ORIGINAL ARTICLE

Diagnostic Value of the Bispectral Index to Assess Sleep Quality after Elective Surgery in Intensive Care Unit

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Abstract

Purpose: Monitoring and improving sleep quality may help recovery from major illness. Polysomnography is a gold standard for measuring sleep quality, but routine use is not practical. The goal of this study is to investigate the diagnostic accuracy of an alternative monitor, the Bispectral Index (BIS), for evaluating the quality of sleep-in postoperative patients in the intensive care unit (ICU).

Study design: An observational study.

Materials and methods: Patients admitted to postoperative ICU after elective major noncardiac surgery were monitored with both BIS and PSG during the first night. The temporally synchronized data from both monitors were obtained for measurement of the association. Clinical outcomes were compared between patients with different postoperative sleep quality.

Results: Thirty-three patients were enrolled in this study. For determining the average BIS index associated with good postoperative sleep quality, receiver operating characteristics (ROC) curve was generated. Area under the ROC curve (AUC) was 0.65. The cutoff with best discriminability was 75 with a sensitivity of 68% and a specificity of 56%. Compared with those with good and poor postoperative sleep quality, there were no differences in main postoperative outcomes including duration of mechanical ventilation and ICU stay. Although the quality of sleep after surgery of all subjects with postoperative delirium was poor, the incidence of delirium between the groups did not significantly differ (0% vs 10.3%; $p = 0.184$).

Conclusion: The monitoring of BIS is a viable tool for evaluating sleep quality in mechanically ventilated patients in the postoperative ICU with acceptable precision.

Trial registration: www.clinicaltrials.in.th, TCTR20200310005.

Keywords: Bispectral index, Consciousness monitors, Intensive care units, Polysomnography, Postoperative care, Sleep stages, Sleep quality.

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Introduction

Good sleep quality is well established as vital for health. Sleep abnormalities occur very frequently in the intensive care unit (ICU), especially in patients who require mechanical ventilation. According to different measurement tools and definitions of sleep disruption, the reported prevalence of sleep disruption is varied from 40 to 100%.[1–3] Prior research both in animals and humans revealed an association between poor sleep quality and untoward clinical outcomes during and after critical illness, for example, a decline in neurocognitive function, immune suppression, and prolonged recovery after illness. For these reasons, monitoring and improving sleep quality can help to improve quality of care and improve recovery from critical illness. Although sleep quality can be assessed by direct observation by clinical personnel, this method usually overestimates sleep quality. There are several validated sleep questionnaires for the assessment of sleep quality, but they are vulnerable to recall bias and confounders. The gold standard for assessing sleep quality today is polysomnography (PSG) which analyzes multiple electrophysiologic modalities including electroencephalogram (EEG), electromyogram (EMG), and electrooculogram (EOG) altogether to classify sleep stages, duration, and quality of sleep, as well as to diagnose sleep-related disorders. In addition to its high cost and bulky equipment, it requires specialized personnel to interpret the results of the studies due to its complexity. These limitations of PSG make it impractical for clinical use, especially in ICU settings.

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Conflict of interest: None

Recently, researchers have attempted to use alternative devices for monitoring sleep. Processed EEG such as Bispectral Index (BIS) is one example. Its main advantages are the simplicity of device setup as well as interpretation which can be done by a clinician, its real-time nature, and lower cost. However, information on its accuracy in assessing sleep quality is scarce, especially in the critical care setting. This knowledge gap may be filled with this proposed study.

Materials and Methods

Study Design

This study was a single-centered observational study conducted at the surgical ICU at King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand. The study protocol was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University (approval No. 275/62) and was registered in the Thai Clinical Trial Registry (registration No. TCTR20200310005).

Participants

In this study, adult patients (at least 18 years old) who underwent elective major surgery and required postoperative admission to the ICU with mechanical ventilation were included. The exclusion criteria were: (1) previously diagnosed sleep-related disorder including obstructive sleep apnea; (2) history of the use of tranquilizers, antidepressants, antiepileptics, or other psychotropic medications within one month before enrollment; (3) inability to communicate in Thai; (4) history of illicit drug use including alcohol more than seven standard drinks per week for women or 14 standard drinks for men; (5) central nervous system disorders or previous traumatic brain injury or history of seizure; (6) pregnant women; (7) unavailability of sleep laboratory services; (8) reoperation within the first night after surgery.

