

Evaluation of Prognosis of Coma Patients With Acute Brain Injury by Electroencephalogram Bispectral Index Monitoring

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ABSTRACT

Background: The high mortality rate of comatose patients with traumatic brain injury is a prominent public health issue that negatively impacts patients and their families. Objective, reliable tools are needed to guide treatment decisions and prioritize resources.

Objective: This study aimed to evaluate the prognostic value of the bispectral index (BIS) in comatose patients with severe brain injury.

Methods: This was a retrospective cohort study of 84 patients with severe brain injury and Glasgow Coma Scale (GCS) scores of 8 and less treated from January 2015 to June 2017. Sedatives were withheld at least 24 hr before BIS scoring. The BIS value, GCS scores, and Full Outline of UnResponsiveness (FOUR) were monitored hourly for 48 hr. Based on the Glasgow Outcome Scale (GOS) score, the patients were divided into poor (GOS score: 1–2) and good prognosis groups (GOS score: 3–5). The correlation between BIS and prognosis was analyzed by logistic

regression, and the receiver operating characteristic curves were plotted.

Results: The mean (SD) of the BIS value: 54.63 (11.76), $p = .000$; and GCS score: 5.76 (1.87), $p = .000$, were higher in the good prognosis group than in the poor prognosis group. Lower BIS values and GCS scores were correlated with poorer prognosis. Based on the area under the curve of receiver operating characteristic curves, the optimal diagnostic cutoff value of the BIS was 43.6, and the associated sensitivity and specificity were 85.4% and 74.4%, respectively.

Conclusion: Taken together, our study indicates that BIS had good predictive value on prognosis. These findings suggested that BIS could be used to evaluate the severity and prognosis of severe brain injury.

Key Words

Bispectral Index, Brain injury, Full Outline of UnResponsiveness, Glasgow Coma Scale, Glasgow Outcome Scale, Prognosis

The high mortality rate of comatose patients with severe brain injury, especially traumatic brain injury (TBI), is a prominent public health issue that negatively impacts patients and their families (Khellaf, Khan, & Helmy, 2019). Objective, reliable tools are needed to guide treatment and prioritize medical

resources to minimize the health care burden, reduce patient suffering, and enable peaceful end-of-life care. Hence, early multimodal assessment of comatose patients with severe brain injury (Chen et al., 2018) is critical to judging the prognosis and deciding the treatment (Ho, 2018).

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All procedures were reviewed and approved by the Ethics Review Committee of the 904 Hospital of PLA. All patients' families gave informed consent to the study. This study had been registered on the Chinese Clinical Trial Register (ChiCTR2000031545).

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responsible for the literature research and statistical analysis; D.C.X. is responsible for the clinical studies; J.J.L. is responsible for the experimental studies and data analysis; and J.H.C. is responsible for the guarantor of integrity of the entire study and manuscript review. All authors read and approved the final manuscript.

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Coma scales are used for consciousness assessment in brain injury. The Glasgow Coma Scale (GCS) is the most commonly utilized in clinical trials. Owing to its merits of convenience and ease of use, GCS has been widely used to assess the depth of coma in brain injury since 1974 (Teasdale & Jennett 1974). However, its accuracy and reliability are often influenced by other factors, including evaluator subjectivity, sedative drugs, and the presence of an artificial airway (Teasdale et al., 2014).

The Full Outline of UnResponsiveness (FOUR) covers the weakness of GCS for the inability to assess language function and lack of brain stem reflex in patients with an artificial airway (Wijdicks, Bamlet, Maramattom, Manno, & McClelland, 2005). It also assesses eye-opening, eye tracking, and blinking, which are helpful to identify specific states of consciousness, including atresia syndrome and vegetative state. The FOUR uses scoring from 0 to 16 and consists of four subscales: eye movement, motor response, brain stem reflex, and respiratory type. The lower the score, the more severe the consciousness disturbance. The FOUR is considered an alternative to the GCS to evaluate consciousness in TBI (Gao et al., 2009).

Bispectral index (BIS) monitoring, a new neuroelectrophysiological technology, is a quantified continuous electroencephalogram (EEG)-monitoring technique. It has historically been used to monitor the depth of anesthesia and sedation during operations. The BIS is based on a composite of measures from EEG signals, including parameters calculated by analyzing the time domain, frequency domain, and high-order spectral subparameters. The BIS monitor provides a single number that ranges from 0 to 100.

