JOURNAL OF NEUROTRAUMA
Volume 22, Number 12, 2005

Pp. 1419–1427

Clinical Performance of NICE Recommendations versus NCWFNS Proposal in Patients with Mild Head Injury

ANDREA FABBRI,[1] FRANCO SERVADEI,[2] GIULIO MARCHESINI,[3] MASSIMO DENTE,[1] TIZIANA IERVESE,[1] MARCO SPADA,[1] and ALBERTO VANDELLI[1]

ABSTRACT

Recommendations on treatment of patients with head injury were recently proposed by the National Institute for Clinical Excellence (NICE). We tested the clinical performance of NICE variables versus the proposal of the Neurotraumatology Committee of the World Federation of Neurosurgical Societies (NCWFNS). Over a 5-year period, the clinical data of 7,955 adolescent and adult patients with mild head injury were prospectively collected and patients were managed according to the NCWFNS proposal. Outcome measures were (a) any post-traumatic lesion; (b) need for neurosurgical intervention; (c) unfavorable outcome (death, permanent vegetative state, severe disability) after 6 months. The predictive value of NICE variables was tested by logistic regression analysis. Three hundred fifty-four patients (6.8%) had intracranial lesions on computed tomography (CT) scan; neurosurgical intervention was needed in 108 patients (1.3%), and an unfavorable outcome occurred in 54 patients (0.7%) at 6-month follow-up. NICE variables were less sensitive than NCWFNS (93.5%; 95% confidence interval 91.0–95.2; vs. 97.8%; 96.1–98.7; $p < 0.001$), but far more specific (70.0%, 69.0–71.0, vs. 45.9%, 44.8–47.0; $p < 0.001$) for predicting intracranial lesions. NICE variables were also more specific (66.5%, 65.5–67.5, vs. 43.5%, 42.4–44.6; $p < 0.001$) in the prediction of neurosurgical intervention. 99.1% of unfavorable outcomes were predicted by both protocols. The CT order rate of NICE was much lower (34.1% vs. 57.1%; $p < 0.001$). In sum, the variables selected by NICE recommendations, when applied to a typical broad sample of emergency medicine, are a reliable, clinically sensible tool in predicting significant outcomes in patients with mild head injury and are resource saving.

Key words: clinical accuracy; head computed tomography; mild head injury; outcomes; predictor variables

INTRODUCTION

NINETY PERCENT OF PATIENTS who have sustained a head injury attend the Emergency Department (ED) for a minor or a mild injury (Glasgow Coma Scale [GCS] >12), but the majority of fatal outcomes will be in the moderate (GCS 9–12) or severe (GCS ≤8) head injury groups, which account for only 10% of attendees (Swann and Teasdale, 1999). Although the incidence of head injury is high, the death rate is low (6–10 per 100,000 pop-

[1]Dipartimento Emergenza-Urgenza Accettazione, Ospedale Morgagni-Pierantoni, Azienda Unità Sanitaria Locale di Forlì, Forlì, Italy.
[2]Divisione di Neurochirurgia per la Traumatologia, Ospedale M. Bufalini, Azienda Unità Sanitaria Locale di Cesena, Cesena, Italy.
[3]*Alma Mater Studiorum*, Università di Bologna, Bologna, Italy.

ulation per year) (Kay and Teasdale, 2001). Of 1,000 patients attending the ED for a mild head injury, only 80 have pathological findings on computed tomography (CT) of the head, nine will require surgery or other interventions, and only one will die. Presumably, a few more are likely to require admission due to other medical, social, ethical, or practical reasons (Geijerstam and Britton, 2003).

Considerable variation is reported in published guidelines and also among physicians with respect to the use of CT scan of the head (Haydel et al., 2000; Stiell et al., 2001; Jagoda et al., 2002). In the United States, CT scan is performed in 75–100% of all patients with normal GCS and some previous mild head injury (MHI) (Livingston et al., 2000). This figure is in sharp contrast to CT scan rates in the United Kingdom, where in past years only 2–12% of all patients attending the ED for head injury had a CT (Nee et al., 1999; Lloyd et al., 1997). The approach to these patients changed recently towards earlier diagnosis, implying a more extensive use of CT, rather than admission and expected observation (National Institute for Clinical Excellence, 2003). The move reflects a general consensus that earlier imaging is associated with improved outcomes. (Miller et al., 1988; Teasdale et al., 1990).

The National Institute for Clinical Excellence (NICE) has recently proposed new evidence-based recommendations on all steps of the management of patients with head injury from initial assessment through to hospital discharge and rehabilitation (National Institute for Clinical Excellence, 2003). Such recommendations are awaiting proper validation in daily practice by prospective studies in different clinical settings.

