Prediction Value of the Canadian CT Head Rule and the New Orleans Criteria for Positive Head CT Scan and Acute Neurosurgical Procedures in Minor Head Trauma: A Multicenter External Validation Study

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Study objective: The New Orleans Criteria and the Canadian CT Head Rule have been developed to decrease the number of normal computed tomography (CT) results in mild head injury. We compare the performance of both decision rules for indentifying patients with intracranial traumatic lesions and those who require an urgent neurosurgical intervention after mild head injury.

Methods: This was an observational cohort study performed between 2008 and 2011 on patients with mild head injury who were aged 10 years or older. We collected prospectively clinical head CT scan findings and outcome. Primary outcome was need for neurosurgical intervention, defined as either death or craniotomy, or the need of intubation within 15 days of the traumatic event. Secondary outcome was the presence of traumatic lesions on head CT scan. New Orleans Criteria and Canadian CT Head Rule decision rules were compared by using sensitivity specifications and positive and negative predictive value.

Results: We enrolled 1,582 patients. Neurosurgical intervention was performed in 34 patients (2.1%) and positive CT findings were demonstrated in 218 patients (13.8%). Sensitivity and specificity for need for neurosurgical intervention were 100% (95% confidence interval [CI] 90% to 100%) and 60% (95% CI 44% to 76%) for the Canadian CT Head Rule and 82% (95% CI 69% to 95%) and 26% (95% CI 24% to 28%) for the New Orleans Criteria. Negative predictive values for the abovementioned clinical decision rules were 100% and 99% and positive values were 5% and 2%, respectively, for the Canadian CT Head Rule and New Orleans Criteria. Sensitivity and specificity for clinical significant head CT findings were 95% (95% CI 92% to 98%) and 65% (95% CI 62% to 68%) for the Canadian CT Head Rule and 86% (95% CI 81% to 91%) and 28% (95% CI 26% to 30%) for the New Orleans Criteria. A similar trend of results was found in the subgroup of patients with a Glasgow Coma Scale score of 15.

Conclusion: For patients with mild head injury, the Canadian CT Head Rule had higher sensitivity than the New Orleans Criteria, with higher negative predictive value. The question of whether the use of the Canadian CT Head Rule would have a greater influence on head CT scan reduction requires confirmation in real clinical practice. [Ann Emerg Med. 2013;61:521-527.]

Please see page 522 for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background and Importance

Mild head injury is one of the most common injuries treated in the emergency department (ED).[1] It is usually defined as a blunt injury to the head, after which the patient may briefly lose his or her consciousness, may have short amnesia, or both, or may have a minimally altered mental state at presentation. Head computed tomography (CT) is commonly considered the method of choice for the diagnosis of neurocranial traumatic lesions. However, systematic prescription of CT scan would not be a cost-effective strategy in mild head injury because potentially life-threatening complications that may require neurosurgical intervention occur in less than 1% of cases.[2-5] In addition, unrestricted use of CT in mild head injury would significantly increase the burden of crowding in the ED. A number of clinical guidelines have been developed to attempt to

Editor's Capsule Summary

What is already known on this topic

Decisions rules have been derived and validated for patients with minor head injury.

What question this study addressed

Whether rules derived in North American are applicable in Tunisia and whether one performs better than the other.

What this study adds to our knowledge

For the prediction of neurosurgical intervention in 1,582 patients, the Canadian CT Head Rule had higher sensitivity (100% versus 82%) and specificity (60% versus 26%) than the New Orleans Criteria.

How this is relevant to clinical practice

This study suggests that not all clinical decision rules may have the same performance characteristics in all populations. It is worthwhile to evaluate new rules' performance before they are adopted in new populations.

decrease the number of normal CT scan results by limiting CT prescription to only those patients who are at risk of developing complications.[6] Available clinical decision rules such as the New Orleans Criteria[7] and the Canadian CT Head Rule[8] were externally validated in studies conducted outside the United States.[2,9,10] However, application of these decision rules may still be limited in populations with different demographic and epidemiologic features. The decision to use the New Orleans Criteria or Canadian CT Head Rule models in different settings should ideally be based on objective and specific validation.

Goals of This Investigation

The aim of the study was to externally validate the New Orleans Criteria and the Canadian CT Head Rule and compare the diagnostic performance of these instruments in different sets of patients with mild head injury.

