SPINE Volume 35, Number 18, pp 1721–1728

Clearance of the Cervical Spine in Clinically Unevaluable Trauma Patients

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Study Design. Meta-analytic costeffectiveness analysis.

Objective. Our goal was to compare the results of different management strategies for trauma patients in whom the cervical spine was not clinically evaluable due to impaired consciousness, endotracheal intubation, or painful distracting injuries.

Summary of Background Data. We performed a structured literature review related to cervical spine trauma, radiographic clearance techniques (plain radiography, flexion/extension, CT, and MRI), and complications associated with semirigid collar use.

Methods. Meta-analytic techniques were used to pool data from multiple sources to calculate pooled mean estimates of sensitivities and specificities of imaging techniques for cervical spinal clearance, rates of complications from various clearance strategies and from empirical use of semirigid collars. A decision analysis model was used to compare outcomes and costs among these strategies.

Results. Slightly more than 7.5% of patients who are clinically unevaluable have cervical spine injuries, and 42% of these injuries are associated with spinal instability. Sensitivity of plain radiography or fluoroscopy for spinal clearance was 57% (95% CI: 57%–60%). Sensitivities for CT and MRI alone were 83% (82%–84%) and 87% (84%–89%), respectively. Complications associated with collar use ranged from 1.3% (2 days) to 7.1% (10 days) but were usually minor and short-lived. Quadriplegia resulting from spinal instability missed by a clearance test had enormous impacts on longevity, quality of life, and costs. These impacts overshadowed the effects of prolonged collar application, even when the incidence of quadriplegia was extremely low.

Conclusion. As currently used, neuroimaging studies for cervical spinal clearance in clinically unevaluable patients are not cost-effective compared with empirical immobilization in a semirigid collar.

Key words: back pain, primary care, cost-of-illness, severity of low back, depression. **Spine 2010;35: 1721–1728**

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Acknowledgment date: March 27, 2009. Revision date: May 9, 2009. Acceptance date: May 15, 2009.
The manuscript submitted does not contain information about medical device(s)/drug(s).
No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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Approximately 2% to 6% of the 800,000 patients whose cervical spines are radiologically assessed in emergency departments and trauma bays yearly[1] have evidence of cervical spinal injury (CSI).[2–4] Many of these injuries compromise spinal stability,[5] and may place patients at high risk for subsequent spinal cord injury and quadriplegia. Accordingly, devices to restrict neck movement such as a semirigid cervical collar are routinely applied to most trauma victims at the scene for extraction and transport. Significant injury to the cervical spine can usually be ruled out in awake and cooperative individuals.[6] However, 18% to 33% of these patients are not clinically evaluable, usually because of impaired consciousness (Glasgow Coma Scale score ≤13), endotracheal intubation or other injuries which are painful and distracting.[7,8] These unevaluable patients are at increased risk for clinically occult CSI, with a nearly 3-fold increase in prevalence of CSI (7.7%) when compared to alert trauma patients (2.8%).[9] No definitive measure exists to rule out CSI in this patient population. Current cervical spine clearance protocols, including the Canadian C-spine rule (CCR) and National Emergency X-Radiography Utilization Study (NEXUS) criteria recommend cervical spine radiography for clearance in all clinically unevaluable patients.[1,10] Until cervical stability can be determined, these patients require neck immobilization. A number of collar designs are employed; the differences among them are relatively small.[11,12]