Procedures

- Adult patients scheduled for major noncardiac surgery the following day were screened for the requirement of postoperative admission to the ICU and possibility of postoperative mechanical ventilation. Eligible patients for this study were visited on their ward on the day before surgery and written informed consent was obtained.
- Preoperative sleep quality was subjectively assessed using Thai version of Pittsburg Sleep Quality Index, the total score more than five defined poor sleep.[4]
- Anesthetic techniques and agents were left to the discretion of in-charge anesthesiologists.
- After postoperative admission to the ICU, BIS, and PSG were recorded during 21:00 to 6:00 the following day. The data were obtained from the monitors for offline analysis.
  - **Polysomnography:** Sleep EEG data was acquired with the Compumedics® system (Grael 4K PSG: EEG, Australia). According to the standard method described by the American Academy of Sleep Medicine (AASM) Manual for scoring of sleep and associated events version 2.6.[5] The recordings consisted of 6 EEG channels (F3, F4, C3, C4, O1, O2) with referenced to mastoid leads (M1, M2) according to 10–20 system, 2 EOG channels, and 3 chin EMG channels. No monitoring of respiratory function was included since the patients were already intubated and mechanically ventilated.
  - **BIS:** BIS data were collected by using BIS Quatro (Medtronic, Ireland) attached with BIS Vista Monitor version 3.01. The adhesive electrodes were placed on the unilateral forehead as described by the manufacturer (Sensor 1 placed at the center of the forehead, approximately 5 cm above the bridge of nose, Sensor 4 directly above eyebrow, and Sensor 3 on temple, between the corner of the eye and hairline). BIS data were recorded in Live Mode which was extracted every 1 second. Time and date of BIS Vista Monitor were set according to the time of PSG for later data synchronization.
- The titration of analgesic and/or sedative agents, as well as liberation from mechanical ventilation and extubation was performed by physicians not involved in this research.
- Subjects were assessed for postoperative delirium using the Thai version of CAM-ICU method[6,7] for 7 days after operation or until patients were discharged from the hospital if their length of hospital admission was less than 7 days.

Sample Size Calculation

To determine an appropriate sample size for assessing diagnostic value of BIS for sleep quality, a power analysis was conducted based on predicted area under ROC curve. Since there was no prior study in our local context, we searched for a study in the Asian region and found that Naik et al. reported a prevalence of good sleep of 53.2% using validated subjective sleep questionnaire.[8] We used MedCalc for Windows, version 20.6 (MedCalc Software, Ostend, Belgium) to calculate the sample size. Given type I error (α level) of 5%, power of 80%, area under the ROC curve of 0.8 and a dropout rate of 20%, the calculated sample size was 33.

Outcome Measures

Polysomnographic sleep stages were scored for 30-second epochs by board-certified sleep technologist and board-certified sleep medicine specialist who were unaware of the BIS data, patient's clinical condition, and current medication use. In this study, the Compumedics Profusion Sleep 3 software was utilized in this study. Criteria for classification of sleep stages are based on AASM Manual version 2.6. BIS data with signal quality index (SQI) less than 50% were excluded from the data analysis. The BIS data were subjected to a synchronization process with EEG epochs, where they were averaged over a duration of 30 seconds. This method ensured temporal alignment between the BIS and the corresponding EEG epochs, facilitating accurate analysis, and interpretation of the data.

The primary outcome of this study was the average BIS index that best predicting good postoperative sleep quality. We defined good postoperative sleep quality by polysomnographic sleep efficiency (percentage of total sleep time divided by total record time) more than 85%.

The secondary outcomes included mean BIS index in each stage of sleep and clinical outcomes related to sleep disturbance including duration of mechanical ventilation, duration of ICU stay, and incidence of delirium.

