

VALIDITY OF A SET OF CLINICAL CRITERIA TO RULE OUT INJURY TO THE CERVICAL SPINE IN PATIENTS WITH BLUNT TRAUMA

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ABSTRACT

Background Because clinicians fear missing occult cervical-spine injuries, they obtain cervical radiographs for nearly all patients who present with blunt trauma. Previous research suggests that a set of clinical criteria (decision instrument) can identify patients who have an extremely low probability of injury and who consequently have no need for imaging studies.

Methods We conducted a prospective, observational study of such a decision instrument at 21 centers across the United States. The decision instrument required patients to meet five criteria in order to be classified as having a low probability of injury: no midline cervical tenderness, no focal neurologic deficit, normal alertness, no intoxication, and no painful, distracting injury. We examined the performance of the decision instrument in 34,069 patients who underwent radiography of the cervical spine after blunt trauma.

Results The decision instrument identified all but 8 of the 818 patients who had cervical-spine injury (sensitivity, 99.0 percent [95 percent confidence interval, 98.0 to 99.6 percent]). The negative predictive value was 99.8 percent (95 percent confidence interval, 99.6 to 100 percent), the specificity was 12.9 percent, and the positive predictive value was 2.7 percent. Only two of the patients classified as unlikely to have an injury according to the decision instrument met the preset definition of a clinically significant injury (sensitivity, 99.6 percent [95 percent confidence interval, 98.6 to 100 percent]; negative predictive value, 99.9 percent [95 percent confidence interval, 99.8 to 100 percent]; specificity, 12.9 percent; positive predictive value, 1.9 percent), and only one of these two patients received surgical treatment. According to the results of assessment with the decision instrument, radiographic imaging could have been avoided in the cases of 4309 (12.6 percent) of the 34,069 evaluated patients.

Conclusions A simple decision instrument based on clinical criteria can help physicians to identify reliably the patients who need radiography of the cervical spine after blunt trauma. Application of this instrument could reduce the use of imaging in such patients. (N Engl J Med 2000;343:94-9.)

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BECAUSE unrecognized injury to the cervical spine can produce catastrophic neurologic disability, clinicians liberally order radiographs of the cervical spine, and as a result the majority of the radiographs are normal.¹⁻⁸ Eliminating even a small proportion of the approximately 800,000 cervical-spine radiographs ordered annually in the United States for patients with blunt trauma could lead to substantial savings and decrease patients' exposure to ionizing radiation.⁹⁻¹¹

Several small studies^{8,12-23} have suggested that patients with blunt trauma have a low probability of injury to the cervical spine if they meet all five of the following criteria: they do not have tenderness at the posterior midline of the cervical spine, they have no focal neurologic deficit, they have a normal level of alertness, they have no evidence of intoxication, and they do not have a clinically apparent, painful injury that might distract them from the pain of a cervical-spine injury.

Although the combination of these five criteria was reported to have a sensitivity of 100 percent for ruling out cervical-spine injury, the lower confidence limit for the sensitivity of the instrument was only 89 percent, which is too low to justify its widespread use.⁸ We organized the National Emergency X-Radiography Utilization Study (NEXUS) to validate this set of criteria and to test the hypothesis that patients with blunt trauma who meet all five of the above criteria have a very low probability of clinically significant injury to the cervical spine.⁹

METHODS

Participating Centers

Twenty-one centers across the United States participated in this prospective, observational study. Among them were university and community hospitals, hospitals with and without residency programs, and public and private hospitals; they varied in size, in the level of activity in the emergency department, and in the level of trauma care they provided. The study was designed to assess the validity of the following five criteria (the decision instrument)

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in ruling out cervical-spine injury in patients with blunt trauma: the absence of tenderness at the posterior midline of the cervical spine, the absence of a focal neurologic deficit, a normal level of alertness, no evidence of intoxication, and absence of clinically apparent pain that might distract the patient from the pain of a cervical-spine injury. Patients who met all five criteria were considered to have a low probability of injury and not to require radiographic or other imaging.

