

ORIGINAL CONTRIBUTION

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Low-Risk Criteria for Cervical-Spine Radiography in Blunt Trauma: A Prospective Study

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Study hypothesis: Cervical-spine radiography does not need to be performed on selected blunt trauma patients who are awake, alert, nonintoxicated, do not complain of midline neck pain, and have no tenderness over the bony cervical spine.

Study population: One thousand consecutive patients seen in the UCLA Emergency Medicine Center with a chief complaint of blunt trauma, for whom cervical-spine films were ordered and for whom prospective data questionnaires were completed.

Methods: Clinicians completed data forms for each patient before radiograph results were known. Data items included mechanism of injury, evidence of intoxication, presence of cervical-spine pain and/or tenderness, level of alertness, presence of focal neurologic deficits, and presence of other severely painful injuries unrelated to the cervical spine. Physicians were also asked to estimate likelihood of significant cervical-spine injury.

Results: Twenty-seven patients with cervical-spine fracture were among the 974 patients for whom data forms were completed. A number of findings were statistically more common in the group of patients with fracture than without, but no single or paired findings identified all patients with fracture. All 27 patients with fracture had at least one of the following four characteristics: midline neck tenderness, evidence of intoxication, altered level of alertness, or a severely painful injury elsewhere. Three hundred fifty-three of 947 (37.3%) patients without cervical-spine fracture had none of these findings.

Conclusion: Cervical-spine radiology may not be necessary in patients without spinous tenderness in the neck, intoxication, altered level of alertness, or other severely painful injury. A policy to limit films in such patients would have decreased film ordering by more than one third in this series, while identifying all patients with fracture.

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INTRODUCTION

Cervical-spine radiography is widely recommended for essentially all patients with blunt multiple trauma, particularly if there is associated "head injury," because of concern that occult injury in individual patients could lead to catastrophic consequences if undiscovered.^{1,2} Although several isolated case reports have claimed to identify patients with asymptomatic cervical-spine fractures³⁻⁹ and a number of retrospective case series have suggested that "low-yield criteria" could be developed to exclude cervical-spine injury, and thus the need for cervical-spine radiography in a selected subset of patients,¹⁰⁻¹⁵ there are very little prospectively gathered data with which to address this issue.^{16,17}

We therefore designed this study to test the hypothesis that clinical low-risk criteria, determined prospectively at the bedside, could be used to identify patients without meaningful risk of cervical-spine fracture. We defined low-risk patients as those who, despite blunt trauma potentially involving the neck, in the presence of a normal level of alertness and without other clinical signs of intoxication, had no midline neck pain or tenderness and no other severely painful injuries remote from the cervical spine.

MATERIALS AND METHODS

Physicians working in the UCLA Emergency Medicine Center (primarily house officers in emergency medicine, but also emergency medicine attending physicians and house officers from other specialties) filled out data forms for blunt trauma patients for whom they decided to order cervical-spine radiography. We stressed that physicians complete these forms before knowing results of cervical-spine radiography. We did not expect clinicians to defer patient care in critical patients to complete data forms but asked that in such cases answers to data questions such as likelihood of fracture be formulated, even if not recorded, before availability of films for review.

Data forms included elements of history and physical examination, prehospital treatment, and estimated likelihood of cervical-spine injury. Historical factors included mechanism of injury, available history of intoxication, and presence and location (midline or lateral) of neck pain. Physical examination data were gathered on presence of midline or lateral paraspinal neck tenderness, level of alertness, evidence of intoxication, and presence of other severely painful injuries. (Precise definitions or instructions as to how to determine answers to these questions were not given to house officers, nor were attempts made to independently verify clinical estimation of such parameters.) Several questions were related to prehospital findings, such as whether the patient was up and about at the scene and whether cervical precautions (hard cervical collar, tape and sandbags, or backboard) were used by paramedics. Clinicians were asked to predict the likelihood of cervical fracture as either less than 10%, 10% to 50%, 51% to 90%, or more than 90%.

We did not develop formal criteria regarding indications for cervical-spine radiography, although residents receive standard educational sessions about the management of trauma, which in our hospital traditionally stress a liberal approach to ordering of these films. There was no specific attempt to modify physician use of cervical-spine radiography before, during, or after the study period. There were no exclusion criteria for enrollment of patients in the study. All patients received at least cross-table lateral, anteroposterior, and odontoid views, supplemented by oblique views, flexion-extension radiographs, and cervical computed tomography as determined by emergency physicians.