Prolonged cervical immobilization interferes with nursing care and may be associated with patient discomfort and complications. These include chin, mandible, chest, and occipital decubiti,[12–16] interference with airway and ventilation due to immobility,[12,17–19] increased risk of infection,[12] inadequate protection and alignment,[11,12,20] as well as reluctance to perform certain operative procedures until spinal clearance is obtained.[21] A rigid collar may even exacerbate elevated intracranial pressure in severe traumatic brain injury.[22] Hence, it is preferable to promptly remove a cervical collar on clearance. However, it has long been recognized that routine plain radiography is inadequate in ruling out cervical instability in patients that are not clinically evaluable.[23] Spinal injuries missed on initial evaluation are not rare[24,25] and can result in catastrophic neurologic injury. Technological advances have fueled the development of radiographic clearance protocols to facilitate removal of cervical collars in unevaluable patients.[26–28] A variety of methods have been examined, including plain radiography and dynamic imaging,[29–59] computed tomogra-

phy (CT),[21,30,31,33,36,38,44,48–50,52,53,55,57–67] and magnetic resonance imaging (MRI).[21,54,65,68–74] However, since the prevalence of unrecognized spinal instability is low, many reported series have not been sufficiently powered to achieve statistical rigor. No clearance strategy has thus proven to be superior to prolonged cervical immobilization in terms of safety or cost-effectiveness.

The purpose of this study is to analyze the operating characteristics (sensitivity and specificity) needed by a clearance strategy to predict whether it can be used more safely and/or cost-effectively than prolonged application of a semirigid cervical collar. Moreover, we calculate the operating characteristics of some reported protocols to determine their relative safety and cost-effectiveness.

■ Materials and Methods

We performed a structured review of the English language literature related to CSI from 1985 to January 2008 using Medline and PubMed search engines. The search employed various combinations of key words, including "spinal injuries," "cervical vertebrae," and expanded the search to include the terms "diagnosis," "clear," "clearance," or "clearing" "epidemiology," "prevalence," "incidence," "plain films," "fluoroscopy," "computed tomography," and "magnetic resonance" in either the title or text fields. The search was expanded using the "Find Similar" and "Find Citing Articles" features of Medline and the "Related Articles" feature of PubMed, as well as the bibliographies of selected publications. Details of the search can be found in our previous report.[9] The same search strategy was used to search for publications with data about complications, life expectancy, costs, and quality of life. In instances where there were multiple estimates of a value, they were tested for heterogeneity and pooled meta-analytically.[75–77] Pooled data were used to create evidence tables, from which we calculated relative risks, benefits, and costs of various management strategies. Clearance tests were compared with reference to sensitivity and specificity for detecting CSI.

Costs were considered from the perspective of society. For one-time costs associated with particular hospital costs or procedures, Medicare reimbursement[78] was employed as a surrogate. In order to reflect the increased costs associated with treatment complications, we ignored recent Medicare rulings denying reimbursement in cases of avoidable complications.[79] All other reported costs were corrected to 2007 dollars.

Outcomes were measured in terms of both cost and quality-adjusted life years (QALYs) as measures of life expectancy and quality of life, respectively.[80] QALYs represent a combined measure of longevity and quality of life. For example, a year of perfect health is given a value of 1 QALY; a year in which health-related quality of life (utility) is only 60% of normal is valued at 0.6 QALYs. The respective utilities of collar-associated complications were estimated. Although wearing a cervical collar causes some discomfort in alert individuals, this effect is unlikely to be significant in patients who are obtunded or in a state of impaired consciousness and was not incorporated into our model. Three common techniques for cervical clearance are dynamic (flexion/extension) radiography or fluoroscopy, computed tomographic (CT), and magnetic resonance imaging (MRI). Sensitivities and specificities of each clearance strategy were obtained from published series. Estimates were pooled and 95% confidence intervals were calculated using the

