The BIG (brain injury guidelines) project: Defining the management of traumatic brain injury by acute care surgeons

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BACKGROUND: It is becoming a standard practice that any "positive" identification of a radiographic intracranial injury requires transfer of the patient to a trauma center for observation and repeat head computed tomography (RHCT). The purpose of this study was to define guidelines—based on each patient's history, physical examination, and initial head CT findings—regarding which patients require a period of observation, RHCT, or neurosurgical consultation.

METHODS: In our retrospective cohort analysis, we reviewed the records of 3,803 blunt traumatic brain injury patients during a 4-year period. We classified patients according to neurologic examination results, use of intoxicants, anticoagulation status, and initial head CT findings. We then developed brain injury guidelines (BIG) based on the individual patient's need for observation or hospitalization, RHCT, or neurosurgical consultation.

RESULTS: A total of 1,232 patients had an abnormal head CT finding. In the BIG 1 category, no patients worsened clinically or radiographically or required any intervention. BIG 2 category had radiographic worsening in 2.6% of the patients. All patients who required neurosurgical intervention (13%) were in BIG 3. There was excellent agreement between assigned BIG and verified BIG. κ statistic is equal to 0.98.

CONCLUSION: We have proposed BIG based on patient's history, neurologic examination, and findings of initial head CT scan. These guidelines must be used as supplement to good clinical examination while managing patients with traumatic brain injury. Prospective validation of the BIG is warranted before its widespread implementation. (*J Trauma Acute Care Surg*. 2014;76: 965–969. Copyright © 2014 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Epidemiologic study, level III.

KEY WORDS: Traumatic brain injury; guidelines for management of traumatic brain injury; neurosurgical consultation; acute care surgeons; repeat head computed tomography.

According to the US Centers for Disease Control and Prevention, the incidence of traumatic brain injury (TBI)–related emergency department visits and hospitalization has increased by 20%.[1,2] TBI is an important clinical entity without well-defined guidelines for nonoperative management.[3]

Acute care surgeons form an integral component in the nonoperative management of TBI; however, their exact role has not been defined.[4,5] As computed tomography (CT) technology continues to improve, more minor intracranial injuries are being identified, resulting in an increased use of health care resources.[4–6] It is becoming standard practice that any "positive" identification of a radiographic intracranial injury requires transfer of the patient to a trauma center for observation and a repeat head CT (RHCT) scan. Studies have highlighted the role of mechanism of injury, age, coagulopathy on admission, severity of TBI, and hypotension as predictors of progression of intracranial hemorrhage (ICH). [5–11] However, at present, no comprehensive guidelines for the management of TBI based on history, physical examination, and radiographic findings exist.[11]

The aim of this study was to define guidelines—based on patient's history, physical examination, and initial head CT findings—regarding which patients require a period of observation, RHCT, or neurosurgical consultation (NSC).

PATIENTS AND METHODS

After approval from the institutional review board at the University of Arizona, College of Medicine, we performed a 3-year (2009–2011) retrospective cohort analysis of 3,803 blunt TBI patients presenting at our level 1 trauma center. All TBI patients with positive initial head CT findings were included in our analysis. Patients transferred from other institutions and patients requiring emergent surgical intervention were excluded from our study. Positive CT findings were defined by the presence of skull fracture and/or ICH.

Data Collection

We reviewed patient's medical records for patient demographics (age and sex), patient's medication history (antiplatelet and anticoagulation therapy), vitals on presentation, Glasgow

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Coma Scale (GCS) score on presentation, intoxication (alcohol use), mechanism of injury, neurologic examination on presentation, findings of initial and RHCT scan, need for NSC, neurosurgical interventions, as well as hospital and intensive care unit (ICU) length of stay. The Injury Severity Score (ISS) and head Abbreviated Injury Scale (h-AIS) score were obtained from the trauma registry.

The initial head CT and RHCT scans were all reviewed by a single investigator to confirm the presence, type, and size of hemorrhage and/or skull fracture.

