Cervical Spine Clearance in Obtunded Blunt Trauma Patients: A Prospective Study

Deirdre Hennessy, MSc, Sandy Widder, MD, FRCSC, David Zygun, MD, MSc, FRCPC, R. John Hurlbert, MD, FRSCS, Paul Burrowes, MD, FRCPC, and John B. Kortbeek, MD, FRCSC

Background: An acceptable algorithm for clearance of the cervical spine (C-spine) in the obtunded trauma patient remains controversial. Undetected C-spine injuries of an unstable nature can have devastating consequences. This has led to reluctance toward C-spine clearance in these patients.

Objective: To objectify the accuracy of computed tomography (CT) scanning compared with dynamic radiographs within a well established C-spine clearance protocol in obtunded trauma patients at a level I trauma center.

Methods: This was a prospective study of consecutive blunt trauma patients (18 years or older) admitted to a single institution between December 2004 and April 2008. To be eligible for study inclusion, patients must have undergone both a CT scan and dynamic plain radiographs of their C-spine as a part of their clearance process.

Results: Among 402 patients, there was one injury missed on CT but detected by dynamic radiographs. This resulted in a percentage of missed injury of 0.25%. Subsequent independent review of the CT scan revealed that in fact pathologic changes were present on the scan indicative of the injury.

Conclusions: Our results indicate that CT of the C-spine is highly sensitive in detecting the vast majority (99.75%) of clinically significant C-spine injuries. We recommend that CT be used as the sole modality to radiographically clear the C-spine in obtunded trauma patients and do not support the use of flexion-extension radiographs as an ancillary diagnostic method.

Key Words: Cervical spine injury, Cervical spine clearance, CT scanning, Dynamic radiographs, Obtunded patients.

(*J Trauma.* 2010;68: 576–582)

Despite marked improvements in patient care, advances in technology, and numerous studies performed during the past decades, an algorithm for clearance of the cervical spine (C-spine) in obtunded trauma patients remains controversial. Awake, alert trauma patients without a distracting injury can be cleared in the presence of a normal neurologic examination and the absence of any pain or tenderness on full range of motion of the neck. Patients with an altered mental status, however, cannot be cleared by clinical examination alone. Missing an unstable C-spine injury can have devastating consequences for the patient and their families. As a result, there has been a defensible reluctance to clear the C-spine in obtunded trauma patients. Multiple studies have focused on the various modalities including plain films, computed tomography (CT) scanning, flexion-extension (F-E) views, and magnetic resonance imaging (MRI).[1–4] To date, there is no gold standard for C-spine clearance in this patient population.

Unfortunately, delays in C-spine clearance contribute to increased patient morbidity by way of prolonged immobilization. These morbidities include decubitus ulcers, deep vein thrombosis, and respiratory complications. In addition, patients can be jeopardized by challenges and complications caused by maintaining cervical immobilization in a collar including skin breakdown, difficult airway, obstructed central venous access, and aspiration risks.[5] Furthermore, there is an economical burden related to these complications and additional costs related to postponed surgical procedures, suspended treatments, and longer lengths of intensive care unit (ICU) and hospital stay.[6]

In 2004, the University of Calgary Trauma Service performed a prospective study of consecutive intubated blunt trauma patients admitted to ICU looking at the utility of CT versus plain radiographs in C-spine clearance in the obtunded trauma patient.[1] The study demonstrated that CT was superior to plain films alone, because plain films tended to be frequently inadequate and unable to visualize the entire C-spine. Based on these results and the Eastern Association for the Surgery of Trauma recommendations at the time,[7] the C-spine clearance algorithm for obtunded blunt trauma patients was redesigned to reflect current best practice by including a CT scan of the entire C-spine and F-E views to rule out ligamentous injury in the absence of any bony pathology. More recent evidence has suggested that CT scanning alone may be adequate to safely discontinue C-spine precautions and that ancillary imaging may substantially delay spinal clearance and increase costs.[2,3,6,8–10] However, these studies have been relatively small,[2,3,10] many of them have been retrospective in design,[8,9] and they did not necessarily compare a protocol including dynamic radiographs with CT scanning.[2,9] This study was unique in two respects; first, it was an effectiveness study that assessed the accuracy of CT scanning within a well-established C-spine clearance protocol in a real practice setting, where radiology reports were not rereviewed, except in the case of a missed injury; second, the study team a priori decided on a rate of missed injury, above

Submitted for publication September 11, 2009.
Accepted for publication December 14, 2009.

