Clearing the cervical spine in patients with distracting injuries: An AAST multi-institutional trial

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BACKGROUND: Single institution studies have shown that clinical examination of the cervical spine (c-spine) is sensitive for clearance of the c-spine in blunt trauma patients with distracting injuries. Despite an unclear definition, most trauma centers still adhere to the notion that distracting injuries adversely affect the sensitivity of c-spine clinical examination. A prospective AAST multi-institutional trial was performed to assess the sensitivity of clinical examination screening of the c-spine in awake and alert blunt trauma patients with distracting injuries.

METHODS: During the 42-month study period, blunt trauma patients 18 years and older were prospectively evaluated with a standard c-spine examination protocol at 8 Level 1 trauma centers. Clinical examination was performed regardless of the presence of distracting injuries. Patients without complaints of neck pain, tenderness or pain on range of motion were considered to have a negative c-spine clinical examination. All patients with positive or negative c-spine clinical examination underwent computed tomography (CT) scan of the entire c-spine. Clinical examination findings were documented prior to the CT scan.

RESULTS: During the study period, 2929 patients were entered. At least one distracting injury was diagnosed in 70% of the patients. A c-spine injury was found on CT scan in 7.6% of the patients. There was no difference in the rate of missed injury when comparing patients with a distracting injury to those without a distracting injury (10.4% vs. 12.6%, $p = 0.601$). Only one injury missed by clinical examination underwent surgical intervention and none had a neurological complication.

CONCLUSIONS: Negative clinical examination may be sufficient to clear the cervical spine in awake and alert blunt trauma patients, even in the presence of a distracting injury. These findings suggest a potential source for improvement in resource utilization. (*J Trauma Acute Care Surg.* 2019;86: 28–35. Copyright © 2018 American Association for the Surgery of Trauma.)

LEVEL OF EVIDENCE: Therapeutic/care management, level IV.

KEY WORDS: Cervical spine injury; distracting injury; blunt trauma; CT scan in trauma.

Cervical spine (c-spine) clearance after blunt traumatic injury poses an ongoing dilemma for trauma surgeons. Most trauma centers have a regimented protocol for evaluation of the c-spine; however, specific algorithms vary widely from center to center. These protocols often involve the liberal use of radiographic tests, the vast majority of which are negative for injury.[1] Adding to the variability is the emergence of data that have called into question some long-held beliefs about the method by which the c-spine can be safely cleared. The recent trend has been toward the more judicious use of radiography, but a consensus on which patients require radiographic evaluation has not been reached. Limiting radiographic testing can lead to improvements in resource utilization, but missed injuries can have catastrophic ramifications.

Screening for c-spine injuries traditionally uses a combination of physical examination and radiographic testing.[2,3] Plain film radiography is unreliable as a screening tool and computed tomography (CT) scan has taken over as the radiographic test of choice for c-spine injury clearance.[4,5] Some trauma centers mandate the use of a c-spine CT scan in any patient with a mechanism concerning for possible c-spine injury.[6–9] However, several studies have suggested that physical examination alone is adequate for c-spine screening in properly selected patients.[3,4,10–15] Current Eastern Association for the Surgery of Trauma (EAST) guidelines recommend the use of physical examination with the selective use of CT scanning for a patient who suffers blunt trauma and does not have altered mental status, a neurologic deficit, nor a distracting injury (DI).[16] Patients that meet these criteria without neck pain or tenderness on physical examination do not require further radiographic evaluation, according to the guidelines.

The concept that a DI precludes the use of physical examination to screen for c-spine injury has very little evidence to support it. The EAST guidelines, Advanced Trauma Life Support

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teaching, and several studies, including the widely cited National Emergency X-Radiography Study (NEXUS), refer to DI as a reason to obtain radiographic studies, regardless of physical examination findings.[1,3,4,8,16,17] Despite these recommendations, the definition of what constitutes a DI remains elusive. It is left to the clinician to determine which type of injuries classify as distracting, leading to a variety of definitions and practice patterns across trauma centers.

Recent single center trials suggest that a negative physical examination may be sufficient to clear the c-spine in awake and alert blunt trauma patients, even in the setting of DI.[18–20] The purpose of this study is to perform a multicenter assessment of the sensitivity of using clinical examination to screen for c-spine injury in the presence of DI.

