The Canadian CT Head Rule for patients with minor head injury

Ian G Stiell, George A Wells, Katherine Vandemheen, Catherine Clement, Howard Lesiuk, Andreas Laupacis, R Douglas McKnight, Richard Verbeek, Robert Brison, Daniel Cass, Mary A Eisenhauer, Gary H Greenberg, James Worthington, for the CCC Study Group

Summary

Background There is much controversy about the use of computed tomography (CT) for patients with minor head injury. We aimed to develop a highly sensitive clinical decision rule for use of CT in patients with minor head injuries.

Methods We carried out this prospective cohort study in the emergency departments of ten large Canadian hospitals and included consecutive adults who presented with a Glasgow Coma Scale (GCS) score of 13–15 after head injury. We did standardised clinical assessments before the CT scan. The main outcome measures were need for neurological intervention and clinically important brain injury on CT.

Findings The 3121 patients had the following characteristics: mean age 38·7 years); GCS scores of 13 (3·5%), 14 (16·7%), 15 (79·8%); 8% had clinically important brain injury; and 1% required neurological intervention. We derived a CT head rule which consists of five high-risk factors (failure to reach GCS of 15 within 2 h, suspected open skull fracture, any sign of basal skull fracture, vomiting ⩾2 episodes, or age ⩾65 years) and two additional medium-risk factors (amnesia before impact >30 min and dangerous mechanism of injury). The high-risk factors were 100% sensitive (95% CI 92–100%) for predicting need for neurological intervention, and would require only 32% of patients to undergo CT. The medium-risk factors were 98·4% sensitive (95% CI 96–99%) and 49·6% specific for predicting clinically important brain injury, and would require only 54% of patients to undergo CT.

Interpretation We have developed the Canadian CT Head Rule, a highly sensitive decision rule for use of CT. This rule has the potential to significantly standardise and improve the emergency management of patients with minor head injury.

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Divisions of Emergency Medicine (Prof I G Stiell MD, G H Greenberg MD, J R Worthington MBBS)**; Departments of Epidemiology and Community Medicine** (Prof G A Wells PhD)**; Division of Neurosurgery** (H Lesiuk MD); **Department of Medicine** (Prof A Laupacis MD)**; Clinical Epidemiology Unit** (K L Vandemheen BScN, C Clement RN)**, University of Ottawa, Ottawa, Canada; Department of Emergency Medicine** (R Brison MD)**, Queen's University, Kingston, Canada; Division of Emergency Medicine** (R Verbeek MD, D Cass MD)**, University of Toronto, Toronto, Canada; Division of Emergency Medicine** (M A Eisenhauer MD)**, University of Western Ontario, London, Canada; and Division of Emergency Medicine** (R D McKnight MD)**; University of British Columbia, Vancouver, Canada**

Correspondence to: Dr Ian G Stiell, Clinical Epidemiology Unit, F6, Ottawa Hospital Loeb Health Research Institute, Ottawa, Ontario, Canada K1Y 4E9
(e-mail: istiell@ohri.ca)

Introduction

An estimated one million cases of head injury are seen yearly in North American emergency departments and most are classified as minimal or minor.[1] Patients with minimal head injuries have not suffered loss of consciousness or amnesia and rarely require admission to hospital. Minor head injury is defined as a patient with a history of loss of consciousness, amnesia, or disorientation and a Glasgow Coma Scale (GCS) score of 13–15.[2] Although most patients with minor head injury can be discharged without sequelae after observation, a small proportion deteriorate and require neurosurgical intervention for intracranial haematoma.[3,4] Early diagnosis of intracranial haematoma by computed tomography (CT) followed by early surgery is very important in the treatment of such patients.

