A multicenter validation of the modified brain injury guidelines: Are they safe and effective?

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BACKGROUND: The modified Brain Injury Guidelines (mBIG) are an algorithm for treating patients with traumatic brain injury and intracranial hemorrhage by which selected patients do not require a repeat head computed tomography, a neurosurgery consult, or even an admission. The mBIG refined the original Brain Injury Guidelines (BIG) to improve safety and reproducibility. The purpose of this study is to assess safety and resource utilization with mBIG implementation.

METHODS: The mBIG were implemented at three Level I trauma centers in August 2017. A multicenter retrospective review of prospectively collected data was performed on adult mBIG 1 and 2 patients. The post-mBIG implementation period (August 2017 to February 2021) was compared with a previous BIG retrospective evaluation (January 2014 to December 2016).

RESULTS: There were 764 patients in the two study periods. No differences were identified in demographics, Injury Severity Score, or admission Glasgow Coma Scale score. Fewer computed tomography scans (2 [1,2] vs. 2 [2,3], $p < 0.0001$) and neurosurgery consults (61.9% vs. 95.9%, $p < 0.0001$) were obtained post-mBIG implementation. Hospital (2 [1,4] vs. 2 [2,4], $p = 0.013$) and intensive care unit (0 [0,1] vs. 1 [1,2], $p < 0.0001$) length of stay were shorter after mBIG implementation. No difference was seen in the rate of clinical or radiographic progression, neurosurgery operations, or mortality between the two groups.After mBIG implementation, eight patients (1.6%) worsened clinically. Six patients that clinically progressed were discharged with Glasgow Coma Scale score of 15 without needing neurosurgery intervention. One patient had clinical and radiographic decompensation and required craniotomy. Another patient worsened clinically and radiographically, but due to metastatic cancer, elected to pursue comfort measures and died.

CONCLUSION: This prospective validation shows the mBIG are safe, pragmatic, and can dramatically improve resource utilization when implemented. (*J Trauma Acute Care Surg.* 2022;93: 106–112. Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic/Care Management; Level III.

KEY WORDS: Traumatic brain injury; intracranial hemorrhage; modified brain injury guidelines.

In today's health care landscape, resource utilization has leapt to the forefront of the national discussion. The COVID pandemic and the resulting strain placed on health care resources have highlighted the need to conserve testing, hospital beds, and other resources for patients that will truly benefit from those resources. One potential area for improvements in resource utilization is through an assessment of traditional management algorithms for traumatic brain injury (TBI). Traumatic brain injury accounted for $92 billion in health care costs with 2.9 million emergency department visits and 224,000 hospital admissions due to TBI.[1] Such an extensive allocation of resources for a single disease process is a natural target to improve utilization.

The Brain Injury Guidelines (BIG) created an algorithm whereby mild TBI with intracranial hemorrhage (ICH) can be treated without a repeat head computed tomography (CT) scan, a hospital admission, or a neurosurgery consult for every patient.[2,3] The modified Brain Injury Guidelines (mBIG) subsequently refined the original algorithm in order to improve patient safety and reproducibility.[4] Under the mBIG, patients with TBI and ICH are stratified into three categories (mBIG 1, mBIG 2, mBIG 3) based on the clinical presentation, radiographic characteristics of the ICH, and other patient factors (Fig. 1). The mBIG 1 patients do not have a planned repeat head CT scan or a neurosurgery consult. They are observed for 6 hours and if they do not have a deterioration in neurological exam and have a Glasgow Coma Scale (GCS) score of 15 or are at their baseline GCS score, they are discharged without a hospital admission. Patients that qualify as mBIG 2 also do not receive a planned repeat head CT or neurosurgery consult and are admitted for a 24-hour observation period. They are discharged if there is no decline in neurological status and their GCS score is 15 or at baseline. The majority of patients with TBI and ICH qualify as mBIG 3. These represent more severely injured patients who do receive planned repeat head CT scans, neurosurgery consults, and hospital admissions.

