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INTRACRANIAL PRESSURE MONITORING AND OUTCOMES AFTER TRAUMATIC BRAIN INJURY

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OBJECTIVE: Uncontrolled intracranial hypertension after traumatic brain injury (TBI) contributes significantly to the death rate and to poor functional outcome. There is no evidence that intracranial pressure (ICP) monitoring alters the outcome of TBI. The objective of this study was to test the hypothesis that insertion of ICP monitors in patients who have TBI is not associated with a decrease in the death rate.

DESIGN: Study of case records.

METHODS: The data files from the Ontario Trauma Registry from 1989 to 1995 were examined. Included were all cases with an Injury Severity Score (ISS) greater than 12 from the 14 trauma centres in Ontario. Cases identifying a Maximum Abbreviated Injury Scale score in the head region (MAIS head) greater than 3 were selected for further analysis. Logistic regression analyses were conducted to investigate the relationship between ICP and death.

RESULTS: Of 9001 registered cases of TBI, an MAIS head greater than 3 was recorded in 5507. Of these patients, 541 (66.8% male, mean age 34.1 years) had an ICP monitor inserted. Their average ISS was 33.4 and 71.7% survived. There was wide variation among the institutions in the rate of insertion of ICP monitors in these patients (ranging from 0.4% to over 20%). Univariate logistic regression indicated that increased MAIS head, ISS, penetrating trauma and the insertion of an ICP monitor were each associated with an increased death rate. However, multivariate analyses controlling for MAIS head, ISS and injury mechanism indicated that ICP monitoring was associated with significantly improved survival ($p < 0.015$).

CONCLUSIONS: ICP monitor insertion rates vary widely in Ontario's trauma hospitals. The insertion of an ICP monitor is associated with a statistically significant decrease in death rate among patients with severe TBI. This finding strongly supports the need for a prospective randomized trial of management protocols, including ICP monitoring, in patients with severe TBI.

OBJECTIF : L'hypertension intracrânienne non contrôlée après un traumatisme cérébral contribue considérablement au taux de mortalité et à une issue médiocre sur le plan fonctionnel. Rien ne démontre que la surveillance de la tension intracrânienne (TIC) modifie l'issue du traumatisme cérébral. Cette étude visait à vérifier l'hypothèse selon laquelle l'implantation d'un moniteur de la TIC chez des patients victimes d'un traumatisme cérébral n'entraîne pas une diminution du taux de mortalité.

CONCEPTION : Étude de dossiers.

MÉTHODES : On a examiné les dossiers de données tirées du Registre ontarien de traumatologie de 1989 à 1995. Les dossiers comprenaient tous les cas dont l'indice de gravité des traumatismes (IGT) dépassait 12 et provenaient des 14 centres de traumatologie de l'Ontario. On a choisi pour les analyser plus à fond les cas indiquant un résultat supérieur à 3 selon l'échelle maximale abrégée de gravité des traumatismes dans la

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région crânienne (MAIS-head). On a procédé à des analyses de régression logistique pour étudier le lien entre la TIC et la mort.

RÉSULTATS : Sur 9001 cas inscris de traumatisme cérébral, on a consigné un résultat MAIS de plus de 3 dans 5507 cas. Sur ce total, on avait implanté un moniteur de la TIC à 541 patients (66,8 % de sexe masculin, âge moyen de 34,1 ans). Leur IGT moyen s'établissait à 33,4, et 71,7 % ont survécu. Le taux d'implantation d'un moniteur de la TIC chez ces patients (qui a varié de 0,4 % à plus de 20 %) a varié énormément entre les établissements. La régression logistique à une seule variable a indiqué un lien entre une élévation du taux de mortalité et chacun des facteurs suivants : l'augmentation du score MAIS pour le crâne, l'IGT, le traumatisme avec pénétration et l'implantation d'un moniteur de la TIC. Toutefois, les analyses à variables multiples servant à contrôler le score MAIS pour le crâne, l'IGT et le mécanise du traumatisme ont indiqué qu'il y avait un lien entre le contrôle de la TIC et une grande amélioration du taux de survie (p < 0,015).