Use of CT for minor head injury has become increasingly common, particularly in North America. In 1992, an estimated 270 000 CT scans of the head were done in US emergency departments for head injury.[5] Typical US hospital charges for unenhanced CT range from US$500 to 800, suggesting a national total cost of US$135–216 million. The US yield of CT for intracranial lesions in minor head injury is estimated to be quite low (0·7–3·7%).[6,7] We have previously shown a four-fold variation among similar Canadian teaching hospitals in the use of CT for minor head injury.[8] More selective use of this expensive high technology investigation for patients with minor head injury could lead to large reductions in health-care costs throughout the western world.

Current guidelines provide conflicting recommendations for use of CT and previous studies to develop guidelines have been methodologically weak and inconclusive. There is a clear need for valid and reliable guidelines to allow physicians to be more selective in their use of CT without compromising care of patients with minor head injury. Clinical decision (or prediction) rules attempt to reduce the uncertainty of medical decision-making by standardising collection and interpretation of clinical data.[9,10] These decision-making tools are derived from original research and incorporate three or more variables from the history, physical examination, or simple tests. We have previously developed decision rules to allow physicians to be more selective in the use of radiography for patients with ankle,[11,12] knee,[13] and cervical spine injuries. We aimed to prospectively derive an accurate, reliable, and clinically sensible decision rule for the use of CT in patients with minor head injury.

Methods

Study setting and population

We undertook a prospective cohort study in ten Canadian community and teaching institutions and enrolled consecutive adult patients if they presented to one of the emergency departments after sustaining acute minor head injury. Eligibility was based upon the patients having all of the following: blunt trauma to the head resulting in witnessed loss of consciousness, definite amnesia, or witnessed disorientation; initial emergency department

GCS score of 13 or greater as determined by the treating physician; and injury within the past 24 h. We excluded patients if they: were less than 16 years old; had minimal head injury (ie, no loss of consciousness, amnesia, or disorientation); had no clear history of trauma as the primary event (eg, primary seizure or syncope); had an obvious penetrating skull injury or obvious depressed fracture, had acute focal neurological deficit; had unstable vital signs associated with major trauma; had had a seizure before assessment in the emergency department; had a bleeding disorder or used oral anticoagulants (ie, coumadin); had returned for reassessment of the same head injury; or were pregnant. The research ethics committees of the study hospitals approved the protocol without the need for informed consent. Patients followed up had the opportunity to give verbal consent to the telephone interview by a study nurse.

Standardised patient assessment

All patient assessments were made by staff physicians certified in emergency medicine or by supervised residents in emergency medicine training programmes. The physician assessors were trained in a 1 h session to assess patients for 22 standardised clinical findings from the history, general examination, and neurological status. These potential predictor variables were selected by a team of investigators at a planning consensus conference based upon a review of the existing literature and the results of a pilot study. We recorded data on sheets before the scan. A subset of patients, when feasible, were independently assessed by a second emergency physician to judge interobserver agreement. For patients transferred from a primary care hospital, study assessments were undertaken after arrival at the study site.

Outcome measures and assessment

The primary outcome was need for neurological intervention and the secondary outcome was clinically important brain injury, on CT. Need for neurological intervention was defined as either death within 7 days secondary to head injury or the need for any of the following procedures within 7 days: craniotomy, elevation of skull fracture, intracranial pressure monitoring, or intubation for head injury (shown on CT). Clinically important brain injury was defined as any acute brain finding revealed on CT and which would normally require admission to hospital and neurological follow-up. This definition has been standardised based upon the results of a formal survey of 129 academic neurosurgeons, neuroradiologists, and emergency physicians at eight study sites. All brain injuries are judged clinically important unless the patient is neurologically intact and has one of these lesions on CT: solitary contusion less than 5 mm in diameter; localised subarachnoid blood less than 1mm thick; smear subdural haematoma less than 4 mm thick; isolated pneumocephaly, or closed depressed skull fracture not through the inner table.

After the clinical examination, patients underwent standard CT of the head according to the judgment of the treating physician. CT scans were interpreted by qualified staff neuroradiologists who were unaware of the contents of the data collection sheet. The reliability of the radiography interpretations was assessed by having abnormal CT scans, and 5% (randomly selected) of normal scans reviewed by a second radiologist who was unaware of the first interpretation. Radiologists showed 100% agreement in their interpretations of 142 abnormal and 103 normal CT scans. We undertook CT without contrast with third generation equipment, and with cuts of 10 mm or less from the foramen magnum to the vertex, and included both soft tissue and bone windows.