We recently assessed the diagnostic accuracy and the clinical validity of the proposal of Neurotraumatology Committee of the World Federation of Neurosurgical Societies (NCWFNS) on the basis of prospective data collected since 1999 (Servadei et al., 2001). The predictors of MHI used to indicate CT scan and disposition are similar to those proposed by NICE, with a more extensive use of CT (Servadei et al., 2001; Fabbri et al., 2004a). This gave us two opportunities: (a) to measure the performance of variables of NICE recommendations in a specific clinical setting; (b) to compare NICE recommendations with the NCWFNS proposal in a typical broad sample of emergency medicine.

MATERIALS AND METHODS

Database

All cases attending the ED of our district hospital with a MHI were treated according to pre-defined procedures (Servadei et al., 2001). Main predictor variables of early complications were systematically registered for outcome purposes in each patient according to a specific protocol which included all variables of NCWFNS. The Head Injury Registry consisted of 9,464 consecutive medical records of all patients attending for acute MHI within 24 h from trauma. MHI was defined as an acute injury of the head, other than any superficial injury to the face, GCS 14 or 15, in adolescent and/or adult inhabitants aged $\geq$10 years.

A total of 1,509 records were excluded because (a) subjects with unclear history of trauma as the primary event (559 cases); (b) subjects with unstable vital signs (239 cases); (c) subjects with GCS $<$14 (172 cases); (d) subjects with penetrating injuries at presentation (22 cases); (e) voluntary discharge (235 cases) because they refused the diagnostic and management procedures; (f) duplicate records of subjects re-attending for post-concussive syndrome within 7 days of admission for mild head injury (282 cases; 3.5%). These last subjects were considered only once in the analysis.

According to NCWFNS, patients were stratified as low, medium and high risk, with different indication for CT and management (Servadei et al., 2001) (Table 1). After clinical evaluation, low-risk patients were sent home without any radiological imaging. Medium-risk patients were submitted to a CT scan and discharged after at least 3–6 h from trauma in the case of negative results. High-risk patients were submitted to CT imaging and managed with a first 24–48-h strict observation period, regardless of CT findings. When the study was started, CT scan was not available out of hours, but only on demand, on the basis of the severity of trauma judged by the attending physician, with additional cost for the system. To limit the use of CT because of budget constraints, age was not considered per se a risk factor in our setting. All patients received written recommendations at discharge for home observation and complaints that would require referral back to hospital for further evaluation. Observers were instructed to seek symptoms, signs and any change in patients' clinical status for 7 days. All patients re-attending the ED were submitted to CT scan.

The final outcome was determined 6 months after injury. Firstly, a systematic search of all patients with intracranial lesions was carried out by checking the death certificates and the medical databases of our local health district. Following this, a member of the ED staff contacted all these patients by means of a structured telephone interview, to determine the presence of disability in patients who survived. Patients without post-traumatic lesions and not re-attending for complaints were considered to have fully recovered.

CT imaging without contrast was performed with

TABLE 1. VARIABLES SELECTED BY NCWFNS PROPOSAL AND BY NICE RECOMMENDATIONS AS ELEVATING THE RISK OF CLINICALLY SIGNIFICANT OUTCOMES IN PATIENTS AFTER MILD HEAD INJURY AND INDICATING CT SCAN

NCWFNS proposal	*NICE recommendations*
GCS 14	GCS 14 or GCS <14 at any point
Suspected skull fracture	Signs of basal skull fracture
Neurological deficits	Neurological deficits
Vomiting	Vomiting
Amnesia	Amnesia before impact >30 min
LOC	Post-traumatic seizures
Headache	Coagulopathy
Coagulopathy	Dangerous mechanism
Previous neurosurgery	Age of ≥65 years
History of epilepsy	
Alcohol/drugs abuse	

According to NCWFNS proposal, CT scan is mandatory in "high risk" patients (a) GCS of 14 with/without other clinical findings; (b) GCS of 15 with neurological deficits, and/or skull fracture and/or one or more risk factors, independently of clinical findings (Servadei et al., 2001). Early CT scan is also recommended in "medium risk" patients: (a) GCS of 15; (b) one or more of the following symptoms: LOC, amnesia, vomiting, diffuse headache; (c) no risk factors.

According to NICE recommendations, CT scan is recommended in the presence of (a) GCS < 14 at any point and/or GCS 14 at least 2 h after injury, (b) any sign of basal skull fracture, (c) any focal neurological deficit, (d) post-traumatic seizure, (e) vomiting (> 1 episode), (f) amnesia of events before impact > 30 min, (g) risk factors (coagulopathy, age of ≥65 years, dangerous mechanism of injury), provided that patients have experienced some LOC or amnesia since injury (National Institute for Clinical Excellence, 2003).