METHODS

During the 42-month study period from July 2014 to December 2017, data were collected prospectively at eight Level I trauma centers in an American Association for the Surgery of Trauma Multi-Institutional Trial. The primary study was designed to evaluate the effect of DI on the sensitivity of physical examination in clearing the c-spine. The participating centers were Loyola University Medical Center, Maywood, IL, University of Colorado Health-Memorial Hospital, Colorado Springs, CO, University of Alabama at Birmingham, Birmingham, AL, University of Missouri, Columbia, MO, University of South Alabama Medical Center, Mobile, AL, University of Texas Health-Tyler, Tyler, TX, New York University Langone Hospital-Brooklyn, New York, NY, and Conjunto Hospitalar de Sorocaba, Sorocaba, Brazil. All patients 18 years and older who sustained a trauma via a blunt mechanism and had a Glasgow Coma Scale (GCS) score of 14 or higher were enrolled in the study. There were no additional exclusion criteria. All participating institutions used multislice CT scanners with a minimum of 32-slice capability to evaluate patients for this study.

Institutional review board approval was obtained at each of the individual institutions. Information regarding the demographics, mechanism of injury, and clinical findings was collected prospectively and documented on the study data form prior to the completion of CT scan evaluation.

Clinical evaluation of the c-spine in patients meeting inclusion criteria was performed in a standardized fashion across all eight centers using the following algorithm: patients were assessed for neurologic deficits through the use of subjective questioning and physical examination. If no neurologic deficit was identified, the patient's cervical collar was removed and manual in-line stabilization of the neck was initiated. The patient was then interrogated for the presence of neck pain. If no pain was present, the posterior neck was then palpated for midline and lateral tenderness. In the absence of tenderness, the patient was then asked to flex and extend the neck and to rotate their neck 90 degrees side to side, with 45 degrees of rotation in each direction. If these ranges of motion maneuvers did not elicit pain, the physical examination was considered negative. At this point, the cervical collar could either be removed or replaced, based on each institution's protocols. If any aspect of the examination was positive, the examination was terminated, the cervical collar was replaced, and the physical examination was considered positive. All patients, regardless of the results of the physical examination, had a CT scan of the c-spine. Plain radiographs or magnetic resonance imaging (MRI) were not performed unless otherwise indicated, based on the clinical judgment of the individual provider (Fig. 1).

Physical examination was performed by an attending trauma surgeon, trauma surgery resident, or trauma surgery advanced practice provider, based on each institution's protocols. No limitation was placed on the level of resident performing the examination. Providers did not undergo any special training or instruction in order to participate in the study. CT scans were evaluated for injury by attending radiologists at each institution. Only finalized, attending radiologist interpretation of CT scan results was used for data collection.

Data regarding the patient's individual injuries were collected after the completion of the full trauma evaluation, including primary, secondary, and tertiary survey. The following injuries were considered "distracting": Skull fracture, >2 facial bone fractures, mandible fracture, intracranial hemorrhage (including subdural hematoma, epidural hematoma, subarachnoid hemorrhage, intraventricular hemorrhage, intraparenchymal hematoma), > 2 rib fractures, clavicle fracture, sternal fracture, pelvic fracture, thoracolumbar spine fracture, intra-abdominal injury (including solid organ injury, hollow viscus injury, or diaphragmatic injury), femur fracture, tibia/fibula fracture, humerus fracture, radius/ulna fracture, and hip or shoulder dislocation.

Patients with a DI were compared to those without a DI. Categorical variables were compared with χ^2 or Fisher's exact