CONCLUSIONS : Les taux d'implantation d'un moniteur de la TIC varient considérablement entre les centres de traumatologie de l'Ontario. On établit un lien entre l'implantation d'un moniteur de la TIC et une diminution significative sur le plan statistique du taux de mortalité chez les patients victimes d'un traumatisme crânien grave. Ce résultat appuie fortement le besoin d'une étude randomisée prospective de protocoles de prise en charge, y compris du contrôle de la TIC, chez les patients victimes d'un traumatisme cérébral grave.

The management of multiply injured patients has undergone many changes and improvements over the past 3 decades. These have resulted from improvements in the systematic approach to trauma management and to emergency medical services, as well as to advances in technology and clinical care. However, the management of patients with severe traumatic brain injury (TBI) remains vexing.

Selig and colleagues[1] and Mendelow and colleagues[2] demonstrated the importance of early surgical intervention for acute extradural and subdural hemorrhage. Subsequent work by Teasdale and colleagues[3] and Warme and collaborators[4] showed improved outcomes among patients admitted to neurosurgical intensive care units. However, management provided in the intensive care unit has not been extensively assessed with respect to its impact on outcome.

TBI treatment protocols vary widely, and few have been subjected to randomized clinical trials. Many such protocols are based on the pathophysiological principle of limiting secondary brain injury by reducing intracranial pressure (ICP). The work by Rosner's group[5,6] at the University of Alabama, suggests good outcomes associated with a management protocol based on the maintenance of cerebral perfusion pressure. However, the protocol has not been subjected to a randomized clinical trial, the numbers in the case series were relatively small, and the only comparative analysis was with previously published results from other centres.

Despite the lack of Level 1 evidence, recent clinical practice guidelines for TBI, such as those of the Brain Trauma Foundation,[7] recommend the insertion of ICP monitoring devices in patients with severe brain injury. The present study was undertaken to assess the correlation between the use of ICP monitoring and outcomes among patients with severe TBI, regardless of treatment decisions made. As such, it is limited in that it represents an evaluation of a monitoring modality rather than a treatment protocol. The null hypothesis therefore was that ICP monitoring would not correlate with improved outcomes among patients with severe TBI.

METHODS

The primary analysis was conducted with data collected for the Ontario Trauma Registry, which is a centralized dataset containing detailed information on all trauma cases (Injury Severity Score [ISS] greater than 12) admitted to 14 level 1 trauma centres in the province of Ontario. Each centre has a data analyst whose primary responsibility is data acquisition and validation. Using hospital charts, ambulance reports, police crash records and autopsy reports, the analyst records data from the accident scene, the referring hospital and the level 1 hospital. These include simple physiologic values such as blood pressure and heart rate, the requirement for stay in an intensive care unit, the use of an ICP monitor during hospitalization, diagnoses made during the hospital stay and functional outcomes. The COLLECTOR[8] software package is used for data storage. The data analyst enters injury diagnoses with information abstracted directly from the medical record. The diagnoses are entered as text, with or without the corresponding ICD-9CM[9] codes. AIS-90[10] scores are then assigned by the TRI-CODE[11] software and confirmed by the data analysts, and the Injury Severity Score (ISS)[12] is derived. The COLLECTOR software also calculates the Revised Trauma Score[13] needed for Trauma and Injury Severity Score (TRISS)[14] analysis of trauma outcomes.

The Ontario Trauma Registry was founded in 1991, and 4 complete years of data (1991 to 1995) plus data from a pilot year (1989) were available for this project. As previously described,[15–18] individual data values were validated and where data were found to be missing or clearly inappropriate, data analysts were contacted and asked to check the original source and resubmit the information. Patients were selected for possible inclusion if the file indicated TBI and were included for further analysis if a maximum AIS[10] score in the head region (MAIS head) greater than 3 was recorded. All patients included in the registry had an ISS greater than 12.

Statistical analysis was conducted using the SAS for Windows program, version 6.08.[19] The following variables were investigated for associations with outcome using univariate logistic regression: age, gender, Glasgow Coma Scale (GCS) score (total and individual components), injury type (blunt or penetrating), ISS, MAIS head, and TRISS (plus all TRISS components individually). Variables with fewer than 10% missing values, where missing value status was not related to outcome, were considered as candidates for inclusion in the final multivariate model, based on a univariate logistic regression probability value less than 0.25.[20] To control for severity of illness and investigate the final effects of ICP monitoring on death rate, a multivariate model was developed using a multiple-step backward elimination method.