NCWFNS, Neurotraumatology Committee of the World Federation of Neurological Societies; NICE, National Institute for Clinical Excellence; CT, computed tomography; GCS, Glasgow Coma Scale; LOS, loss of consciousness.

third-generation equipment, with cuts of 10 mm or less from the foramen magnum to the vertex, and including both soft tissue and bone windows. CT scans showing intracranial post-traumatic lesions were real-time reviewed by a neurosurgeon of the nearest Neurosurgical Unit (Cesena, 17 km away), consulted via a teleradiology system. The protocol was carried out according to the Helsinki Declaration and approved by the senior staff Committee of the Azienda Unità Sanitaria Locale of Forlì.

Outcome Measures

Main outcome measures were (a) any post-traumatic lesion at CT within 7 days from trauma; (b) need for neurosurgical intervention within 7 days from the diagnosis of intracranial lesion; (c) unfavorable outcome (death, vegetative state, or severe disability in subjects with intracranial lesions at 6 months after injury).

Post-traumatic lesions, requiring admission to hospital and follow-up, included (a) depressed skull fracture (DSF); (b) intracerebral hematoma/brain contusion(s) (ICH); (c) subarachnoid hemorrhage (SHA); (d) subdural hematoma (SDH); (e) epidural hematoma (EDH); (f) intra-ventricular hemorrhage (IVH) (Stiell et al., 2001). In patients who returned after discharge with complaints a time limit of 7 days was set to consider the event as directly related to the initial head injury. Neurosurgical intervention of hematoma evacuation and/or skull fracture elevation were only considered in the first 7 days after diagnosis. Late events were not considered in the present analysis.

The final outcome at 6 months was considered unfavorable if the patient died for head injury–related causes, remained in a vegetative state, or had a permanent severe disability, measured by the Glasgow Outcome Scale (GOS) (Thornill et al., 2000). The follow-up GOS was rated by an expert physician unaware of the study protocol, on the basis of the response to a structured telephone call.

Statistical Analyses

Mean value, standard deviation (SD), median, interquartile range (IQR), and frequencies were used to describe data distribution. Univariate and multivariate stepwise logistic regression analysis was used to identify factors related to different outcomes. The odds ratio (OR) and 95% confidence intervals (95% CI) were also calculated. Sensitivity and specificity were evaluated, together with the negative predictive value (NPV). Proportions were compared between protocols by means of unadjusted chi-square analysis. Statistical analyses were performed running the SPSS/PC+ statistical package on a personal computer (Norusis, 1992). Two-tailed p values of <0.05 were considered statistically significant.

RESULTS

Database

The median age of the 7,955 patients was 44 years (IQR, 27–71), with 736 (9.3%) patients between 10 and 18 years and 2,497 subjects (31.4%) ≥65 years. The median injury-to-admission time was 60 min (IQR, 42–110), and GCS score was 14 after at least 2 h since injury in 529 cases (6.6%). A total of 2,095 patients (35.8%) required a prolonged observation in a recovery setting. Adherence to protocol was nearly complete; the CT scan was performed in 4,168/4,540 cases (91.8%). According to NICE, the CT scan performing rate was 2,536/2,733 patients (92.8%).

Intracranial Lesions

Intracranial lesions were detected in 542 patients (6.8%), with a single lesion in only 356 (65.7% of positive CT). Patients with intracranial injuries were more frequently males 65.3% versus 34.7% (OR 1.55; 95% CI, 1.29–1.86; $p < 0.001$).

In 518 patients (6.5% of total patients), the diagnosis was performed at first evaluation, after a median of 234 min (175–335 min) from injury. In 15 cases, the diagnosis was obtained only after second CT scan because imaging was uncertain at first evaluation. Finally, there were nine patients discharged following a brief ED observation (median, 252 min; IQR, 181–381) with no clinical symptoms or signs and no indication for CT scan, who re-attended with complaints (median, 48 h; IQR, 24–89) and had intracranial lesions diagnosed by a second CT (ICH, one case; SDH, five cases; ICH + SDH three cases).

Neurosurgical Intervention

Hematoma evacuation and/or depressed skull fracture elevation were performed in 108 patients (1.3%). The diagnosis at first evaluation was ICH (67 cases), SDH (40 cases), EDH (18 cases), DSF (13 cases), alone or in combination. Neurosurgical intervention was performed in only two of the nine patients revisited for complaints and found to have previously undiagnosed lesions (0.1%) (EDH + ICH, one case, revisited after 8 h; SDH, one case, revisited after 36 h, respectively).