MATERIALS AND METHODS

Study Design

Between June 2008 and August 2011, data were prospectively collected for consecutive patients presenting to the ED of teaching (n=4) and nonteaching (n=3) hospitals after sustaining acute mild head injury. In these nonspecialized EDs, trauma patients represent 30% to 40% of all admissions. The research ethics board at each participating institution approved the study and waived the requirement for written informed consent.

Selection of Participants

Acute mild head injury was defined as a patient having a blunt trauma to the head within 24 hours, with a Glasgow Coma Scale (GCS) score of 13 to 15 and at least 1 of the following risk factors: history of loss of consciousness, short-term memory deficit, amnesia for the traumatic event, posttraumatic seizure, vomiting, headache, external evidence of injury above the clavicles, confusion, and neurologic deficit. Patients were excluded from the study if they were younger than 10 years, had a GCS score of less than 13 or instable vital signs, presented to the ED more than 24 hours after head trauma, were pregnant, were receiving warfarin or had a bleeding disorder, had an obvious penetrating skull injury, or had contraindications for CT.

Data Collection and Processing

All the data were prospectively collected by an emergency physician or by a supervised resident in an emergency medicine training program. Baseline data were recorded on a standard form and included clinical criteria required to define the New Orleans Criteria and Canadian CT Head Rule decision rule. All the physicians participating in the study were asked to indicate at the end of their initial clinical assessment whether the patient was rule positive or rule negative. After clinical assessment, a standard CT scan of the head was performed at the discretion of the treating physician. Neither the New Orleans Criteria nor the Canadian CT Head Rule was used in routine practice in the hospitals involved in this study. Two senior radiology residents, who were blinded to patient data, independently interpreted the CT scan. If they had any doubt about the presence of intracranial injury, then a third physician (ie, neurosurgeon) reviewed the CT scan for a definitive conclusion. To ensure that data collection occurred before the CT was performed, the radiologists were requested to keep their CT interpretation confidential until the clinical data collection phase had been completed. Follow-up information for patients who did not undergo CT scanning was collected by structured telephone interview. Patients who were discharged home received instructions for observation and return to the ED for clinical reassessment and CT scan control of the head if they met these criteria: headache, memory or concentration problems, seizure, focal motor findings, or inability to return to usual daily activities (sleeping, eating, working, sports, etc).

Outcome Measures

These outcomes were aligned with initial outcomes in rule development.[7,8] Need for a neurosurgical intervention was defined as the primary outcome, and the presence of traumatic lesions on head CT scan was a secondary outcome. The need for neurosurgical intervention was defined as either death or need for any of the following procedures within 30 days of the traumatic event: craniotomy, monitoring of intracranial pressure, or the need for intubation for the treatment of head injury. Brain lesions were defined as any acute intracranial finding revealed on CT that was attributable to acute injury.

Patients who did not undergo imaging procedure were classified as having no clinically important brain lesions if, at 15 days after ED discharge, none of the abovementioned criteria requiring return to the ED were present.

Primary Data Analysis

Patient data entered in the database were checked for correct patient inclusion and for completeness of the data. Any case without a complete data sheet was excluded. We evaluated the study group for demographic characteristics, mechanism of injury, traumatic findings at CT, and neurosurgical intervention. Descriptive statistics with means or proportions as appropriate were performed. We then calculated the sensitivity, specificity, and predictive values with 95% confidence intervals (CIs) for performance of each decision rule for predicting neurosurgical intervention and CT scan intracranial traumatic findings. The Canadian CT Head Rule and the New Orleans Criteria were also assessed in the subgroup of patients who presented with a GCS score of 15. Prediction of neurologic procedures and clinical outcomes on imaging was applied in a manner consistent with the original studies of both decision rules. To determine the interrater agreement for each variable and the final interpretation of the rules (ie, whether the outcome prediction was positive or negative for injury), 100 randomly enrolled patients were examined by a second physician at the initial evaluation. For patients who did not have CT, medical records and imaging results were obtained if a missed traumatic brain injury was suggested at follow-up. If a clinically important brain injury was identified, the patient's outcome was classified accordingly. Using a sensitivity of more than 95% for both rules and an estimated 10% prevalence of combined adverse outcomes, we calculated a sample size requirement of at least 1,200 patients, which provided at least 120 significant events for analysis. For all comparisons, 2-sided $P<.05$ was considered statistically significant. When appropriate, CIs were calculated with a 95% confidence level. Statistical analysis was performed with SPSS (version 11.0; SPSS, Inc., Chicago, IL).