The preliminary reading by the emergency department and radiologic house-staff was used to define tentative fracture and nonfracture groups. The presence of fracture was confirmed by review of the final radiologic diagnosis of the ED studies as well as any additional studies performed in the inpatient setting. Cases for which the initial diagnosis of fracture proved incorrect were reclassified to the nonfracture group.

Preliminary diagnoses of "no fracture" were confirmed in three ways. First, quality assurance logs, which contain lists of significant findings noted on the official radiology reading that were missed on preliminary reading, were reviewed. Second, risk management records through May 1991 were reviewed to determine if there were any pending or closed cases of missed cervical-spine fracture. Third, the diagnoses of all patients discharged from the hospital during and up to three months after each study period were searched, and all cervical-spine fractures were identified. The chart of each patient admitted to the hospital through the ED was reviewed to determine if it was included in the study, and if so, whether it had been classified as a fracture.

Sensitivity and specificity were calculated in the standard fashion; confidence intervals were derived using the exact method described by Fleiss.¹⁸ Comparisons between fracture and nonfracture groups were made by χ^2 testing or Fisher's exact test when any cell had less than five subjects. Because these analyses were performed for descriptive purposes rather than hypothesis testing, no Bonferroni adjustment was made. Bayesian meta-analysis was performed using the confidence profile method with FAST*PRO meta-analysis software.^{19,20}

Table 1.

Historical findings at the scene in 974 patients receiving cervical-spine films for blunt trauma

	Fracture (N=27)	No Fracture (N=947)	P
Associated head injury	17	504	.32*
Direct blow to neck	3	90	.74†
"Whiplash" mechanism†	0	283	< .001†
Immobilization in the field	26	576	< .001*
Up and about at the scene	6	416	< .025*

P by two-sided χ^2 * or Fisher's exact† testing.
 †Whiplash, extension, or rotation without direct blow to head or neck.

RESULTS

The study took place during 19 months in 1987, 1988, and 1989 and by design was terminated when 1,000 data forms had been completed. Subsequent review revealed that 26 forms had incomplete data; thus, 974 cases were suitable for inclusion in the study. There were no fractures among the 26 patients who were excluded.

Men comprised 59.3% of the study group, and the median age of our patients was 25 years (range, 6 months to 98 years). Twenty-seven study patients had cervical-spine injury; in this group there were 21 men, and the median age was 23 years (range, 17 months to 89 years). Only seven patients were younger than 5 years old, and four patients were younger than 3 years old; neck tenderness was recorded as present in three of the seven, including one of those younger than 3 years old. The one child with fracture was recorded as not having neck tenderness but did have altered level of alertness and other injuries.

Radiology department records revealed that 555 cervical-spine radiography studies were performed in the ED during eight study months in 1988; precise data in this regard were not available for the remainder of the study period. Using these eight months as a proxy for the entire study, we estimate that 1,342 cervical-spine studies were performed during the time of the study, of which 1,000 were entered into the study. Thirty-one patients with cervical-spine fracture were admitted to the hospital during the entire study period: 27 were among the 974 study subjects, two were from the estimated 368 patients seen in the ED but not included in the study, and two were direct admissions to the hospital not seen in the ED. Cases with fractures who were seen in the ED but not included in the study were reviewed, and each one had at least one high-risk criterion for radiography.

The only historical finding regarding events at the scene that distinguished patients with from those without fracture was mechanism of injury described as "whiplash," which occurred in 283 (29.9%) patients without fracture but was entirely absent in the fracture group (Table 1). More patients without fracture were up and about at the scene,

but this was also reported to be true in six patients with fracture. Cervical immobilization by field paramedics was frequent in both groups, although more so in those with fracture; however, one fracture patient was brought to the hospital by private car and was thus not immobilized.

Each of two specific signs and symptoms was statistically more common in the fracture group (Table 2), but no individual finding identified all fracture patients. Midline neck tenderness was statistically more common in the fracture group, whereas tenderness over the posterolateral neck muscles tended to occur more frequently in patients without fracture. Complaint of neck pain was very frequent in both groups.