Unfavorable Outcome

A complete follow-up was obtained in 491/542 cases with intracranial lesions (91.6%). Of the remaining 51 cases, 10 patients had died because of complications unrelated to head trauma (major orthopedic injuries, four cases;

Table 2. Predictor Variables for Intracranial Lesions by NCWFNS Proposal and NICE Recommendations in Patients after Mild Head Injury

	Lesion,[a] n = *542*	*No lesion,* n = *7413*	*OR (95% CI)*	p *value*
NCWFNS proposal				
GCS 14	360 (66.4%)	169 (2.3%)	84.8 (67.1–107.2)	<0.001
Suspected skull fracture	180 (33.2%)	68 (0.9%)	53.7 (39.9–72.4)	<0.001
Neurological deficits	295 (54.4%)	90 (1.2%)	97.2 (74.2–127.0)	<0.001
Vomiting	87 (16.1%)	191 (2.6%)	7.2 (5.5–9.5)	<0.001
Amnesia	364 (67.2%)	3162 (42.7%)	2.7 (2.3–3.3)	<0.001
LOC	291 (53.7%)	1300 (17.5%)	5.5 (4.6–6.5)	<0.001
Headache	93 (17.2%)	1229 (16.6%)	1.0 (0.8–1.3)	0.720
Coagulopathy	67 (12.4%)	198 (2.7%)	5.1 (3.8–6.9)	<0.001
Previous neurosurgery	19 (3.5%)	151 (2.0%)	1.7 (1.1–2.8)	0.030
History of epilepsy	14 (2.6%)	185 (2.5%)	1.0 (0.6–1.8)	0.886
Alcohol/drugs abuse	146 (26.9%)	622 (8.4%)	4.0 (3.3–5.0)	<0.001
NICE recommendations				
GCS 14 or <14 at any time	415 (76.6%)	220 (2.8%)	106.8 (84.1–135.8)	<0.001
Signs of basal skull fractures	90 (16.6%)	5 (0.1%)	295.0 (119.3–729.6)	<0.001
Neurological deficits	242 (44.6%)	37 (0.5%)	160.8 (111.7–231.6)	<0.001
Vomiting	87 (16.1%)	191 (2.6%)	7.2 (5.5–9.5)	<0.001
Amnesia >30 min	184 (35.0%)	341 (4.6%)	10.7 (8.7–13.1)	<0.001
Post-traumatic seizures	46 (8.5%)	49 (0.7%)	13.9 (9.2–21.1)	<0.001
Coagulopathy[b]	42 (7.7%)	140 (1.9%)	4.4 (3.1–6.2)	<0.001
Dangerous mechanism[b]	241 (44.5%)	827 (11.2%)	6.4 (5.3–7.7)	<0.001
Age of ≥65 years[b]	185 (34.1%)	1094 (14.8%)	3.0 (2.5–3.6)	<0.001

[a]Lesions were depressed skull fracture, 19 (0.5%); intracerebral hematoma/brain contusion(s), 379 (9.1%); subarachnoid hemorrhage, 97 (2.3%); subdural hematoma, 179 (4.3%); epidural hematoma, 43 (1.0%); intra-ventricular hemorrhage, 16 (0.4%).

[b]Risk factors were considered only in patients who experienced LOC or amnesia since the injury.

See Table 1 for abbreviations.

TABLE 3. RISK OF INTRACRANIAL LESIONS IN PATIENTS AFTER MILD HEAD INJURY PREDICTED BY VARIABLES INCLUDED IN NCWFNS PROPOSAL AND IN NICE RECOMMENDATIONS

Multivariate analysis	*Odds ratio*	*95% CI*	p *value*
NCWFNS proposal			
GCS 14	19.2	14.1–26.0	<0.001
Suspected skull fracture	10.0	6.3–15.8	<0.001
Neurological deficits	19.2	13.3–27.6	<0.001
Vomiting	4.9	3.1–7.6	<0.001
Amnesia	—	—	0.695
LOC	2.0	1.5–2.7	<0.001
Diffuse headache	—	—	0.179
Coagulopathy	8.4	5.5–12.6	<0.001
Previous neurosurgery	—	—	0.568
History of epilepsy	—	—	0.366
Alcohol/drugs abuse	—	—	0.329
NICE recommendations			
GCS 14 or <14 at any time	28.8	21.4–38.7	<0.001
Signs of basal skull fractures	30.1	9.3–97.7	<0.001
Neurological deficits	26.1	15.7–43.4	<0.001
Vomiting	4.4	2.9–6.9	<0.001
Amnesia >30 min	8.4	6.0–11.9	<0.001
Post-traumatic seizures	2.8	1.6–4.9	<0.001
Coagulopathy[a]	4.8	2.6–8.6	<0.001
Dangerous mechanism[a]	3.2	2.4–4.4	<0.001
Age of ≥65 years[a]	2.0	1.4–2.8	<0.001