RESULTS

Characteristics of Study Subjects

Data were collected for 1,664 patients. Of these, 82 were excluded because of missing variables required to define the New Orleans Criteria or the Canadian CT Head Rule model, resulting in 1,582 patients in the data analysis (Figure). Table 1 shows the demographic and clinical characteristics of the overall study group (n=1,582) and the subgroup of patients with a GCS score of 15 (n=1,249). Most of the patients were men, and the mean age of the cohort was 32 years, with more than 90% younger than 60 years. The κ values for interobserver agreement (n=100) of the clinical predictors included in the Canadian CT Head Rule and New Orleans Criteria ranged from 0.15 to 1.0.

Main Results

Neurosurgical intervention was performed in 34 patients (2.1%) in the entire cohort and 25 patients (2.0%) in the subgroup of patients with a GCS score of 15. Neurosurgical intervention was performed for epidural hematoma (n=18), subdural hematoma (n=11), and depressed skull fracture

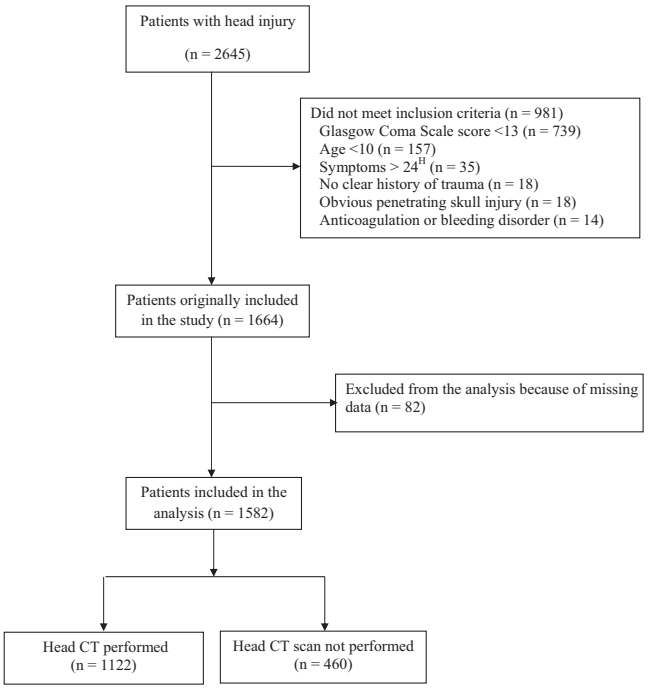

Figure. Study flow diagram.

(n=5). All deaths (n=1) and intubations (n=5) were observed in the group of patients in whom neurosurgical intervention was performed. CT scan was performed in 1,122 patients (70.9%); results were positive in 218 patients (13.8%), 68 of whom had a GCS score less than 15. All these patients were contacted to obtain 15-day follow-up data. Their demographic characteristics were not statistically different from those of patients who received CT scan. Six patients from this group returned to the ED and received a diagnosis of isolated linear fracture (n=5) and subdural hematoma (n=1). Findings for primary and secondary outcome are summarized in Table 2. No patient experienced an adverse outcome among those who were discharged from the ED without CT scan imaging. The sensitivity for need for neurosurgical intervention was 100% (95% CI 90% to 100%) for the Canadian CT Head Rule and 82% (95% CI 69% to 95%) for the New Orleans Criteria. Specificity was 60% (95% CI 44% to 76%) and 26% (95% CI 24% to 28%), respectively, for the Canadian CT Head Rule and the New Orleans Criteria (Table 3). The negative predictive values for the abovementioned clinical decision were 100% (95% CI 99% to 100%) for Canadian CT Head Rule and 99% (95% CI 98% to 100%) for the New Orleans Criteria (Table 3). With regard to clinically significant head CT findings, the sensitivity was 95% (95% CI 92% to 98%) for the Canadian CT Head Rule and 86% (95% CI 81% to 91%) for the New Orleans Criteria; the specificity was 65% (95% CI 62% to 68%) and 28% (95% CI 26% to 30%), respectively, for the Canadian CT Head Rule and the New Orleans Criteria. The negative predictive values for the abovementioned clinical decision were 99% (95% CI 98% to 100%) for the Canadian CT Head Rule and 93% (95% CI

Table 1. Patients' characteristics.

