

## External validation of the updated Brain Injury Guidelines for complicated mild traumatic brain injuries: a retrospective cohort study

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**OBJECTIVE** Approximately 10% of patients with mild traumatic brain injury (mTBI) have intracranial bleeding (complicated mTBI) and 3.5% eventually require neurosurgical intervention, which is mostly available at centers with a higher level of trauma care designation and often requires interhospital transfer. In 2018, the Brain Injury Guidelines (BIG) were updated in the United States to guide emergency department care and patient disposition for complicated mild to moderate TBI. The aim of this study was to validate the sensitivity and specificity of the updated BIG (uBIG) for predicting the need for interhospital transfer in Canadian patients with complicated mTBI.

**METHODS** This study took place at three level I trauma centers. Consecutive medical records of patients with complicated mTBI (Glasgow Coma Scale score 13–15) who were aged  $\geq 16$  years and presented between September 2016 and December 2017 were retrospectively reviewed. Patients with a penetrating trauma and those who had a documented cerebral tumor or aneurysm were excluded. The primary outcome was a combination of neurosurgical intervention and/or mTBI-related death. Sensitivity and specificity analyses were performed.

**RESULTS** A total of 477 patients were included, of whom 8.4% received neurosurgical intervention and 3% died as a result of their mTBI. Forty patients (8%) were classified as uBIG-1, 168 (35%) as uBIG-2, and 269 (56%) as uBIG-3. No patients in uBIG-1 underwent neurosurgical intervention or died as a result of their injury. This translates into a sensitivity for predicting the need for a transfer of 100% (95% CI 93.2%–100%) and a specificity of 9.4% (95% CI 6.8%–12.6%). Using the uBIG could potentially reduce the number of transfers by 6% to 25%.

**CONCLUSIONS** The patients in uBIG-1 could be safely managed at their initial center without the need for transfer to a center with a higher level of neurotrauma care. Although the uBIG could decrease the number of transfers, further refinement of the criteria could improve its specificity.

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**KEYWORDS** mild traumatic brain injury; intracranial hemorrhage; neurosurgical intervention; Brain Injury Guidelines

EVERY year, more than 300 cases of mild traumatic brain injuries (mTBIs) per 100,000 Canadians are treated in emergency departments (EDs).<sup>1</sup> Most of these patients undergo head CT, of whom approximately 10% have positive findings of intracranial hemorrhage

(ICH) or skull fracture<sup>2</sup> and therefore experience a complicated mTBI. Ultimately, only 3.5% of patients with complicated mTBI and only 0.2% of patients with a Glasgow Coma Scale (GCS) score of 15 require neurosurgical intervention.<sup>3</sup>

**ABBREVIATIONS** BIG = Brain Injury Guidelines; ED = emergency department; EDH = epidural hematoma; GCS = Glasgow Coma Scale; ICH = intracranial hemorrhage; IPH = intraparenchymal hematoma; IVH = intraventricular hemorrhage; mTBI = mild traumatic brain injury; SAH = subarachnoid hemorrhage; SDH = subdural hematoma; uBIG = updated BIG.

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Current guidelines in the province of Québec (Institut national d'excellence en santé et en services sociaux [INESSS]—2011) recommend a neurosurgical consultation for every patient presenting with mTBI with a significant lesion on initial head CT defined as a contusion  $\geq 5$  mm, subarachnoid hemorrhage (SAH)  $\geq 1$  mm, subdural hematoma (SDH)  $\geq 4$  mm, epidural hemorrhage, intracerebral hemorrhage, intraventricular hemorrhage (IVH), displaced skull fracture, diffuse edema, and pneumocephalus.<sup>4</sup> Since most neurosurgical resources are concentrated in centers with higher levels of trauma care designation, it appears that some transfers may provide limited benefits and may even be deleterious to patients. In 2017, more than 50% of patients assessed by neurosurgeons in all of Québec's level I trauma centers originated from interhospital transfers.<sup>5</sup> Several studies have questioned the relevance of specialized clinical and radiological follow-up of patients presenting with complicated mTBIs, which imply radiation exposure and inefficient hospital resource utilization.<sup>6–15</sup>