When the patient is awake, the value is from 90 to 100, and during rapid eye movement sleep, the BIS value fluctuates between 75 and 92 (Mahmood et al., 2014). A BIS value between 70 and 80 indicates that the patient is in mild to moderate sedation, that is, patients respond to loud calls, mild pain stimulus, or shaking. A BIS value between 60 and 70 indicates deep sedation, and a number between 40 and 60 suggests routine anesthesia. When the value is below 40, the patient is in a deep hypnotic state, and a BIS value of 0 suggests no EEG activity (Medical Advisory Secretariat, 2004).

The BIS is closely related to the EEG, which reflects the functional state of the cerebral cortex and is intuitive, sensitive, and objective in assessing the state of consciousness (Bigham, Bigham, & Jones, 2012; Duarte & Saraiva, 2009; Yang, Ge, Wang, & Wu, 2011). Studies report that BIS has advantages in predicting the prognosis of TBI comatose patients in the matter of specificity, sensitivity, and accuracy (Dou, Gao, Lu, & Chang, 2014). However, the accuracy of BIS in reflecting the depth of sedation and consciousness level is still not well validated (Mahmood et al., 2014; Medical Advisory Secretariat, 2004).

OBJECTIVE

This study aimed to evaluate the prognostic value of the BIS in comatose patients with severe brain injury.

METHODS

Patients

In this retrospective cohort study, data were collected from patients' medical records admitted from January 2015 to June 2017. Inclusion criteria include (a) clinical diagnosis of severe brain injury resulting from various causes such as trauma, cerebral vascular disease, cerebrovascular malformation, brain tumor, and (b) unconscious and unable to respond to verbal commands with GCS scores of 8 and less. Exclusion criteria were as follows: (a) patients with nonintact skin preventing sensor attachment; (b) past diagnosis of dementia; (c) patients with severe psychiatric symptoms unable to tolerate BIS sensors; and (d) continuous monitoring time of less than 24 hr. All procedures were reviewed and approved by the hospital ethics review committee. All patients' families gave informed consent to the study.

BIS Monitoring

All patients included in the study were evaluated for GCS, FOUR scales with concurrent continuous BIS monitoring for 48 hr. The noninvasive, Mindray BeneView T 8 quantitative Electroencephalogram (Mindray Biomedical Electronics, China) monitor with BIS module was used (Lopez et al., 2017). A four-electrode BIS sensor (Covidien, Boulder, CO) was attached to the forehead of the healthier brain hemisphere, as located by computed tomographic scan. The first electrode was placed at the center of the forehead, approximately 5 cm above the bridge of the nose, and the second at the inferolateral side to the first. The third electrode was placed over the temporal region behind the lateral canthus and the fourth directly above and adjacent to the eyebrow. The signal quality index was calculated by the BIS monitor based on impedance data, artifacts, and other variables. It was displayed in the form of a bar graph. Patient care such as suction, chest percussion, or turning was avoided for 5 min before the BIS value was recorded to avoid interference with the BIS value. The BIS level was recorded hourly for 48 hr while the signal quality index was 80% and more and the electromyography was 40 and less. Afterward, the mean of the BIS index was calculated.

Meanwhile, the neurologists evaluated the GCS and FOUR scores hourly for 48 hr, and the mean of GCS and FOUR scores was counted, respectively. We recorded whether the patients underwent surgery or whether they had a cerebral hernia or not. The patients were followed up for 6 months after the injury or until they were deceased. Consciousness recovery was evaluated by measuring an individual patient's ability to respond to

verbal commands, independent of the degree of disability. The Glasgow Outcome Scale (GOS) score was used to define neurological status at the end of the follow-up period. Two groups were identified: poor prognosis (GOS scores of 1–2) and good prognosis (GOS scores of 3–5).

Glasgow Outcome Scale Score

The GOS score is routinely used to evaluate the state of consciousness of patients with brain injury. However, this score is easily affected by the subjectivity of the evaluator, especially in intubated patient situations. The GOS is used to judge the prognosis of patients. For surviving patients, the GOS was evaluated 6 months after the onset of the disease. The GOS uses a 5-point scoring system. Five points is good recovery with return to normal life, despite mild defects. Four points is mild disability, disabled but able to live independently and work under protection. Three points is severe disability, needing care in daily life. Two points is considered survival with only minimal response (e.g., eyes open with sleep or wake cycle), and one point is death.