Progression on RHCT was defined as an increase in the size of previous ICH or the development of a new ICH. We defined abnormal neurologic examination result as focal neurologic examination, abnormal pupillary examination result, and GCS score of 12 or less. Neurosurgical intervention was defined as craniotomy, craniectomy, and/or extraventricular drain (EVD) placement.

Development of Brain Injury Guidelines

The brain injury guidelines (BIG) consisted of three categories as follows: BIG 1, BIG 2, and BIG 3 (Fig. 1). We reviewed 3,803 patient charts and then categorized each patient meeting inclusion criteria into one of the three BIG categories based on the patient's history (antiplatelet/ anticoagulation therapy, loss of consciousness, intoxication), physical examination (focal neurologic examination, pupillary examination, and GCS on admission), and CT scan findings (size and location of ICH and type of skull fracture). We defined a definitive therapeutic management plan for each category based on the requirements of hospitalization, need for an RHCT scan, and need for an NSC. The therapeutic plan for each category was developed after consensus among acute care surgeons and neurosurgeons at our institution based on the published literature defining the management of TBI. It is important to note that patients had to meet all the criteria for categorization into one of the three BIG categories. Failure to meet even one criterion (in BIG 1 or BIG 2) upgraded the patient to the BIG 3 category and altered the therapeutic management plan of the patient based on the BIG 3 category.

Patients categorized as BIG 1 (minor head injury) had a normal neurologic examination finding, were not on any antiplatelet or anticoagulation medications, and had minuscule findings on initial head CT scan (ICH $\leq$ 4 mm and no skull fracture). The management of these patients with minor head injury without the need for NSC has been well defined.[12] We proposed a period of observation (6 hours) for patients categorized as BIG 1 without the need for NSC or an RHCT scan.

Patients categorized as BIG 3 had severe head injury, and the optimal therapeutic plan for these patients consisted of hospitalization, an NSC, and a follow-up RHCT. Patients categorized as BIG 3 were on antiplatelet or anticoagulation medications, had an abnormal neurologic examination finding, and concerning CT scan findings (displaced skull fractures, and diffused ICH $\geq$ 8 mm). Nonexaminable patients, intubated patients, and patients with more than one CT scan finding were also categorized as BIG 3.

The BIG 2 category was composed of the moderately injured patients with a nondisplaced skull fracture and a localized ICH of 7 mm or less. Studies have shown that neurosurgical examination is a critical tool in assessing the need for

Brain Injury Guidelines			
Variables	**BIG 1**	**BIG 2**	**BIG 3**
LOC	Yes/No	Yes/No	Yes/No
Neurologic examination	Normal	Normal	Abnormal
Intoxication	No	No/Yes	No/Yes
CAMP	No	No	Yes
Skull Fracture	No	Non-displaced	Displaced
SDH	$\leq$ 4mm	5 - 7 mm	$\geq$ 8 mm
EDH	$\leq$ 4mm	5 - 7 mm	$\geq$ 8 mm
IPH	$\leq$ 4mm, 1 location	3 – 7 mm, 2 locations	$\geq$ 8 mm, multiple locations
SAH	Trace	Localized	Scattered
IVH	No	No	Yes
THERAPEUTIC PLAN			
Hospitalization	No Observation (6hrs)	Yes	Yes
RHCT	No	No	Yes
NSC	No	No	Yes

BIG, brain injury guidelines; CAMP, Coumadin, Aspirin, Plavix; EDH, epidural hemorrhage; IVH, intraventricular hemorrhage; IPH, intraparenchymal hemorrhage; LOC, loss of consciousness; NSC, neurosurgical consultation; RHCT, repeat head computed tomography; SAH, subarachnoid hemorrhage; SDH, subdural hemorrhage

Figure 1. BIG. *CAMP*, coumadin, aspirin, plavix; *EDH*, epidural hemorrhage; *IPH*, intraparenchymal hemorrhage; *IVH*, intraventricular hemorrhage; *LOC*, loss of consciousness; *SAH*, subarachnoid hemorrhage; *SDH*, subdural hemorrhage.