General Characteristics	Overall Study Population, N=1,582	Patients With GCS Score=15, N=1,249	κ Value (95% CI), N=100
Men, No. (%)	1,212 (76.6)	1,017 (81.4)	NA
Age, mean (range), y	32 (15–97)	31 (15–88)	NA
Mechanism of injury, No. (%)			NA
Road accident	737 (46.6)	528 (42.2)	
Home accident	462 (29.2)	393 (31.4)	
Assault	255 (16.1)	180 (14.4)	
Accident in the work	88 (5.6)	85 (6.8)	
Sports accident	22 (1.4)	19 (1.5)	
Other	18 (1.1)	44 (3.5)	
Findings from the Canadian CT Head Rule, No. (%)			
GCS <15 at 2 h after injury	333 (21.0)	17 (1.3)	0.22 (0.03–0.41)
Signs of basal skull fracture	47 (2.9)	44 (3.5)	0.81 (0.63–0.99)
Suspected open skull fracture	37 (2.3)	35 (2.8)	0.83 (0.67–0.99)
Vomiting >1 episode	259 (16.4)	207 (16.5)	0.31 (0.11–0.51)
Age >65 y	93 (7.4)	64 (5.1)	1.0 (0.94–1.0)
Amnesia before impact >30 min	166 (10.5)	4 (0.3)	0.38 (0.18–0.58)
Dangerous mechanism of injury*	639 (40.4)	415 (33.2)	0.39 (0.17–0.61)
Findings from the New Orleans Criteria, No. (%)			
Headache	617 (39.0)	582 (46.5)	0.44 (0.27–0.61)
Vomiting	284 (17.9)	226 (18.0)	0.77 (0.62–0.92)
Age >60 y	155 (9.8)	94 (7.5)	1.0 (0.94–1.0)
Drug or alcohol intoxication	63 (5.0)	33 (2.6)	0.88 (0.76–1.0)
Persistent anterograde amnesia	82 (6.5)	53 (4.2)	0.63 (0.36–0.90)
Trauma above the clavicle	807 (51.0)	586 (46.9)	0.59 (0.44–0.74)
Seizure	9 (0.6)	6 (0.4)	0.79 (0.62–0.96)
Others findings, No. (%)			
Witnessed loss of consciousness	824 (65.5)	651 (52.1)	0.51 (0.32–0.70)
Neurologic deficit	24 (1.5)	14 (1.1)	0.15 (0.05–0.25)
Anticoagulation	0	0	1.0 (0.95–1.0)

NA, Not applicable.
*Pedestrian hit by motor vehicle, ejected from motor vehicle, or fall from height of more than 1 m or 5 stairs.

Table 2. Outcome.*

Outcome	No. (%)
Primary outcome (neurosurgical intervention)	
Epidural hematoma	18
Subdural hematoma	11
Depressed skull fracture	5
Ventricular drainage	2
Intubation for head injury	2
Death as a result of head injury	1
Secondary outcome (traumatic lesions on head CT scan)	
Skull fracture	133 (61.0)
Linear	71
Depressed	43
Skull base	29
Subdural hematoma	41 (18.8)
Epidural hematoma	45 (20.6)
Subarachnoid hemorrhage	60 (27.5)
Hemorrhagic contusion	9 (4.1)
Cerebral edema	1 (0.5)
Pneumocephalus	1 (0.5)

*Some patients had more than 1 event.

Table 3. Performance of the Canadian CT Head Rule and the New Orleans Criteria in predicting neurosurgical intervention in the overall population.

	Neurosurgical Intervention		
Predictor	**Positive**	**Negative**	**Total**
Canadian CT Head Rule*			
Positive	34	622	656
Negative	0	926	926
Total	34	1,548	1,582
New Orleans Criteria†			
Positive	28	1,152	1,180
Negative	6	396	402
Total	34	1,548	1,582

*Sensitivity 100% (95% CI 90% to 100%), specificity 60% (95% CI 44% to 76%), positive predictive value 5% (95% CI 3% to 7%), and negative predictive value 100% (95% CI 99% to 100%).
†Sensitivity 82% (95% CI 69% to 95%), specificity 26% (95% CI 24% to 28%), positive predictive value 2% (95% CI 1% to 3%), and negative predictive value 99% (95% CI 98% to 100%).

90% to 96%) for the New Orleans Criteria (Table 4). Accuracy of both rules in the subgroups of patients with a GCS score of 15 is summarized in Tables 5 and 6. The same trend of results was found in this category of patients.

LIMITATIONS

Our study has limitations, although most apply to both decision rules. First, we did not enroll all eligible patients and we lack the baseline characteristics of the excluded patients. Second, our results

Table 4. Performance of the Canadian CT Head Rule and the New Orleans Criteria in predicting clinically significant head CT findings in the overall population.