Because not all patients with minor head injury routinely undergo CT at the study sites, we could not ethically mandate universal CT for all eligible patients. Consequently, all enrolled patients who did not have imaging underwent the structured 14 day telephone proxy outcome measure administered by a registered nurse. According to this tool, we classified patients as having no clinically important brain injury if they met all the following explicit criteria at 14 days: headache absent or mild; no complaints of memory or concentration problems; no seizure or focal motor findings; weighted error score of no more than 10 out of 28 on the Katzman Short Orientation-Memory-Concentration Test;[14] and had returned to normal daily activities (work, housework, or school). The assessment of these criteria was made by a registered nurse who was unaware of the patients' status for the individual predictor clinical variables. Patients who did not fulfil these criteria were recalled for clinical reassessment and CT. Patients could only be classified as having brain injury based upon their CT findings. Patients who could not be reached were excluded from the final analysis. The validity of these criteria to exclude acute brain injury was confirmed by applying the telephone follow-up questionnaire to a random sample of 172 study patients, who had all undergone CT. The proxy outcome measure proved to be 100% sensitive for identifying patients requiring neurological intervention and 87% sensitive for patients having clinically important brain injury.

Data analysis

We measured interobserver agreement for each variable by calculating the κ coefficient, the proportion of potential agreement beyond chance, along with 95% CI. κ values were not calculated for variables created by cut-point (eg, amnesia before ⩾30 minutes) or collected from the medical record (eg, age or mechanism of injury). We used univariate analyses to determine the strength of association between each variable and the primary outcomes to aid selection of the best variables for the multivariate analyses. We used the χ^2 test with continuity correction for nominal data; the Mann-Whitney U test for ordinal variables; and the unpaired two-tailed *t* test for continuous variables using pooled or separate variance estimates as appropriate.

Those variables found to be both reliable ($\kappa > 0{\cdot}6$) and strongly associated with the outcome measures ($p < 0{\cdot}05$) were combined using one of two different multivariate techniques, recursive partitioning or logistic regression. The objective was to find the best combinations of predictor variables highly sensitive for detecting the outcome measure while achieving the maximum possible specificity. Regression model building proceeded with forward stepwise selection until no variables met the entry ($p < 0{\cdot}05$) or removal ($p < 0{\cdot}10$) criteria for the significance level of the likelihood-ratio test. We did recursive partitioning as an alternative technique using KnowledgeSEEKER (Version 2·1) software. Our experience suggests that recursive partitioning may be more suitable than logistic regression when the objective is to correctly classify one outcome at the expense of the other—ie, where high sensitivity is more important than overall accuracy.

We cross-validated the derived decision rule by comparing the classification of each patient with their actual status for the primary outcomes allowing an

Characteristics	Number of patients
Mean (SD) age in years	38·7 (18)
Age range (years)	16–99
Men	2135 (69%)
Mean (SD) time injury to assessment by doctor (h)	3·1 (4·3)
Arrived by ambulance	2268 (73%)
Transfer from another hospital	400 (13%)
Witnessed loss of consciousness	1435 (46%)
Amnesia	2722 (87%)
Initial GCS	
15	2489 (80%)
14	522 (17%)
13	110 (4%)
Mechanism of injury	
Fall	963 (31%)
Motor vehicle collision	805 (26%)
Assault	334 (11%)
Sports	307 (10%)
Bicycle	207 (7%)
Pedestrian struct	187 (6%)
Head struck/hit by object	182 (6%)
Motorcycle	105 (4%)
Other	31 (1%)

Table 1: **Characteristics of the 3121 patients with head injuries**

estimate, with 95% CI of the sensitivity and specificity of the rule. The a priori sample size was estimated to be 2500 patients based upon the desired precision of 100% sensitivity for clinically important brain injury with 95% CI of 97–100%.