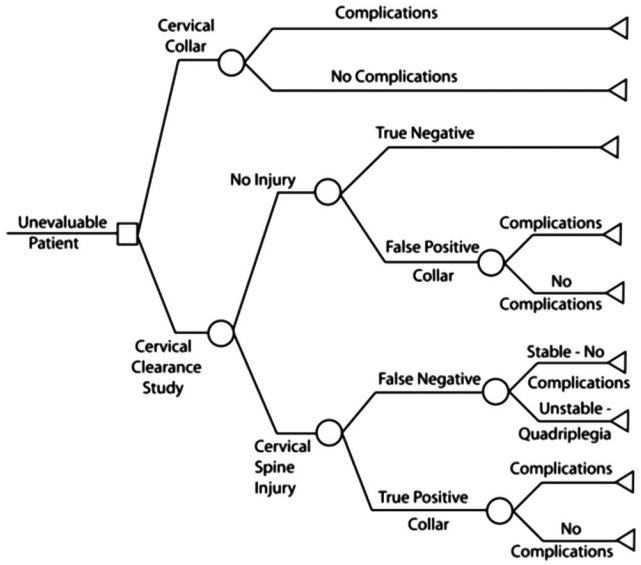

Figure 1. Decision tree for managing possible spinal injury in a clinically-unevaluable patient. The branches of the tree cover potential outcomes of management choices.

software program MetaDiSc.[81] In keeping with convention, future costs and utilities were discounted at 3% per year.[80]

We constructed and analyzed a decision analytic model of the various possible outcomes based on a decision to empirically immobilize the neck with a semirigid collar or to employ a radiographic cervical clearance strategy. As a base case, we examined outcomes in an obtunded or otherwise unevaluable 25-year-old (Figure 1). The model was run for collar applications of 2, 7, and 10 days. Cost-effectiveness analyses of the model employed TreeAge Pro 2008 (Tree Age Software, Inc, Williamstown, MA). To supplement and evaluate the validity of point estimates, we performed a number of sensitivity analyses, varying the values of important variables to determine the impact on calculated outcomes. We also performed a 2-dimensional Monte Carlo simulation (1000 trials of 1000 subjects each) to approximate the results of clinical trials.[82] The simulations employed beta distributions of all measured variables.

Our model makes several assumptions. These include no complications from cervical collar immobilization occur before the decision about neck clearance. Performing clearance tests are assumed to involve no direct risks to the patient. We further assume that all patients whose cervical spine instability is diagnosed by an abnormal screening test or after return of normal consciousness are treated and suffer no long-term consequences. A false-negative clearance study is defined as a study read as normal. Without any evidence to the contrary, unevaluable patients are assumed to have the same proportion of unstable cervical spine injuries as the general trauma population. Finally, we assume that after collar removal, all patients with unstable injuries develop permanent quadriplegia. Measures of lifetime costs, life expectancy, and quality of life in quadriplegics represent pooled estimates for both complete and incomplete quadriplegia and for lesions at both upper and mid-cervical levels.

■ Results

Table 1 summarizes the values used to calculate the output of the model. These include the probabilities that trauma patients who are unevaluable clinically (*i.e.*, ob-

Table 1. Values Used in Decision Analysis and Cost-Effectiveness Models

Parameter	N	Mean Value	95% CI	References
Probabilities				
Collar complications				13–18, 83
2 d	656	0.0129	0.011–0.015	
7 d	754	0.0488	0.045–0.053	
10 d	754	0.0712	0.065–0.077	
Cervical spine lesion in clinically unevaluable* patients	49,879	0.0766	0.076–0.078	9
Cervical spine lesions which are unstable	3550	0.4187	0.415–0.423	9
Life expectancy (yr)				
Average 25 yr old	—	55.6	—	96
Quadriplegic 25 yr old	39,247	36.09	35.98–36.21	97–105
Utilities				
Normal health	—	1.0	—	80
Collar complications				(Calculated utility for entire year—see Discussion)
2 d	—	0.999	0.95–1	
7 d	—	0.9960	0.95–1	
10 d	—	0.9959	0.95–1	
Quadriplegia	2345	0.5602	0.51–0.61	94–115
Costs (2007 US$)				
Semi-rigid cervical collar with liner	—	19.97	—	78
Additional daily costs associated with collar	—	15	—	(Calculated from model)
Collar complications (additional costs)	—	228.88	—	(Calculated from model)
Cervical spinal plain radiographs	—	61.14	—	78
Cervical spinal CT	—	283.27	—	
Cervical spinal MRI	—	507.20	—	
Quadriplegia, year one	1728	238,311.40	172,812.40–303,810.31	116–119, 121–123
Quadriplegia, per year thereafter	1936	135,005.80	126,727–143,284.51	116, 117, 119, 120, 123