In the present study, delirium was defined as a positive confusion assessment method for the intensive care unit (CAM-ICU) test result. The test has been previously translated into Thai and validated against DSM-IV-TR criteria.

Data Analysis and Statistics

Quantitative data were tested for normality by Shapiro–Wilk test and presented as mean ± SD or median (IQR) where appropriate. Qualitative data were presented by count and percentage. The level of significance was taken at *p*-value of less than 0.05.

The primary analysis was to evaluate the ability of the BIS index to predict good postoperative sleep quality, which was determined by assessing the area under the ROC curve (AUC). Sensitivity, specificity, and cutoff of BIS index were estimated by using Youden Index.

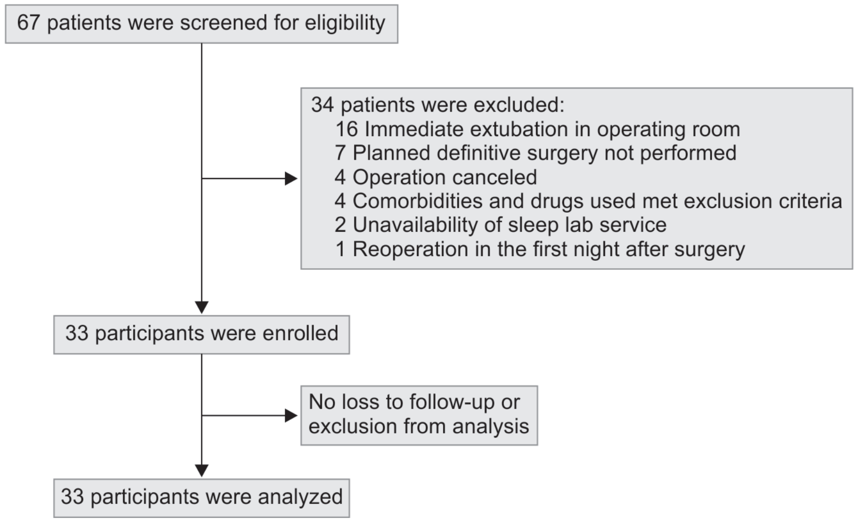

Fig 1: Participant flow diagram

For secondary outcomes, we use linear mixed-effect regression model to adjust for the data for the clustering effect due to repeated measurement in each subject. The mean BIS index for each sleep stage and the mean change in the BIS index relative to the wakefulness stage were calculated and presented as mean, standard error of the mean, and 95% confidence interval (95% CI). Generalized estimating equations (GEE) with population-based modeling was used to predict the probability of being in each stage of sleep at a certain BIS cutoff.

Factors associated with postoperative sleep quality were explored using Chi-square test. Comparison of clinical outcomes was made between patients with good and poor postoperative sleep quality. The differences in mechanical ventilation and length of stay in the ICU were tested by the Mann–Whitney *U* test. The incidence of postoperative delirium was compared to the Chi-square test. Time to delirium was assessed using Kaplan–Meier failure curves and log-rank test. Hazard ratio with 95% confidence interval was planned to be estimated by Cox-proportional-hazards model.

All statistical analyzes were performed with Stata version 17 (StataCorp LLC, Texus, USA).

Results

A total of 67 subjects were screened for eligibility. Of these, 34 subjects were excluded for multiple reasons as described in Figure 1. The remaining 33 participants were included in the study. The mean age was 64 (26) years; 13 (39.4%) were male; 20 (60.6%) reported good preoperative sleep quality assessed by sleep questionnaire; median preoperative pain score assessed by a numerical rating scale was 0 with a range of 0–3; Charlson Comorbidity Index was 4.30 ± 2.34. Of the total 33 participants, 23 (69.7%) underwent open abdominal surgery, 7 (21.2%) underwent intrathoracic surgery, and the remaining 3 (9.1%) underwent head and neck surgery.