Results

Between October, 1996, and December, 1999, 3121 patients were enrolled and 100% of these had complete assessment of the primary outcome measure, need for neurological intervention (tables 1 and 2). We scanned 2078 (67%) patients to assess the secondary outcome measure, clinically important injury on CT. The remaining 33% patients, who were all discharged directly from the emergency department, underwent the structured 14-day telephone proxy outcome measure administered by a registered nurse. Of all patients, 44 (1%) required neurological intervention including four patients who died of their head injury. In addition, 254 (8%) patients were judged to have clinically important brain injury—this frequency of brain injury is higher than in previous studies because we included transfers from other hospitals. An additional 94 (4%) patients were judged to have clinically unimportant lesions—mainly

Outcome	Number of patients
Computed tomography of head done	2078 (67%)
Cases followed by telephone	1043 (33%)
Skull radiography done	78 (3%)
Skull fracture	
Basal	55 (2%)
Linear	53 (2%)
Any acute brain injury	348 (11%)
Clinically important brain injury*	254 (8%)
Cerebral contusion	157 (5%)
Subarachnoid haemorrhage	113 (4%)
Subdural haematoma	79 (3%)
Epidural haematoma	37 (1%)
Pneumocephalus	23 (0·7%)
Intracerebral haematoma	18 (0·6%)
Depressed skull fracture	16 (0·5%)
Intraventricular haemorrhage	15 (0·5%)
Diffuse cerebral oedema	6 (0·2%)
Clinically unimportant brain injury*	94 (3%)
Subarachnoid haemorrhage, focal	43 (1%)
Cerebral contusion <5 mm diameter	36 (1%)
Subdural haematoma <4 mm thick	17 (0·5%)
Pneumocephalus, isolated	6 (0·2%)
Depressed skull fracture	2 (0·1%)
Neurological intervention	44 (1%)
Craniotomy	27 (0·9%)
Elevation of skull fracture	9 (0·3%)
Intubation for head injury	5 (0·2%)
Death secondary to head injury†	4 (0·1%)

*Some patients have more than one lesion.†One patient also had a craniotomy.

Table 2: **Patient management and outcomes**

Questions from history	Brain injury (n=254)	No brain injury (n=2867)	χ^2 value	κ (n=101)
Mean (SD) age (years)	49·7 (22)	37·7 (18)	··	··
Age ⩾65 years	75 (30%)	281 (10%)	89·8	··
Men	189 (74%)	1946 (68%)	4·6	··
Arrived by ambulance	238 (94%)	2030 (71%)	61·6	··
Witnessed loss of consciousness	132 (55%)	1303 (46%)	6·8	0·83
Mean (SD) duration/loss of consciousness (min)	3·6 (4)	2·6 (3)	··	··
Loss of consciousness ⩾ 5 min	41 (16%)	277 (10%)	10·7	··
Any type of amnesia (yes/no)	236 (95%)	2486 (87%)	12·1	0·52
Mean (SD) duration of amnesia before impact (min)	62·2 (166)	56·8 (293)	··	··
Amnesia before ⩾ 30 min	97 (38%)	553 (19%)	50·5	··
Mean (SD) duration of amnesia after impact (min)	45·2 (73)	29·9 (66)	··	··
Amnesia after ⩾ 30 min	102 (40%)	665 (23%)	36·2	··
Headache (n=1408)†	61 (66%)	761 (58%)	2·5	0·61
Suspected chronic alcohol abuse	44 (18%)	296 (10%)	11·8	0·71
Repeated vomiting (⩾two episodes)	77 (30%)	224 (8%)	135·9	0·86
Mean (SD) serum ethanol concentration (mmol/L; n=575)†	32·6 (27)	32·3 (27)	··	··

*Data applicable to some patients only. †Data collected in some patients only.