From the Departments of Critical Care Medicine (D.H., S.W., D.Z., J.B.K.), Clinical Neurosciences (D.Z., R.J.H.), Radiology (P.B.), and Surgery (J.B.K.), University of Calgary, Calgary, Alberta.
Presented at the Annual Scientific Meeting of the Trauma Association of Canada, March 5–7, 2009, Auckland, New Zealand.
Address for reprints: J. B. Kortbeek, Department of Surgery, Faculty of Medicine, University of Calgary, 10th Floor, North Tower, 1403-29th St. NW, Calgary, AB, T2N 2T9; email: john.kortbeek@albertahealthservices.ca.

DOI: 10.1097/TA.0b013e3181cf7e55

which dynamic radiographs could not be eliminated as a screening modality. Therefore, the purpose of this study was to describe the accuracy of assessment of the C-spine by CT scanning compared with F-E radiographs in obtunded trauma patients admitted to a level I trauma center. We hypothesized that F-E views of the C-spine would not identify clinically significant injuries in obtunded patients with normal C-spine CT scans.

PATIENTS AND MATERIALS

Sample

All intubated blunt trauma patients (18 years or older) who were admitted to the ICU at the Foothills Medical Center in Calgary, Alberta, Canada were considered for the study. Those who had undergone a CT scan and F-E views of their C-spines were deemed eligible to participate. The project was approved by the Conjoint Health Research Ethics Board at the University of Calgary and Calgary Health Region. Patient accrual occurred from December 2004 until April 2008. Patients were excluded if they had a known C-spine injury (clinically or seen on CT scan) or if they died in the ICU before the completion of imaging. The Foothills Medical Center operates as the sole trauma center with neurosurgical/spine specialty capability for people living in southern Alberta and southeastern British Columbia.

Design and Data Sources

Prospective study design with linked clinical and outcomes data from three databases. Blunt trauma patients who were admitted to ICU were screened by a research assistant for inclusion in the study. Basic demographic and radiologic data were collected manually during ICU stay and inputted into the study database. Radiologic data was manually collected from a diagnostic imaging database (picture archival communication [PACS] system) was used to confirm that patients underwent both CT scan and F-E radiographs and to confirm whether the results of both tests could be accessed. Our study database was subsequently linked with the local Trauma Registry that contained demographic and diagnostic data for all trauma admissions of patients with an Injury Severity Score (ISS) $\geq$12. In addition, ICU specific data were obtained for all patients through linkage with the ICU Tracer database, which stored prospectively collected demographic, diagnostic, and treatment data on patients admitted to ICU.

Radiologic Imaging

The protocol for C-spine evaluation in obtunded trauma patients admitted to ICU consisted of lateral C-spine x-rays followed by CT images of the C-spine from skull base to T4. Studies were initially performed on a 4-slice GE CT scanner, which was subsequently updated to a 40 and then to a 64-slice Somatom Siemens scanner. Patients with normal CT examinations defined as absence of fracture, subluxation, or disc prolapse underwent dynamic F-E radiographs to rule out ligamentous injury. These were performed by a staff trauma surgeon, neurosurgeon, intensivist, or a trauma/critical care fellow by gently flexing and extending the patient's neck until significant resistance was encountered, typically in the neighborhood of 45° to 60° for both flexion and extension. If the C7–T1 junction could not be visualized, a 45° angle radiograph was taken. Dynamic views were examined for abnormal translation ($\geq$3.5 mm) or angulation ($>$20°) at each excursion endpoint through individual motion segments.

Measurements

The primary outcome measure of interest in this study was the proportion of abnormal F-E views obtained in the setting of a CT scan interpreted as normal. Demographic variables analyzed included age, gender, mechanism of injury, ISS, Acute Physiology and Chronic Health Evaluation II (APACHE II) score, Glasgow Coma Scale, and ICU and hospital length of stay (LOS). Patients were followed up from hospital admission to hospital discharge. Readmissions to ICU required for any reason were rescreened for C-spine pathology.