Figure 2 shows that BIS index was the highest in awake stage (85.1, 95% CI, 83.2–87.0) and progressively decreased as non-rapid eye movement (NREM) sleep stages deepened from stage I (78.5, 95% CI, 76.6–80.4), stage II (73.3, 95% CI, 71.4–75.2), stage III (63.2, 95% CI, 61.2–65.1), and increased when transitioning to rapid eye movement (REM) sleep (75.9, 95% CI, 73.7–78.1). When considering awake as the baseline, the transition from awake to each stage of sleep made BIS change in different magnitude. For example,

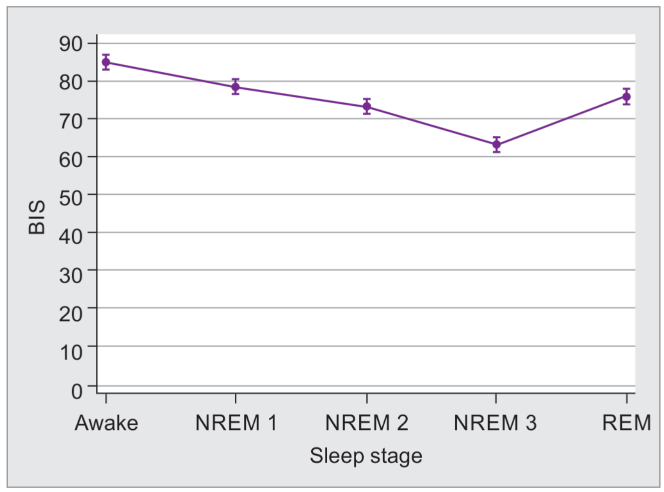

Fig. 2: Estimation of mean Bispectral Index (BIS) index in each stage of sleep

Table 1: Relative change of BIS index relative to awake stage

Stage	*Mean change*	*95% CI*
Awake	Ref	Ref
NREM stage I	−6.55 ± 0.13	−6.81 to −6.28
NREM stage II	−11.75 ± 0.11	−11.96 to −11.53
NREM stage III	−21.91 ± 0.30	−22.50 to −21.31
REM	−9.20 ± 0.58	−10.34 to −8.05

BIS decreased by 6.5, 11.8, 21.9, and 9.2 when transitioned from awake to NREM stages I, II, III, and REM sleep, respectively (Table 1).

While using a threshold of sleep efficiency of at least 85% to define good postoperative sleep quality, it was determined that 32.3% of the patients in the study achieved this criterion and thus had good postoperative sleep quality.

Receiving operator characteristics curves were created to evaluate the discriminative ability of the averaged BIS index to assess sleep quality. The AUC of BIS in predicting good postoperative sleep quality was 0.65 (Fig. 3). The cutoff point with best differentiation of good sleep determined by Youden Index was

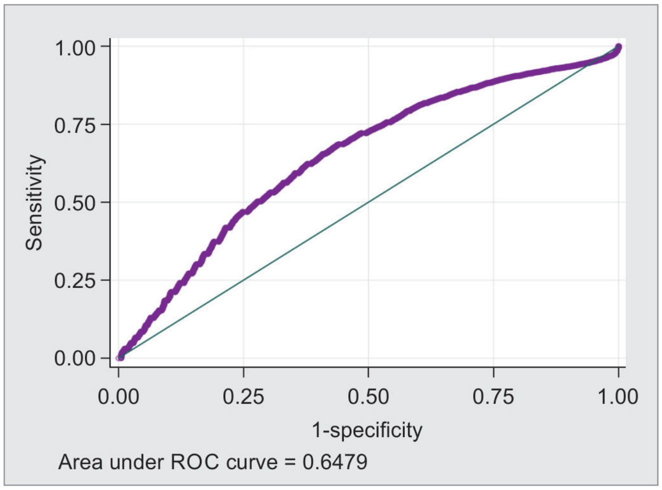

Fig 3: Receiving operator characteristics (ROC) curve of BIS in predicting good postoperative sleep quality