The mBIG treatment algorithm constitutes a substantial change from the standard treatments used by most trauma centers. Most centers mandate repeat head CTs, neurosurgery consults, and hospital admission (often to the intensive care unit [ICU]) for all patients with TBI and ICH.[5–12] The mBIGs were previously analyzed in a multicenter retrospective study that suggested substantial improvements in resource utilization could be realized if the guidelines were implemented.[4] The purpose of this study is to assess the safety of the mBIG and to examine changes in resource utilization after they were implemented at multiple centers. The hypothesis for this project is that the mBIGs are safe to implement and will considerably improve resource utilization in TBI.

METHODS

A retrospective observational analysis of prospectively collected data was performed for all TBI patients from 8/2017 to 2/2021 admitted to one of three urban, Level I trauma centers. All 3 centers are verified by the American College of Surgeons as Level I trauma centers. Institutional Review Board approval for the study was obtained at all three institutions. Data were abstracted using the trauma registry and electronic medical record at each respective institution. This study was designed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for

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	mBIG 1	mBIG 2	mBIG 3
Initial GCS	13-15	13-15	any
Abnormal neurological exam	no	no	yes
intoxication[1]	no	yes	yes
anticoagulation/ antiplatelet (excluding ASA)[2]	no	no	yes
Skull fx	no	non-displaced	displaced
SDH	≤4mm	4-7.9mm	≥8mm
EDH	no	no	yes
IPH	≤4mm	4-7.9mm	≥8mm or multiple
SAH	≤3 sulci and <1mm	Single hemisphere or 1-3mm	Bi-hemispheric or >3mm
IVH	no	no	yes

Figure 1. mBIG. [1]Intoxication defined as serum ETOH level >80. [2]Anticoagulation/antiplatelet—any patient taking antiplatelet therapy, warfarin, a direct oral anticoagulant, heparin, or enoxaparin; aspirin or NSAID use is NOT considered antiplatelet therapy. ASA, aspirin; fx, fracture; SDH, subdural hematoma; IPH, intraparenchymal hemorrhage; SAH, subarachnoid hemorrhage; IVH, intraventricular hemorrhage; NSAID, nonsteroidal anti-inflammatory.

reporting observational studies (Supplemental Digital Content, http://links.lww.com/TA/C460). Patients older than 15 years with an ICH or skull fracture on CT scan were classified as mBIG 1, 2, or 3 based on the modified Brain Injury Guidelines (Fig. 1). The mBIG 1 and 2 patients were then compared to a cohort from a previously published retrospective evaluation of the original Brian Injury Guidelines.[4] That retrospective analysis classified patients as BIG 1, 2, or 3 according to the BIG, based on the published criteria for those guidelines.[2,3] The mBIG 3 patients were excluded from further analysis as the care for these patients remained unchanged from the standard care at each institution prior to the initiation of the mBIG. Other exclusion criteria include intubation within the planned observation period (6 hours for mBIG 1, 24 hours for mBIG 2), previous operation on the brain or skull, penetrating injury, transfers from outside hospitals without available images, or patients who presented more than 48 hours from injury. Variables collected included demographics, mBIG classification, admission GCS score, admission neurological exam findings, blood alcohol level, anticoagulation or antiplatelet therapy, Injury Severity Score (ISS), type of ICH, number of head CTs, presence of neurosurgical consult, radiographic progression, change in neurological exam, neurosurgical interventions performed, hospital length of stay (LOS), ICU LOS (ICU LOS), discharge GCS score, and mortality. An abnormal neurological examination was defined as a GCS score of less than 13 or the presence of focal neurologic or abnormal pupillary findings on examination. Clinical progression was defined as a deterioration in neurologic or pupillary exam. Radiographic progression was defined as an increase in the size of the ICH on CT scan and was consistent between the two study groups.

Statistical Analysis

Categorical variables were compared using χ^2 test or Fisher's exact test where appropriate. Continuous variables were analyzed using the Student's *t* test or Wilcoxon rank sum test based on the distribution of the data. Multivariable analysis was not performed because of the low event rate. Statistical analysis was performed using SAS version 9.4 (SAS Institute, Cary, NC) with significance was established at a p value less than 0.05. Institutional review boards at each respective institution approved the study.