*Unable to cooperate due to impaired consciousness, confusion, endotracheal intubation, etc.
n indicates number of cases used for pooled means; CI, confidence interval; CT, computed tomography; MRI, magnetic resonance imaging.

tunded, confused, intubated, *etc.*) have CSI and that their injuries are unstable,[9] as well as the probabilities that an obtunded patient with cervical spine immobilization will develop complications after 2, 7, or 10 days.[13–18,83] Also calculated are the life expectancies of healthy and quadriplegic 25 year olds[84–93] and the quality of life of normal individuals[80] and those with complications from wearing a collar or quadriplegia.[94–115] Finally, Table 1 considers costs associated with a collar and complications of its use,[78] as well as short-term and long-term costs of quadriplegia.[116–123]

Pooled sensitivities and specificities of the 3 common methods of cervical spine clearance, static and dynamic radiography,[29–59] CT scanning,[21,30,31,33,36,38,44,48–50,52,53,55,57–67] and MRI[21,54,65,68–74] were obtained from the literature. The results are summarized in Table 2.

We used the model to calculate expected costs and outcomes in a 25-year-old patient treated in a semirigid collar for 10 days, compared to clearance strategies using plain radiography/fluoroscopy, CT, and MRI. These results are shown in Table 3. Strategies are arranged by increasing cost and decreasing effectiveness. For reference, a typical uninjured 25-year-old, who lives an additional 55.6 years[84] can expect 27.6502 QALYs. This is because future costs and utilities are discounted, as is customary in studies of this type.[80] Costs are significantly lower and effectiveness significantly greater in the collar group, thus dominating the other strategies. We also ran the model for shorter durations of collar application (2 and 7 days); the collar strategy was associated with even lower costs and greater effectiveness than the clearance strategies.

Finally, we tested the cost-effectiveness of a theoretical "improved" clearance test, one whose sensitivity was so high that it outperformed the cervical collar. Expected added costs of applying a collar to the average patient for 10 days is $186.40 (cost of the collar itself plus added costs of nursing care and a proportional cost of collar-related complications). Using a test with perfect (100%) sensitivity and 80% specificity would cost this much if the test itself cost $139.27. This cost plus the collar-related costs for patients with positive tests would also total $186.40. To improve outcome over a collar cost-effectively, the test would need to cost no more than

Table 2. Operating Characteristics of Cervical Spinal Clearance Strategies

Strategy	N	Sensitivity (95% CI)	Specificity (95% CI)	References
Plain radiography/fluoroscopy series	51,053	0.568 (0.566–0.607)	0.997 (0.996–0.997)	29–59
CT scan series	18,894	0.832 (0.820–0.843)	0.999 (0.998–0.999)	21, 30, 31, 33, 36, 38, 44, 48–50, 52, 53, 55, 57–67
MRI scan series	3164	0.867 (0.844–0.887)	0.997 (0.994–1.0)	21, 54, 65, 68–74

n indicates number of cases used for pooled means; CI, confidence interval; CT, computed tomography; MRI, magnetic resonance imaging.

Table 3. Costs and Effectiveness of Management Strategies for Suspected Cervical Spine Injury

	Cost (2007 US$)		Effectiveness (QALYs)	
Strategy	Mean	95% CI	Mean	95% CI
10 d in collar	186.40	182–192	27.65	27.65–27.65
CT clearance	26,892.54	5255–64,803	27.57	27.44–27.64
MRI clearance	21,460.25	521–45,182	27.59	27.49–27.65

QALY indicates quality-adjusted life year; CI, confidence interval; CT, computed tomography; MRI, magnetic resonance imaging.