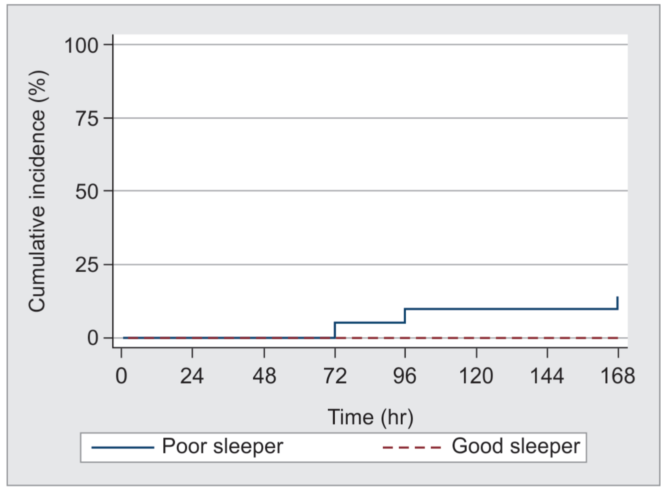

Fig. 4: Kaplan–Meier curve of the cumulative incidence of delirium by postoperative day 7

Table 2: Probability of being in each stage of sleep given BIS less than 75

Sleep stage	*Predicted probability*	*95% CI*
Awake	14.1%	8.0–20.3%
NREM stage I	31.2%	23.0–39.4%
NREM stage II	57.8%	49.1–66.5%
NREM stage III	80.1%	72.6–87.5%
REM	47.1%	36.2–58.0%

75 with sensitivity 68% and specificity 56%. When dichotomizing the mean BIS index in each individual, if it was less than 75, the AUC in predicting good postoperative sleep quality was 0.62. We analyzed the probability of being in each stage of sleep given BIS less than 75 (Table 2). Subjects were more likely in NREM stage III with predicted probability of 80.1%, and least likely awake with predicted probability of 14.1%.

When comparing subjects with good and poor postoperative sleep quality, the main postoperative outcomes were not significantly different. The duration of mechanical ventilation was 16.5 (70) vs 18 (28) hours ($p = 0.801$). The length of stay in the ICU was 51.5 (73) vs 43 (43) hours ($p = 0.581$). The overall incidence of postoperative delirium up to postoperative day 7 was 9.1%. Although all subjects with delirium had poor postoperative sleep quality, the incidence of delirium between the groups was not significant ($p = 0.184$). There were no statistically significant differences in the cumulative incidence of postoperative delirium between the groups (Fig. 4). We did not perform Cox-proportional hazard model to compare time to delirium due to the zero incidence of delirium in patients with poor postoperative sleep quality.

We explored the a few factors that might affect postoperative sleep quality. These factors were found to be not associated with good sleep quality, that is, preoperative sleep quality ($p = 0.880$), old age ($p = 0.709$), sites of operation ($p = 0.170$), use of inotropes or vasopressors ($p = 0.525$), use of sedatives ($p = 0.416$), modes of mechanical ventilation ($p = 0.301$), route of analgesics ($p = 0.242$) or mode of analgesia ($p = 0.140$).

Discussion

Poor sleep is frequently observed in the ICU settings. Multiple factors including environmental factors (e.g., light, noise, unfamiliarity), the severity of the illness (e.g., extent of surgery, comorbidity), and patient care activities can contribute to sleep disruption in ICU.[9,10] In our cohort, we found that the distribution of sleep stages was mostly awake (35%) and NREM stage II (41%). On the contrary, REM sleep and NREM stage III were regarded as deep and restorative sleep stages, were scarce. These findings resemble previous literature on sleep loss in patients admitted to the ICU in our local context[8, 11–13] and highlight the importance of monitoring sleep quality in ICU patients. We chose processed EEG as a monitor of interest not only because it directly reflects brain activity as well as conscious level,[14,15] it is also commonly available and is stated to be 'best suited' for sedative titration in specific conditions.[16,17] Additionally, unlike actigraphy, it may be able to differentiate sleep from motionless wakefulness in the bedbound or paralyzed state, which was common in ICU.[18]