[a]Risk factors were considered only in patients who experienced loss of consciousness (LOC) or amnesia since the injury.
See Table 1 for abbreviations.

myocardial infarction, three; stroke, one; pulmonary embolism, one; gastrointestinal hemorrhage, one), 28 were lost to follow-up, and in 13, GOS was unreliable, due to either a previous disability (seven cases) or a trauma-related disability independent of head injury (six cases).

The outcome was unfavorable in 54 cases (0.7%). Twenty-nine patients died (21 (74%) during the hospitalization period. Four patients resulted in a permanent vegetative state, and 21 were severely disabled. The large majority of cases (437 cases, 89%) had a favorable outcome, with moderate disability being present in 42 cases.

Outcome Prediction

Six out of the 11 variables of NCWFNS were independently associated with intracranial lesions as independent factors at multivariate stepwise logistic regression analysis. In contrast, all the nine variables included by NICE were significantly associated with intracranial lesions (Tables 2 and 3). Neurosurgical intervention was predicted by five variables in both protocols (Table 4). Finally, an unfavorable outcome 6 months after injury was significantly associated with skull fracture (OR, 3.7; 95% CI, 2.0–6.8; $p < 0.001$) and neurological deficits (2.6, 1.3–5.1; $p < 0.001$) according to NCWFNS, and signs of basal skull fracture (3.7, 1.98—6.78; $p < 0.001$) and age ≥65 years (2.9, 1.6–5.1; $p < 0.001$) in NICE recommendations.

NICE recommendations showed much higher specificity and a slightly lower sensitivity in detecting intracranial lesions (Table 5). This was achieved by much lower CT ordering rate (1,280 examinations less than NCWFNS) (Table 5). Similar results were observed when neurosurgical interventions were considered. Only one case (0.9%) with unfavorable outcome was undetermined by the variables of both protocols.

DISCUSSION

The variables selected by NICE recommendations, when applied to our database, were nearly as sensitive and far more specific than those considered by NCWFNS, significantly reducing unnecessary use of CT scanning rate in MHI patients.

The validity of any protocol relies on clinically meaningful outcomes, important in terms of care and prognosis of patients, and the need for neurosurgical intervention is the most important event to predict in a mildly

Table 4. Risk of Neurosurgical Intervention in Patients after Mild Head Injury Predicted by Variables Included in NCWFNS Proposal and in NICE Recommendations

Multivariate analysis	*Odds ratio*	*95% CI*	p *value*
NCWFNS proposal			
GCS 14	14.3	7.5–27.6	<0.001
Suspected skull fracture	3.0	1.8–4.6	<0.001
Neurological deficits	3.0	1.7–5.2	<0.001
Vomiting	3.7	2.1–6.4	<0.001
Amnesia	—	—	0.679
LOC	1.6	1.0–2.6	0.037
Diffuse headache	—	—	0.222
Coagulopathy	—	—	0.134
Previous neurosurgery	—	—	0.069
History of epilepsy	—	—	0.288
Alcohol/drugs abuse	—	—	0.949
NICE recommendations			
GCS 14 or <14 at any time	40.2	21.2–76.1	<0.001
Signs of basal skull fractures	1.9	1.1–3.4	0.022
Neurological deficits	2.5	1.5–3.9	<0.001
Vomiting	3.3	1.9–5.5	<0.001
Amnesia >30 min	1.7	1.1–2.7	0.025
Post-traumatic seizures	—	—	0.679
Coagulopathy[a]	—	—	0.847
Dangerous mechanism[a]	—	—	0.052
Age of ≥65 years[a]	—	—	0.117

[a]Risk factors were considered only in patients who experienced some LOC or amnesia since the injury.
See Table 1 for abbreviations.

injured patient (Stiell et al., 1999, 2001). Our sample size was *a priori* considered large enough to test the protocol, and also included cases usually defined trivial by NICE: this explains the lower-than-expected number of events. All cases were inhabitants of the health district referring to our hospital, and it is very unlikely that neurosurgical interventions were missed. The number of injuries was as expected; and the number of deaths was not higher-than-expected. This might reflect a more conservative approach of neurosurgeons, without any detrimental effect on survival. The comparison of different series concerning surgical indications is frequently biased by a number of non-craniotomy procedures, such as intracranial pressure (ICP) monitoring (Stein and Ross, 1992), which are not used in our area in MHI patients. Our data confirmed the results obtained by other studies conducted in the south of Europe (Gomez et al., 1996).