Clinical judgment correlated well with film results (Table 3), although two patients with fracture (described below) were thought to have less than 10% pretest probability of fracture. More than two thirds of patients without fracture were thought to have less than 10% pretest probability, and the vast majority of such patients (98.5%) were estimated to have 50% or less pretest probability of fracture.

By combining data elements we were able to identify most, and in some cases all, of the patients with fracture (Table 4). Twenty-five of 27 patients with fracture had either midline neck tenderness or altered level of alertness, whereas 479 (50.6%) of the patients without fracture had neither of these (Table 3). One of the two patients in the cervical-spine injury group (with C2 facet fracture) had other severely painful injuries (pelvic and femoral shaft fractures) but was awake and alert and did not complain of either neck pain or tenderness. The second patient (with fracture of the lateral mass of C5) was reported to be intoxicated (and proved to have a blood alcohol level of more than 200 mg/dL) but was noted by the examining physician to have a normal level of alertness; he had been up and about at the scene, denied neck pain or tenderness, and also did not complain about lacerations and ecchymoses on his face and scalp. Thus, 26 fracture patients had at least one of midline neck tenderness, altered level of alertness, or another severely painful injury, and all 27 had at least one of these or evidence of intoxication.

Of the 949 patients without fracture, 479 (50.6%) had neither midline neck tenderness nor altered level of alertness (Table 4). Three hundred ninety-six of these patients (41.8%) were without either of these characteristics and also without a severely painful injury elsewhere, and 353 (37.3%) were without all these and also without evidence of intoxication.

Table 2.

Signs and symptoms in 974 patients receiving cervical-spine films for blunt trauma

	Fracture (N=27)	No Fracture (N=947)	P*
Neck pain	18	562	.44
Midline neck tenderness	19	272	< .001
Tenderness over posterolateral neck muscles	10	431	.38
Evidence of intoxication	7	187	.43
Altered level of alertness	8	234	.56
Soft tissue injury to face, scalp, or neck	11	387	.99
Other severely painful injuries (away from neck)	11	225	.04

*By two-sided χ^2 testing.

Table 3.

Estimated pretest probability of cervical-spine fracture in 974 patients with blunt trauma

Probability (%)	% Fracture (N=27)	% No Fracture (N=947)
< 10	7	69.6
10 to 50	37	28.9
50 to 90	44	1.3
> 90	11	0.2
Total	100	100

P < .001 between patients with and without fractures, using two-tailed χ^2 testing, with three degrees of freedom.

A variety of strategies to limit cervical-spine radiography could have dramatically reduced the number of films taken, but most would have failed to identify at least one patient with fracture (Table 4). All fractures would have been identified, and the number of negative films reduced by 12.5%, with a strategy to obtain films on patients with any of the following: midline neck pain or tenderness, altered level of alertness, intoxication, or other severely painful injuries. The number of films needed would be further greatly reduced, without missing any fractures, by eliminating neck pain (but not tenderness) from this list (total reduction of 37.3% of negative films) or by excluding all patients with a whiplash mechanism of injury (total reduction of 52.2% of negative films).

Although no other strategy would have identified all patients with fracture, clinicians' estimates of fracture likelihood performed with greater accuracy than any other criterion or combination of criteria in both limiting the number of negative films while identifying the greatest number of positive films (those with fracture) (Table 4). If films were obtained only in those patients with a more than 10% pretest clinical probability of cervical-spine injury, more than two of every three negative films would have been eliminated, whereas only two (7%) of patients with fracture would not have been radiographed.

DISCUSSION

It is mandatory to identify all patients with cervical-spine fractures to prevent the possibility of neurologic deterioration. Concern about potential failure to do so has been heightened by sporadic case reports suggesting that rare patients may have not only occult, but also truly asymptomatic, cervical-spine fractures.³⁻⁹ This has led to practice policies stating that virtually all patients with blunt trauma of any consequence receive spinal radiographs, strategies that typically result in large numbers of negative radiographs for each positive film.^{10-13,15-17}

Careful evaluation of published reports claiming to have identified cases of asymptomatic cervical fracture raises questions about the existence of such an entity in every case. Although Maull and Sachatello refer only to unspecified personal experiences,⁶ each patient in the other case reports had either positive signs or symptoms,^{3-5,7} incomplete evaluation,⁸ altered mentation,^{3,7-9} evidence of intoxication,^{1,5} or other major injuries^{3,5,7,9} that were likely to obscure complaints regarding the neck.