	CT Findings		
Predictor	**Positive**	**Negative**	**Total**
Canadian CT Head Rule*			
Positive	207	472	679
Negative	11	892	903
Total	218	1,364	1,582
New Orleans Criteria†			
Positive	187	976	1,163
Negative	31	388	419
Total	218	1,364	1,582

*Sensitivity 95% (95% CI 92% to 98%), specificity 65% (95% CI 62% to 68%), positive predictive value 30% (95% CI 27% to 33%), and negative predictive value 99% (95% CI 98% to 100%).
†Sensitivity 86% (95% CI 81% to 91%), specificity 28% (95% CI 26% to 30%), positive predictive value 16% (95% CI 14% to 18%), and negative predictive value 93% (95% CI 90% to 96%).

Table 5. Performance of the Canadian CT Head Rule and the New Orleans Criteria in predicting neurosurgical intervention in patients with a GCS score of 15.

	Neurosurgical Intervention		
Predictor	**Positive**	**Negative**	**Total**
Canadian CT Head Rule*			
Positive	25	515	540
Negative	0	709	709
Total	25	1,224	1,249
New Orleans Criteria†			
Positive	24	909	933
Negative	1	315	316
Total	25	1,224	1,249

*Sensitivity 100% (95% CI 86% to 100%), specificity 58% (95% CI 55% to 61%), positive predictive value 5% (95% CI 3% to 7%), and negative predictive value 100% (95% CI 99% to 100%).
†Sensitivity 96% (95% CI 88% to 100%), specificity 26% (95% CI 23% to 28%), positive predictive value 3% (95% CI 2% to 4%), and negative predictive value 99% (95% CI 98% to 100%).

Table 6. Performance of the Canadian CT Head Rule and the New Orleans Criteria in predicting clinically significant head CT findings in patients with a GCS score of 15.

	CT Findings		
Predictor	**Positive**	**Negative**	**Total**
Canadian CT Head Rule			
Positive	138	402	540
Negative	10	699	709
Total	148	1,101	1,249
New Orleans Criteria†			
Positive	126	807	933
Negative	22	294	316
Total	148	1,101	1,249

*Sensitivity 93% (95% CI 89% to 97%), specificity 63% (95% CI 61% to 65%), positive predictive value 25% (95% CI 22% to 28%), and negative predictive value 98% (95% CI 97% to 99%).
†Sensitivity 85% (95% CI 79% to 91%), specificity 26% (95% CI 24% to 28%), positive predictive value 14% (95% CI 11% to 17%), and negative predictive value 93% (95% CI 90% to 96%).

did not apply to the pediatric population as children younger than 10 years were excluded in our study because we believe that this category of patients would require specific decision rules. Of note, the youngest patient in our study was aged 15 years. Third, for evident reasons, not all enrolled patients with mild head injury underwent CT; nonetheless, the frequency of patients for whom we performed cranial CT scan and the frequency of positive results (ie, with significant CT scan findings) were within the range reported in previous investigations. Fourth, we did not prospectively assess the confidence of the physicians in predicting the need of neurosurgical intervention or positive CT result, which would be a good comparison between an external decision rule and physician diagnostic performance.

DISCUSSION

The present prospective validation study demonstrated that, for patients with mild head injury, the Canadian CT Head Rule had a higher sensitivity for predicting both the need for neurosurgical intervention and clinically significant neurocranial traumatic CT lesions compared with the New Orleans Criteria. However, both decision rules demonstrated excellent and similar negative predictive value with regard to the need for neurosurgical intervention (99% and 100%, respectively). These results were similar for patients with a GCS score of either 15 or less than 15.

A number of studies have been conducted to identify a set of high-risk factors that would clearly indicate which patient with mild head injury should undergo CT scan, yet no consensus has been reached. Current guidelines on the use of cranial CT scanning vary from mandatory scanning for all patients to more selective use based on clinical examination findings. The selective approach should normally decrease costs by avoiding unnecessary normal CT scan results and would increase patient satisfaction by decreasing length of stay in the ED.

In previous studies, the New Orleans Criteria and Canadian CT Head Rule have demonstrated 100% sensitivity in identifying patients who required neurosurgical intervention, as well as most patients with clinically significant intracranial lesions on a CT scan.[9,10] However, there is still debate about whether these decision rules could be applied worldwide because their validation has not been performed in populations with different demographic and ethnic characteristics compared with those of the original research. Nonetheless, our findings were in accordance with those reported in Canada by Stiell et al[9] and in the Netherlands by Smits et al.[10]

The higher sensitivity of the Canadian CT Head Rule compared with the New Orleans Criteria in our study with regard to neurocranial CT findings seems to be mainly because GCS was not included in the New Orleans Criteria decision rule. Indeed, this difference was reduced in the subgroup of patients with a GCS score of 15. In a recent meta-analysis, a GCS score less than 15 within 2 hours after mild head injury

was found to be one of the strongest risk clinical correlates that predict intracranial hemorrhage in adults.[11] In our study, the rate of clinically significant neurocranial traumatic CT findings was 21.1% in patients with GCS score less than 15 compared with 11.8% in patients with a GCS score equal to 15.