At each center, a physician in the emergency department served as a liaison to the study investigators, and a designated radiologist ensured that the collection of radiologic data was carried out completely and correctly. The liaison physician at each center attended a one-hour training session led by the regional study coordinator, at which the overall study design was presented and the decision instrument and each of the five criteria were explained. The liaison physicians were then responsible for training the participating clinicians in their emergency departments, in some cases through similar brief, formal training sessions and in others, informally. Searchable information and guidelines ("help" screens) were available on computer to assist all the participating clinicians.

Patients

All the patients with blunt trauma who underwent radiography of the cervical spine in a participating emergency department were included in the study. Patients with penetrating trauma and those who underwent cervical-spine imaging for any other reason, unrelated to trauma, were not eligible for inclusion. The participating clinicians were reminded at training sessions that although use of clinical criteria for risk assessment ("clinical clearance") of patients with trauma had come into wider practice, there was no definitive evidence regarding the safety of the clinical decision instrument on which the study focused. They were also cautioned against using the set of criteria being tested as the sole determinant of whether patients needed imaging. The ultimate decision whether to order radiography was made at the discretion of the treating physician, according to the criteria he or she ordinarily used, and was not determined in any way by participation in the study.

The study was prospective and observational. The protocol neither required nor directed any element of the care of enrolled patients and thus posed no risk to the patients. For purposes of confidentiality, the data on the patients were transformed with the use of unique identifying numbers before this information was downloaded into the central data bank, such that it was impossible for individual patients to be identified on the basis of study data. A waiver of informed consent was granted by each institution participating in the study.

Cervical-Spine Radiography

A standard series of three views of the cervical spine (cross-table lateral view, anteroposterior view, and open-mouth view of the odontoid) was obtained in all patients, unless computed tomography (CT) or magnetic resonance imaging of the entire spine was performed because plain-film radiography was impractical or impossible. Other imaging studies (oblique views, flexion-extension radiographs, or CT images) could be ordered in addition to the three-view series of radiographs at the discretion of the treating physician.

Collection of Data

The clinicians prospectively recorded demographic data for each study patient and noted whether each of the study criteria was present, was absent, or could not be assessed. For criteria that could not be assessed (for example, tenderness in a comatose patient), the patient was considered not to have met that criterion.

The results of all the evaluations were recorded on data forms before imaging of the cervical spine. Every patient with a completed data form underwent imaging. All the study sites agreed to obtain the radiographs only after a voucher attesting that the data form had been completed had been issued. If an attending

physician believed that even the minimal delay associated with completing the brief data form might be harmful to the patient, the physician could obtain the study voucher before imaging by indicating that the patient was "unstable." In such cases, the clinicians were encouraged to complete an assessment of the patient with respect to the five criteria as soon as possible, preferably before the results of radiography were known. Designating a patient as "unstable" was considered equivalent to identifying a clinically significant injury (defined below) and was a reason for considering the patient not to have a low probability of injury.

The five criteria for a low probability of injury were not explicitly defined, but possible interpretations of the criteria were reviewed during the training sessions at each center. In addition, information provided to the liaison physician and clinicians at each site included descriptions of possible characteristics that could exclude patients from being classified as having a low risk. This information was included in the guidelines available to the clinicians on the computer (and is available on request from the authors).

Assessment of Injuries

All the radiographs were formally interpreted by the designated radiologists at the study sites. Diagnoses of cervical-spine injury and determination of the type of any fracture were made according to the final interpretation of all the imaging studies. When the results they reported were ambiguous, the radiologists reviewed both their reports and the original radiographs to make the final determination of the type of any fracture. Neither the formal interpretation by the radiologists nor the classification of injuries was done with knowledge of findings recorded on study data forms.

A list of potential cervical-spine injuries was created before data were collected, and each injury on this list was categorized as clinically significant or not clinically significant (Table 1). Injuries that were not clinically significant were those that typically require no specific treatment and those that, if not identified, would be expected to result in no harm. Radiographically documented cervical-spine injuries were categorized as not clinically significant only if they were isolated and there was no evidence of other bony injury or ligamentous or spinal cord injury. All other cervical-spine injuries were considered clinically significant. In any case in which the radiologists' report was unclear as to the exact nature of the injury, the injury was classified as clinically significant. During the study, the cervical-spine injuries were reviewed on an ongoing basis to identify any patient with a clinically significant injury in whom use of the decision instrument had failed (i.e., had indicated that the patient had a low probability of injury). A rule for stopping the study was in place, to be activated if five such cases were identified.