RESULTS

A total of 764 patients were included from the two study periods. During the 42-month prospective period after mBIG implementation, 496 patients were included. A total of 268 patients were included from the previous retrospective analysis as a comparison group. Overall, the mean age was 53.7 years (±20.9 years) and 44.0% of the patients were female. These findings were similar between the two groups. No differences were identified in ISS (12.2 [±6.7] vs. 11.9 [±6.8]) or admission GCS score (15 [14.5–15] vs. 15 [15–15]) between the post-mBIG implementation group and the preimplementation group. There were no differences seen in the rates of subdural hematoma (53.0% vs. 51.5%, p = 0.686), subarachnoid hemorrhage (SAH) (50.8% vs. 51.5%, p = 0.856), intraparenchymal hematoma (15.3% vs. 17.2%, p = 0.507), skull fracture (16.3% vs. 21.6%, p = 0.069), or midline shift (1.6% vs. 3.0%, p = 0.206) between the two groups (Table 1).

More patients qualified as mBIG 1 after the mBIG were implemented than were classified as BIG 1 in the preimplementation period (45.0% vs. 36.9%, p = 0.032). There were fewer epidural hematomas (EDHs) after the mBIG were implemented (0% vs. 2.6%, p = 0.0006). Fewer head CT scans (2 [1,2] vs. 2 [2,3], p < 0.0001) and neurosurgery consults (61.9% vs. 95.9%, p < 0.0001) were obtained in the post-mBIG implementation period. Both the hospital (2 [1,4] vs. 2 [2,4], p = 0.013) and ICU (0 [0,1] vs. 1 [1,2], p < 0.0001) LOS were shorter after mBIG implementation. No differences were seen in the rate of clinical (1.6% vs. 0.4%, p = 0.172) or radiographic progression

TABLE 1. Comparison of Patient Characteristics and Outcomes Before and After mBIG Implementation

	Total Study, N = 764	Pre-mBIG, Implementation, n = 268	Post-mBIG Implementation, n = 496	*p*
Age	53.7 (±20.9)	54.7 (±20.2)	59.1 (±15.5)	0.544
Female	44.0% (336)	44.4% (119)	43.8% (217)	0.086
BIG 1/mBIG 1	42.2% (322)	36.9% (99)	45.0% (223)	0.032
BIG 2/mBIG 2	57.9% (442)	63.1% (169)	55.0% (273)	0.032
EtOH Level	80.3 (±123.1)	86.7 (±128.5)	77.2 (±)	0.458
ISS	12.1 (±6.7)	11.9 (±6.8)	12.2 (±6.7)	0.630
ICU LOS	0 (0,2)	1 (0,2)	0 (0,1)	<0.0001
LOS	2 (1,4)	2 (2,4)	2 (1,4)	0.013
Admit GCS	15 (15,15)	15 (15,15)	15 (14.5,15)	0.746
D/C GCS	15 (15,15)	15 (15,15)	15 (15,15)	0.510
NSG Consult	73.8% (564)	95.9% (257)	61.9% (307)	<0.0001
OR NSG	0.5% (3)	1.1% (3)	0.2% (1)	0.127
Total Head CTs	2 (1,2)	2 (2,3)	2 (1,2)	<0.0001
SDH	52.5% (263)	51.5% (138)	53.0% (263)	0.686
SAH	51.1% (390)	51.5% (138)	50.8% (252)	0.856
EDH	0.9% (7)	2.6% (7)	0	0.0006
IPH	16.0% (122)	17.2% (46)	15.3% (76)	0.507
Skull Fx	18.2% (139)	21.6% (58)	16.3% (81)	0.069
Midline shift	2.1% (16)	3.0% (8)	1.6% (8)	0.206
Clinical Prog	1.2% (9)	0.4% (1)	1.6% (8)	0.172
Rad Prog	12.6% (71)	11.9% (30)	13.2% (41)	0.650
Mortality	0.1% (1)	0	0.2% (1)	0.999

EtOH, blood alcohol; D/C, discharge; NSG, neurosurgery; OR NSG, neurosurgery operation; Fx, fracture; Prog, progression; Rad, radiographic.

(13.2% vs. 11.9%, $p = 0.650$), neurosurgery operative intervention (0.2% vs. 1.1%, $p = 0.127$), or mortality (0.2% vs. 0%, $p = 0.999$) between the two groups (Table 1).