RESULTS

From 1989 and from 1991 to 1995, the Ontario Trauma Registry recorded 12 058 (Table I) patient admissions with an ISS greater than 12. Of these, 5507 had an MAIS head greater than 3 and a mean (and standard deviation) ISS of 28 (12). The mean (and SD) age was 40 (24) years. Seventy-two percent of these patients were male and the overall death rate was 25.4%.

Of all patients with MAIS head greater than 3, 10% had an ICP monitoring device inserted. At one large centre, less than 1% of all patients received ICP monitors whereas another centre reported using ICP monitors in 20% of these patients (Table II).

The characteristics of the ICP-monitored patients are detailed in Table III. Process variables such as average length of stay, number of days on a ventilator and prehospital time were not analysed further. In addition, because functional outcome variables such as the Functional Independence Measure, the Ranchos Los Amigos score of cognitive function, and the Glasgow Outcome Score were not consistently available, they also were not analysed further.

The mean (and SD) GCS score at admission was 10.7 (4.5). However, complete GCS scores were available for only 61% of all admissions (Table IV). The eye component of the GCS was available for 92% of admissions, the motor component for 83% and the verbal component for only 61%. Patients with a missing verbal GCS component had a significantly higher death rate (36% versus.18%, p = 0.0013) and a significantly higher ICP monitor usage rate (16% versus 5.8%,

Table I

Ontario Trauma Registry Admissions (1989 and 1991 to 1995)

Demographic factor	Number
Total cases	12 058
Cases of TBI	9 001
Cases of severe TBI (MAIS head > 3)	5 507
Cases of severe TBI in which ICP monitoring was used	541*

TBI = traumatic brain injury, MAIS head = Maximum Abbreviated Injury Scale score in the head, ICP = intracranial pressure.
*561 had ICP monitoring, but 18 had an Abbreviated Injury Scale score < 4, and in 2 cases the MAIS head was not specified.

Table II

Practice Patterns of Intracranial Pressure (ICP) Monitoring Among 14 Trauma Centres in Ontario

Trauma centre	No. of cases	With MAIS head > 3, no. (and % of total)	With ICP monitoring, no. (and % of those with MAIS head > 3)
A	25	14 (56.0))	3 (21.4)
B	1 056	554 (52.5)	67 (12.1)
C	502	204 (40.6)	18 (8.8)
D	513	302 (58.9)	33 (10.9)
E	1 692	810 (47.9)	96 (11.9)
F	820	412 (50.2)	36 (8.7)
G	495	185 (37.4)	17 (9.2)
H	331	185 (55.9)	1 (0.5)
I	1 248	525 (42.1)	2 (0.4)
J	664	402 (60.5)	81 (20.1)
K	758	269 (35.5)	3 (1.1)
L	455	217 (47.7)	15 (6.9)
M	2 338	973 (41.6)	140 (14.4)
N	1 161	455 (39.2)	29 (6.4)
Total	12 058	5 507 (45.7)	541 (9.8)

MAIS head = Maximum Abbreviated Injury Scale score in the head.

$p < 0.00001$). Missing verbal scores were significantly more likely in patients who were more severely injured, as measured by the mean (and SD) ISS (32.8 [13] versus 26.3 [10], $p < 0.00001$) and whose head injuries were significantly worse, as measured by the mean (and SD) MAIS head (4.7 [0.5] versus 4.5 [0.5], $p < 0.00001$). Because missing GCS components were significantly related to outcome, inclusion in the multivariate model would have introduced significant bias into the results. For this reason, the GCS, its components and any scores relying on the GCS could not be used to control for severity of illness in the entire population.

Other physiologic variables such as respiratory rate, systolic blood pressure and heart rate showed similar trends toward incomplete recording in more severely injured patients. A complete tabulation of missing values can be found in Table IV.

MAIS head, ISS and injury type (blunt versus penetrating) were consistently available in all patients and were all significantly associated with death (Table V). In univariate analysis, the use of an ICP monitor was significantly related to an increased risk of mortality (odds ratio = 1.23, $p < 0.032$). In order to clarify to what degree this was due to the severity of injury, further analysis was conducted. Using a multivariate model to control for severity of illness, we found that blunt versus penetrating trauma, MAIS head, ISS and the use of an ICP monitor were all significantly associated with death. Blunt trauma was found to significantly decrease the chance of death ($p < 0.001$). Increasing ISS scores increased the likelihood of death ($p < 0.0001$). Increasing MAIS head increased the death rate ($p < 0.0001$). Controlling for severity of illness, the use of an ICP monitor was significantly associated with a decrease in the death rate ($p < 0.0151$).