$150.17. This assumes a cost-effectiveness threshold of $50,000 per QALY, a number frequently used in cost-effectiveness studies.[124] The cost would need to be below $160.94 per test, even if a more liberal threshold of $100,000 per QALY is chosen. For a test to be cost-effective compared to shorter durations of collar application, it would have to cost even less.

■ Discussion

For the trauma patient who cannot be evaluated clinically, the empirical application of a semirigid collar is significantly more cost-effective than currently-employed radiographic screening procedures. The operating characteristics (sensitivity and specificity) of flexion/extension radiography, CT scan, and MR imaging are inadequate for them to be relied on singly to safely clear the cervical spine in clinically unevaluable trauma patients. Table 2 demonstrates the low sensitivity of plain and flexion/extension radiography. CT and MRI perform better; however, the insensitivity of the former to ligamentous injury and of the latter to osseous injury limits their utility as solo clearance tests.[71,125,126] Our findings are particularly relevant to the trauma patient who is likely to be clinically cleared from cervical spine injury at our 10-day interval. We strongly advise continuing cervical spine immobilization in such patients and not relying on currently available radiographic studies for clearance to remove the collar.

The application of a cervical collar protects against inadvertent spinal manipulation at very little cost. Quadriplegia following iatrogenic injury exerts disproportionate effects on life expectancy, quality of life and lifetime medical costs. Therefore, a clearance study must possess almost 100% sensitivity. Even if a study meets this requirement, it must also be quite inexpensive to exhibit a cost-effectiveness equivalent to several days of cervical spine immobilization. Strategies employing multiple clearance tests, such as combining CT and MRI scans, result in increased costs that outweigh any marginal increases in sensitivity.

Admittedly, a semirigid collar is not an entirely benign intervention, and can cause complications such as skin abrasion and ulceration or airway interference. These complications are more frequent with extended periods of collar application. Although the literature allowed us to estimate the complication incidence associated with various durations of collar use, we could find no information on the quality of life (QOL) of patients with these complications. Our model considered a skin lesion as decreasing QOL by 10% for an average of 2 weeks and the need for close airway monitoring as also decreasing QOL 10% for the duration of collar application. We considered a range of QOL between 80% and 100% of normal. Lower values were not used, as they are extremely unlikely. Since permanent quadriplegia has a QOL of approximately 60% of normal (Table 1), a patient with complications related to a collar would require the same degree of impairment for 6 months to lower that year's QOL to 80%. Even if the QOL was this low with collar complications, a clearance test would need sensitivity of at least 97.5% to result in better outcomes. We chose not to consider the effects of the collar's presence itself on QOL; most patients are obtunded and therefore unable to express their preferences. It must be emphasized that, by convention, QOL is considered from the perspective of the patient. Although a collar requires additional care and places a burden on the nursing staff, this is reflected in increased costs rather than decreased utility.

Our model is limited by its assumptions and is at best an estimate of actual costs and outcomes with the different strategies. However, the superiority of the collar over radiographic clearance tests appears robust. The numbers reported as the specificities of the tests are likely to be overestimates. Most commonly, such studies compared the diagnostic accuracy of one test with that of another, rather than with some gold standard. While clinical follow-up is commonly accepted as the gold standard for injury, it is not infallible, as missed unstable injures that do not result in quadriplegia are not recorded as diagnostic errors. We elected not to incorporate data from follow-up studies for 2 reasons. First, we are unaware of any literature documenting what percentage of patients requires additional radiologic studies after becoming evaluable clinically. Second, there is also a proportion of radiographically-cleared patients whose continued symptoms raise clinical doubts and who require further studies. We suspect that these 2 opposed proportions may be of similar magnitude and indeed equilibrate. It might be argued that we underestimated costs from hospital perspective. The amount of additional nursing care required by a collar is not adequately reimbursed by society. However, a societal perspective also discounts the enormous costs of malpractice defense and awards a hospital would inevitably incur in the event of a iatrogenic spinal cord injury. We have also anticipated enhancements of present tests or new tests and have shown they are unlikely to improve their performance to the point they can replace a cervical collar cost-effectively.