After the implementation of the mBIG, eight patients (1.6%), two mBIG 1 patients, and six mBIG 2 patients, had a deterioration in their neurological examination during the observation period. One mBIG 2 patient had a clinical and radiographic decompensation and required craniotomy. That patient was ultimately discharged from the hospital with a GCS score of 15. Another mBIG 2 patient worsened clinically and radiographically, but due to a pre-existing diagnosis of metastatic cancer, the family elected to pursue comfort measures and the patient subsequently died. The remaining six patients that clinically progressed did not have progression of their ICH on repeat head CT and were discharged with a GCS score 15 without needing neurosurgical intervention. Clinical progression in these patients was likely, at least in part, due to nontraumatic causes as they appeared to have delirium or alcohol withdrawal.

DISCUSSION

This study shows that the mBIGs are safe to implement. There was only one in-hospital mortality, which was in a patient whose family elected not to pursue operative intervention, although the utility of operative intervention for ICH is controversial.[13–16] One patient underwent surgical intervention and was discharged with a GCS score of 15. Most patients that had a change in neurological examination appeared to have nontraumatic reasons for altered mental status and did not have a progression of their ICH. The readmission rate in the post-mBIG implementation period was also low (3.2%). This rate is notably lower than the published readmission rate of 6.5% to 8.6% for trauma patients.[17,18] These findings show that the mBIGs do not pose an undue risk to patients who are treated by the algorithm. Preserving safety is paramount in instituting any new algorithm regarding TBI, as the ramifications of missed injury or delayed diagnosis can be catastrophic. The observation periods for mBIG 1 and mBIG 2 patients are adequate to ensure that patients are not subjected to potential missed injury or progression.

As the mBIGs are safe to implement, the next question that must be answered is if they are effective in improving resource utilization. After implementation, patients with small ICHs following TBI had shorter hospital and ICU LOS, fewer CT scans, and fewer neurosurgery consults after the mBIGs were implemented. This study shows that implementing the mBIG leads to an improvement in resource allocation for any institution that chooses to do so.

TBI is responsible for a substantial burden of resource utilization in the US. In 2017, TBI accounted for $92 billion in health care costs with 2.9 million emergency department visits, 224,000 hospital admissions, and 61,000 deaths due to TBI. The rate of admission for TBI is highest in patients greater than 55 years old and the rate of hospitalization increases with age. Individuals aged 55 years to 64 years had an admission rate of 67.5/100,000 in 2017, those 65 years to 74 years had a hospitalization rate of 102.7/100,000, and adults 75 years or older had a TBI related admission rate of 320.8/100,000.[1] As the population continues to age, TBI patients are expected to consume an increasing quantity of health care resources. The COVID-19 pandemic has posed an unprecedented burden on the health care system. Resources that previously had been readily available, and at times were taken for granted, became scarce and hard to come by.[19,20] This has forced a reexamination of many practice patterns to ascertain the true utility of many tests and interventions that are commonly ordered. Traumatic brain injury consumes such a vast quantity of health care resources that a reevaluation of common practice patterns surrounding TBI is warranted. The mBIGs offer a proven framework that institutions can use to improve resource allocation, and thereby free up hospital and ICU beds, CT scanners, and consultants for patients that are more likely to benefit from those resources.

The management of patients suffering from TBI with ICH is far from standardized. The traditional model mandates repeat head CT scans, neurosurgery consults, and hospital admissions, often to the ICU, for all patients with ICH. The debate over whether all patients with an ICH require a repeat head CT has been present for some time, but there is no consensus on which patients need repeat scans and those that do not.[5–8] Likewise, controversy exists as to whether a neurosurgical consultation is required for all TBI patients.[9–11] Clarity regarding the optimum method for deciding which patients benefit from repeat head CTs and neurosurgery consults was needed.

In 2013, Joseph et al.[2,3] introduced the BIG and subsequently published a single center prospective validation of the guidelines in 2014. Those studies represented the first comprehensive strategy for improving resource utilization in TBI with ICH. This innovative work represented a departure from the standard treatment at most centers and laid the groundwork to improve the quantity of resources used in TBI.