Discussion

ICP monitoring as a guide to care of the severely brain injured patient has been used for more than 40 years. Since Guillaume and Janny[21] reported their early results in 1951, several authors have reported their experience. Yet from its early days, there have been enthusiasts and skeptics. Johnston and Jennett,[22] in 1973, concluded that ICP monitoring "...has a definite place in neurosurgical practice ... in patients after severe head injury...." However, Fleischer and associates[23] from Emory University in Atlanta concluded that "it is the degree of brain stem involvement that is the prime determinant of outcomes and the presence of elevated pressure ... may be an epiphenomenon." They further concluded that its value may not justify the risks of infection — 10% in their series.

The debate continues today. Eddy and her group[24] from Vanderbilt University in Nashville reported in 1995 a retrospective case series of 98 patients. They utilized fibreoptic technology and reported no complications and that 81% of patients had interventions based on the monitoring. Rossi and colleagues[25] in 1998 reported a series of 542 head injured patients with a GCS score of 8 or less with ICP monitors. Of these, 81.7% exhibited at least 1 episode of ICP 20 mm Hg or more, yet their complication rate was 2.6%. Others such as Stuart and colleagues[26] reported good results without ICP monitoring and argued that

Table III

Characteristics of Patients Who Had Intracranial Pressure (ICP) Monitoring

Patient characteristic	ICP monitoring, n = 541	No ICP monitoring, n = 4946
Mean age, yr	34.1	40.7
Male, %	66.8	72.5
Survival, %	71.7	75.3
Mean MAIS head	4.8	4.46
Mean ISS	33.4	28.3
Mean Glasgow Outcome Score	2.5	2.9
Mean Ranchos Los Amigos score*	5.2	6.5
Mean FIM at discharge	62.1	86.8
Mean length of hospitalization, d	44.0	22.8
Mean length of stay in intensive care unit, d	9.7	4.3
Mean time on ventilator, d	9.4	4.57
Mean time of ICP monitoring, d	7.9	N/A

*Mean Ranchos Los Amigos score of cognitive function
MAIS head = Maximum Abbreviated Injury Scale score in the head region, FIM = = Functional Independence Measure score.

Table IV

Missing Data Elements

Element	No. (and %)
GCS	
eye	416 (7.6)
motor	896 (16.3)
verbal	2123 (38.6)
Systolic blood pressure	181 (3.3)
Pulse rate	168 (3.1)
Respiratory rate	2225 (40.4)

GCS = Glasgow Coma Scale score.

the resource requirements are unjustifiable. Naredi and associates[27] from Sweden reported a series of 38 patients with severe TBI who were treated with a “standardized neurosurgical and neurointensive therapy” directed to vasogenic edema that included ICP monitoring in all patients. They reported that 71% of these patients (GCS less than 9) survived with moderate or no disability.

Recent efforts to develop clinical practice guidelines for the management of TBI, both in Europe and in the USA, have recommended the use of ICP monitors in comatose patients. However, both sets of guidelines acknowledge the lack of Level 1 (randomized controlled trial) evidence. Furthermore, because of cost and sample-size considerations, it is unlikely that any such trial will be conducted in the foreseeable future.[28,29]

Most of the relevant studies use the GCS score developed by Teasdale and Jennett[30] to define which patients should be considered as severely injured. Several studies have shown that admission GCS scores correlated well with outcomes.[31–35] Most recent and ongoing drug trials in brain injury stratify patients according to admission GCS score. Rosner and colleagues,[5,6] among others, identified patients with an admission GCS score of less than 8 as being severely injured. However, the GCS is a physiological measure and scores change quite significantly in the first few hours after injury. Changes occur as a result of clinical and iatrogenic factors. Most studies avoid defining a specific time interval at which the relevant GCS score is determined.[32,33] Some indicate that the determination is made on admission[31,34] or “after resuscitation,”[5,6] whereas some stated that there was a range of times at which it was measured.[35] None of the studies cited here identified how the GCS is calculated for patients who have been intubated or sedated before hospital admission. This could be explained by the fact that all head injured patients arrive at the hospital directly from the scene of injury without any airway stabilization or that an estimate is somehow made. Similarly, none included consideration of intoxicants, which are very common among this population worldwide. Marion and Carlier[36] addressed this problem by surveying medical and nursing staff in 17 major traumatic brain injury centres in the United States, chosen on the basis of the number of head trauma journal articles generated by their facility. They were able to demonstrate remarkable inter- and intracentre variations regarding the assignment of scores. More recently, Buechler and associates[37] were able to demonstrate the same thing in a national telephone survey of US level I trauma centres — “Wide variation in GCS scoring among Level I trauma centers was identified….Use of state and national databases and outcome research may be adversely affected by the lack of consistent GCS scoring.” As a result of these concerns, our study stratified head injury severity by a multivariate model incorporating MAIS, ISS and blunt or penetrating injury.