TABLE 1. Patient Demographics

	BIG 1 (n = 121)	BIG 2 (n = 313)	BIG 3 (n = 798)
Age, mean (SD), y	43.1 (22.3)	35.5 (25.1)	46.5 (26.4)
Male, %	57	66	68
Antiplatelets, %			
Aspirin	Nil	Nil	15
Clopidogrel	Nil	Nil	3.4
Ibuprofen	Nil	Nil	2.5
Anticoagulants	Nil	Nil	3.9
Intoxication	Nil	30	26
GCS score	15 (15–15)	15 (15–15)	15 (7–15)
Abnormal neurologic examination finding, %	Nil	Nil	23
Loss of consciousness, %	68	50	65
ISS	12 (10–18)	16 (10–18)	18 (14–25)
Head AIS score	2 (2–3)	3 (2–3)	3 (3–4)

neurosurgical intervention in TBI patient with moderate head injury.[13] In addition, patients with progression on RHCT without clinical deterioration do not require a neurosurgical intervention. We recommended management of these patients with in-hospital admission, without the need for an NSC, and without an RHCT. It is important to note that we had safety net in place within our BIG guidelines. Patients who had a neurologic deterioration, irrespective of their initial categorization (BIG 1 or BIG 2), were upgraded to BIG 3 and followed the therapeutic plan based on the BIG 3 category.

Guideline Versus Actual Therapeutic Plan

After categorization of the patients into BIG 1, BIG 2, or BIG 3, the patients had to follow a guideline therapeutic plan based on the BIG category. This guideline therapeutic plan was then compared with the actual hospital course of the patient; which we defined as the actual therapeutic plan. Failure of guideline therapeutic plan was when the patient's actual hospital course deviated from the guideline-based therapeutic plan.

Statistical Analysis

Data are reported as mean (SD) for continuous descriptive variables, median (range) for ordinal descriptive variables, and as proportions for categorical variables. We used Cohen's κ statistics to assess agreement between the guideline therapeutic plan and the actual therapeutic plan. κ values greater than 0.75 indicates high agreement. For all of our statistical analyses, we used STATA Data Analysis and Statistical Software version 11.0 (College Station, TX).

TABLE 2. Initial Head CT Findings

	BIG 1 (n = 121)	BIG 2 (n = 313)	BIG 3 (n = 798)
Skull fracture, %			
Nondisplaced	Nil	41.2	12.5
Displaced	Nil	Nil	39.5
ICH, %			
SDH	34.7	29	48.4
EDH	1	5.4	11.5
SAH	47	42	52.4
IPH/contusion	19	20	47
IVH	Nil	Nil	10.7

EDH, epidural hemorrhage; IPH, intraparenchymal hemorrhage; IVH, intraventricular hemorrhage; SAH, subarachnoid hemorrhage; SDH, subdural hemorrhage.

TABLE 3. RHCT Findings

	BIG 1 (n = 121)	BIG 2 (n = 313)	BIG 3 (n = 798)
Progression on RHCT with neurologic deterioration, %	Nil	Nil	4.2
Progression on RHCT, %	Nil	2.6	21.6
New management per RHCT, %			
Craniectomy	Nil	Nil	1.6
EVD	Nil	Nil	1.4

RESULTS

A total of 3,803 patients with TBI were evaluated, of whom, 1,232 patients with positive head CT scan findings were included. These patients were then divided into one of the three BIG categories; BIG 1 (n = 121), BIG 2 (n = 313), and BIG 3 (n = 798). Table 1 highlights the demographics of the study population.

Subarachnoid hemorrhage, followed by subdural hemorrhage, was the most common type of ICH in all the three BIG categories. Table 2 highlights the findings on initial head CT.