The BIG are not perfect, however. A multicenter retrospective assessment found that improvements were needed to ensure patient safety and to clarify several aspects of the BIG to allow them to be consistently reproduced.[4] The mBIGs were created to accomplish both of these tasks. In order to improve patient safety, all EDHs are characterized as mBIG 3 under the modified guidelines. The mBIGs were found to be safe in patients with concomitant injuries and, unlike the BIG, the mBIGs are not limited to patients with isolated neurological injuries. The algorithm is applied to patients with additional injuries provided they have a reliable neurologic examination. This requires additional considerations for patients that would otherwise qualify as mBIG 1 or 2. Patients who are intubated, such as for an orthopedic procedure, or whose neurological examination cannot be reliably assessed during the entire observation period (6 hours for mBIG 1, 24 hours for mBIG 2) are upgraded to mBIG 3. The inclusion of patients with non-neurologic injuries likely dampened the improvement in LOS that would have been seen if only isolated TBI patients were included, since these other injuries may have required hospitalization. By applying the guidelines to patients with additional injuries, the mBIG can be used for a larger cohort of patients. Although the resource savings may be more modest per patient, applying the guidelines to more patients will lead to a larger total improvement in resource utilization.

There are several aspects of the original BIG that make reproducing the guidelines across multiple institutions challenging.[2,3] First, the characterization of SAH as trace, localized, and scattered do not adhere to any accepted radiographic definition for SAH and would be left up to interpretation that may vary widely between providers or institutions. The mBIGs classify SAH based on the number of involved sulci and hemispheres, as well as by measurement of the thickness of the SAH. Intoxication is not defined in the original guidelines. As alcohol is the only intoxicant for which there is a readily available and accurate test for acute intoxication, the mBIGs define intoxication as an alcohol level greater than 80 mg/dL (Fig. 1).

Although the observation plan for BIG 1 patients is clear in the original BIG, the only criterion stated as a requirement for discharge is that there is no deterioration in neurologic examination. This suggests that a patient can be discharged with a GCS score of 13 if that was the presenting GCS, even if that is not the patient's baseline GCS. Under the mBIGs, patients must have a GCS 15, or be at their previous baseline for GCS in order to be discharged. This ensures a safer discharge and also prevents a patient from being discharged while still severely intoxicated from an unmeasurable substance. The treatment algorithm for BIG 2 patients is much less clear than for BIG 1 in the original guidelines. The mBIGs clarify that mBIG 2 patients are admitted to the floor for a 24-hour observation period. As in the original guidelines, if there is any change in neurologic examination for an mBIG 1 or 2 patient, that patient is upgraded to the mBIG 3 treatment arm with a repeat head CT and a neurosurgery consult.

The original BIG do not address direct oral anticoagulant (DOAC) medications that have become more ubiquitous in recent years for patients requiring long term anticoagulation. Although the risk for patients with ICH taking DOACs may not be as significant as with other anticoagulant medications, the mBIGs include DOAC use as a criterion for classification as mBIG 3.[21–23] Recent studies, including one specifically looking at mBIG 1 and 2 patients, do not show an increased risk for ICH progression with aspirin use.[24–26] As a result, aspirin use, including both 81 mg and 325 mg, is no longer a reason to designate a patient as mBIG 3. The current study saw a higher rate of mBIG patients than the rate of BIG 1 patients seen in the retrospective study. The removal of aspirin is likely the reason for this finding.