Others have investigated the cost and outcome implications of studies to clear the cervical spine in these patients. A number of comparative studies have shown greater sensitivity of CT scans over plain radiographic

techniques for cervical injury.[31,38,44,49,50,55,127] A meta-analysis by Holmes and Akkinepalli showed this difference was significant.[66] Most authorities consider plain radiography (static or dynamic) unreliable as a screening tool.[40,43,58,128] Several investigators have suggested that CT scanning may also be more cost-effective than plain radiography.[29,30,129–131] Accordingly, many centers prefer to screen high risk patients with CT[30,45,63,132] or even MRI scans.[133,134] A survey of sixteen emergency departments by Holmes *et al* showed that most such patients receive neuroimaging studies, including a number whose plain radiographs were normal.[71]

A recent meta-analysis of MRI for cervical spine clearance in trauma deserves further discussion. Muchow *et al* pooled the results of 5 studies of trauma patients in whom clinical evaluation of the cervical spine was either suspicious or impossible.[135] All patients in these studies had cervical MRI scans performed and all had clinical follow-up. Among the 464 cases pooled, there were no false-negative MRI scans. The authors concluded that a normal MRI was established as the gold standard for cervical spine clearance. However, the study raises several questions. Because of the small number of cases, the 95% confidence intervals allow for MRI sensitivity as low as 89.5% and call the gold standard status of MRI into question. The reviewed reports excluded patients with abnormal plain cervical radiographs or CT scans. Hence, the meta-analysis of Muchow *et al* applies only to prescreened patients. This is important, as direct comparison of MRI and CT scans reveals MRI to miss as many as 50% of cervical fractures seen on CT scan.[71,72] At least some of these missed fractures may be unstable. As mentioned above, the combined costs of CT and MRI scans greatly exceed those of a collar, with little improvement in test sensitivity or resulting QOL.

To our knowledge, this is the first cost-effectiveness analysis to compare prolonged application of a cervical collar to various clearance procedures. Three previous similar studies have been done for potential CSI. Ajani *et al* studied 100 critically ill trauma patients prospectively, following a protocol that involved flexion/extension films.[136] Although they suggest reasons their protocol might yield better outcomes at lower cost than either a cervical collar or neuroimaging studies, they provide no formal analysis. Blackmore *et al* performed a formal cost-effectiveness analysis of patients at low, medium and high risk of CSI.[129] Obtunded patients corresponded to their high risk group. Their analysis compared plain radiography to CT scans to screen the cervical spine; no comparison was made to prolonged collar application. A cost-effectiveness study by Grogan *et al* compared plain radiography with helical CT scanning as screening tools, again without a comparison to a collar.[130]

■ Conclusion

We constructed a mathematical model to compare outcomes of various management strategies for possible cervical spine trauma in clinically unevaluable patients. Tests commonly used to clear the spine lack sufficient sensitivity to compete with empirical application of a semirigid collar until normal responsiveness is regained. Even a theoretical test or combination of tests with perfect sensitivity is unlikely to be cost-effective compared with a collar.

■ Key Points

- Clinically unevaluable patients are at higher risk of occult cervical spinal injury than are patients with reliable clinical examination findings.
- Current cervical spinal clearance protocols rely heavily on the use of radiographic studies in the clearance of unevaluable patients.
- Radiographic clearance protocols may not be sufficiently sensitive to justify their expense given the risk of quadriplegia resulting from a missed unstable injury.
- Empiric immobilization in a semirigid collar is associated with only minor and short-lived complications.

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