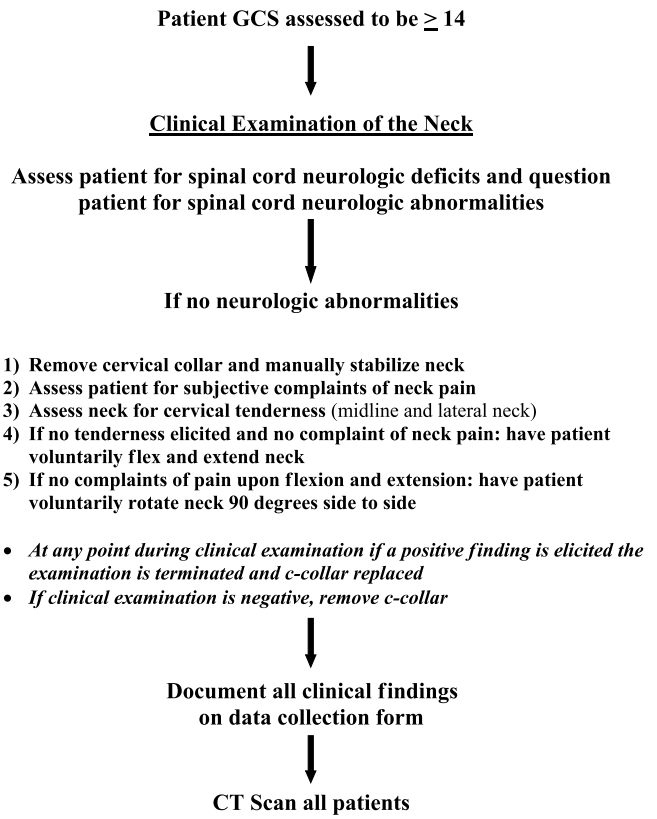

Figure 1. Algorithm for cervical spine assessment.

TABLE 1. Demographics/Physical Findings—Total Study Population

	Total Study, N = 2,929	DI, n = 2,058	No DI, n = 871	*p*
Age	46.7 (±20.7)	48.3 (±20.7)	42.8 (±20.2)	<0.0001
Female (n = 1,016)	34.7%	32.9%	39.0%	0.001
Presence of c-spine injury (n = 222)	7.6%	6.6%	10.0%	0.001
Clinical missed injury (n = 25)	0.8%	0.7%	1.3%	0.117
Clinical examination finding (n = 585)	20.0%	16.4%	28.4%	<0.0001
Neck pain (n = 497)	17.0%	13.5%	25.3%	<0.0001
Neck TTP (n = 474)	16.2%	13.0%	23.8%	<0.0001
Pain with Flex/Ex (n = 284)	9.7%	8.0%	13.7%	<0.0001
Pain with rotation (n = 267)	9.1%	7.6%	12.6%	<0.0001
Operative treatment (n = 51)	1.7%	1.4%	2.6%	0.016

Continuous variables expressed as means (SD) and categorical variables expressed as percentages.
TTP, tender to palpation on examination; Flex/Ex, flexion and extension.

test where appropriate. Continuous variables were compared with Student's *t* test or Wilcoxon Rank Sum test based on the distribution. Multivariable analysis was not performed due to the limited number of events. The primary outcome variable was clinical missed injury, defined as an injury that was missed by physical examination but subsequently detected by CT scan. A *p* value less than 0.05 was considered significant.

RESULTS

During the study period, 2929 blunt trauma patients with a GCS ≥14 were enrolled in the study. The mean age was 46.7 (±20.7) and approximately ⅔ were male (65.3%). Two thousand fifty-eightv patients had at least one DI. C-spine injuries were found on CT scan in 222 (7.6%) patients. When examining the entire population, clinical missed injuries were found in 25 (0.8%) of patients and there was no difference in the rate of clinical missed injury between those with and without DI (0.7% vs. 1.3%, $p = 0.117$). Patients with DI were less likely to have c-spine injuries than patients without DI in this series (6.6% vs. 10.0%, $p = 0.0016$). Additionally, patients with DI were less likely to have positive findings on clinical examination (16.4% vs. 28.4%, $p < 0.0001$), and to undergo operative intervention for a c-spine injury (1.4% vs. 2.6%, $p = 0.016$).(Table 1)

Motor vehicle collision was the most common mechanism of injury (45.1%) followed by falls (26.1%), motorcycle collisions (8.5%), pedestrian struck by motor vehicle (7.2%), assaults (4.9%), all-terrain vehicle accident collisions (2.8%), bicycle crashes (2.4%), crush injuries (2.1%), found down (0.4%), explosions (0.2%), and boat collisions (0.2%). There were no significant differences between these groups.

