Critical Review Form

Diagnostic Test

Helical Computed Tomography Alone Compared with Plain Radiographs with Adjunct Computed Tomography to Evaluate the Cervical Spine After High-Energy Trauma, *J Bone Joint Surgery* 2005; 87A: 2388-2394

Objective: "To determine if helical computed tomography alone could be used to initially evaluate the cervical spine for acute osseous injury following trauma." (p 2389). However, there were three additional endpoints

1. **determine the percentage of patients in whom 3-view x-rays alone would have been sufficient to clear the cervical spine**
2. **determine the sensitivity, specificity, PPV, and NPV of 3-view x-rays, "adequate" x-rays, and helical CT**
3. **compare costs of plain CT alone to costs of plain x-rays when used with adjunct CT.**

Methods: Prospective non-blinded study at one level I trauma center which included all level I and level II blunt traumas presenting from June 2002-February 2004 (criteria unavailable) with the following inclusion criteria: Age > 18, both plain x-rays (CRS) of neck and CT c-spine (CTC) obtained. At least one month post- injury, 2 radiologists independently reviewed the initial plain films and CT blinded to the original reading and to each others' interpretation looking for "acute processes" (defined as any fracture, subluxation or, dislocation of occiput, c spine or T1). Spondylolisthesis of unknown etiology was not considered a finding nor were other bony injuries. Total charges and length of stay (LOS) in the Radiology department were also included. The sole exclusion criteria were patients who did not get both CRS and CTC.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did clinicians face diagnostic uncertainty?**	Yes. The questioned whether c-spine CT could replace the initial 3-view plain x-ray c-spine study and/or modified c-spine with additional views to ensure adequacy. They prospectively studied non-consecutive patients (total of 409 from 4489 total trauma patients) and evaluated the sensitivity of CT study, its cost, and time factor when compared for traditional plain radiography divided as 3-view traditional and "adequate" when additional views were necessary.

B.	**Was there a blind comparison with an independent gold standard applied similarly to the treatment group and to the control group?** **(Confirmation Bias)**	No. The gold standard test (here, c-spine CT) was also the modality being investigated. The problem is that plain x-rays have traditionally been used as a screen for c spine trauma and the CT was used as a gold standard for missed or high-risk trauma patients. Other studies like MRI or flexion/extension dynamic CT's are not mentioned in the study. Any study that uses the gold standard as part of the evaluation it is studying has the potential to inflate the estimate of the test's diagnostic power. In addition, it sounds like there was significant *spectrum bias* in selecting patients (p 2393) since it only evaluated patients that got both plain x-rays AND CT's (sicker/higher risk mechanism traumas). There was no blinding of physicians to the original patients-to-study selection. In the study's defense, the subsequent over-reads of the CT's and plain X-rays that were done by 2 radiologists blinded to the original results (1 for plain x-rays and 1 for CTs) done several weeks later is an attempt to make study results "blinded".
C.	**Did the results of the test being evaluated influence the decision to perform the gold standard?** **(Ascertainment Bias)**	Again, there was the *selection bias* mentioned above. Although the gold standard was done for every plain x-ray c spine patient, not all trauma patients had the studies or were enrolled (the authors could not justify exposing low risk patients to extra radiation). YES. Patients that were enrolled had both studies by design. We can surmise that people that had additional CT imaging probably had other factors on the plain x-ray or the exam which made it unsafe to rely on the initial screen study.
II.	**What are the results?**	

A.	**What likelihood ratios were associated with the range of possible test results?**	**Plain x-rays**
		Sensitivity = 26/26+32 = 0.45
		Specificity = 340/340+9 = 0.97
		
		LR + = 0.45/1-0.97 = 15
		LR - = 1-0.45/0.97 = .57
		
		Adequate X-rays
		Sensitivity = 13/13+12 = 0.52
		Specificity = 166/166 + 3 = 0.98
		
		LR+ = 0.52/1-0.98 = 17
		LR - = 1-0.52/0.98 = = 0.49
		
		Helical CT
		Sensitivity= 57/57+1 = 0.98
		Specificity = 342/342+7 = 0.98
		
		LR + = 0.98/1-0.98 = 49
		LR - = 1-0.98/0.98 = 0.2
		
		• 407 patients underwent both CSR and CTC (67% male, 92% Level II, average age 40, average ISS 12.5)
		• CT and X-ray demonstrated injuries on 14% (58/407)
		• Plain x-rays were considered adequate in only 48% of cases and missed an injury in 55% (32/58) (p 2391 lists missed injuries)
		• X-rays missed fractures in 5/12 studies that had more than 1 injury
		• CT missed 1/58 (2%) – this was an obvious misread picked up by review radiologists and not so much a modality insufficiency
		• Charges for the study & interpretation:
		  o CT $1151
		  o Plain x-ray $268
		  o Overall plain x-ray charges (including secondary shots to attain "adequate" films $870
		• Time
		  o CT – 14 minutes +/- 3
		  o X-rays (total) 19 minutes +/- 11