Statistical Analysis

To determine the sensitivity of the decision instrument to within 0.5 percent, we needed to enroll at least 737 patients with cervical-spine injury.⁹

Patients were considered to have a low probability of cervical-spine injury if they were clinically stable and met all five of the clinical criteria. For patients who did not meet all five of the criteria and who were reported to have a radiographically documented cervical-spine injury, the decision instrument was considered to have yielded a true positive result. For patients who did not meet one or more of the five criteria and who had a radiographically documented injury, the result was considered false negative. The result was true negative for patients who met all the criteria for a low probability of injury and who had no evidence of cervical-spine injury on radiography, whereas it was false positive for those who did not meet all the criteria but who had no injury.

Because we enrolled only patients who underwent imaging, we reviewed the neurosurgical records and quality-assurance logs of each participating site three months after the completion of the study, in order to identify any cases in which cervical-spine injury was missed because of an initial failure to obtain imaging studies.

TABLE 1. RADIOGRAPHICALLY DOCUMENTED CERVICAL-SPINE INJURIES CATEGORIZED AS NOT CLINICALLY SIGNIFICANT.*

Spinous-process fracture
Simple wedge-compression fracture without loss of 25 percent or more of vertebral-body height
Isolated avulsion without associated ligamentous injury
Type I (Anderson-D'Alonzo) odontoid fracture
End-plate fracture
Osteophyte fracture, not including corner fracture or teardrop fracture
Injury to trabecular bone
Transverse-process fracture

*Injuries categorized as not clinically significant were those that, if not identified, would be extremely unlikely to result in any harm to patients, that required no specific treatment, and that occurred in isolation, without evidence of other bony injury or ligamentous or spinal cord injury.

RESULTS

The study population consisted of 34,069 patients evaluated by imaging of the cervical spine after blunt trauma. Of these 34,069 patients, 818 (2.4 percent) had radiographically documented cervical-spine injury. The majority of the patients overall (58.7 percent) and the majority of the patients with cervical-spine injury (64.8 percent) were male. The patients ranged in age from less than 1 year to 101 years (mean, 37; interquartile range, 23 to 47); 2.5 percent were 8 years old or younger. Among the patients with a cervical-spine injury, the mean age was 40 years (range, 2 to 100; interquartile range, 27 to 56); 1.3 percent were 8 years old or younger.

The distribution of the patients according to the presence or absence of cervical-spine injury and the results of assessment with the clinical decision instrument is shown in Table 2. The resulting performance of the decision instrument is shown in Table 3. The instrument yielded a false negative result for 8 of the 818 patients with radiographically documented cervical-spine injury; 2 of these 8 patients were among 578 patients who met the predefined criteria for clinically significant injury.

The eight patients whom the decision instrument identified as having a low probability of injury but who did have radiographically documented cervical-spine injury are described more fully in Table 4. Of the two patients who had a clinically significant injury, one was a 54-year-old man with a history of multiple motorcycle accidents who had no symptoms but whose plain films showed a fracture of the anteroinferior portion of the second cervical vertebra. The fracture was not accompanied by anterior soft-

TABLE 2. PATIENTS WITH BLUNT TRAUMA WHO HAD OR DID NOT HAVE EVIDENCE OF CERVICAL-SPINE INJURY ON RADIOGRAPHY, ACCORDING TO THE RESULTS OF ASSESSMENT WITH THE CLINICAL CRITERIA.

OUTCOME WITH CLINICAL CRITERIA*	RADIOGRAPHICALLY DOCUMENTED INJURY	
	YES	NO
Screening for any injury		
Positive	810	28,950
Negative	8	4,301
Screening for clinically significant injury		
Positive	576	29,184
Negative	2	4,307

*“Positive” indicates that the patient was considered to require imaging to detect a possible cervical-spine injury, and “negative” that the probability of such injury was considered so low that imaging was unnecessary.

TABLE 3. PERFORMANCE OF THE CLINICAL CRITERIA IN RULING OUT CERVICAL-SPINE INJURIES IN PATIENTS WITH BLUNT TRAUMA.