Statistical Analysis

Statistical data analysis was performed with SPSS version 24 (IBM, Armonk, NY). Data were expressed as mean (*SD*) and analyzed by *t* test, whereas grouped or enumerated data were expressed as percentages and analyzed with χ^2 test. The multivariate logistic regression model was used for multivariate analysis, with *p* < .05 statistically significant. The receiver operating characteristic (ROC) diagnostic curve was examined for patients with GCS scores of 8 and less.

RESULTS

Patient Characteristic

A total of 84 patients were enrolled on the basis of the inclusion criteria (Figure 1). Fifty-five (65.5%) patients were males and 29 (34.5%) patients females with ages ranging from 14 to 80 years and mean (*SD*) of 52.5 (15.8). Of these patients, 42 (50%) were TBI patients, 10 (11.9%) patients with spontaneous subarachnoid hemorrhage, and 18 (21.4%) patients sustained cerebral hemorrhage. Among the remaining patients, 10 were diagnosed with massive cerebral infarct, two with dural arteriovenous fistula, and two with hypoxic-ischemic encephalopathy (see Supplemental Digital Content 1, available at: <http://links.lww.com/JTN/A37>).

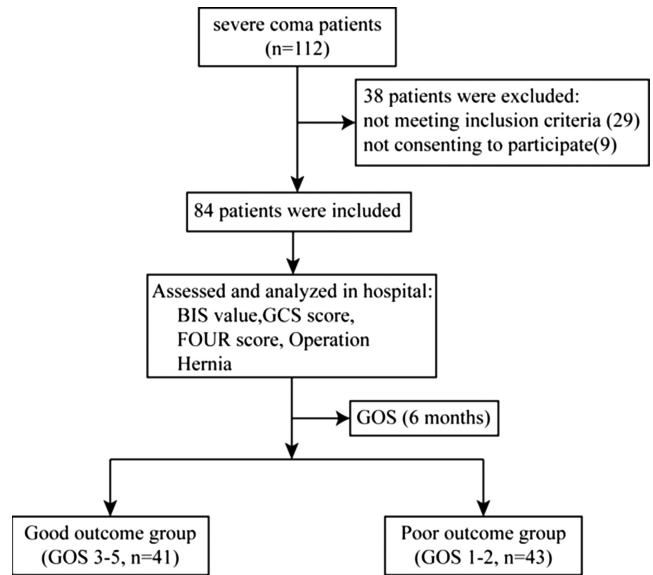


Figure 1. Screening process for enrolled patients. BIS = bispectral index; FOUR = Full Outline of UnResponsiveness; GCS = Glasgow Coma Scale; GOS = Glasgow Outcome Scale.

Comparison Between Two Groups

The mean (*SD*) of the BIS value 54.63 (11.76), *p* = .000; and GCS score of 5.76 (1.87), *p* = .000, were higher in the good prognosis group than in the poor prognosis group. Based on GOS score 43 had a poor prognosis and 41 had a good prognosis. Between the two groups, gender and mean age showed no statistical difference (Table 1). The BIS value (*p* < .001), GCS score (*p* < .001), and FOUR scores (*p* < .001) of the good prognosis group were significantly higher than those of the poor prognosis group. The proportion of brain herniation of the good prognosis group was significantly lower than that of the poor prognosis group (*p* = .001). There was no significant difference in the operation rate between the two groups (Table 2). The GCS score distribution is shown in Supplemental Digital Content 2, available at: <http://links.lww.com/JTN/A38>, and the BIS value distribution is shown in Supplemental Digital Content 3, available at: <http://links.lww.com/JTN/A39>. In the poor prognostic group, 33 patients died, including 23 pronounced dead from brain death and 10 patients from other complications. Brain death was confirmed by clinical examination, EEG, and transcranial Doppler ultrasonography. Another 10 patients were in a vegetative state.