Table 3 demonstrates the findings of RHCT. Seventy-two percent of the patients (888 of 1,232) received an RHCT. No patient in BIG 1 category had worsening finding on RHCT or clinical deterioration prompting the need for RHCT. Worsening on RHCT was seen in 2.6% of the patients in BIG 2; however, none required neurosurgical intervention. Of the patients in BIG 3, 21.6% had worsening finding on RHCT, with subsequent neurosurgical intervention in 3%. For our entire study population, the rate of neurosurgical intervention was 13% (n = 159) (craniectomy/craniotomy in 109 patients; EVD in 50 patients). All these patients met BIG 3 category criteria.

All patients categorized as BIG 1 and BIG 3 were consistent with the BIG. Nine patients categorized as BIG 2 were not in concordance with the established BIG 2. Table 4 describes in detail the 9 patients who failed the BIG 2 criteria. Seven patients had no change in neurologic examination and failed because of progression on RHCT. The remaining two patients had worsening finding on clinical examination, resulting in an upgrade of the patient to BIG 3 classification. The agreement between assigned and verified BIG categories was excellent (κ = 0.98; 95% confidence interval, 0.97–0.99; Table 5).

DISCUSSION

The current standard of practice for the management of nonoperative TBI is variable and has not adapted to the new defined role of the acute care surgeons. In this study, we have defined guidelines for the management of TBI based on clinical and radiologic findings and developed a therapeutic management plan based on the need for hospitalization, NSC, and RHCT. If our BIG had been followed, 342 RHCT scans, 121

TABLE 4. Nine Patients Not Meeting BIG 2 Criteria*

Patient Number	Age, y	CAMP	Neurologic Examination on Presentation	ICH	Reason for the RHCT	Worsening RHCT	Worsening Status	Neurosurgical Intervention
1	48	No	Normal	IPH, localized	Routine	Yes	New SAH	No
2	82	No	Normal	SDH, 5 mm	Routine	Yes	New SAH	No
3	43	No	Normal	IPH, localized	Routine	Yes	Larger IPH (15 mm)	No
4	21	No	Normal	IPH, localized	Routine	Yes	Diffuse IPH	No
5	14	No	Normal	IPH, localized; SDH, 4 mm	Neurodecline	Yes	Larger SDH (8.5 mm)	No
6	95	No	Normal	IPH, localized; SAH, 2 mm	Routine	Yes	Larger SAH (7 mm)	No
7	95	No	Normal	IPH, localized; SAH, 2 mm	Neurodecline	Yes	Larger SAH (8 mm)	No
8	75	No	Normal	IPH, localized; SDH, 5 mm	Routine	Yes	New SAH	No
9	22	No	Normal	IPH, localized	Routine	Yes	Diffuse IPH	No

*All these 9 patients were assigned to the BIG 2 category.
CAMP, coumadin, aspirin, plavix, motrin; IPH, intraparenchymal hemorrhage; SAH, subarachnoid hemorrhage; SDH, subdural hemorrhage.

inpatient hospital admissions, and 434 NSCs could have been avoided. The guidelines establish a clear therapeutic plan for the acute management of TBI at a Level 1 institution.

Because of the advancements in CT technology, many head trauma patients present to our trauma centers with minuscule findings on head CT. The clinical significance of these minuscule findings is unknown. Several studies have questioned the need for routine RHCT scanning in the absence of abnormal neurologic examination findings. [14–20] We believe that head injury patients should undergo RHCT only as a result of neurologic deterioration or anticoagulation or antiplatelet status because these patients are more likely to need a subsequent change in the management based on the findings of RHCT. Of the nine patients who failed BIG 2 criteria, seven were caused by findings of worsening on routine RHCT; however, it is worth mentioning that the failure was related to radiographic findings and not neurologic deterioration. The remaining two patients who failed BIG 2 did have a worsening neurologic examination finding prompting an RHCT. However, based on abnormal neurologic examination finding itself, they would have been categorized as BIG 3, resulting in an NSC. It is important to note that none of the patients who failed BIG 2 required a neurosurgical intervention.