At the same time a number of published retrospective¹⁰⁻¹⁵ and prospective^{16,17} series have identified low-risk criteria whose presence has not been associated with cervical fracture in any case. Such criteria have generally included absence of midline neck pain or tenderness in patients with normal mentation. Absence of severe injuries away from the neck has also been included in some studies, as has absence of intoxication.

Despite such previous studies, we thought that a larger prospective evaluation of this issue was important for several reasons. First, although there are more than 6,100 total subjects in the collected series to date, only 214 patients had cervical fractures. Of even greater concern is the possibility that information obtained from retrospective reviews may be both incomplete and tainted, particularly because only a total of 36 patients with fracture are in the combined prospective series.^{16,17} In our own retrospective series of 1,003 cases,¹⁵ important data elements were very frequently missing or incomplete, making it impossible to know whether the absence of a specific finding recorded on a patient's chart meant that finding was truly absent or merely that it had not been evaluated or documented. This could introduce significant bias regarding the value of these findings in predicting or excluding fracture.

Furthermore, it was often difficult on the basis of chart review to be certain of the presence or absence of low-risk elements. Although some patients had other major injuries (eg, broken bones or life-threatening hemorrhage) that could

Table 4.

Sensitivity, specificity, and negative predictive value of combinations of signs and symptoms for cervical fracture in 974 patients with blunt trauma

	Sensitivity (95% CI) (N=27) (%)	Specificity (95% CI) (N=947) (%)	Negative Predictive Value (95% CI) (%)
Midline neck tenderness or altered level of alertness	93 (76-99)	50.6 (47.3-53.8)	99.6 (98.5-100)
Any of above or other severely painful injury	96 (81-100)	41.8 (38.6-45.0)	99.7 (98.6-100)
Any of above or intoxication	100 (87-100)	37.3 (34.2-40.4)	100 (99.0-100)
Any of above or midline neck pain	100 (87-100)	12.5 (10.4-14.7)	100 (96.9-100)
Any of midline neck tenderness or altered level of alertness or intoxication but exclude all patients with whiplash mechanism	100 (87-100)	52.2 (48.9-55.4)	100 (99.3-100)
More than 10% pretest clinical prediction of fracture	93 (77-100)	69.6 (66.6-72.5)	99.4 (99.0-100)
More than 50% pretest clinical prediction of fracture	56 (35-75)	98.5 (97.6-99.2)	98.7 (97.8-99.3)
More than 90% pretest clinical prediction of fracture	7 (1-24)	99.8 (99.2-100)	97.4 (96.2-98.3)

clearly distract patient attention away from the neck, many more had more minor remote injuries (eg, lacerations and abrasions). It is virtually impossible in such cases to know, on the basis of chart review alone, whether such injuries were sufficiently painful to obscure the presence of a cervical fracture or were relatively trivial. We thus believed that only prospective analysis by a physician at the bedside could be used to determine this important parameter.

We therefore undertook this study to document prospectively the clinical presentation of patients who were to receive cervical-spine radiography in the evaluation of blunt trauma. We emphasized the importance of completion of data forms before knowledge of film results and had clinicians complete every element of the data form to eliminate the presence of unknown or unrecorded characteristics. We also asked them to prospectively judge the presence of painful injuries away from the neck, clinical suspicion of intoxication, and impairment of alertness; although different physicians might answer these questions differently about a single patient, our results reflect the actual practice of physicians at the time a decision of whether to order films is made.

In this study, clinical judgment, primarily on the part of house officers, performed extremely well, because limiting films to only patients predicted by clinicians to have more than a minimal (10%) chance of fracture would have eliminated more than two of every three negative films while still capturing almost all (25 of 27) the fractures (Tables 3 and 4). Unlike the extremely low accuracy of house officer judgment in the only previous series to evaluate this,²¹ clinical judgment in fact provided the most efficient way identified in our series of both limiting excessive radiographs while capturing most of the important films.

However, two of our 27 patients with fracture had clinically occult presentations, ostensibly because of the presence of either intoxication or other distracting injuries, which led them not to complain about their necks and led their physicians to discount any real likelihood of cervical-spine injury. Because it is generally considered unacceptable to miss any cervical fractures, a policy based purely on clinical suspicion is therefore not practical, as it could miss as many as 23% of these injuries (Table 4).