In 2014, Joseph et al. developed and validated the Brain Injury Guidelines (BIG) for the management of patients with complicated mild to moderate TBI at one level I trauma center in the US.<sup>16,17</sup> In 2018, Martin et al. updated the BIG (uBIG).<sup>18</sup> These guidelines classified patients into three categories according to neurological examination findings, antiplatelet or anticoagulant use, skull fracture type, and ICH size and type. The uBIG-1 category included patients who had a GCS score of 14 or 15; were not intoxicated; were not on a regimen of anticoagulant or antiplatelet medication; had no skull fracture or IVH; and had an SDH or epidural hematoma (EDH) of 4 mm or less, a single intraparenchymal hematoma (IPH) of 4 mm or less, or a trace SAH. The uBIG-2 category included patients who had a GCS score of 12 or 13; or had a nondisplaced skull fracture, a 5- to 7-mm SDH or EDH, a maximum of 2 IPHs of 5–7 mm, or localized SAH; and had no IVH. Finally, the uBIG-3 category included patients with a displaced skull fracture; or a GCS score  $< 12$ ; or an SDH, EDH, or IPH of at least 8 mm; multiple IPHs (more than 2); an IVH; or a scattered SAH.

A suggested therapeutic plan was defined for each category, including 1) in-hospital observation length, 2) need for repeat head CT, 3) need for neurosurgical consultation, and 4) transfer to a higher level of care. An external validation of the safety and efficacy of the uBIG is necessary before their implementation in our Canadian setting.

The aim of our study was to validate the sensitivity and specificity of the uBIG to predict the need for interhospital transfer for patients with complicated mTBI. We also assessed reduction of potentially avoidable transfers and radiological and clinical deterioration.

## Methods

### Study Design and Setting

We performed a retrospective multicenter cohort study of patients assessed for a complicated mTBI at all three level I trauma centers in the province of Québec (Hôpital de l'Enfant-Jésus de Québec, Hôpital Sacré-Coeur de Montréal, and Hôpital Général de Montréal). The CHU

de Québec—Université Laval Research Ethics Board approved this study.

### Population

Consecutive medical records of patients aged  $\geq 16$  years with a diagnosis of complicated mTBI (GCS score  $\geq 13$  and one of the following criteria: altered state of consciousness, loss of consciousness  $\leq 30$  minutes, posttraumatic amnesia  $< 24$  hours, focal neurological deficit, and an ICH or a skull fracture on the initial head CT scan).<sup>19</sup> Records of patients who presented directly or were transferred to one of the participating centers between September 2016 and December 2017 were reviewed. Patients were excluded if they presented with a penetrating trauma or had a documented cerebral tumor or aneurysm.

### Data Collection

Patients' medical records were reviewed by three trained research assistants (V.P., E.F., and J.N.T.). Sociodemographic and clinical data were collected, including the presence of neurosurgical consultation, neurosurgical intervention, death within 3 months of the ED visit, clinical deterioration, and radiological deterioration.

The initial and repeat head CT reports were reviewed to extract ICH types and sizes as well as fracture types using the initial radiology reports. SAH was classified into three distribution types (trace, localized, and scattered), according to the original BIG and uBIG classifications. Since no definition of these distributions are given in the original and updated BIG, we defined them as follows: trace SAH was defined as an insignificant hemorrhage on initial CT, localized SAH was defined as a single significant hemorrhage on initial CT, and scattered SAH was defined as multiple significant hemorrhages on initial CT. The research assistants then classified patients in the appropriate uBIG category based on their initial clinical and radiological characteristics.

### Outcome Measures

The need for interhospital transfer was determined via our primary outcome, a combination of neurosurgical intervention and/or mTBI-related death before hospital discharge. Intracranial pressure monitoring was the only intervention that was not considered a neurosurgical intervention. Therefore, patients who died of their injuries before discharge and/or underwent neurosurgical intervention were considered appropriate for transfer in this study.