Table 3: **Univariate correlation and κ values of variables from history for clinically important brain injury**

Questions from history	Brain injury (n=254)	No brain injury (n=2867)	χ^2 value
Mechanism of injury (%)			152·3
Motor vehicle collision	41 (16%)	764 (27%)	
Motorcycle collision	2 (0·8%)	51 (2%)	··
Bicycle collision	6 (2%)	30 (1%)	··
Bicycle struck	2 (0·8)	54 (2%)	··
Other bicycle	2 (0·8)	113 (4%)	··
Pedestrian struck	43 (17%)	114 (5%)	··
Pedestrian struck and thrown	24 (10%)	71 (3%)	··
Fall from an elevation <3 ft/five stairs	43 (17%)	466 (16%)	··
Fall from an elevation ⩾3–10 ft/five–15 stairs	41 (16%)	276 (19%)	··
Fall from an elevation >10 ft/15 stairs	23 (9%)	114 (4%)	··
Assault fist/feet	10 (4%)	229 (8%)	··
Assault blunt object	16 (6%)	79 (3%)	··
Sports	2 (0·8%)	228 (8%)	··
Contact sports (axial load)	4 (2%)	73 (3%)	··
Heavy object onto head (axial load)	5 (2%)	12 (0·4%)	··
Fall onto head (axial load)	1 (2%)	3 (0·1%)	··
Diving	0	3 (0·1%)	··
Head struct by other object	10 (4%)	107 (4%)	··
Hit head on object	1 (0·4%)	64 (2%)	··
Other motorised vehicle	2 (0·8%)	50 (2%)	··
Other	0	7 (0·2%)	··
Dangerous mechanism*	135 (53%)	658 (22%)	118·4
No seatbelt (n=805)†	15 (37%)	128 (17%)	··
Bicycle helmet used (n=207)†	4 (40%)	62 (32%)	6·3
Motor vehicle collision	41 (16%)	764 (27%)	··
Ejected	12 (29%)	283 (4%)	65·9
Rollover	11 (27%)	110 (14%)	14·6
Death in same collision	10 (2%)	191 (3%)	12·2
Head-on collision	4 (10%)	688 (9%)	8·5
Simple rearend	0	199 (3%)	3·9
Highway speed (60–100 km/hr)	14 (34%)	154 (20%)	20·0
High speed (>100 km/hr)	11 (27%)	78 (10%)	20·0

*Pedestrian struck, assault with blunt object, fall from a height >3 ft/5 stairs, heavy object fall onto head, ejected from vehicle.†Data applicable to some patients only.

Table 4: **Univariate correlation values of variables from mechanism of injury for clinically important brain injury**

Questions from physical examination	Brain injury (n=254)	No brain injury (n=2867)	χ^2 value	κ (n=101)
Initial Glasgow Coma Scale score	··	··	243·5	0·84
13	45 (18%)	65 (2%)	··	··
14	90 (35%)	432 (15%)	··	··
15	119 (47%)	2370 (83%)	··	··
GCS score less than 15 after				
2 h (n=1898)*	133 (65%)	227 (13%)	312·6	··
4 h (n=2300)*	89 (65%)	142 (7%)	481·7	··
6 h (n=2510)*	65 (38%)	102 (4%)	288·2	··
Deterioration in GCS score	54 (21%)	38 (1%)	324·1	··
Pupils equal and reactive	242 (97%)	2827 (99%)	5·7	0·66
Lateralising motor weakness	2 (0·8%)	31 (1%)	0·2	0·66
Possible open skull fracture	30 (12%)	74 (3%)	61·3	0·85
Sign of basal skull fracture	77 (30%)	133 (5%)	245·0	0·76
Unreliable score due to suspected drug/ethanol	46 (18%)	337 (12%)	8·7	0·54
Object recall score 3/3	58 (28%)	1420 (58%)	109·5	0·64
Seizure while in emergency department (n=941)**	1 (0·8%)	3 (0·4%)	0·5	··

*Data applicable to some patients only. **Data available for some patients only.