Ordering cervical-spine radiography on all patients with midline neck pain or tenderness, altered level of alertness, suspicion of intoxication, or other potentially distracting injury would have identified all patients with fracture but would have required films on almost 90% of all patients (Table 4). Because the complaint of neck pain was not required to capture all fracture patients, exclusion of this criterion would retain 100% sensitivity, while allowing avoidance of films in a far greater number (more than 37%) of negative patients. Similarly, because no patient with fracture had a "whiplash" mechanism of injury (without direct contact between the head or neck and a hard object), obtaining radiographs only on patients without such a mechanism but with one of the four above-mentioned findings would

capture all 27 patients with fracture but limit radiographs to only 453 patients (47.8%) in the entire group. (There are other reports, however, of fractures in patients with such a mechanism²²; although the frequency of this event is undoubtedly rare, the risks involved in using this criterion to limit films is likely to be real, even if small.)

Although our numbers suggest that cervical-spine radiography can be substantially limited in patients with certain low-risk criteria, the confidence intervals for our sensitivity remain relatively wide because of the limited number of patients with fracture in our study (Table 4). These confidence intervals can be modified by performing a Bayesian meta-analysis including data from this and the two other prospective studies that address the same question.^{15,16} The posterior probability distribution derived in this manner reveals that there is a 97.5% chance that the false-negative rate, using low-risk criteria, is at most less than 4% and a 74% chance that it is at most less than one in 100.

Negative predictive values for each of several possible strategies are much more impressive (Table 4), considering the more than 900 patients with negative results, and suggest that the vast majority of patients falling into one of these patterns (low pretest clinical probability, or presence of only low-risk criteria) do not have cervical fracture (with much tighter confidence intervals as well). Negative predictive values, however, reflect the prevalence of disease in the population (less than 3% of those tested had fracture) and not merely the performance of the screening test. Thus, the negative predictive value of merely being a patient in this study before performance of any clinical screens is more than 97%, and the numbers cited in Table 4 could change greatly in a population with a higher incidence of fracture. Nevertheless, although some populations might conceivably have a greater number of patients with fracture, our prevalence is similar to that reported by others (3.5% in the combined series cited).¹⁰⁻¹⁷ Furthermore, there is really no reason to believe that the prevalence of occult fractures with absent clinical indicators would or should be higher from one group to another. Thus, we believe that the powerful negative predictive values obtained, suggesting that patients with all these low-risk elements have (with 95% confidence) at worst less than a 1% chance of fracture, should not be dismissed entirely.

Threats to the internal validity of this study related primarily to factors that could have biased our estimates of the sensitivity and specificity of the various screening strategies. Bias in the sensitivity estimate could have occurred through misclassification of patients regarding their fracture status or by physicians changing their answers on the data forms once they were aware that the patient had a fracture. The presence of fracture was confirmed in each of the 27 cases, and review of hospital discharge diagnoses, quality assurance records, and risk management records revealed no evidence of other misclassification. The 27 data forms for patients with fracture contained no scratch-outs or revisions

that would suggest retrospective manipulation of answers. Thus, it appears that the sensitivity measures were accurate.

Bias in the specificity measurements could result from misclassification of subjects or from selection bias that could occur if physicians entered or excluded patients from the study in a nonrandom manner. As discussed above, misclassification of subjects does not appear to be a problem. Selection bias could have occurred, however, if the 72% of eligible patients who were entered into the study were not representative of the entire group. The 2.7% prevalence of fracture in the study group was significantly higher than that for the nonstudy group (two of 378 = 0.5%, $P = .01$ by Fisher's exact test), suggesting that physicians tended to enroll those patients with a higher likelihood of fracture. If the group of patients omitted from the study had very few of the high-risk criteria, then our measure of specificity was too low; the converse is also possible. Thus, it is impossible to determine the direction of possible bias in our specificity measurements. Nevertheless, because only 366 of 1,313 (27.9%) nonfracture patients were excluded from the study, differences between the excluded and included patients could modify the specificity by a maximum of 28%. If excluded patients were 20% more or less likely to meet the high-risk criteria than the included patients, the specificity estimate would change only by about 5%. Thus our specificity estimates, even if biased, would be very unlikely to change enough to substantially alter our conclusions.