The mean age of patients that had a c-spine injury on CT scan was 53.2 (±21.2) and 65.3% of those with c-spine injuries were male. One hundred thirty-five (60.8%) patients with a documented c-spine injury also had at least one DI. Clinical missed injuries were identified in 11.3% of patients who had a c-spine injury. There was no difference in the rate of clinical missed injury when comparing patients with a DI to those without a DI (10.4% vs. 12.6%, $p = 0.601$). There was no difference in the rate of operative intervention for c-spine injury between those with and without DI (26.4% vs. 19.3%, $p = 0.208$). (Table 2) Only 1 of the 25 patients with a clinical missed injury required operative intervention for their c-spine injury and no patient had a complication from a clinical missed injury. (Table 3)

The sensitivity of physical examination in detecting c-spine injury was 89.6% in patients with DI and 87.4% in those without DI. The specificity of physical examination was 88.7% in patients with DI and 78.0% in patients without DI. The negative predictive value of a negative physical examination was 99.2% in patients with DI and 98.2% in patients without DI. The positive predictive value of a positive c-spine examination was 35.8% and

TABLE 2. Demographics/Physical Findings—Patients With Documented C-Spine Injuries

	Total Injuries, N = 222	DI, n = 135	No DI, n = 87	*p*
Age	53.2 (±21.2)	53.5 (±20.3)	52.6 (±22.6)	0.756
Female (n = 77)	34.7%	31.9%	39.1%	0.269
Clinical missed injury (n = 25)	11.3%	10.4%	12.6%	0.601
Clinical examination finding (n = 197)	88.7%	89.6%	87.4%	0.601
Neck pain (n = 169)	76.1%	73.3%	80.4%	0.224
Neck TTP (n = 174)	78.4%	75.5%	82.8%	0.203
Pain with Flex/Ex (n = 154)	69.4%	69.6%	69.0%	0.917
Pain with rotation (n = 144)	64.9%	64.4%	65.5%	0.870
Operative treatment (n = 49)	22.1%	19.3%	26.4%	0.208

Continuous variables expressed as means (SD) and categorical variables expressed as percentages.

TABLE 3. Clinical Missed Injuries

Age, y	Sex	Mechanism of Injury	GCS	DI	Level of Injury	Type of Injury	Treatment	Type of DI
64	M	MVC	15	No	C7	Vertebral Body Fx	C-Collar	None
64	F	Fall	14	No	C7	Vertebral Body Fx	C-Collar	None
26	M	MVC	15	No	C6	Facet Fx	CTO Brace	None
74	F	Fall	15	No	C1	Vertebral Body Fx	C-Collar	None
26	M	MCC	14	No	C5	Transverse Process Fx	C-Collar	None
31	F	MVC	15	No	C2	Pedicle Fx	C-Collar	None
58	F	Fall	15	No	C4	Vertebral Body Fx	none	None
22	F	MCC	15	No	C6	Pedicle Fx	C-Collar	None
26	M	MCC	14	No	C7	Spinous Process Fx	none	None
55	M	MVC	15	No	C7	Facet Fx	C-Collar	None
55	F	MVC	15	No	C6	Pedicle Fx	none	None
63	M	MCC	15	Yes	C2	Vertebral Body Fx	ORIF	Mandible fx, ICH, Femur fx
41	M	ATV	15	Yes	C7	Facet Fx	C-Collar	Mandible fx
46	M	MVC	15	Yes	C6	Vertebral Body Fx	C-Collar	Tib/Fib fx
66	M	MVC	15	Yes	C5	Facet Fx	none	ICH, Diaphragm Injury
30	M	MVC	14	Yes	C2	Spinous Process Fx	CTO Brace	Pelvis fx
28	M	MVC	15	Yes	C2	Spinous Process Fx	C-Collar	Clavicle fx
42	F	MVC	15	Yes	C7	Transverse Process Fx	None	ICH, >1 Rib fx, clavicle fx, Pelvis fx, Femur fx
79	F	Fall	14	Yes	C1	Arch Fx	none	Skull fx
55	M	MVC	15	Yes	C7	Transverse Process Fx	none	Pelvis fx, Diaphragm injury
27	M	MVC	14	Yes	C6	Spinous Process Fx	none	Femur fx
38	M	Fall	15	Yes	C5	Spinous Process Fx	C-Collar	Pelvis fx
38	M	MVC	15	Yes	C1	Transverse Process Fx	none	Mandible fx, ICH, >1 Rib fx, Sternal fx, T spine fx, Tib/Fib fx
46	M	MCC	15	Yes	C5	Pedicle Fx	none	Pelvis fx, Diaphragm injury
53	M	ATV	15	Yes	C7	Transverse Process Fx	none	ICH, Diaphragm injury