Statistical Analysis

By consensus of the study team (trauma surgery, neurosurgery-spine, neuroradiology, and intensive care), the endpoint of this investigation was to identify the rate of abnormal F-E views per 1,000 obtunded patients admitted for blunt trauma. A clinical significance level for occult injuries missed by CT but discovered on F-E images was also a priori determined to be $\geq$3/1000 (0.3%). In this case, F-E x-rays as a modality for C-spine clearance in the obtunded trauma patient could not be discarded. The predicted sample size was, therefore, 1,000 patients with a proposed maximum study duration of 4 years. In the statistical analysis, data are presented as means, followed by standard deviations (SD) and medians followed by interquartile ranges (IQRs) as appropriate. A one-sided 95% confidence interval for the observed proportion of missed injuries was calculated, because we were interested in establishing the maximum rate of missed injuries.

RESULTS

During the study period, a total of 4,037 patients were admitted to ICU at the Foothills Medical Center. Of these, 948 (25%) were blunt trauma admissions. All 948 blunt trauma patients were screened for inclusion in the study. CT scans and F-E radiographs were performed on 402 patients (42%) who also met the other inclusion criteria (Fig. 1). Overall, the patients entered into this study were representative of the blunt trauma group as a whole (Table 1). Two notable exceptions were a longer LOS in ICU and a longer LOS in hospital for the study group. Patients were predominantly men (80%) with a mean age of 40 ($\pm$18) years. The mean APACHE II score was 17 ($\pm$7) and mean ISS was 30 ($\pm$10). Median LOS in ICU was 7 days (IQR 4–13) and in hospital was 23 days (IQR 13–45). Because we recruited only patients who survived through their ICU stay, mortality in the study group was zero. Approximately 15% of all blunt trauma patients died while in ICU.

One of 402 patients was identified as having abnormal F-E radiographs subsequent to a negative CT scan. Four

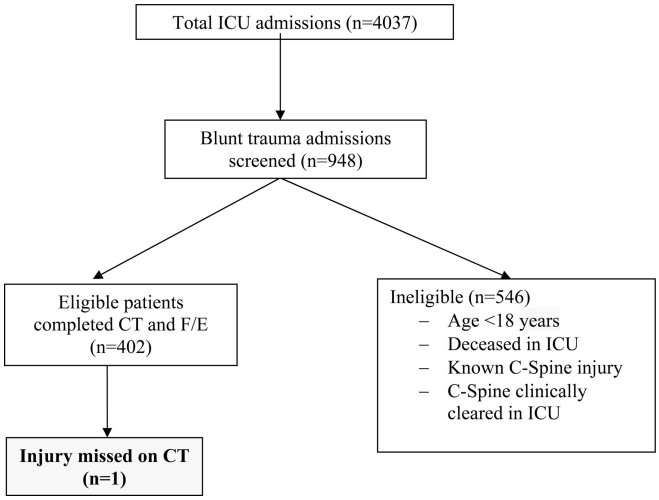

Figure 1. Breakdown of ICU admissions, blunt trauma admissions, and eligible or ineligible patients.

TABLE 1. Characteristics of All Blunt Trauma Patients Admitted to ICU Compared With Eligible Patients

Variable	All Blunt Trauma Patients	Eligible Patients
N	948	402
Age (yr), mean (SD)	41.2 (19.3)	40.0 (17.7)
Sex, % male	74.3	79.9
APACHE II score (SD)	17.2 (7.4)	16.7 (6.7)
ISS (SD)	30.2 (10.8)	30.2 (10.3)
GCS at trauma centre (SD)	12.1 (3.9)	11.8 (3.8)
Postoperative (%)	36.2	36.3
Length of ICU stay (d), median (IQR)	4.8 (2.0–11.2)	6.9 (3.5–12.6)
Length of hospital stay (d), median (IQR)	16 (7–34)	23 (13–45)
ICU mortality (%)	14.7	0.0

APACHE, Acute Physiology and Chronic Health Evaluation; ISS, injury severity score; GCS, Glasgow Coma Scale; SD, standard deviation; ICU, intensive care unit; IQR, interquartile ranges.