III.	How can I apply the results to patient care?	
A.	**Will the reproducibility of the test result and its interpretation be satisfactory in my clinical setting?**	Probably but hard to ascertain. Although the study does not specify, it appears that the initial people reading the x-rays and CT's were radiologists. Were EP's or surgeons or neurosurgeons involved? Were reads by attendings or residents? Furthermore, the blinded testing was done over one month later by two independent radiologists. Both were blinded to each others' reads and to the initially interpretation – however there is no mention of inter-observer variability (kappa score). Therefore, if you are practicing in a trauma center where dedicated attending radiologists are giving immediate readings then chances are this study is applicable. If your initial reads are non-radiologists or Radiology residents, it is unclear whether this study could impact you if your have minimal expertise at interpreting plain x-rays and CT of c-spines.
B.	**Are the results applicable to the patients in my practice?**	Yes. Similar level 1 and level 2 traumas. Considering the bias which seemed to excludes low-mod risk patients, this certainly applies to some of the higher end traumas. One additional drawback was that the study did not go into details for the patients that had missed findings on x-rays (i.e. – would the missed injury been clinically consequential?). They provide rather loose criteria of what is considered an "acute process" findings (page 2389)
C.	**Will the results change my management strategy?**	Yes – CT appears to be the preferred study method both from diagnostic and interventional stand points in the mod-high risk trauma patient. However, the low-mod risk patient was not addressed and can't be inferred from the data.

D.	**Will patients be better off as a result of the test?**	**Costs:** The costs provided display the pure CT cost ($1150) and the x-ray et al costs ($870), noting a small but substantial price difference. **Time:** Although also not formally addressed in terms of significance, this study suggests a very strong trend in favor of CT evaluation (14 +/- 3 min) versus plain x-rays (18 +/- 11 min). I can't tell from the study whether this included the repeat trips to radiology for "inadequate" studies or whether all time factors were included. For example, did they just record time spent in the Radiology department? Did they record transport time? Time between decision to get repeat films and film availability? Overall, the answer is yes. Patients are getting a better diagnostic study (CT had LR 0.2-49) in a shorter time for roughly the same cost.

Limitations

1) **Convenience sampling.**

2) **Poor description of high risk c-spine trauma (physical exam signs? Tenderness? Limitation on exam? Intoxication? Were low risk clinical rules like NEXUS and CCSR used?)**

3) **Selection bias of much sicker patients. Since only patients that had both CSR and CTC were included, there were no a priori criteria to determine who was going to get additional CT's. Since by pre-existing ATLS and EAST guidelines initial screens should be 3-view x-rays with CT reserved for inadequate visualization, "soft calls" or persistent pain despite negative x-rays, the patients who would end up getting both studies were already more likely to have injury. This is further reflected in the much higher prevalence of fractures (14%) than in traditional literature (5%) and higher ISS.**

4) **No follow-up of excluded patients to ascertain whether cervical spine injured patients were not detected because they were not imaged at all.**

5) **CT is both the Gold standard and a diagnostic modality under study. Alternative Gold standards might better be employed.**

6) **Patient important endpoints (surgery, deficits, pain course) were not evaluated. Such endpoints are particularly important (for patients, physicians, and lawyers) among those who had a fracture missed.**

7) **CT cost is higher (monetarily and radiation-exposure). A cost-benefit analysis of the $280 difference would have been informative for physicians and policy-makers.**

Bottom Line

Compared with plain x-rays for cervical spine vertebral injury, CT is a superior screening tool for moderate to high-risk patients. The NNT for CT as a diagnostic tool for all fractures (regardless of patient impact) is 2; NNT for CT in identifying additional important fractures on patients with adequate plain x-rays is 3. For low-risk patients (like the one in our scenario), the diagnostic-value and cost-effectiveness of CT-screening remains undefined. CT appears to be the preferred imaging modality for moderate –high risk c spine trauma for multiple reasons:

1. **superior sensitivity**
2. **detection of injuries missed by positive x-rays (multiple injuries)**
3. **significantly shorter time spent on imaging**

Future research should include patient important endpoints and a cost-benefit analysis.