The current standard practice of consulting neurosurgery for traumatic ICH patients is changing. The concept of managing TBI without NSC has been supported by many investigators. Rhodes et al.[11] developed NSC criteria, concluding that patients with a nondepressed skull fracture, a 3-mm ICH, and/or solitary contusions do not require urgent NSC. Similarly; Huynh et al.[4] concluded that solitary contusions less than 5 mm in diameter or subdural hematomas less than or equal to 4 mm thick, are clinically "irrelevant" and can be managed without NSC. Similarly, in a retrospective analysis of all mild TBI patients presenting at our trauma center, we found that patients cared for by our acute care surgery team without NSC were less likely to be admitted to an ICU and less likely to need routine RHCT, hence saving valuable resources.[12] The key and most important factor in fact is not only the size but also the associated factors such as neurologic examination and anticoagulants or antiplatelets status.

As a result of many factors, the availability of neurosurgeons to care for trauma patients is increasingly decreasing. Second, there is a "functional lack" in neurosurgeons covering for trauma patients.[21,22] In a 2007 survey of members of the American Association of Neurological Surgeons, more than half of the respondents (52%) preferred not to care for trauma patients.[18]

Acute care surgeons are an integral part of the management of mild TBI patients as approximately 99% of the patients with mild TBI are routinely managed nonoperatively.[5,12,20] In our study, no patient underwent a neurosurgical intervention based on progression on RHCT in the absence of an abnormal neurologic examination result. We believe that an acute care surgeon can safely and appropriately monitor patients in BIG 1 or BIG 2 for neurologic decline and need for NSC.[20] Clearly, mandatory NSC and routine RHCT can be defined as defensive medicine to avoid malpractice suits.

We established the BIG criteria in a conservative manner understanding this is a dramatic change in today's practice. Our institution has adopted this practice and is moving forward with verifying these guidelines prospectively. It is important to prospectively validate our guidelines before the implementation of these guidelines in nontrauma and rural hospitals.

We have found that our BIG system is relatively easy to implement clinically and helps us achieve our "best practice" goals. We accept that the BIG 2 category may be controversial; however, sufficient evidence already exists to support our BIG 1 category. Again, we emphasize the importance of clinical examination and the role of acute care surgeons in early clinical decisions. Even if only the BIG 1 category were to be applied, hospital and ICU admission rates would decline, the use of unnecessary RHCT would decrease, and the burden of trauma on our neurosurgical colleagues would be eased.

TABLE 5. Agreement Between Guideline and Therapeutic Plan

	Verified Therapeutic Plan		
Guideline Therapeutic Plan	BIG 1	BIG 2	BIG 3
BIG 1	121	0	0
BIG 2	0	304	9
BIG 3	0	0	798

$\kappa = 0.97$; 95% confidence interval, 0.97 to 0.99

Our study comes with the inherent limitations of a retrospective study design, and a prospective validation of these guidelines is required before expanding the scope of its implementation. Second, we did not assess for long-term outcomes in patients included in our study. Third, there was no set protocol for the management of patients without neurosurgeons. Despite these limitations, our study defines guidelines for the acute management of TBI.

CONCLUSION

We have proposed BIG based on patient's history, neurologic examination, and findings of initial head CT scan. Our guidelines emphasize the importance of using both clinical and radiographic findings for managing patients with TBI. These guidelines must be used as supplement to good clinical examination while managing patients with TBI. The adoption of BIG reserves health care resources for patients who actually need them. Prospective validation of the BIG is warranted before its widespread implementation.

AUTHORSHIP

B.J., R.S.F., M.S. and P.R. designed this study. B.J., M.S., H.A., N.K., V.P. and R.S.F. searched the literature. B.J., M.S., H.A., V.P., A.T., J.W., and T.O. collected the data. B.J., R.S.F., M.S., H.A., V.P., N.K., and T.O. analyzed the data. All other authors participated in the data interpretation and manuscript preparation

DISCLOSURE

The authors declare no conflicts of interest.

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