M, male; F, female; MVC, motor vehicle collision; MCC, motorcycle collision; ATV, all-terrain vehicle accident; fx, Fracture; C-Collar, cervical collar; CTO brace, cervical-thoracic orthosis brace; ORIF, open reduction and internal fixation; ICH, intracranial hemorrhage; Tib/Fib, tibia/fibula.

30.8% in patients with and without DI, respectively. No significant differences were found between these groups.

DISCUSSION

In today's medical landscape, increasing emphasis is being placed on resource utilization. Decreasing the number of radiographic studies used in c-spine clearance can have obvious cost benefits, but a missed injury can lead to devastating consequences for the patient, physician, and hospital. Deciding which patients truly require radiographic evaluation of the c-spine and which patients can be cleared without radiographic testing is a difficult but important task.

Removal of hard cervical collars as soon as is safely possible is in a patient's best interest. A longer time in a cervical collar has been associated with a prolonged ICU and overall hospital length of stays and with more ventilator days.[21] Multiple studies have found an increase in decubitus ulcers with extended time in a cervical collar.[22–24] Studies have also shown a decrease in intracranial pressure in head injured patients after cervical collar removal.[25–27] There are clearly advantages to removing cervical collars as soon as clinically significant injuries have been excluded, but the question remains: when is it safe to remove the collar? The answer to this question has been evolving over the past several years.

Historically, evaluation of the c-spine involved a combination of examination and plain radiography. Plain film radiography was found to have an unacceptably high rate of missed injury with sensitivities as low as 35% for all radiographs and as low as 63% for plain radiographs deemed "adequate."[5,28–31] Computed tomography scan has supplanted plain film as the radiographic test of choice for c-spine evaluation in blunt trauma. The sensitivity of CT scan for detecting c-spine injury is >99% in most recent series.[6–8,12,14,30] Although CT has proven to be very sensitive, there has been a steady trend toward less radiographic testing in a variety of patient populations prior to cervical collar removal. Several studies have proven the safety of physical examination alone as a method of clearing the c-spine in the awake and alert patient.[3,4,10–16] A variety of publications, including an EAST practice management guideline, recommend the removal of cervical collars in obtunded patients based on negative CT scan results without subsequent MRI.[32–35] A 2017 WTA multi-institutional trial suggested that intoxication is no longer an indication pursue further workup after a negative c-spine CT and a negative examination.[36] A recent single center trial suggested that MRI is unnecessary if a patient has a negative CT scan and no focal neurological findings, even with pain or tenderness on examination.[37]

The idea that a DI limits the sensitivity of physical examination is a principle that has been long held by trauma surgeons. The EAST guidelines, Advanced Trauma Life Support teaching, the NEXUS study, and multiple other studies claim that a painful DI precludes the safe use of physical examination as a screening tool for c-spine injury and that radiographic evaluation is

required in these patients.[1,3,4,16,17] Among the problems with this recommendation is that none of these publications defines specifically what qualifies as a DI. This has left the individual clinician to determine which injuries qualify as "distracting," resulting in a wide range of practice patterns across the trauma landscape.

The confusion surrounding the definition of a DI is compounded by the lack of evidence that a painful injury actually limits the sensitivity of clinical c-spine examination. The majority of literature assessing the role that DI plays in the reliability of physical examination findings would suggest that clearance based on negative physical examination findings alone is safe. Rose et al.[18] performed a single center prospective study that suggested that DI did not interfere with the sensitivity of physical examination as a screening tool. Distracting injury was identified in 464 patients, 86 of which were also found to have a c-spine injury. Of those 86 patients with both a DI and a c-spine injury, 85 had a positive physical examination. The single patient with a clinical missed injury did not suffer a neurologic complication and did not require surgical intervention. The authors concluded that a negative physical examination was sufficient to clear the c-spine in patients with DI. Similarly, Konstantinidis et al. found that patients with a DI, other than those to the upper chest, did not require c-spine imaging if physical examination did not illicit concern for a c-spine injury.[19] They found that 4% of patients found to have c-spine injuries did not have pain or tenderness on examination. All of these patients with clinical missed injury had bruising and pain to their upper anterior chest. None of the patients with clinical missed injury had complications or required surgery. Velmahos et al.[8] studied 549 patients that were able to follow complex commands, 409 of whom suffered at least one DI. They found that DI did not affect the reliability of their examination. Stiell et al,[10] in developing the Canadian C-spine Rule, found that physical examination had a 100% sensitivity in the setting of DI.