TABLE 1 Patient Characteristics				
Characteristic	Poor Prognosis Group	Good Prognosis Group	Test Value	<i>p</i>
Male	26 (60.5%)	29 (70.7%)	0.979	.323
Age	52.72 (16.37)	47.39 (14.36)	0.311	.117

TABLE 2 Comparison of Major Indicators Between Prognosis Groups

Variable	Poor Prognosis Group	Good Prognosis Group	Test Value	<i>p</i>
BIS value	30.00 (18.48)	54.63 (11.76)	−7.248	<.001
GCS score	3.85 (0.58)	5.76 (1.87)	−7.751	<.001
FOUR score	3.45 (2.91)	7.57 (3.52)	−5.848	<.001
Operation	32 (74.4%)	28 (68.3%)	0.386	.534
Cerebral hernia	31 (72.1%)	15 (36.6%)	10.682	.001

Note. BIS = bispectral index; FOUR = Full Outline of UnResponsiveness; GCS = Glasgow Coma Scale.

Multivariate Logistic Regression Analysis

To analyze the risk factors associated with prognosis, the relationship between BIS value, GCS, FOUR, and cerebral hernia was investigated. The result showed that BIS value and GCS score were significantly correlated with poor prognosis, whereas FOUR score and cerebral hernia had no association with poor prognosis (Table 3).

The BIS Value as a Prognostic Predictor

Given that the BIS value had a remarkable correlation with poor prognosis, further examination of BIS was performed. The ROC curve was plotted among the patients with GCS scores of 8 and less, and the area under the curve (AUC) is equal to 0.86 so that the sensitivity and specificity of the BIS value could be predicted (Figure 2). With a cut point value of 43.6 calculating from the maximum Youden Index method (Hayashi & Sawa, 2019), the sensitivity and specificity were 85.4% and 74.4%, respectively.

DISCUSSION

This study showed that low BIS and GCS scores were significantly associated with adverse outcomes in comatose patients with severe brain injury. Our results are consistent with previous studies, which revealed that for patients with severe brain injury, the BIS value of patients who had a return of consciousness was significantly higher than that of those who did not (Mahmood et al., 2017), suggesting that BIS value had predictive prognosis value

(Li et al., 2019). In addition, consistent with our study, Li et al. (2019) found that BIS value was highly associated with GCS score, especially with a GCS score of less than 9, indicating that BIS was more sensitive in patients with severe brain injury (Mahadewa et al., 2018). In this study, the BIS value was applied to predict the prognosis of patients with severe brain injury.

The result revealed that BIS had high specificity in predicting the prognosis. With the AUC of the ROC curve of 0.86, the cut point value of BIS for predicting poor prognosis was 43.6, which was close to a previous study (Dou et al., 2014). However, Dunham et al. (2006) discovered that patients with BIS over 60 had a significantly higher survival rate and good neurological prognosis. The BIS values reflect the activity of the cortical structure of the brain but do not reflect the activity of subcortical structures, such as the brain stem (Jain et al., 2020). Moreover, it was noticed that BIS value dropping to 0 (indicating no EEG activity) preceded the disappearance of spontaneous breathing in some patients who were later confirmed brain death by EEG and transcranial Doppler ultrasonography, which suggests that BIS could be used as a detector for brain death (Mahmood et al., 2017; Miao, Sun, Wang, & Li, 2018).

It was observed in this study that BIS, as an indicator of real-time observation, was more direct and objective than GCS, and BIS could capture patient's condition changes earlier than the GCS score. The BIS showed heterogeneity in patients with the same GCS score, suggesting a greater

TABLE 3 Logistic Regression Analysis

Variable	Regression Coefficient	OR Value	95% CI	<i>p</i>
BIS value	0.063	1.065	1.009–1.124	.021
GCS score	0.931	2.537	1.150–5.593	.021
FOUR score	−0.026	0.975	0.750–1.267	.847
Cerebral hernia	0.882	2.415	0.637–9.152	.195
Constant	−7.334	0.001		<.001

Note. BIS = bispectral index; CI = confidence interval; FOUR = Full Outline of UnResponsiveness; GCS = Glasgow Coma Scale; OR = odds ratio.