CHARACTERISTIC	VALUE (95% CI)*
All patients	
Sensitivity	99.0 (98.0–99.6)
Negative predictive value	99.8 (99.6–100)
Specificity	12.9 (12.8–13.0)
Positive predictive value	2.7 (2.6–2.8)
Patients with clinically significant injuries	
Sensitivity	99.6 (98.6–100)
Negative predictive value	99.9 (99.8–100)
Specificity	12.9 (12.8–13.0)
Positive predictive value	1.9 (1.8–2.0)

*CI denotes confidence interval.

tissue swelling or any other abnormal finding on either plain films or CT scans; the injury was described in most of the radiology reports as an avulsion of the end plate of this vertebra. However, it was also described in one report as an “extension-teardrop” fracture and thus met our criteria for clinically important injury. The patient remained asymptomatic during a 24-hour hospitalization and refused any treatment other than a soft cervical collar, which he removed at discharge. He reported no symptoms at a six-week follow-up visit.

The second patient who had a clinically significant, radiographically documented injury was a 57-year-old man who had been driving a car while wearing a seat belt and transiently lost consciousness after a

TABLE 4. EIGHT PATIENTS WHO WERE FOUND TO HAVE CERVICAL-SPINE INJURY DESPITE A NEGATIVE RESULT WITH THE CLINICAL CRITERIA.*

PATIENT'S SEX/AGE (YR)	CERVICAL-SPINE INJURY		COMMENT
	VERTEBRAE	TYPE OF INJURY	
M/38	C6	Spinous-process fracture	
M/53	C6-C7	Chipped osteophyte	
M/54	C2	Extension (teardrop) fracture; normal alignment without soft-tissue swelling	
M/20	C7	Anterosuperior end-plate avulsion, without soft-tissue swelling	Treatment with soft collar only; no sequelae
F/18	C5	Wedge compression fracture	Minimal loss of body height
F/81	C2	Isolated lateral-mass avulsion	Treatment with soft collar
M/84	C2	Isolated lateral-mass avulsion	Treatment with hard collar for 2 days, followed by soft collar
M/57	C6	Lamina fracture	

*A negative result indicated that the patient was considered to have such a low probability of cervical-spine injury that imaging was not necessary.

head-on collision. He reported only pain in the right shoulder and had tenderness of paraspinal muscles and tenderness in the area of the right clavicle and scapula. Plain films revealed a fracture of the right lamina of the sixth cervical vertebra, as well as a fracture of the right clavicle. Paresthesias then developed in the right arm; the patient subsequently underwent a laminectomy and fusion at this level and did well.

All of the 810 patients with injury who were correctly identified by the decision instrument met at least one of the five criteria for a low probability of injury, whether or not they also had clinical instability (i.e., none of these patients were identified only because of clinical instability). In addition, assessment of all five criteria in each patient was necessary for the decision instrument as a whole to achieve high sensitivity, since fulfillment of a single criterion was the only finding in some of the patients with injury, including some with clinically significant injury; this was the case for each of the five criteria.

Through our review of neurosurgical records and quality-assurance logs, we were able to identify two patients with injury (odontoid fracture) that was predicted by the decision instrument but that was not initially diagnosed by the clinicians. In one of these two patients, the fracture was not apparent on the plain films and was subsequently discovered by further testing, whereas in the second patient the film

was misread by clinicians at the study site. No injuries were known to have been missed among the patients who did not undergo radiographic evaluation.

According to classification with the decision instrument, 4309 patients (12.6 percent) could have been spared radiographic evaluation. Imaging of the cervical spine would have been appropriate for the remaining 29,760 patients (87.4 percent).