Threats to the external validity of this study arise from ambiguities regarding the selection of the study population. Because individual physicians decided whether each patient needed radiographs, our population could have differed from that selected by a different group of physicians. Despite our traditional teaching of liberal criteria for cervical-spine radiography, there is a competing tradition in our department favoring "clinical clearance" of patients with low-risk findings similar to those studied; because no such patient was ultimately identified as having cervical fracture, we believe that elimination of this potential bias would if anything strengthen our results by narrowing the confidence interval of the specificity of our low-yield criteria. The patients in this study were taken from an urban ED case mix that includes predominantly blunt vehicular trauma (both highway and surface street), some falls, and a few industrial accidents. The predictive value of the various screening strategies may change when they are applied to different patient populations.

Other limitations of this study were related to the small denominator for sensitivity calculations. Despite a sample size of nearly 1,000 patients, only 27 had fractures, resulting in a rather wide confidence interval for sensitivity estimates. A sensitivity quotient of roughly 200 of 200 would be needed to be 95% certain that the true sensitivity is no less than 99%; assuming similar prevalence of fractures, this would require a sample size of almost 7,000 patients. Although such a study would limit the confidence interval for the sen-

sitivity of low-risk criteria, it too would be subject to the criticism that false-negatives might occur at a rate less than 1% but more than zero. Thus, ultimately a value judgment must be made weighing the costs of excessive radiographs (in terms of timeliness of patient care, radiation exposure, distribution of scarce resources, and actual dollars spent) against the potential costs (human suffering, additional health care expenses, litigation) resulting from any missed fractures that produced subsequent morbidity because they were not identified.

We estimate the annual nationwide reduction in charges resulting from a policy to limit cervical-spine radiography to high-risk cases to be in the range of \$45 million or more. Because our annual ED census represents approximately 0.05% of the more than 92 million yearly ED visits in the United States and because we order more than 800 cervical-spine series each year, we can assume that the number of such radiographs ordered throughout the country is in the range of 600,000, even if we, as a trauma center, order on average more than three times as many films per patient visit as the national average. Charges for each cervical-spine series at our institution are \$225, so this degree of savings would be accomplished if the number of films were reduced by as little as one third.

The monetary benefits derived from such a policy must be weighed against any excess morbidity incurred by patients who suffer neurologic consequences because of a failure to diagnose occult cervical fractures. There would be no cost if the sensitivity of the low-yield criteria was 100% for fractures capable of producing deterioration, in which case such a strategy would obviously be of great benefit. Alternatively, the disadvantages of this approach would increase with any increase in the number of missed fractures that later produced otherwise preventable morbidity. Assuming a fracture prevalence of 3%, there should be about 20,000 fractures throughout the country; if the sensitivity of low-yield criteria is only 99%, 200 patients with fracture would be among those not radiographed. If even 10% of these are unstable fractures, and half again of these suffered consequences from the failure to perform a radiograph at the initial visit, the fairly large monetary gain would be greatly offset by the costs (human and economic) associated with these ten cases.

As the sensitivity of low-yield criteria increases, the balance of any cost-benefit analysis would shift toward use of a screening policy based on them. At what point the decrease in costs would override the rare failure to diagnosis cervical fracture is not for physicians alone to judge. However, by making explicit estimates of both costs and benefits of various health care strategies, we can provide the public and policy makers information needed to make informed and intelligent decisions. We believe our data are encouraging, in that they suggest that the true sensitivity of low-yield criteria may well be in the range above 99%. This finding, if confirmed, would justify selective ordering of cervical-spine films on the basis of these criteria and provide a clear

rationale for the multicenter study we are currently organizing to further define the upper limit of the number of missed fractures with which it might conceivably be associated.

CONCLUSION

In this prospective series of 1,000 patients undergoing cervical-spine radiography following blunt trauma, all 27 patients with fracture had at least one of the following four clinical findings: midline neck tenderness, altered level of alertness, evidence of intoxication, or a separate severely painful injury. All these characteristics were able to be judged at the bedside, before the films were taken; a policy of withholding radiographs in patients without any one of them would have decreased the number of radiographs by more than one third, without failing to identify any patient with cervical-spine fracture. It is important to confirm these results in even larger studies so that clinicians can adopt such a policy with confidence in its safety.

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