The current study shows that the modifications made to the original BIG under the mBIGs are safe and effective. Attempts to validate and implement the BIG are *also* an ongoing effort. Two presentations at the 2021 meeting of the American Association for the Surgery of Trauma (AAST) in Atlanta addressed the BIG. The first was a AAST multi-institutional trial validating the BIG by Joseph et al. (Joseph B et al. & the AAST BIG Multi-Institutional Group. Abstract Presented at the 2021 AAST Annual Meeting, Atlanta, GA. September 29, 2021). That trial found the BIG to be safe, but unlike the current study, did not directly compare changes in resource utilization. The AAST trial found a lower rate of radiographic progression (1.3% for BIG 1 and 7.1% for BIG 2) than the current study did (12.6%). That study likewise showed a lower rate of clinical progression than the current study (0% for BIG 1 and 0.7% for BIG 2 vs. 1.2% in the current study). Overall, that multicenter validation found the BIG to be safe, like the current study's findings regarding the mBIGs, although the two guidelines are not identical, and the patients are different between the two studies. An additional difference between these two studies is that the BIG were not actually implemented in that prospective observational study, unlike the current study where the guidelines were implemented and then assessed. A second study presented at the 2021 AAST meeting evaluated the BIG after implementation. Kuruvilla et al. implemented the BIG and compared resource utilization before and after implementation. (Kuruvilla K, et al. Abstract Presented at the 2021 AAST Annual Meeting, Atlanta, GA. 9/29/2021) Similar to the current study, they found a decrease in the rate of repeat head CT, rate of neurosurgery consult, and ICU LOS. That study highlights one of the difficulties also observed in the current study. Although both studies found a decrease in the number of CT scans and neurosurgery consults obtained, the numbers were not as low as would be expected if the guidelines were rigorously implemented. Any change in practice pattern takes time to implement. As these institutions gain experience with the BIG and mBIGs, improvements in resource utilization should continue materialize.

As experience with the mBIGs grows, the next step in realizing the full potential of the guidelines is to use them outside of the setting of a Level I trauma center. The COVID pandemic has burdened the health care system in many ways, but one of the most tangible effects has been on bed capacity. This is particularly true of larger tertiary referral centers where Level I trauma centers are usually found. Currently, most smaller hospitals and lower level trauma centers will transfer patients with any ICH to a Level I trauma center. For patients classified as mBIG 1 or 2, these transfers consume far more resources than the disease process warrants. These patients take up valuable hospital beds at the referral hospital that would be better saved for patients that are more in need of tertiary referral center resources. Transport of these patients can also use a variety of resources in short supply, including flight teams, critical care transport, and other resources best reserved for other patients. If the mBIGs can be implemented at smaller referring centers, valuable resources can be redirected toward patients who may benefit more from those resources. Although there will be trepidation in keeping patients with ICH further from neurosurgery coverage, the potential benefit in resource conservation is too great to ignore.

The current study must be viewed in light of some limitations. As a combined retrospective and prospective cohort study using institutional databases, all the inherent limitations of database studies need to be recognized. As a multicenter trial, differences in practice patterns between the institutions may have confounded some of the findings. In addition, analysis for clustering was not performed due to the low event rate and lack of multivariable analysis. The comparison group comes from a previous retrospective assessment of the BIG and only 2 of the 3 institutions that participated in the original study made up the 3 institutions participating in this trial. Differences in patient populations and practice patterns between the third institution that participated in the original assessment and the third institution in this study may have had unintended consequences. As these guidelines were new and introduced at 3 different institutions, compliance with all aspects of the guidelines was variable over time and across the institutions. Information on hospital costs for testing was not available for these institutions. Ideally, a true assessment of cost could also be made to find the true monetary savings realized by implementation of the mBIGs. Finally, multivariable analysis with adjustment for confounders was not performed due to the low event rate.

CONCLUSION

The mBIGs provide an algorithm by which some TBI with small ICH can be managed using fewer resources. These guidelines are shown to be safe in this multicenter trial. Under the mBIG, hospital and ICU LOS were shorter and fewer CT scans and neurosurgery consults were obtained. These resources were made available to be used by other patients. Institutions that adopt the mBIGs can expect to enjoy similar improvements in resource utilization while maintaining patient safety.

AUTHORSHIP

A.D.K., R.C.MI., R.P.G., T.J.S. participated in the study design. A.D.K., J.L., K.G., J.D.B., V.D., P.P.P. participated in the literature search. A.D.K., J.L., K.G., J.D.B., V.D., P.P.P. participated in the data collection. A.D.K., R.C.MI., R.P.G., T.J.S. participated in the data analysis/interpretation. A.D.K. participated in the drafting of the article. A.D.K., J.L., K.G., J.D.B., V.D., P.P.P., R.C.MI., R.P.G., T.J.S. participated in the critical revision. A.D.K., J.L., K.G., J.D.B., V.D., P.P.P., R.C.MI., R.P.G., T.J.S. participated in the final approval.

DISCLOSURE

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