TABLE 2. Proportion of Injuries Missed on CT

	No. Events	Proportion With One-Sided Confidence Limit
Negative CT and Positive F-E	1	0.00248 (0.0117458)
Positive CT and Negative F-E	401	n/a

CT, computed tomography; F-E, flexion extension.

hundred one patients (99.75%) had normal CT and F-E images facilitating clinical clearance of their C-spine and discontinuation of spinal precautions. The point estimate for the proportion of missed injury was 0.00248 (0.25%) with a one-sided confidence interval of 0.0117458 (1.12%; Table 2). Although the point estimate fell below the decision rule identified a priori for retention of F-E views as a screening test for C-spine injury, the one-sided 95% confidence interval

Figure 2. CT sagittal view of C-spine in patient with missed C-spine injury.

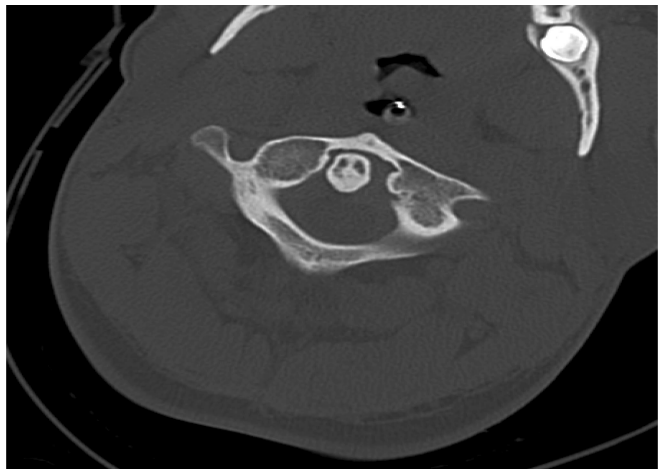

Figure 3. CT coronal view of C1 and C2 in patient with missed C-spine injury.

did not. The CT scans and F-E views for the missed injury were subsequently independently reviewed by three of the authors (trauma surgery, neurosurgery and radiology) and one blinded radiologist. All independently concluded that the injury was indeed apparent on the original CT scan but had been missed by the reporting neuroradiologist at the time.

The patient with a missed injury was a 23-year-old man who was involved in a motor vehicle collision. He presented with an ISS of 43 with concomitant head and abdominal injuries. His initial CT was reported as "no evidence of abnormality" by a staff neuroradiologist. The patient underwent F-E views on day 10 after injury and was found to have widening of the predental space and instability at C1 to C2 (Figs. 2–7). The patient underwent surgical treatment on day 12 after injury, comprised of C1/2 transarticular screw fixation with posterior wiring and iliac crest bone graft. He was immobilized in an Aspen collar for 3 months postoperatively. On follow-up 9 months postinjury, the patient remained neurologically intact with no pain and had returned to work.

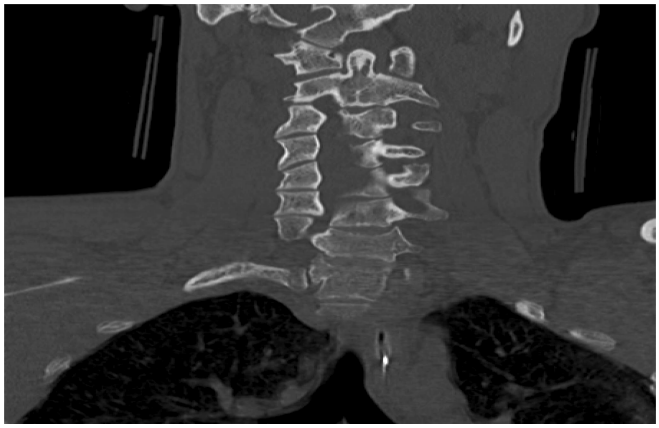

Figure 4. Frontal reformations of CT C-spine in patient with missed C-spine injury.

Figure 5. Radiograph of C-spine in patient with missed C-spine injury in the neutral position.