Most practitioners would agree that if the concept of a DI is relevant, then major long bone or pelvic fractures would qualify as such. However, studies looking at particular injury patterns have found that femur or pelvic fractures do not negatively impact the sensitivity of physical examination findings in clearing the c-spine.[38,39]

These studies all suggest that clearing the c-spine in the setting of DI is safe. The suggestion that the c-spine can be safely cleared in the presence of a DI is further augmented by the results of the current study, which found no difference in the rates of clinical missed injury when DI was present versus when no DI was present. When looking at the overall study cohort, the rate of patients with a clinical missed injury who had operative fixation was a minuscule 0.03%.

Eleven percent of patients that had a c-spine injury had an injury that was missed on clinical examination. Although there was no difference in the frequency of clinical missed injury in patients with and without a DI, the overall rate is higher than has been found in previous investigations.[3,4,10–16] This highlights the importance of a good physical examination when evaluating the c-spine for traumatic injury. Institutions participating in this study were given the freedom to develop their own protocols regarding whether to remove cervical collars after a negative physical examination or to replace them. Some institutions adopted a policy of replacing the collars. Since all patients had a subsequent CT scan, the risk of incomplete assessment of the c-spine was low and may have contributed to the high rate of clinical missed injury. Additionally, any member of the trauma team was permitted to perform the physical examination, according to the study protocol. No restriction was placed on residents or advanced practice providers conducting the examination. Less experienced providers performing initial assessment may have led to a higher rate of clinical missed injury than was seen in other studies.

Despite a higher rate of clinical missed injury than in previous studies, the rate was similar in patients with and without DI. The negative predictive value of a normal physical examination of the c-spine was high, at 99.2% for patients with DI and 98.2% for patients without DI. Even when a clinical missed injury was present, these injuries appeared to be of limited clinical significance, as only 1 (0.4%) of the 222 patients with c-spine fractures had a clinical missed injury that subsequently underwent operative fixation. The remaining patients with injuries not detected by physical examination were treated either with a cervical collar or not at all.

Patients without a DI were more likely to have positive physical examination findings than those with a DI. While at first glance this may suggest that physical examination was more sensitive in patients without DI, this is not actually the case. Patients without DI had a significantly higher rate of c-spine injury which accounts for the higher rate of positive physical examination findings. As already stated, the rate of clinical missed injury was the same in patients with and without DI.

Some previous studies evaluating c-spine injuries, including the NEXUS study and the Canadian c-spine rule, exclude patients 65 years of age and older.[4,10] Older patients were included in the analysis of the current study. A subgroup analysis was performed on patients 65+ and they were not found to have a higher rate of clinical missed injury.

There are some limitations to this study. The definition of DI was chosen to be consistent with previous studies assessing the role of DI in c-spine evaluation.[14,18] The intent was to include only injuries that most practitioners would see as distracting. Since there is no consensus definition of DI, it is likely that some practitioners would consider additional injuries as a DI, while others would not consider all of the included injuries to be a DI. Defining DI based on the presence of specific injuries is consistent with previous studies evaluating DI, but does not account for the subjective difference in pain perception between patients.

As this study is a multicenter trial, intrainstitutional differences in protocols, policies, and biases could have led to inconsistency in examination technique, reporting of results, and patient enrollment. Additionally, patients were not followed long term, so there is the possibility that some clinical missed injuries presented at a different institution after discharge. Finally, since no a priori power analysis was performed and the true effect size is unclear, it is possible this study is underpowered. A more adequately powered study may have yielded different results.