A highly sensitive proposal would also reduce the risk of an unfavorable outcome (Thornhill et al., 2000), as defined by the dichotomized GOS at 6 months (Thornhill et al., 2000; Teasdale et al., 1998). This time limit is considered a reasonable time frame for this outcome (Teasdale et al., 1998; Wilson et al., 1998), and the scale we used has proved to correctly classify disability independently of the way of administration (Wilson et al., 2002). The outcome was tested only in patients with intracranial lesions, where the more specific NICE recommendations did not miss positive cases.

NICE reached a consensus in favor of a modified version of the Canadian CT head rules (Stiell et al., 2001). The original model was based on five variables (GCS, suspected or open DSF, any sign of basal skull fracture, vomiting, and age of ≥65 years), with a CT scan in 32.2%. Two additional variables (amnesia of >30 min and dangerous mechanism) guaranteed a sensitivity of 98.4% and a specificity of 49.6% for predicting clinically important brain lesions with an ordering rate for head CT of 54.3% (Stiell et al., 2001). In order to improve the clinical accuracy, NICE adapted the seven-point Canadian CT rule including patients with post-traumatic seizure and focal neurological deficits (National Institute for Clinical Excellence, 2003).

NICE criteria are stricter than those of NCWFNS, where patients with risk factors (coagulopathy, alcohol and/or drug abuse, previous neurosurgery, history of epilepsy) are candidates for a head CT scan independently of loss of consciousness (LOC) or amnesia (i.e., the main signs and symptoms used to screen patients for

TABLE 5. SENSITIVITY, SPECIFICITY, AND NEGATIVE PREDICTIVE VALUE OF THE VARIABLES INCLUDED BY NCWFNS PROPOSAL AND NICE RECOMMENDATIONS IN THE PREDICTION OF INTRACRANIAL LESIONS AND NEUROSURGICAL INTERVENTION AFTER MILD HEAD INJURY

	NCWFNS proposal		*NICE recommendations*	
	Yes	*No*	*Yes*	*No*
Intracranial lesions				
Variables present	530	4010	507	2223
Variables absent	12	3403	35	5190
Sensitivity (%)	97.8 (95% CI, 96.1–98.7)		93.5 (95% CI, 91.0–95.2)*	
Specificity (%)	45.9 (95% CI, 44.8–47.0)		70.0 (95% CI, 69.0–71.0)*	
NPV (%)	99.6		99.4	
CT ordering rate (%)	57.1		34.4*	
Neurosurgical intervention				
Variables present	107	4433	102	2628
Variables absent	1	3414	6	5219
Sensitivity (%)	99.1 (95% CI, 94.2–99.7)		94.4 (95% CI, 87.8–97.1)	
Specificity (%)	43.5 (95% CI, 42.4–44.6)		66.5 (95% CI, 65.5–67.5)*	
NPV (%)	100		99.9	

*$p < 0.001$.

CI, confidence interval; NPV, negative predictive value. See Table 1 for abbreviations.

inclusion in the NICE criteria). According to our database, this increases the CT ordering rate from 34.4% to 57.1%.

The NICE and NCWFNS protocols differ in several items. First, a transient GCS <14 is only considered by NICE, but the inclusion of severe patients does not impact on resources. Ninety-three % of our patients had GCS 15 and most patients with lower GCS have other reasons requiring CT scan. Secondly, the predictive value of headache considered by NICE is questionable (Haydel et al., 2000; Miller et al., 1997), because the symptom is difficult to define in terms of both duration and severity (Stiell et al., 2001; Jeret et al., 1993). It was present in 23.7% of cases, without any association with main outcomes. Thirdly, LOC is considered by NCWFNS independently of its characteristics. It moderately increases the risk of intracranial complications (Teasdale et al., 1990; Servadei et al., 2001) and is frequently considered an inclusion criterion, resulting in a surfeit of literature on this topic. Fourthly, NICE only includes pre-traumatic amnesia, whereas NCWFNS also includes post-traumatic short-term memory deficit. Amnesia, mainly retrograde amnesia (Stiell et al., 2001), represents an important area of debate (Teasdale et al., 1990; Servadei et al., 2001), but it did not predict outcome in our series.

