**: have a clear purpose, be relevant, demonstrate content validity, be concise, and be easy to use in the intended clinical application.
7. The **accuracy** of the decision rule in classifying patients with (sensitivity) and without (specificity) the targeted outcome should be demonstrated.
8. **Prospective validation** on a new set of patients is an essential test of a new decision rule.
9. **Implementation** to demonstrate the true effect on patient care is the ultimate test of a decision rule; transportability can be tested at this stage.

34 000 patients.^{19,55,56} These guidelines state that no C-spine radiography is required if patients satisfy 5 low-risk criteria: absence of midline tenderness, normal level of alertness, no evidence of intoxication, no neurological findings, and no painful distracting injuries. However, while NEXUS is the largest relevant study to date, there are concerns about the specificity, reliability, and sensitivity of these criteria.

Specificity is a primary concern. The NEXUS criteria are only 12% specific; consequently, their adoption may lead to increased radiography utilization in most countries outside the US. In addition, clinicians may find that some of the criteria are poorly reproducible — particularly “presence of intoxication” and “distracting painful injuries.” We recently attempted a retrospective validation of the NEXUS criteria based on our database of 8924 patients and found that the criteria missed 10 of 148 clinically important injuries, yielding a sensitivity of only 93%.⁵⁷ We believe that these criteria should be further evaluated, prospectively and explicitly, for sensitivity, specificity and interobserver agreement in multiple sites before they can be accepted for widespread clinical use.

The Canadian CT Head and C-Spine (CCC) Study

Rationale for the CCC Study

Previous studies have been methodologically weak and inconclusive. Existing C-spine radiography guidelines for alert, stable trauma patients are contradictory or ambiguous, and the NEXUS criteria may have limited sensitivity and reproducibility. Furthermore, when the Canadian study was designed in 1994, the NEXUS criteria had not been validated. This study builds upon our previous research in which we derived, validated, and successfully implemented decision rules for ankle radiography (Ottawa Ankle Rule)^{47,58–65} and for knee radiography (Ottawa Knee Rule).^{66–70} An accurate, reliable, clinically sensible decision rule for C-spine radiography would permit physicians to provide more standardized and efficient care for trauma patients. Furthermore, physicians could be much more selective in their use of C-spine radiography without jeopardizing patient care. Such a decision rule should, therefore, lead to improved patient care and considerable savings for North American health care systems.^{65,69} We estimate that a 25% to 50% relative reduction in the use of C-spine radiography could be safely achieved with the Canadian C-Spine Rule.

Our preliminary studies clearly show that, although physicians in Canadian EDs are already selective, they

are also variable in their use of C-spine radiography for alert, stable trauma patients.^{6,49} An overwhelming majority of respondents to our survey stated that there is a need for better guidelines and that they would be very comfortable using an accurate, reliable decision rule for C-spine radiography in their own ED practice. Although many guidelines have had little influence on physician practice,⁷¹ we have demonstrated that accurate, reliable, clinically sensible decision rules, such as the Ottawa ankle and knee rules, have been readily implemented by many physicians and have led to a real change in clinical behaviour.^{62,64,70} We believe that a well-derived, validated, highly sensitive decision rule for the use of C-spine radiography would be widely adopted by emergency physicians and improve the quality and efficiency of patient care.

Preliminary work by the CCC Study Group

In 1994, we conducted a workshop that convened experts in emergency medicine, neurosurgery, research methodology and research coordination to discuss important methodological issues for the C-spine radiography project. In 1995, we conducted a pilot study that reviewed data from the EDs of 8 Canadian hospitals over a 12-month period.^{6,72} This study provided estimates of the number of eligible alert, stable trauma patients (6855), the referral rate for C-spine radiography (58.0%), the prevalence of acute C-spine injury (0.9%), the negative x-ray rate (98.5%), and the large x-ray utilization variability among similar sites (37.0%–72.5%) and among attending physicians (15.6%–91.5%). The analyses also showed, after controlling for injury severity by logistic regression analysis, that the variation in use of radiography was highly site specific.

We conducted 2 mail surveys to assess the attitudes of emergency physicians toward decision rules. In 1995, we surveyed 300 members of the Canadian Association of Emergency Physicians, with an 81% response rate.⁵⁰ Only 21.5% agreed with recommendations that all alert, stable trauma patients with high-risk mechanism of injury should have C-spine radiography, whereas 98% indicated they would consider using a sensitive and reliable clinical decision rule for the use of C-spine radiography. Not surprisingly, the physicians would require a higher sensitivity for a rule to predict clinically important fractures or dislocations (100%) than for a rule to predict any C-spine injury (median 96%). In 1998, we conducted mail surveys of 500 emergency physicians in Canada, the US, the UK, France and Spain.⁵⁰ The majority of them indicated strong support for a C-spine radiography decision rule.