Secondary outcomes were radiological deterioration and clinical deterioration. Radiological deterioration was defined as ICH worsening or a new ICH on repeat head CT according to the attending radiologists, who were blinded to the patient outcome. Repeat head CT and clinical management were left to the attending emergency or neurosurgical team. Clinical deterioration was defined as any significant new symptom (such as loss of consciousness, confusion, amnesia, convulsion, paresthesia, dizziness, unilateral weakness, unilateral sensory loss, abnormal cranial nerve examination, positive pronator drift, pupillary asymmetry, balance disorder, aphasia, and hemispatial ne-

glect) between initial evaluation by the emergency physician and patient discharge.

We also assessed reduction in potentially avoidable transfers, which was defined as the absence of neurosurgical intervention and mTBI-related death in patients who were discharged from their respective trauma center ED.

### Statistical Analysis

Sensitivity and specificity were calculated for the ability of the uBIG to predict patients who required transfer to a high-level trauma center. Since the uBIG-2 category only suggests considering transfer to a high-level trauma center, specificity and sensitivity for the need for transfer were calculated for worst-case (transferring all patients in uBIG-2) and best-case (transferring no patient in uBIG-2) scenarios. A total of 10% of our cohort was assessed by two independent research assistants to determine interrater agreement, and kappa coefficient calculations were performed.

## Results

A total of 477 patients met our inclusion criteria. Forty patients were classified as uBIG-1 (8%), 168 were classified as uBIG-2 (35%), and 269 (56%) were classified as uBIG-3 according to the uBIG clinical and radiological characteristics. Table 1 shows the sociodemographic characteristics of our study population, stratified by uBIG category. The study cohort was predominantly male (68% total; 55% uBIG-1, 65% uBIG-2, and 72% uBIG-3). The mean age was 63 years: 56 years in uBIG-1, 60 years in uBIG-2, and 66 years in uBIG-3. The most frequent mechanism of trauma was fall from height (44%).

For the entire cohort, 8.4% underwent a neurosurgical intervention, and 3% died as a result of their mTBI. Most patients had a neurosurgical consultation (94%), all patients had an initial head CT, and 69% of patients had a repeat head CT, for a total of 331 repeat head CT scans. Initial head CT findings are presented in Table 1. The most common findings on initial head CT were SDH (60%) and SAH (55%). Other findings included IPH (35%), IVH (8%), EDH (8%), and skull fracture (28%).

### Safety of the uBIG

Note that the sensitivity and specificity for predicting the need for transfer change according to worst-case and best-case scenarios. This is because the uBIG-2 category lets clinicians decide whether or not to transfer a patient. The best-case scenario assumes that no patients classified as patients in uBIG-2 are transferred, in which case patients in uBIG-2 who received neurosurgery and/or died are undertriaged, and therefore sensitivity decreases. The worst-case scenario assumes that all patients in uBIG-2 are transferred, in which case patients in uBIG-2 who did not receive neurosurgery and/or died were overtriaged, and therefore specificity decreases.

Table 2 shows the primary and secondary outcomes of the study. No patient in uBIG-1 underwent neurosurgery and/or died as a result of their injuries before discharge. Therefore, the sensitivity was 100% (95% CI 93.2%–100%), assuming all patients in uBIG-2 would have been

transferred to a high-level trauma center. This sensitivity decreases to 96.2% (95% CI 86.8%–99.5%) if we assume that no patients in uBIG-2 would have been transferred, as 1 patient in this group underwent neurosurgery and 1 patient died as a result of their injury. Note that intracranial pressure monitoring was not considered as a neurosurgical intervention. However, none of the 40 patients in uBIG-1 received intracranial pressure monitoring.

Moreover, patients in uBIG-1 (which only warrants a 6-hour observation) did not show radiological deterioration, and only 1 patient in uBIG-1 clinically deteriorated 6 hours after initial assessment in the ED, which means that this patient would have benefited from being classified in a higher uBIG category. This 74-year-old male mTBI patient had no medical history except for hypertension, presented with a GCS score of 15 and an SDH of 2 mm, and deteriorated clinically based on a significant new-onset balance disorder.