This study evaluated the clinical utility of BIS as an assessment tool for sleep monitoring in the ICU. The current study is the first of its kind, based on review of existing literature, exploring the relationship of BIS index and sleep stages as well as sleep quality in the context of ICU setting. Regarding the BIS index in each stage of sleep, our finding on the pattern of change in BIS in sleep stages was in concordance with previous studies conducted on healthy volunteers or individuals undergoing assessments for sleep-related disorders within sleep laboratories.[19,20] However, discriminating among NREM stages I, II, and REM sleep by using BIS may be challenging due to the overlap of the range of BIS indices in each stage from one another. Additionally, REM sleep was undoubtedly poorly predicted by BIS because of a similar EEG pattern of REM sleep to wakefulness or NREM stage I.[21] In addition to patients' settings, the demographic composition of the subjects in earlier studies differs from that of the present study. While earlier findings primarily focused on young adults and occasionally pediatrics, the current study's median participant age was 64 years old with moderate comorbidities evident by the average Charlson's comorbidity score of 4.3, which corresponds with predicted 10-year mortality of 53%. For this reason, the variations in sleep architecture and inherent sleep quality attributed to aging could potentially contribute to the disparities observed in EEG patterns and BIS index values.

Despite a small number of patients, the number of datasets included in our statistical models for BIS and sleep stages analysis was more than 28,000 pairs of data. We also considered the clustering effect of the data within each subject making the model more valid. However, this clustering effect was not mentioned and adjusted in prior studies. From our data, the BIS index less than 75 is the most optimal cutoff to predict good sleep quality with acceptable sensitivity. At this cutoff point, the patient was most likely in NREM stage III or NREM stage II sleep. This finding suggests that BIS monitoring may be a possible alternative to PSG in clinical practice or medical research to detect NREM stage II and NREM stage III sleep. Multiple randomized-control trials regarding sleep and sedation in the ICU have adopted percentage of NREM stage II sleep as a primary endpoint. Subsequent investigations may be logically directed focuses toward measuring the percentage or duration of BIS falling below this threshold value. In addition to this cutoff, the decremental change in the BIS index from the baseline wakefulness stage to each stage of sleep may be used as a guide for monitoring sedation in ICU patients. However, larger controlled studies are needed to evaluate this application.

It was found that physiological homeostasis and integrity of multiple organ functions were disrupted in patients with poor sleep quality resulting in worse clinical outcomes.[22] Neurocognitive functions are one of the most widely investigated clinical problems associated with sleep quality.[3] In general, perioperative settings, sleep disturbance increase the odd of postoperative delirium by more than five times.[23] This link was further reinforced by recent studies evaluating sleep quality improvement intervention in ICU. Sleep promotion by avoiding unnecessary noise and light by adaptation of ICU environment as well as the use of earplug and eye mask during nighttime were shown to improve sleep quality.[24–26] In one study conducted in surgical ICU, there were less patients with delirium during the time of sleep bundle implemented.[25] In our study, we did not find any difference in clinical outcomes between subjects with poor and good sleep quality. This might be explained by a small sample size and low statistical power. For the same reason, we did not perform regression analysis to quantify the effects of factors associated with sleep quality.

Limitations

There were several limitations of our study that deserved to be mentioned. Firstly, our study was a single-center study with a relatively small sample size. The inherent homogeneity within a single-center study setting may not accurately reflect the broader diversity of healthcare practices and patient populations across regional disparities. Furthermore, its power was not calculated to detect a difference in clinical outcomes related to sleep quality. Secondly, while postoperative sleep disturbance may last for several months after surgery, we did not investigate the long-term clinical outcomes. Lastly, due to the nature of the observational study, our main clinical outcomes were subjected to be confounded by many factors such as sedatives, pain management strategies, surgical techniques, and comorbidities. For these reasons, a larger controlled trial focused on the effect of using BIS as a sleep quality monitoring or sedation guidance on short-term and long-term clinical outcomes is warranted.

Conclusion

Bispectral Index monitoring is a feasible tool to assess sleep quality with acceptable accuracy in postoperative patients requiring mechanical ventilation in the ICU. While this study contributes valuable insights into the use of BIS for sleep quality monitoring and sedation guidance, continued research endeavors focusing on both short- and long-term clinical outcomes related to postoperative sleep quality monitoring and sedation guidance by processed EEG are needed.

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