Overview of the Canadian C-Spine Rule Study

The results of the phase I derivation component of the Canadian C-Spine Rule Study have been recently published.⁷³ In this phase, more than 200 emergency physicians at 10 Canadian teaching and community hospitals systematically evaluated 8924 alert and stable trauma patients for 20 clinical variables. Variables were evaluated for interobserver agreement and for univariate statistical

association with the primary outcome: clinically important C-spine injury. The strongest variables were further analyzed by multivariate recursive partitioning analysis to develop the final Canadian C-Spine Rule (Fig. 1). This decision rule was shown to be 100% sensitive for identifying the 151 clinically important injuries and would require that only 58.2% of alert, stable patients undergo C-spine radiography. The phase II prospective validation

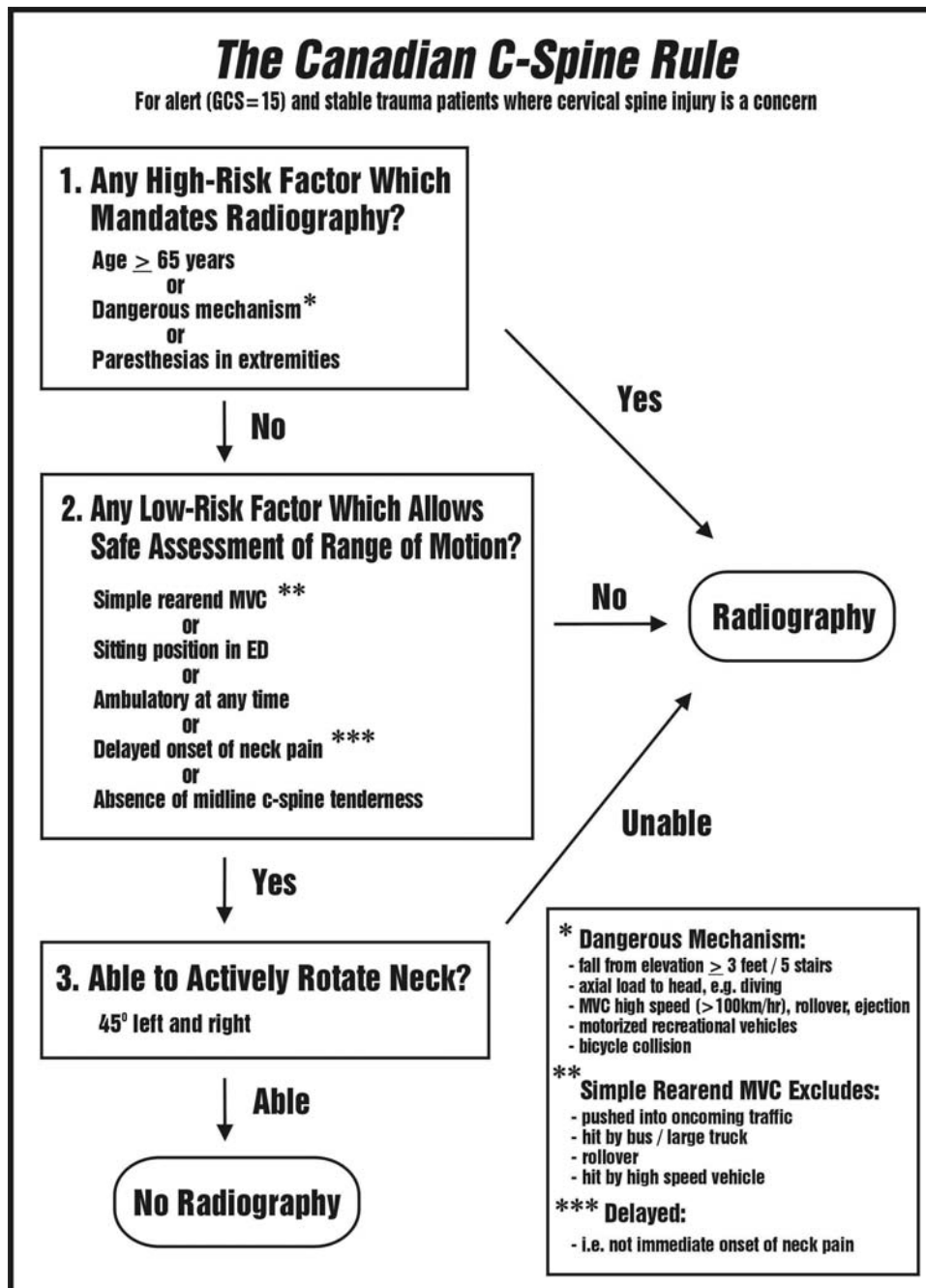


Fig. 1. The Canadian C-Spine Rule for alert (Glasgow Coma Scale score = 15) and stable trauma patients where cervical spine injury is a concern

component of the study is now underway at 8 hospitals in Ontario, Alberta and British Columbia.

Conclusions

The use of C-spine radiography in alert, stable trauma patients is inefficient and highly variable. Previous studies in this area are limited by poor methodology and small sample size. The Canadian C-Spine Rule is a highly sensitive clinical prediction rule now being validated at several Canadian centres.

Competing interests: None declared.

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