### Efficacy of the uBIG

Assuming that all patients in uBIG-2 are transferred, the uBIG showed a specificity of 9.4% (95% CI 6.8%–12.6%) and a positive predictive value of 11.9% in predicting the need for interhospital transfer, as 53 of the 437 patients classified under uBIG-2 and uBIG-3 underwent a neurosurgical intervention or died as a result of their mTBI before discharge. Assuming that no patient in uBIG-2 is transferred, the specificity for predicting the need for a transfer is 48.5% (95% CI 43.6%–53.3%), with a positive predictive value of 18.6%, as 51 of the 269 patients in uBIG-3 underwent a neurosurgical intervention or died as a result of their mTBI before discharge. The specificity of the uBIG for predicting neurosurgical intervention and mTBI-related death, and, therefore, the possible need for a transfer, ranges between 9.4% and 48.5%.

The proportion of transfers that could have been potentially avoided in the cohort was 39%. Under a uBIG application, this proportion would have been 33%, at most. This means that at least 26 patients in uBIG-1 could have potentially avoided being transferred and/or cared for at a center with a higher level of trauma care designation. As mentioned, the proposed therapeutic plan for patients in uBIG-2 only suggests that transfer to a center with a higher level of trauma designation should be considered. Therefore, assuming that not all patients in uBIG-2 would require transfer, as many as 118 patients could have avoided being transferred and/or being cared for in a center with a higher level of trauma care designation, translating into a 14% proportion of potentially avoidable transfers.

Using the uBIG would have safely avoided a total of 18 repeat head CT scans (5.4%) and 14 hospitalizations (4.9%) in patients in uBIG-1.

### Reproducibility of the uBIG Classification

We assessed interrater agreement in 10% of our cohort, and our results show excellent agreement ( $\kappa = 0.84$ , 95% CI 0.71–0.98). The reviewers disagreed on only 5 patients; 4 of these disagreements were in regard to SAH distribution.

**TABLE 1. Population characteristics and demographics**

	uBIG-1 (n = 40)	uBIG-2 (n = 168)	uBIG-3 (n = 269)	Total (n = 477)
Age, yrs				
Mean (SD)	56 (18)	60 (22)	66 (20)	63 (21)
Range	18–85	16–96	16–98	16–98
Male sex, n (%)	22 (55)	110 (65)	193 (72)	325 (68)
Transfers, n (%)	21 (52)	81 (48)	154 (57)	256 (54)
Disposition after ED stay, n (%)				
Released	26 (65)	95 (57)	68 (25)	189 (40)
Hospitalized	13 (32)	65 (39)	154 (57)	232 (49)
ICU	1 (2)	8 (5)	44 (16)	53 (11)
Injury mechanism, n (%)				
Fall from height	11 (28)	69 (41)	129 (48)	209 (44)
Fall from other than height	9 (23)	24 (14)	73 (27)	106 (22)
Motorized vehicle accident (driver/passenger)	7 (18)	26 (15)	22 (8)	55 (11)
Motorized vehicle accident (pedestrian)	3 (8)	18 (11)	15 (6)	36 (8)
Sport accident	0	4 (2)	8 (3)	12 (3)
Recreational activities accident	10 (25)	16 (10)	13 (5)	39 (8)
Physical abuse	0	10 (6)	6 (2)	16 (3)
Other traumatism, n (%)				
Cervical	1 (3)	5 (3)	8 (3)	14 (3)
Thoracic	11 (28)	30 (18)	31 (12)	72 (15)
Abdominal	0	0	1 (0)	1 (0)
Lumbar	0	7 (4)	9 (3)	16 (3)
Facial	8 (20)	36 (21)	32 (12)	76 (16)
Medical history				
Coagulopathy, n (%)	1 (2)	0	1 (0)	2 (0)
Neoplasia, n (%)	0	6 (4)	14 (5)	20 (4)
Hypertension, n (%)	11 (28)	71 (42)	136 (51)	218 (46)
Thrombophlebitis or pulmonary embolism, n (%)	1 (2)	0	1 (0)	2 (0)
Diabetes, n (%)	2 (5)	21 (12)	62 (23)	85 (18)
Coronary artery disease, n (%)	3 (7)	26 (15)	54 (20)	83 (17)
Dyslipidemia, n (%)	7 (17)	55 (33)	105 (39)	167 (35)
Stroke, n (%)	0	7 (4)	14 (5)	21 (4)
Hepatic deficiency, n (%)	1 (2)	2 (1)	2 (1)	5 (1)
Initial GCS score 13, n (%)	0	7 (4)	23 (9)	30 (6)
Initial GCS score 14, n (%)	7 (17)	39 (23)	100 (37)	146 (31)
Initial GCS score 15, n (%)	33 (82)	122 (73)	146 (54)	301 (63)
Intoxication, n (%)	0	40 (24)	35 (13)	75 (16)
Anticoagulant use, n (%)	0	19 (11)	34 (13)	53 (11)
Antiplatelet use, n (%)	0	54 (32)	72 (27)	126 (26)
Initial head CT finding				
SDH, n (%)	22 (55)	79 (47)	186 (69)	287 (60)
EDH, n (%)	3 (7)	13 (8)	23 (9)	39 (8)
SAH, n (%)	15 (37)	91 (54)	157 (58)	263 (55)
IPH/contusion, n (%)	10 (25)	34 (20)	121 (45)	165 (35)
IVH, n (%)	0	0	38 (14)	38 (8)
Skull fracture	2 (5)	44 (26)	89 (33)	135 (28)
Displaced, n (%)	0	0	27 (10)	27 (6)
Nondisplaced, n (%)	0	42 (25)	60 (22)	102 (21)