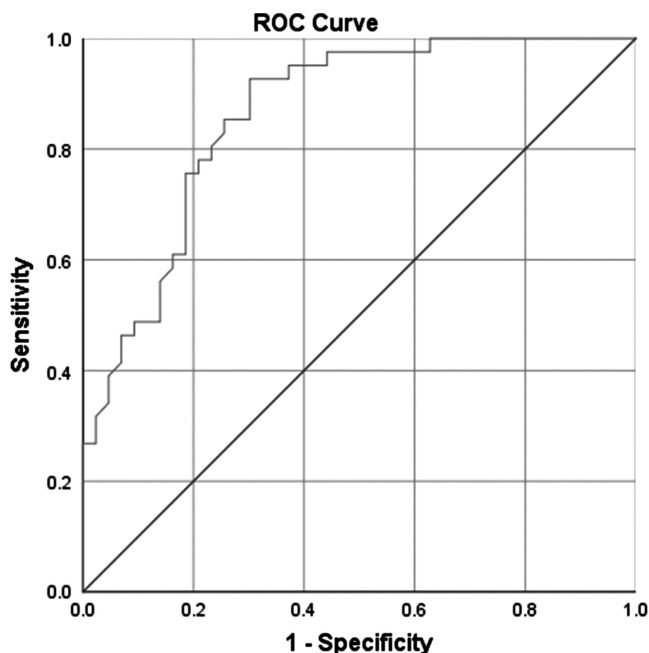


Figure 2. The ROC curve. Based on the area under the curve (AUC), the optimal diagnostic cutoff value was 43.6; sensitivity and specificity were 85.4% and 74.4%. ROC = receiver operating characteristic curve.

sensitivity than the GCS. Early studies found that some factors may influence the accuracy of BIS values. Factors that may contribute to the false reduction of BIS values are the application of sedatives (Duarte & Saraiva, 2009), or neuromuscular blockers (Vivien et al., 2003), or hypothermia (Mathew, Weatherwax, East, White, & Reves, 2001), and/or hypoglycemic coma (Xi, Pan, & Li, 2018), both which could cause decreased brain activity as well as decreased BIS value. During the monitoring process, low-frequency electromyography signal might be mistakenly recognized as high-frequency EEG signal due to electromyography interference, resulting in false elevation of BIS value (Baladesi, Bruder, Velly, & Gouin, 2004).

Error in the placement of electrodes and high electrode impedance from poor adhesion of electrodes could also bring the false raise of BIS value (Johansen & Sebel, 2000). In this study, before measuring BIS value, the interfering factors mentioned previously, such as data collection of BIS, were performed 24 hr after withdrawal of sedatives and neuromuscular blockers. During the monitoring period, the patients were treated to ensure hemodynamic stability to maintain sufficient brain perfusion. Also, a new-generation BIS Quantitative EEG Monitor (Mindray T 10; Shenzhen Mindray Biological Medical Electronics Co., LTD, Shenzhen, China) machine was used to minimize electromyographic interference.

Abnormally high intracranial pressure is likely to result in cerebral herniation, and significantly decreased

global cerebral perfusion secondary to cerebral herniation may result in abnormal EEG changes (Sanz-García et al., 2018). The EEG could be changed before the development of clinical signs (Mullaguri, Beary, & Newey, 2020). Using BIS to detect early physiologic harbingers of herniation may improve patient outcomes as it may allow earlier intervention (Rogers, Bechara, Middleton, & Johnstone, 2019). The FOUR scale, first designed by American scholar Wijdicks et al. (2005), aims to remedy the shortcomings of GCS in an inability to assess the language function and lack of brain stem reflex for patients with artificial airway by adding a series of brain stem reflex assessments to make it more sensitive in judging patients' condition. In this study, there was no correlation between the FOUR scales and BIS prognosis, which would be explained by poor conditions of selected cases, and overall FOUR scores were low with limited differences between individuals.

Limitations

There are limitations to this study. Previous studies have shown that high intracranial pressure, low BIS, and high severity injury are associated with poor prognosis in patients with severe craniocerebral injury (Dong et al., 2016; Yan et al., 2018). However, invasive intracranial pressure monitoring was performed only in part of enrolled patients, and the association of BIS within transcranial pressure and cerebral perfusion pressure was not evaluated. Furthermore, the number of cases in the study was small, and no further subgroup analysis was carried out for the lesion sites of the brain. Therefore, further larger studies are needed to support our findings.

CONCLUSION

Our study finds that BIS had a good predictive value on the prognosis for patients with acute severe brain injuries and GCS scores of 8 and less. The findings suggested that it would be beneficial to use BIS as an additional monitoring tool to evaluate the severity and prognosis of brain injury. However, in practice, confounding factors may result in the possible inaccuracy of the BIS value. Therefore, it remains paramount for clinicians to include all assessment parameters when making patient determinations for treatment.

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