Although our findings suggest that the Canadian CT Head Rule outperforms the New Orleans Criteria, it would be interesting to perform the same comparison with other available rules such as CT in Head Injury Patients (known as CHIP)[12] and the Scandinavian[13] or National Institute for Clinical Excellence[14] guidelines. Currently, no study has clearly shown one decision rule to perform significantly better than the others in cost-saving terms. It was suggested that cost savings would be possible only if the sensitivity for the identification of patients who require neurosurgery were extremely high.[15] In our study, we report a 100% sensitivity for the Canadian CT Head Rule, but the associated 95% CI was relatively wide (95% to 100%), which means that the risk of missing patients with trauma-related complications would still be significant with the Canadian CT Head Rule.

Refitting the Canadian CT Head Rule by introducing new items such as severity of headache would improve the model. In their meta-analysis, Dunning et al[11] showed that severe headache is one of the factors associated to the highest relative risk of intracranial hemorrhage in adults with minor head trauma. Based on the fact that the actual CT rate indications was 70.9% (n=1,122) and 43% for the estimated proportion of patients requiring CT scans according to Canadian CT Head Rule, the use of the Canadian CT Head Rule would result in an approximately 30% reduction of CT imaging. Nonetheless, whatever the prediction value of a given decision rule, we must confirm our findings in actual clinical practice. Indeed, in one Australian study, Rosengren et al[16] showed that neither the New Orleans Criteria nor the Canadian CT Head Rule appeared suitable to reduce the number of CT scans requested for mild head injury. Moreover, in a cost-effectiveness study using a decision analytic model of 6 management strategies in mild head injury, Stein et al[17] demonstrated that the liberal use of CT scan and a selective CT scan strategy based on the Canadian CT Head Rule performed equally well. In another study conducted in a British ED, Boyle et al[18] found that the Canadian CT Head Rule would result in an increase in the number of CT scans, suggesting that reduction of unnecessary cranial CT depends greatly on local practice.

In summary, our study represents a new external validation of the 2 main classification systems used worldwide in mild head injury. We demonstrate that the Canadian CT Head Rule has high reliability in predicting cranial CT lesions in patients with mild head injury. The Canadian CT Head Rule had higher sensitivity than the New Orleans Criteria, with higher negative predictive value, and would have a significant influence on CT scans testing reduction. Although Tunisian clinicians may now choose to use this decision rule in routine practice, more research is probably warranted to clearly establish its benefit in actual behavior.

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Author contributions: BB and SN conceived the study and designed the trial. SM, MM, RB, NR, and SN supervised the conduct of the trial and data collection. SS, HK, HH, SK, KB, MHG, MNT, WK, NC, IH, and IR undertook recruitment of participating centers and patients and managed the data, including quality control. ML and SN provided statistical advice on study design and analyzed the data. ML chaired the data oversight committee. SN drafted the article, and all authors contributed substantially to its revision. SN takes responsibility for the paper as a whole.

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IMAGES IN EMERGENCY MEDICINE

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DIAGNOSIS:

Squamous cell carcinoma. The patient underwent a tonsillectomy and excision of his right-sided peritonsillar mass. Pathologic analysis of the mass demonstrated poorly differentiated squamous cell carcinoma requiring chemoradiation treatments.

Bedside ultrasonography is extremely useful in discriminating between peritonsillar cellulitis versus abscess.[1] It can localize abscess pockets and help guide drainage attempts.[2,3] A partially treated peritonsillar abscess can appear similar to an undifferentiated peritonsillar mass on ultrasonography and clinical examination. Squamous cell carcinoma of the soft palate occurs rarely and is observed in only 1% to 4% of all head and neck tumors. This patient's mass had a distinct border with adjacent tissue that did not appear inflamed like a usual peritonsillar abscess. The atypical appearance of the mass and the lack of expected purulent material drained during the aspiration raised concern that the mass was the result of neoplastic growth instead of a peritonsillar abscess.[4,5]

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