**TABLE 2. Primary and secondary outcomes of the original uBIG**

	uBIG-1 (n = 40)	uBIG-2 (n = 168)	uBIG-3 (n = 269)	Total (n = 477)
Neurosurgical intervention, n (%)	0	1 (0.6)	39 (14)	40 (8.4)
Death 3 mos after mTBI, n (%)	0	7 (4)	26 (10)	33 (7)
mTBI-related death, n (%)	0	1 (0.6)	12 (4)	13 (3)
Repeat head CT, n (%)	18 (45)	113 (67)	200 (74)	331 (69)
Radiological deterioration, n (%)	0	20 (12)	64 (24)	84 (18)
Clinical deterioration, n (%)	1 (2)	8 (5)	40 (15)	49 (10)
Potentially avoidable transfers, n (%)	26 (65)	92 (55)	66 (25)	184 (39)

## Discussion

The uBIG was developed to improve the management of patients with complicated mild to moderate TBI across all trauma centers by targeting patients at higher risk of requiring transfer to a center with a higher level of trauma care designation, neurosurgical consultation, repeat head CT, and hospitalization. In this study, we attempted to assess the efficacy and safety of the uBIG in patients presenting or transferred with mTBI to the three level I trauma centers in the province of Québec. We chose to perform this external validation of the uBIG in mTBI only to improve the management of mTBI, specifically because provincial recommendations state that all patients with moderate TBIs seen in our EDs must undergo initial neurosurgical management and are therefore transferred.<sup>4,20</sup> Our study is the first to perform an external validation of the uBIG in a Canadian setting.

We found that the proposed uBIG could lead to a safe improvement in resource utilization. Its use in our study population could have avoided between 1 in 17 and 1 in 4 unnecessary and costly transfers and/or care in a higher-level trauma center. Moreover, the uBIG are accurate at identifying patients at low risk of requiring transfer to a center with a higher level of trauma care designation and neurosurgical management. In fact, no patient in uBIG-1 died of mTBI-related injuries, and none required neurosurgical intervention. Two patients in uBIG-2 required neurosurgical intervention. This means that patients in uBIG-1 may not need to be transferred, and they certainly do not need a neurosurgical consultation. Several studies have questioned the relevance of transfers to a center with a higher level of trauma care designation and neurosurgical consultations in patients with complicated mTBI. Many authors, including the uBIG authors, have identified a subgroup of low-risk patients who could potentially be treated without immediate transfer and neurosurgical management.<sup>3,21–26</sup>