DISCUSSION

This study helps to objectify the accuracy of CT scanning compared with the previous gold standard of dynamic X-rays in radiographic clearance of the C-spine in obtunded trauma patients. F-E or dynamic radiographs are advocated because of the worry of missing an isolated unstable ligamentous injury. Although these injuries are relatively rare, failure to detect them can have devastating consequences.[11,12] Therefore, there has been an understandable reluctance to abandon dynamic imaging. However, continued evolution in technology during the past few years has increased the sensitivity of CT for detecting bony and soft tissue abnormalities.

Figure 6. Radiograph of C-spine in patient with missed C-spine injury in the flexed position.

The percentage of patients who had a missed injury revealed on F-E views after a negative CT scan in our series was 0.25%, with a one-sided 95% confidence interval of 1.12%. This proportion of missed injuries fell below our 0.3% definition of clinical significance, suggesting that dynamic films can be eliminated as an additional screening test for C-spine injury. However, the confidence interval was approximately 3 orders of magnitude higher, indicating that a much larger study would be required to establish absolute confidence in elimination of screening with F-E radiographs. In fact, this study planned to enroll 1,000 patients from multiple Canadian centers; however, in trying to recruit other trauma centers, we discovered that practice patterns for C-spine clearance were not uniform across the country and in some cases were changing to exclude dynamic radiographs. Although we did not reach our recruitment target within the study period, an interim analysis of 402 patients demon-

Figure 7. Radiograph of C-spine in patient with missed C-spine injury in the extended position.

strated equivalence of CT screening compared with dynamic radiographs, based on the 0.3% rate identified by the study committee. As a result of these data and other emerging evidence,[2,9] the study committee decided that F-E films were no longer indicated as an investigation for spinal clearance in obtunded patients. Equally as important is the observation that the single injury missed by CT in our study was due to interpretive error and, therefore, not truly occult. This finding is reassuring and suggests CT is an efficacious modality, with a sensitivity of 100% compared with dynamic radiographs if human error is ignored. However, our purpose was to assess the effectiveness of a C-spine clearance protocol in a real practice setting where human error cannot be ignored. Interpretation of our results in this context also suggests a goal for potential quality improvement initiatives. The rate of missed injury (0.25% [1.12%]) at our institution could possibly be reduced or altogether eliminated by an intervention targeting interpretation of CT scans.

Although consensus regarding the optimal method of C-spine clearance in obtunded blunt trauma patients remains elusive, recent evidence, including this study, establishes CT as the methodology of choice for clearance of C-spines in this difficult population.[2,9,13–17] Multiple studies have demonstrated the superiority of CT over static and dynamic radiography in detection of cervical pathology. Collectively these studies have reported very few missed injuries on CT and have observed that this modality is superior to static X-rays in excluding abnormalities in alignment, bony structures, cartilaginous elements, and even soft tissue. Notably, Harris et al.[9] found that CT had a negative predictive value of 99.7% and recommended that C-spine clearance in obtunded patients be based on CT alone as nothing is gained from additional imaging with physiologic loading and that these types of modalities represent risks to patients.

Similarly, Padayachee et al.[10] demonstrated that dynamic F-E did not identify any more patients with cervical fracture or instability that were not already identified by plain radiographs or fine-cut CT scans. Both authors demonstrated that using ancillary radiographs in addition to CT scanning, substantially delayed C-spine clearance. Prolonged immobilization due to delayed clearance is one of the main disadvantages of using any kind of ancillary imaging, including F-E, static views, and MRI. A review by Morris et al.[18] outlines in detail the risks of immobilization, including occurrence of pressure sores, increased intra-cranial pressure, venous obstruction, difficulties with airway management, and difficulties with central venous access. These authors go further to suggest that the risks of prolonged immobilization, beyond 48 hours to 72 hours, are poorly appreciated and exceed those of a serious missed C-spine injury.[18] Moreover, recent reports have demonstrated substantial delays in clearance and associations between complications and time to clearance in ICU patients.[2,9] Specifically, Harris et al. reported that time spent immobilized due to spinal precautions exceeded 48 hours in approximately 50% and 14 days in approximately 1.2% of their sample. In addition, Stelfox et al.[2] demonstrated in a comparison study of CT alone versus a protocol including CT and MRI that complications of immobilization increased with increasing duration of spinal precautions. Stelfox et al. concluded that in addition to timeliness, decreased complications, and morbidity, there was no difference in hospital mortality or missed significant injuries and that CT should be used as the sole imaging modality for C-spine clearance.