Table 5: **Univariate correlation and κ values of variables from examination for clinically important brain injury**

localised subarachnoid haemorrhage or isolated contusions less than 5 mm in diameter. Another 1358 eligible patients were seen at the study sites but not enrolled by the treating physicians. All characteristics of these non-enrolled patients are very similar to those of the patients enrolled except for slightly higher rates of arrival by ambulance (80% *vs* 73%) and transfer from another hospital (18% *vs* 13%). Finally, another 363 eligible patients were not included in the final analysis because they did not undergo CT and could not be reached for the proxy outcome measure.

Tables 3, 4, and 5 show the association between the predictor variables and clinically important brain injury as determined by univariate analyses. Overall, we assessed 24 primary predictor variables as well as another 20 created by combinations or cut-points. Tables 3 and 5 also show the interobserver agreement for some primary variables.

Logistic regression (table 6) provided a model with good overall accuracy for discriminating cases with clinically important brain injury (area under receiver operating characteristic curve 0·91; Hosmer and Lemeshow goodness-of-fit, p=0·19). This model, however, contained nine variables which was more than we had hoped for. We also did recursive partitioning analyses, which ultimately resulted in a highly satisfactory model. The variables in this final statistical model were then combined into a simple, clinically sensible list to present the decision rule, entitled the Canadian CT Head Rule (panel 1). This rule asks seven simple questions stratified as high-risk and medium-risk. Interestingly, deterioration in GCS score, despite a very high univariate χ^2 value did not contribute to the final model.

Variable	Coefficient	Odds ratio (95% CI)
Intercept	−4·27	
Vomiting	1·33	3·8 (2·5–5·7)
Initial GCS score 13	0·79	2·2 (1·2–4·0)
Suspected open or depressed skull fracture	1·29	3·6 (2·0–6·5)
Any sign of basal skull fracture	1·65	5·2 (3·4–8·0)
GCS score <15 at 2 h after injury	1·99	7·3 (5·0–10·7)
Age ⩾65 years	1·42	4·1 (2·8–6·1)
High-risk mechanism of injury	1·02	2·8 (2·0–3·8)
Loss of consciousness ⩾5 min	0·50	1·6 (1·0–2·6)
Amnesia before impact ⩾30 min	0·66	1·4 (1·4–2·8)

Table 6: **Model developed by stepwise logistic regression analysis to predict clinically important brain injury**

Panel 1: **Canadian CT Head Rule**

CT Head Rule is only required for patients with minor head injuries with any one of the following:

High risk (for neurological intervention)
- GCS score <15 at 2 h after injury
- Suspected open or depressed skull fracture
- Any sign of basal skull fracture (haemotympanum, 'racoon' eyes, cerebrospinal fluid otorrhoea/rhinorrhoea, Battle's sign)
- Vomiting ⩾two episodes
- Age ⩾65 years

Medium risk (for brain injury on CT)
- Amnesia before impact >30 min
- Dangerous mechanism (pedestrian struck by motor vehicle, occupant ejected from motor vehicle, fall from height >3 feet or five stairs)

Minor head injury is defined as witnessed loss of consciousness, definite amnesia, or witnessed disorientation in a patients with a GCS score of 13–15.

Panel 2 shows the potential classification performance of the risk factors for predicting need for neurological intervention and clinically important brain injury. The four cases of clinically important brain injury not identified included four small contusions—these patients required no treatment and none had neurological sequelae. The rule would also have identified 320 of 348 patients with any injury on CT (including clinically unimportant injuries), yielding a sensitivity of 92·0% (95% CI 88–94%).