Finally, risk factors were considered as component variables in NICE, in association with clinical findings, namely amnesia and/or LOC, and as independent risk factor in NCWFNS. In particular patients with coagulopathy were deliberately excluded in the original Canadian study, considered *a priori* at high risk and candidates for early CT imaging (Stiell et al., 2001). The inclusion of coagulopathy as an independent variable in NICE recommendations requiring early CT scanning would lead to the diagnose of 10 additional lesions. Only 67 additional CT (0.8%) would be required in our total cohort of 7,955 patients, and these extra examinations would result in a 15% chance of identifying an otherwise undetermined intracranial lesion.

High-energy injury mechanisms have an intuitive appeal in determining the risk of intracranial complications, and Canadian rules defined a few conditions (Stiell et al., 2001), which were accepted by NICE as component variables (National Institute for Clinical Excellence, 2003).

The same crucial role might be played by age, but a large number of total cases (2,497 cases, 31%) exceed the NICE threshold of 65 years (Stiell et al., 2001; Munro et al., 2002) which was significantly associated with events in our database. However, we did not consider *a priori* age as a risk factor, independently of signs and symptoms after head injury. Its consideration according to NCWFNS threshold (>60 years) would increase CT ordering rate to 70.6%. Considering age independently of symptoms, the number of indeterminate intracranial lesions would be reduced from 35 to 14, but the CT rate would increase from 34 to 48%. Were the three risk factors (coagulopathy, high-energy mechanism and age ≥65) considered independently of clinical symptoms, in particular LOC or amnesia, patients with indeterminate intracranial lesions would be reduced to only four (sensitivity 99.6%, specificity 50.6, NPV 99.9%), with a further increase of CT rate to 53%. Given that not all patients had a CT scan and the retrospective structure of the analysis, we assumed that no lesions were present in patients who did not have a scan and were not readmitted later needing a scan. Accordingly, the above sensitivity values refer to clinically significant lesions, and are likely to overestimate the true sensitivity of risk factors for intracranial lesions.

Strategies leading to increased head CT ordering rate could reduce costs if patients with negative scans are discharged without in-hospital monitoring. We recently reported that asymptomatic patients after negative CT can be safely discharged for home observation (Fabbri et al., 2004b). However, the imprecision of available data (unit costs and test frequencies) do not univocally identify the strategies increasing or decreasing costs. The benefit of the piece of information gained by CT scan must be weighed against the disadvantages, which are difficult to quantify (radiation exposure, unnecessary use of space and resources in crowded EDs). The large majority of favourable outcome in these patients does not indicate a more aggressive diagnostic protocol.

In conclusion, the NICE recommendations remain a reasonable compromise between what should be done and what can be done by busy physicians in ED. The variables proposed by NICE might be full accepted, possibly with the reconsideration of coagulopathy as an independent risk factor. The small increase in CT scan ordering rate is worth in the light of very high risk of intracranial lesions.

AUTHORS' CONTRIBUTIONS

A.F. conceived the study, wrote the protocol, coordinated the data collection, the interpretation of results, and wrote the paper. F.S. contributed to interpretation of the results and to critical review of the paper. G.M. contributed to study design, carried out the statistical analyses, the interpretation of the results, and co-wrote the paper. M.D., T.I., and M.S. were recruited in protocol design, study coordination, data collection, and interpretation of results. A.V. contributed to study design, study coordination, interpretation of the results, and to critical review of the paper. All authors approved the final manuscript.

REFERENCES

FABBRI, A., SERVADEI, F., MARCHESINI, G., et al. (2004a). Prospective validation of a proposal for diagnosis and management of patients attending the emergency department for mild head injury. J. Neurol. Neurosurg. Psychiatry **75,** 410–416.

FABBRI, A., SERVADEI, F., MARCHESINI, G., et al. (2004b). Which type of observation for patients with high-risk mild head injury and negative computed tomography? Eur. J. Emerg. Med. **11,** 65–69.

GEIJERSTAM, J.L., and BRITTON, M. (2003). Mild head injury—mortality anc complication rate: meta-analysis of findings in a systematic literature review. Acta Neurochir. **145,** 843–850.

GOMEZ, P.A., LOBATO, R.D., ORTEGA, J.M., and DE LA CRUZ, J. (1996). Mild head injury: differences in prognosis among patients with a Glasgow Coma Scale score of 13 to 15 and analysis of factors associated with abnormal CT findings. Br. J. Neurosurg. **10,** 453–460.

HAYDEL, M.J., PRESTON, C.A., MILLS, T.J., LUBER, S., BLAUDEAU, E., and DEBLIEUX, P.M. (2000). Indications for computed tomography in patients with minor head injury. N. Engl. J. Med. **343,** 100–105.

JAGODA, A.S., KANTRILL, S.V., WEARS, R.L., et al. (2002). Clinical policy: neuroimaging and decision making in adult mild traumatic brain injury in the acute setting. Ann. Emerg. Med. **40,** 231–249.