Conclusion

Negative clinical examination is sufficient to clear the c-spine in awake and alert, blunt trauma patients, even in the

presence of a DI. The unproven concept that a DI precludes the use of physical examination as a screening tool is based on dogma alone and is not supported by evidence. Implementation of a policy of using physical examination to clear the c-spine in blunt trauma patients with a DI has the potential to reduce the number of radiographic tests used and can improve resource utilization at an institution that adopts such a policy.

AUTHORSHIP

R.P.G. participated in the study design. A.D.K., S.C.L., H.C.R., R.P.G. participated in the literature search. A.D.K., T.J.S., S.C.L., H.C.R., M.J.A., P.L.B., S.L.C., J.A.Q., S.L.B., J.S., J.M., N.M., M.G., H.C., R.P.G. participated in the data collection. A.D.K., T.J.S., R.P.G. participated in the data analysis/interpretation. A.D.K. and R.P.G. participated in the drafting of the article. A.D.K., T.J.S., S.C.L., H.C.R., M.J.A., P.L.B., S.L.C., J.A.Q., S.L.B., J.S., J.M., N.M., M.G., H.C., R.P.G. participated in the critical revision. A.D.K., T.J.S., S.C.L., H.C.R., M.J.A., P.L.B., S.L.C., J.A.Q., S.L.B., J.S., J.M., N.M., M.G., H.C., R.P.G. participated in the final approval.

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DISCLOSURE

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DISCUSSION

Kenji Inaba, MD (Los Angeles, California): President Rotondo, Dr. Reilly, and members, thank you so much for the privilege of discussing this manuscript.

The authors present a prospective study conducted through the AAST Multi-Institutional Trials group examining this concept of distracting injuries in the assessment of the cervical spine. I've got four specific questions for the authors.

Number one, the analysis really hinges on a comparison of those with and without distracting injuries, and because no two patients can be expected to react in the same way to a given injury, and because of the endless combination of injuries that could occur, NEXUS, and really our common practice, use individual patient assessment to decide whether or not a patient had a distracting injury or not.

In this study, however, a list of distracting injuries was compiled. How was this created? What evidence is there to support, for example, that greater than two facial bone fractures would be distracting, while only two or less than two would not.

A forearm fracture is on the list. Is this truly distracting for all patients, and conversely, many injuries are not on this list. What about a large, very painful soft tissue avulsion without a fracture, not uncommon and highly distracting, but not on the list.

I think this is a critical factor to consider, because being on this list led to more than 70 percent of patients being categorized as distracting, and therefore in need of imaging according to our contemporary standards.

Now the big comparison that was done was for those with and without a distracting injury. Perhaps a more germane series of questions would be the following: Can you tell us, in this series of 2,929 patients, were there not any patients, not even one, that had an injury or a combination of injuries that was distracting enough to preclude a definitive examination of the cervical spine, both for tenderness and for neurologic deficits? And secondly, if there was at least one of these patients in this group, what was the missed injury rate?

Number three: Did you utilize any of the standard exclusion criteria that we would normally use in a spine study such as patients with a prior injury or instrumentation or those with a concurrent T or L spine fracture?

And then, finally, I'm curious, just methodology-wise, you state that all patients, regardless of the results of their physical examination, underwent a CT scan of the cervical spine. That is a significant radiation burden for the patients that would normally have been cleared by the NEXUS low-risk criteria. How was this justified?

Thank you again. It was a great paper and a fantastic presentation. And I would like to thank everybody for the privilege of the podium and congratulations for this very important work on a very important topic. Thank you.

Sheldon H. Teperman, MD (Bronx, New York): Good morning. What a fascinating study. You noted in your manuscript that physical examination is a sensitive screening method for cervical spine injury, yet if you add up both of your arms fully 25 percent of the time physical examination missed cervical spine injury. I would say a broken neck is a broken neck. Maybe physical exam isn't as good as we think it is.

Christopher P. Michetti, MD (Falls Church, Virginia): Thank you, and congratulations on the study. I'm curious about the whole concept of using the actual injury and not pain as the determinant of your exam. Were pain scores measured on these patients? And was that taken into account in their clearance?

Peter Rhee, MD, MPH (Atlanta, Georgia): One comment and one question. There are standards of when a spine surgeon performs operative repairs that are extremely elusive, and we don't know what really needs repair at this point.