Our study was conducted retrospectively using a trauma registry database. All of the trauma centres in the province of Ontario participated, and hence it can be assumed that most of the severely injured patients in the province were included. Attempts to standardize the assignment of admission GCS scores were not and are not feasible. Similarly, as reported previously,[15–18] the majority of patients in Canada are referred from a primary hospital, and many have received prehospital advanced life support — many are intubated and pharmacologically paralysed before arrival at the trauma centre. As such, many of the data elements for the GCS were incomplete or unreliable.

The AIS[38] and the derived ISS[12] have long been used to estimate the severity of injury in trauma populations. The scores are based on specific anatomical diagnoses and are not affected by treatment, time or intoxicants. Data analysts in the Ontario trauma hospitals contributing to the registry have been trained to a consistent standard by instructors from the Association for the Advancement of Automotive Medicine (AAAM) and utilize the same software (TRICODE[11]). Walder and colleagues[39] in a 1995 study concluded that the maximum AIS score in the head region correlated strongly with outcome and was more predictive than the GCS. Ross and associates[40] in a study of 503 consecutive head-injured patients found a strong statistical relationship between MAIS head and outcomes.

Table V

Risk Factor Analyses

Risk factor	Univariate analysis: *p* value <	Univariate analysis: Odds ratio	Multivariate analysis: *p* value <	Multivariate analysis: Odds ratio
ICP monitor	0.0321	1.239	0.015	0.769
MAIS head 4	Referent		Referent	
MAIS head 5	0.0001	7.95		5.4
MAIS head 6	0.0001	119.8	0.0001	13.4
ISS	0.0001	1.068	0.0001	1.042
Blunt injury	0.0001	0.411	0.0001	0.41

ICP = intracranial pressure, MAIS head = Maximum Abbreviated Injury Scale score in the head, ISS = Injury Severity Score.

As a result of the above considerations, the MAIS head was used as an independent variable to define the severity of the traumatic brain injury, and the ISS was used to define the overall severity of injury.

The strength of the results was surprising. The fact that in the univariate analysis, ICP monitor use was associated with an increase in the death rate was expected: the more severely injured patients were more likely to be monitored. However, when the severity of injury was controlled for, the use of ICP monitors was protective and the significance ($p < 0.0151$) was stronger than expected. A number of possible conclusions exist. Although the insertion of the monitor itself has no therapeutic benefit, it is certainly possible to conclude that the information gained allows more informed decisions regarding management. Another possibility is that the monitor is more likely to be inserted in patients judged to have a better chance of survival clinically, although with both age and severity of injury controlled for, it is unclear what other factors would bias results in that direction. It is certainly quite likely that hospitals with a higher ICP monitoring rate are likely to be more aggressive generally in their neurosurgical intensive care management protocols, and that such protocols include ICP and cerebral perfusion pressure (CPP) management.

The other major finding of the study was the significant variation in ICP monitoring rates among the hospitals, even among severely injured patients. A recent survey of neurosurgical centres in the United Kingdom demonstrated a similar variation in that only 57% of such centres routinely monitor ICP in severely brain injured patients.[41]

These results provide strong support for the use of ICP monitoring as a component of treatment protocols for the management of severe TBI. They suggest that there is some benefit to those protocols. However, because TBI management varies quite substantially among the hospitals involved and because data regarding details of that management are not collected in the registry, no conclusions can be drawn regarding components of the treatment protocols that are producing the improved results. There is a clear need for evaluation of standardized TBI management protocols such as the CPP approach utilizing the randomized clinical trial methodology. These results also support the contention that TBI protocols be stratified using MAIS head as a severity of injury stratification variable.

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