JERET, J.S., MANDELL, M., ANZISKA, B., et al. (1993). Clinical predictors of abnormality disclosed by computed tomography after mild head trauma. Neurosurgery **32,** 9–16.

KAY, A. and TEASDALE, G., (2001). Head injury in the United Kingdom. World J. Surg. **25,** 1210–1220.

LIVINGSTON, D.H., LAVERY, R.F., PASSANNANTE, M.R., et al. (2000). Emergency department discharge of patients with a negative cranial computed tomography scan after minimal head injury. Ann. Surg. **232,** 126–132.

LLOYD, D.A., CARTY, H., PATTERSON, M., BUTCHER, C.K., and ROE, D. (1997). Predictive value of skull radiography for intracranial injury in children with blunt head injury. Lancet **349,** 821–824.

MILLER, J.D., TOCHER, J.L., and JONES, P.A. (1988). Extradural haematoma—earlier detection, better results. Brain Inj. **2,** 83–86.

MILLER, E.C., HOLMES, J.F., and DERLET, R. (1997). Utilising clinical factors to reduce head CT scan ordering for minor head trauma patients. J. Emerg. Med. **15,** 453–457.

MUNRO, P.T., SMITH, R.D., and PARKE, T.R.J. (2002). Effect of patients' age on management of intracranial haematoma: a prospective national study. B.M.J. **325,** 1001–1005.

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE. (2003). Head injury in infants, children and adults: triage, assessment, investigation and early management. National Collaborative Centre for Acute Care [On-line]. Available: ⟨http://www.nice.org.uk/pdf/headinjury_full_version_completed.pdf⟩.

NEE, P.A., HADFIELD, J.M., YATES, D.W., and FARAGHER, E.B. (1999). Significance of vomiting after head injury. J. Neurol. Neurosurg. Psychiatry **66,** 470–473.

NORUSIS, M.J. (1992). *SPSS/PC+. Base System and Advanced Statistics User's Guide*, version 5.0. SPSS Inc.: Chicago.

SERVADEI, F., TEASDALE, G., and MERRY, G., on behalf of the Neurotraumatology Committee of the World Federation of Neurosurgical Societies. (2001). Defining acute mild head injury in adults: a proposal based on prognostic factors, diagnosis and management. J. Neurotrauma **18,** 657–664.

STEIN, S.C., and ROSS, S.E. (1992). Mild head injury: a plea for routine early CT scanning. J. Trauma **33,** 11–13.

STIELL, I.G., and WELLS, G.A. (1999). Methodologic standards for the development of clinical decision rules in emergency medicine. Ann. Emerg. Med. **33,** 437–447.

STIELL, I.G., WELLS, G.A., VANDEMHEEN, K., et al. (2001). The Canadian CT head rule for patients with minor head injury. Lancet **357,** 1391–1396.

SWANN, I.J., and TEASDALE, G.M. (1999). Current concepts in the management of patients with so-called "minor" or "mild" head injury. Trauma **1,** 143–145.

TEASDALE, G.M., MURRAY, G., ANDERSON, E., et al. (1990). Risks of acute traumatic intracranial haematoma in children and adults: implications for managing head injuries. B.M.J. **300,** 363–767.

TEASDALE, G.T., PETTIGREW, L.E.L., WILSON, J.T.L., MURRAY, G., and JENNETT, B. (1998). Analysing outcome of treatment of severe head injury: a review and update on advancing use of the Glasgow outcome scale. J. Neurotrauma **15,** 587–597.

THORNHILL, S., TEASDALE, G.M., MURRAY, G.D., McEWEN, J., ROY, C.W., and PENNY, K.I. (2000). Disability in young people and adults one year after head injury: prospective cohort study. B.M.J. **320,** 1631–1635.

WILSON, J.T., PETTIGREW, L.E., and TEASDALE, G.M. (1998). Structured interviews for the Glasgow Outcome Scale and the extended Glasgow Outcome Scale: guidelines for their use. J Neurotrauma **15,** 573–85.

WILSON, J.T., EDWARDS, P., FIDDES, H., STEWART, E., and TEASDALE, G.M. (2002). Reliability of postal questionnaires for the Glasgow Outcome Scale. J. Neurotrauma **19,** 999–1005.

Address reprint requests to:
Andrea Fabbri, M.D.
Dipartimento Emergenza-Urgenza Accettazione
Ospedale Morgagni-Pierantoni, Azienda USL Forlì
Via Forlanini 34
I-47100 Forlì, Italy

E-mail: andfabbri@libero.it