Having said that, the question is, does your database really have any granularity on the type of injuries, meaning, what we're really interested in are unstable fractures, not just the most common injuries, which are stable fractures.

Samir M. Fakhry, MD (Mclean, Virginia): Thank you. Great presentation. I know it's hard to do a study like this, but I think it's really important to point out that you're a little bit under-powered.

If your goal is to avoid missing an injury that results in significant neurologic deficit, you are going to need a much bigger number of patients. And three in a thousand patients, which was the missed rate requiring surgery, is still a lot because large trauma centers that do 2,000 or 3,000 (or more) patients a year are going to miss three or more patients each year that would have needed an operation to prevent neurologic deficit.

So, I would like to propose an alternate conclusion to your study because of the bias from being under-powered. The conclusion I would suggest is that the current methodologies we use to evaluate the spine and rule out injuries that in a small minority of patients cause neurologic deficit are grossly inadequate. They're expensive, they're complex, and we're still missing this very small number, which is still material, because that patient

that you miss will eventually end up with a neurologic deficit in some center that has a big enough volume, or a collection of centers that add up to a big enough volume. Thank you.

David H. Livingston, MD (Newark, New Jersey): With respect to the distracting injuries, one problem is that you had to take the patient to CT scan to discover that they had a distracting injury.

That seems to contrary to what most people mean by a distracting injury. That is, a clinically obvious injury at the time of primary or secondary survey. If you're going to take them to the CT scanner anyway what was the point? Did you analyze the data looking at clinical distracting injuries that were present on exam in the trauma bay from the laundry list that you presented?

Abid Khan, MD (Colorado Springs, Colorado): Thank you everyone, for those interesting questions.

First, to address Dr. Inaba's question about how the list of distracting injuries was compiled. This definition of distracting injury is consistent with some single center studies that have been published. There is no consensus of what constitutes a distracting injury. So the challenge in designing this study was to come up with an objective set of criteria that could be used across multiple centers that would define a distracting injury. Some practitioners certainly will say that there are too many injuries listed, and some practitioners will certainly say that there are injuries that are not listed for this study that should have been considered distracting injuries. It is a limitation to the study, but we needed to standardize the definition across eight different centers. We felt that it would be reasonable to assume that the injuries selected would cause a fair amount of pain in most people, but you certainly will have patients with femur fractures that have minimal outward signs of pain. Likewise, there will be patients with contusions or other unlisted injuries that are essentially inconsolable due to pain.

Dr Inaba asked if there was not even a single patient that was too distracted to be assessed. Undoubtably, there were patients in too much pain to cooperate with an exam. If the exam could not be completed, the patient was not included in the study.

There were no additional exclusion criteria. We took all comers, and previous instrumentation was not a contraindication to inclusion.

Dr Inaba also commented that too many CT scans were performed based on NEXUS criteria. This is true if you use NEXUS criteria. However, there are several centers around the country that perform CT scans on all patients who have adequate mechanism for cervical spine injury. This policy has been recently published and we felt that since this was an accepted policy at some trauma centers, that we could use the same criteria for this study.

Dr Teperman stated that 25% of the patients had a clinical missed injury. He came up with 25% by adding the individual rates in the distracting and no distracting injury groups. Adding the two groups rate does not give you the overall rate. The actual overall rate was 11.3%. And again, only 1 out of 2929 patients had a missed injury that needed operative repair.

Dr Michetti asked if we measured subjective pain scores and we did not. This was an attempt to keep the data collection as objective as possible.

To answer Dr Rhee's question, we used need for operative intervention as a surrogate for an unstable fracture. While there is not a 100% correlation between instability and operations, we believed that any injury considered unstable would likely be fixed operatively.

Dr Fakhry noted that the study may be underpowered, and it very well might be. Centers that see a high volume of patients may have more than one clinical missed injury a year. This underlies the importance of a good clinical exam when clearing the cervical spine, regardless of whether a distracting injury is present or not. Since all patients received a CT scan, some providers may not have been as meticulous as necessary during the physical exam.

Dr Livingston noted that the patient had to be taken to CT scan in order to find a distracting injury in this study. This was done in order to provide an objective way to assess for distracting injury. Thank you very much.