Our results also show that a nonnegligible number of repeat head CT scans and hospitalizations would have been avoided with the use of uBIG, which could reduce unnecessary radiation and overcrowding. While the percentage of avoidable repeat head CT scans and hospitalizations is

low, it is reasonable to assume that avoiding them would be safe, as none of uBIG-1 patients had neurosurgical intervention, died as a result of their injuries, or showed radiological deterioration. Only 1 patient showed clinical deterioration. Although clinical deterioration seems to be useful in the management of patients with complicated mTBI, the clinical relevance of radiological deterioration remains unclear. In fact, many studies have suggested that repeat head CT scans in patients with complicated mTBI are probably only beneficial when patients exhibit clinical deterioration.<sup>6–15</sup> The purpose of repeat head CT scans in the management of complicated mTBIs remains uncertain, especially in the absence of clinical deterioration, and could be more than solely detecting radiological deterioration, the value of which is being challenged.

While our external validation showed interesting results regarding the safety of the uBIG in complicated mTBI patients with its high sensitivity for detecting patients needing care at a center with a higher level of trauma designation, the low specificity would likely result in limited improvement in resource utilization. The uBIG could be refined to include more patients in the low-risk uBIG-1 category, thus improving its specificity while maintaining an acceptable sensitivity. Furthermore, the small sample of 40 patients in uBIG-1 may limit our ability to draw strong conclusions. Moreover, it is probable that concomitant injuries play an important role in determining the need for patient transfer. While the uBIG do not take this element into consideration, many of our patients sustained polytrauma and adding a concomitant injury description in uBIG categories might be useful in a future guideline refinement.

## Limitations

Since this was a retrospective study, clinical management was left to the attending emergency or neurosurgical team, and indications for repeat head CT, neurosurgical consultation, interhospital transfer, and neurosurgical intervention were heterogeneous. Willingness of patients and/or families to continue with neurosurgical intervention and their level of care were unknown. It is possible that some of our patients who did not undergo neurosurgical intervention had an indication for such a procedure according to the attending physician. Also, we considered that transfer to a center with a higher level of trauma designation was appropriate in cases in which patients received neurosurgery or died as a result of their injuries. It is possible that other indications for transfer exist but were not taken into consideration in this study. Moreover, since our study group comprises patients who were already transferred or presented to one of the three level I trauma centers in the province of Québec, it is possible that our cohort represents a more severe subgroup of mTBI patients. While highly unlikely due to the current provincial guidelines, some patients with mTBI might not have been transferred to one of our centers and may have deteriorated at the initial center, which we would not have known. Lastly, we have not studied which subgroup of patients in uBIG-2 would require transfer to a center with a higher level of trauma designation. This explains our wide sensitivity and specificity confidence intervals, which reflected

both worst-case (transferring all patients in uBIG-2) and best-case (transferring no patient in uBIG-2) scenarios. While the worst-case scenario of transferring all patients in uBIG-2 would decrease the rate of bad outcomes compared with the best-case scenario of not transferring any patients in uBIG-2, it would still lead to the initial problem, which is the overtriage of patients and inappropriate use of healthcare resources. Modifying the uBIG to include more low-risk patients in the uBIG-1 category may help solve this problem.

## Conclusions

The uBIG accurately identified patients at low risk of requiring a neurosurgical intervention or mTBI-related death with a high sensitivity but a low specificity. The patients in uBIG-1 could be safely managed at their initial center without the need for a neurosurgical consultation and/or transfer to a higher level of neurotrauma care. Although implementing the uBIG could potentially reduce some healthcare expenditures while providing safe care for patients with complicated mTBI patients, further refinement of the criteria could improve specificity and efficiency at a system level.

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## Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

## Author Contributions

Conception and design: Émond, Malo. Acquisition of data: Tourigny, Paquet, Fortier. Analysis and interpretation of data: Émond, Tourigny, Carmichael. Drafting the article: Tourigny. Critically revising the article: Émond, Boucher, Paquet, Fortier, Malo, Mercier, Chauny, Clark, Blanchard, Gariépy, D'Astous. Reviewed submitted version of manuscript: Boucher, Carmichael. Approved the final version of the manuscript on behalf of all authors: Émond. Statistical analysis: Carmichael. Administrative/technical/material support: Boucher. Study supervision: Émond, Boucher, Chauny, Clark.

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