DISCUSSION

Although there have been several case reports of occult injury to the cervical spine,^{1-7,24-33} most of these cases involved patients who either were inadequately evaluated or did not meet at least one of our criteria for low risk.¹ Nevertheless, fear of missing a clinically occult injury has prompted physicians to order images of the cervical spine for virtually all patients who have blunt trauma.^{1,2} As a result, for each injury detected, a large number of films with negative findings are ordered.¹⁻⁸ Because of the consequent human and economic losses, combined with medicolegal issues and concern about quality assurance, validation of selective criteria for ruling out probable cervical-spine injury requiring radiography in patients with blunt trauma is an important priority.^{8-11,34,35}

This study is the culmination of a series of investigations designed to derive and validate to a high level of confidence a set of clinical criteria that identify cervical-spine injury requiring radiography.^{8,9,12,36} Although it had already been demonstrated that an instrument based on the criteria we used has very high negative predictive value, a study of this size (with more than 737 patients with a fracture) was required for reliable estimation of its sensitivity.

In rare instances, this decision instrument will undoubtedly miss individual cases of cervical-spine injury. In this study, the overall rate of missed cervical-spine injuries was less than 1 in 4000 patients. To place the characteristics of the decision instrument in perspective, we can consider that every full-time emergency physician orders cervical-spine imaging in approximately 32 patients annually (given that approximately 25,000 full-time-equivalent emergency physicians in the United States order about 800,000 films each year^{9,37}); physicians can therefore expect to encounter a case of occult cervical-spine injury (which occurs less than once for every 4000 radiographs obtained) perhaps once in every 125 years of clinical practice. Missed cases of clinically significant cervical-spine injury (which occurred in only two patients in our study) and those requiring specific therapy (one patient) appear to be even more rare.

Two of our patients did have clinically significant injury, according to our formal definition, that was missed, although one of them seemed clearly not to have had an acute injury and had no clinical sequelae even though he essentially refused treatment. Only one patient with a false negative result underwent spe-

cific treatment for the injury; this case may actually represent misapplication, rather than failure, of the decision instrument, since the patient had loss of consciousness, a clavicular fracture, and neurologic symptoms (paresthesias).

Nevertheless, on extremely rare occasions, a missed injury may lead to profound consequences for an individual patient. We believe that although clinicians can generally adhere to the clinical criteria in the decision instrument, they should be free to make exceptions for individual patients on clinical grounds. In any case, no decision instrument is ever likely to be 100 percent sensitive, and the medical and economic costs of a quixotic search for absolute diagnostic certainty can lead to more harm than good.³⁸

In this study, application of the decision instrument would have decreased the overall ordering of radiographs by only 12.6 percent. This decrease is far smaller than the reduction of almost one third in the use of radiography that would have been predicted by the results of our previous study, conducted in a single hospital,⁸ and may reflect an influence of the previous study on the ordering of radiographs at institutions participating in this study. In emergency departments with more liberal use of imaging, the effect of the adoption of the decision instrument could be greater than that seen here. In any case, even a reduction of one eighth in the ordering of radiographs, as our study indicates is possible, would translate into a substantial decrease (by about 100,000) in the number of cervical-spine radiographs obtained each year in the United States.

For a decision instrument to be valuable, it must be shown to be reliable when used by different practitioners.^{39,40} Each of the criteria of our decision instrument has been shown to have good-to-excellent interobserver reliability (kappa, 0.58 to 0.86), and interobserver agreement for the decision instrument as a whole is excellent (kappa, 0.73).³⁶ In this study, the decision instrument had an extremely high sensitivity when applied by a very large number of clinicians at various sites. Although physicians who participate in a multicenter trial are not perfectly representative of all physicians, the participation of physicians at all levels of training and in many different environments in this study provides powerful evidence of the external validity of the clinical criteria. Furthermore, the ability of such clinicians to apply the criteria with high sensitivity, despite minimal formal training, suggests that the use of the decision instrument can be widely taught, without undue expenditure of human or economic resources.

We chose not to define the individual criteria of the decision instrument explicitly, for two reasons. First, we do not believe such criteria can be precisely defined in a clinically meaningful way. An attempt to define a “distracting” injury, for example, with a long list of various injuries that could distract a patient

from a cervical-spine injury would be extremely misleading. Some contusions, for example, may be associated with extreme pain, whereas not all long-bone fractures are particularly painful. Therefore, we allowed the clinicians to judge whether the patients had an injury that could produce distracting pain and thus required cervical-spine imaging. Similarly, we believe that evidence of intoxication and the level of alertness are best evaluated on the basis of clinical judgment, rather than laboratory tests or uniform criteria.