Discussion

We have successfully developed a highly sensitive clinical decision rule for the use of CT in patients with minor head injuries. This rule would allow doctors in emergency departments to order CT for their patients based upon strong evidence and to provide consistent management without jeopardising optimum patient care. Patients with minor head injuries can be identified at two levels of risk. Those patients with any one of five high-risk factors are at substantial risk for requiring neurosurgical intervention and we believe that CT is mandatory in these cases. Patients with either of two additional medium-risk characteristics could have clinically important lesions that would be seen on CT but are not at risk for needing neurological intervention. Whether these patients are

Panel 2: **Classification performance**

Classification performance of five high risk factors in the Canadian CT head rule for neurological intervention

	Neurological intervention	
Decision rule	**Yes**	**No**
Yes	44	962
No	0	2115

Sensitivity	100% (95% CI 92–100%)
Specificity	68·7% (95% CI 67–70%)
CT ordering proportion	32·2%

Classification performance of all seven factors in the Canadian CT head rule for clinically important brain injury

	Clinically important injury	
Decision rule	**Yes**	**No**
Yes	250	1446
No	4	1421

Sensitivity	98·4% (95% CI 96–99%)
Specificity	49·6% (95% CI 48–51%)
CT ordering propotion	54·3%

managed with CT or with close observation, depends upon local resources. The Canadian CT Head Rule has been derived according to strict methodological standards and in a large sample of patients. Nevertheless, we intend to prospectively and explicitly validate the rule in multiple sites in a future study.

There has been considerable disagreement about indications for CT in the large number of head trauma cases classified as minor.[15] In the USA, opinions are divided into three groups. The first group, which consists primarily of neurosurgeons, feel that CT is indicated for all patients with minor head injury regardless of clinical findings.[2,15–17] The second group of neurosurgeons, emergency physicians, and radiologists, recommend a very selective approach to use of CT in minor head injury.[7,18–20] This group also points out that even a normal CT scan in the emergency department does not preclude later development of intracranial haematoma, although this is extremely uncommon.[21] The third group offer no clear recommendations for use of CT in minor head injury cases and often suggest that more studies are required.[6,22,23] In Europe and Canada, use of CT has been much more selective for minor head injury cases. In Italy, CT is only recommended if a fracture has been shown on skull radiography.[24] In Denmark, CT is rarely ordered and then only by a neurosurgeon.[25] In the UK and Spain, CT is only recommended for cases with documented skull fracture, focal neurological deficit, or deterioration in mental status.[26] In Canada, we have previously shown a low overall CT ordering proportion but a marked variation among similar teaching hospitals with rates varying from 16·2–70·4%.[8]

A number of studies have been done in the past ten years by neurosurgeons, emergency physicians, and radiologists to identify high risk findings that would clearly indicate which group of patients with minor head injury should have CT. Unfortunately, these studies vary greatly in design and could not be judged robust according to methodological standards for the development of clinical decision rules.[27] Haydel and colleagues' proposed guidelines have received attention but we think that they are not reliable, sensitive, or specific enough to safely and efficiently guide clinicians in their use of CT.[28] Although the predictor variables in phase one of that study were well standardised, no assessment of their interobserver agreement was made and some potentially valuable findings were not assessed (mechanism of injury, chronic alcohol abuse, signs of basal skull fracture, signs of open skull fracture). The outcome measure, any acute findings on CT, was well defined, but certainly could not be deemed a clinically important outcome in terms of patient care. The sample size of 909 in the validation phase two was fairly large but there were far too few clinically important outcomes to measure sensitivity with an acceptably narrow 95% CI. In the derivation and validation phases combined, there were six patients who required surgery, meaning that the 95% CI around the sensitivity was 54–100%. Finally, the specificity of the rule is so low that 77% of patients presenting with a score of 15 would require CT. This would actually lead to an increase in use of CT in most Canadian and European sites.