Furthermore, the resources consumed by dynamic X-rays are not insignificant. At our institution, F-E X-rays of an obtunded patient requires transport out of the unit, the presence of a physician who is capable of performing the F-E maneuvers, and extra personnel to aid with the patient's care and positioning. Although the timing of C-spine clearance and the downstream effects of delay were not specifically looked at in this study, the demographics and admission profiles of our study group differed from our entire population of blunt trauma patients with respect to the length of ICU and hospital stay. A possible explanation for this discrepancy is that F-E radiographs may extend LOS because of the logistics of organizing the test and the subsequent delay in C-spine clearance. A domino effect from such a scenario is easy to imagine even including delayed weaning from mechanical ventilation. Another

limitation of F-E views is that they are reported to be inadequate in up to 40% of evaluations.[19,20]

The fact that dynamic X-rays provide real time views of the C-spine under physiologic loads, which can render isolated unstable ligamentous injuries more apparent is believed to be an advantage of the modality. However, there have been case reports of exacerbation of injuries secondary to the use of F-E films.[21] In our series of more than 400 patients, we did not encounter any neurologic injuries arising as a result of this investigation. Manipulation of an obtunded patient is especially concerning as they lack the protective reflex muscle spasm or the ability to report symptoms. Acute disk herniations, epidural hematomas, spondylosis, and spinal stenosis may also render a patient's spinal cord more susceptible to injury.[20] These types of pathology are not readily visible on F-E, and as a result, they often go unrecognized.

The sensitivity of CT in uncovering isolated ligamentous injuries compared with other modalities such as MRI has been challenged,[22] and MRI has been proposed as an alternative modality to clear C-spine injuries.[23–25] Several prospective studies have compared radiologic and clinical findings of CT versus MRI. Como et al.[5] compared MRI with CT for C-spine clearance in obtunded trauma patients. Of the patients analyzed, six patients were found to have acute ligamentous injuries seen on MRI only. However, none of these injuries were clinically significant. Several studies have demonstrated little benefit in obtaining MR images in the setting of an obtunded patient without clear evidence of motor or sensory loss, or abnormality on CT.[15,26] Evaluation by MRI may lead to a 25% to 40% rate of false positive examinations, which in turn may lead to increased morbidity from prolonged C-spine immobilization.[23,27] Additional evidence exists that suggests MR imaging has a low sensitivity for detecting posterior fractures and tends to be prone to false-positive results in the upper C-spine.[28,29]

This study is the largest prospective study comparing CT and F-E views to date. The strengths of this study include a rigorously defined C-spine clearance protocol including both CT and F-E imaging. Indications for and definitions of abnormal F-E views were defined a priori. High quality data sources such as the ICU Tracer database, the Alberta Trauma registry, and the PACS radiology library were key elements to the success of the study. In addition, we were able to capture an entire trauma population as the sole adult trauma referral center in a large geographic catchment area.

This study was limited in that we did not attain our planned sample size during the study period. Although this study may be too small in itself to establish absolute confidence in eliminating F-E views, when one consider these results in the context of emerging evidence, as suggested by Harris et al.,[9] they add to a body of evidence that has established CT as the modality of choice for C-spine clearance in obtunded patients.

CONCLUSION

In summary, this study demonstrates that CT imaging possesses a high degree of accuracy in the determination of C-spine injuries and that F-E views of the C-spine do not substantively contribute to identifying injuries in obtunded patients. The only injury missed by CT and established by F-E films was as a result of an error in interpretation. On the basis of these results and other recent evidence, we recommend against the routine use of F-E views for C-spine clearance in the obtunded trauma patient, CT can be used as the sole modality for this purpose. Additional investigations may be indicated on a case-by-case basis for patients with preexisting pathology such as subluxation, degenerative change, soft tissue pathology, or focal neurologic deficit.

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