Second, if physicians were required to consult precise definitions for each criterion whenever evaluating a patient with blunt trauma — for example, to check the exact length a laceration needed to be to qualify as a distracting injury — the decision instrument would rapidly fall into disuse. We believe our limited number of criteria are straightforward, logical, and easy to remember, and that they thus can be readily applied at the bedside.

Because this study was strictly observational, it is possible that there were patients with cervical-spine injury at the study sites who met the decision-instrument criteria but did not undergo radiography and were thus not included in the study. It is impossible to identify every patient with a potential illness or injury, since some patients may have symptoms so minor that they do not seek medical care or their presentation does not suggest the possibility of the disease or injury in question. Such patients cannot be identified by this or any other decision instrument. The question we wished to address was whether some of the many patients who are currently considered candidates for cervical-spine imaging can be safely classified as having such a low probability of injury on clinical grounds that radiography need not be performed, with consequent cost savings and medical benefits. Our methods have allowed us to answer this question.

In summary, this prospective, multicenter study confirms the validity of a decision instrument based on five clinical criteria for identifying, with a high degree of confidence, patients with blunt trauma who have an extremely low probability of having sustained injury to the cervical spine. The sensitivity of this set of criteria approaches 100 percent for clinically important injuries, and its general application should result in both clinical and economic benefit. As with any other clinical tool, it should be applied with great care and should not replace clinical judgment in the care of individual patients. There may be compelling reasons to order cervical-spine images in individual cases, even if all the criteria for a low probability of injury are met.

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APPENDIX

The following centers and investigators collaborated in the NEXUS study: Principal investigator — W. Mower; Co-investigator — J. Hoffman; Steering Committee — J. Hoffman, W. Mower, K. Todd, A. Wolfson, and M. Zucker; Site investigators — Antelope Valley Medical Center (Los Angeles): M. Brown and R. Sisson; Bellevue Hospital (New York): W. Goldberg and R. Siegmann; Cedars-Sinai Medical Center (Los Angeles): J. Geiderman and B. Pressman; Crawford Long Hospital (Atlanta): S. Pitts and W. Davis; Egleston Children's Hospital (Atlanta): H. Simon and T. Ball; Emory University Medical Center (Atlanta): D. Lowery and S. Tigges; Grady Hospital (Atlanta): C. Finney and S. Tigges; Hennepin County Medical Center (Minneapolis): B. Mahoney and J. Hollerman; Jacobi Medical Center (Bronx, N.Y.): M. Touger, P. Gennis, and N. Nathanson; Maricopa Medical Center (Phoenix, Ariz.): C. Pollack and M. Connell; Mercy Hospital of Pittsburgh (Pittsburgh): M. Turturro and B. Carlin; Midway Hospital (Los Angeles): D. Kalmanson and G. Berman; Ohio State University Medical Center (Columbus): D. Martin and C. Mueller; Southern Regional Hospital (Decatur, Ga.): W. Watkins and E. Hadley; State University of New York at Stony Brook (Stony Brook): P. Viccellio and S. Fuchs; University of California, Davis, Medical Center (Sacramento): E. Panacek and J. Holmes; University of California, Los Angeles, Center for the Health Sciences (Los Angeles): J. Hoffman and M. Zucker; University of California, San Francisco, Fresno University Medical Center (Fresno, Calif.): G. Hende and R. Lesperance; University of Maryland Medical Center (Baltimore): B. Browne and S. Mirvis; University of Pittsburgh Medical Center (Pittsburgh): A. Wolfson and J. Towers; Hermann Hospital, University of Texas Health Sciences Center (Houston): N. Adame, Jr., and J. Harris, Jr.

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CORRECTION

Validity of a Set of Clinical Criteria to Rule Out Injury to the Cervical Spine in Patients with Blunt Trauma

Validity of a Set of Clinical Criteria to Rule Out Injury to the Cervical Spine in Patients with Blunt Trauma . On page 95, the sentence that begins 12 lines from the bottom of the right-hand column should have read, "For patients *who met all five criteria* but had a radiographically documented injury, the result was considered false negative," not "For patients *who did not meet one or more of the five criteria*," as printed.