We believe that an important strength of our study was adherence to methodological standards for decision rules.[9,10,27] Study participants were selected without bias and not based upon the subjective decision of individual physicians to order CT. These patients represented a wide spectrum of characteristics and sites, hence increasing generalisability. The mathematical techniques for deriving the rule were explicit and appropriate. We believe that the format of the rule, a simple list of variables, makes it clinically sensible for the intended audience of busy emergency physicians. Furthermore, the rule seems to be highly sensitive for important outcomes, making it safe for use in patient care. It is also fairly specific, making it an efficient tool for clinicians. The true value of the Canadian CT Head Rule, however, can only be established in a prospective study, which assesses the accuracy, interobserver agreement, clinician acceptability, and potential impact in a new patient population.[29]

What are the potential limitations of our study? Some may question our definition of clinically important brain injury. We believe that we have good acceptance of our definition by Canadian academic neurosurgeons and emergency physicians and that this represents a pragmatic and very safe approach to patient care. The priority should be to identify lesions with CT that require intervention or observation in hospital. Clinically unimportant brain lesions, according to academic neurosurgeons in our survey, require neither admission nor specialised follow-up and are not correlated with longer term problems such as post-concussion syndrome.[30] These sequelae only become apparent with the passage of time and cannot be predicted by the presence of minor CT lesions found at the time of injury. More importantly, we doubt that any clinician would disagree with the importance of the primary study outcome, need for neurological intervention. We would argue that our decision rule is designed to improve patient care and depends upon an evidence-based approach rather than dealing with medicolegal concerns.

Although not all patients underwent CT, all patients were fully assessed for the primary outcome measure, need for neurological intervention. Furthermore we believe it is very unlikely that clinically important CT findings were missed. Although 2078 study patients did undergo CT scanning, all the remaining 1043 patients underwent the validated and structured 14 day telephone proxy outcome measure administered by a registered nurse.[31] Any patient who could not be completely and adequately followed was excluded from the study analyses. In addition, we repeated our analysis using only the 2078 patients who actually underwent CT and reported exactly the same results as for the main study. Although not all eligible patients were enrolled in the study, this is not unusual for a clinical study, and we could not see any systematic difference between the patients enrolled and those not enrolled.

Some clinicians may be surprised that drug or ethanol ingestion is not a feature of our rule. Our data showed, however, that unreliable examination due to suspected intoxication was neither reliable nor discriminating and that serum ethanol concentration was not associated with important brain injury. We believe that the Canadian CT Head Rule will be effective regardless of possible intoxication. On the other hand, intoxication is one reason why patients presenting with a GCS score of 13 or 14 do not automatically require a CT. Our data clearly show that patients are at risk and should undergo CT if they do not improve to a GCS level of 15 within 2 h of the injury. Hence, our results do not support the view that all patients with an initial GCS score of 13 or 14 necessarily require CT.

What are the potential implications of a decision rule or guidelines for the use of CT in patients with minor head injury? First, patient care would be standardised and improved. The great variation in current practice and the fact that important lesions are being missed suggests the need for accurate and reliable guidelines. A highly sensitive decision rule would reduce or eliminate the likelihood of patients being discharged from the emergency department with an undiagnosed intracranial haematoma. Physicians working in smaller hospitals without CT scanners (70% of Canadian acute care hospitals) would have clear directions about which patients require costly and time consuming transfers for a CT scan. We anticipate that CT would be judged mandatory for patients with any of the high-risk criteria. On the other hand, management of patients with medium-risk criteria might reasonably include either careful observation in sites where access to CT is limited or urgent CT.

Second, an accurate decision rule could lead to large savings for health-care systems. The current variation in practice and the low yield of CT scans among patients with minor head injury suggests great potential for reducing use of CT. Our survey of Canadian emergency physicians clearly indicates their willingness to adopt a decision rule for CT in patients with minor head injury.[32] On the basis of our findings of large reductions in the use of ankle radiography after the implementation of our Ottawa Ankle Rules,[11,12] we estimate that a 25–50% relative reduction in CT head use could be safely achieved. On the other hand, without selective guidelines, there is a very strong likelihood that use of CT for minor head injury will increase markedly in the next 5 years. CT scanners are becoming increasingly available in hospitals outside the USA. Furthermore, recent editorials and articles have strongly suggested that all patients with minor head injury should undergo CT[2,15–17]—such a standard of practice would eventually lead to a greater than 300% increase in the use of CT for Canadian and European patients with minor head injury.

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