

Use of Bispectral Index Score for Interventional Bronchoscopy Procedures

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Background: Interventional bronchoscopic procedures are novel diagnostic and therapeutic methods in pulmonology, which may be unpleasant and dangerous to the patients; therefore, sedation and in some cases general anaesthesia are recommended. But adjusting the level of sedation is a challenge. In this study we intended to define a range of bispectral index (BIS) score suitable for these procedures.

Materials and Methods: All patients referred to our interventional bronchoscopy unit were enrolled in the study. Sedation was induced using midazolam, sufentanil, and propofol with the patient breathing spontaneously. The target level of sedation was to reach a Ramsay sedation score of 3 and patient tolerance in performing the procedure. The BIS score was recorded at baseline and every five minutes thereafter. Correlation between different BIS values, propofol dosage, duration of procedure, and awakening time was evaluated.

Results: A total of 70 patients were enrolled in this study with a mean age of 50 ± 16 years and 34 (48.6%) of them were males. The mean baseline BIS was 96 ± 3.7 , and the mean time to reach "stable BIS" ("stable time") was 7.9 ± 6 minutes. The mean "stable BIS" was 52 ± 13.5 and 70% of patients had stable BIS between 40 and 60.

Conclusion: BIS is a useful objective tool for evaluation of sedation, which can guide us through bronchoscopy and related procedures. According to our observational study, reaching the mean BIS level of 52 ± 13.5 is required to prevent complications and ensure feasibility of the procedure.

Key words: Bispectral index, Bronchoscopy, Intervention, Anaesthesia

INTRODUCTION

Interventional fiberoptic bronchoscopic procedures have been increasingly applied in pulmonology for both diagnosis and treatment in tracheobronchial tree. These procedures are quite unpleasant for the patients and experience of cough, sore throat, nose pain, asphyxiation, and agitation is not uncommon (1, 2). Therefore, in order to improve patient tolerance, eliminate recall, avoid bronchoscopy disturbance by reflexes like cough, improve the quality of the procedure, and more importantly to

prevent serious complications, most clinicians prefer to perform these procedures under anaesthesia (3). Moreover, thanks to the amnesia created by anaesthesia, it is more likely that patients consent to repeat the procedure, if required (3). However, adjusting the level of sedation is very important since it should be deep enough to ease patient discomfort and prevent intraoperative awareness, yet not too deep to result in prolonged recovery time and serious complications such as haemodynamic disturbances and respiratory depression (4, 5).

Depth of anaesthesia and sedation assessment has been an issue of discussion for several decades, and a number of methods and scores have been used for its estimation. Subjective tools like Ramsay Scale, Sedation-Agitation Scale (SAS), or Motor Activity Assessment Scale, which are based on patient response to stimulation have been the most well-known measures for assessment of sedation depth; But they are not useful for evaluating anaesthesia depth during procedures (6,7).

The BIS monitor is an objective tool for monitoring the depth of anaesthesia, which was first introduced in the 1990s. The first application of BIS was to monitor the depth of anaesthesia and thereafter, it was used as a guide for adjusting drug dosage during different operations, but recently it has been used for assessment of sedation depth during procedures such as bronchoscopy and endoscopy.

Performing interventional bronchoscopic procedures under sedation or general anaesthesia has become a routine in our centre but the exact level of consciousness suitable for these procedures has not been documented. This study was conducted to examine the BIS level of patients undergoing interventional bronchoscopy procedures with the aim of defining the best patient status for performing the procedure.

MATERIALS AND METHODS

This observational study was approved by the ethical committee and performed at the Interventional Bronchoscopy and Laser Unit of our centre during a three-month period. Within this period, all patients with indications of diagnostic and/ or therapeutic flexible interventional bronchoscopy and with no contraindications for sedation were enrolled in this study.

Patients with poorly controlled cardiovascular disease, severe respiratory distress, severe neurologic disorders, less than eight hours nil per orally (NPO) time, and also those unwilling to participate were excluded from the study. Written informed consent was obtained from all participating patients.

Fiberoptic bronchoscopy was performed by a pulmonologist through swivel connector attached to

facemask. Patients were oxygenated via facemask attached to anaesthesia machine using 5 l/min O₂ flow [fraction of inspired oxygen (FiO₂) 1]. Before beginning the procedure, BIS sensor electrode was placed on the patient's forehead and the baseline BIS score was recorded using BIS monitor (Aspect Medical Systems, Natick, MA). Non-invasive blood pressure, pulse oximetry, heart rate and electrocardiogram (ECG) were monitored throughout the procedure. Pharynx was locally anesthetized with lidocaine spray (10%) with a maximum dosage of 1 mg/kg and midazolam (1 mg) and sufentanil (5 µg) were injected intravenously (IV) as premedication. After three minutes, propofol (0.5-1mg/kg) was injected as hypnotic. Infusion of propofol (up to a total dose of 40 µg/kg/min) was also used for maintenance of hypnosis. Extra bolus doses of propofol (10-20 mg IV injection) were administered if required to ensure adequate level of sedation. No muscle relaxant was used and the patients were breathing spontaneously but if any difficulties with breathing occurred, laryngeal mask airway (LMA) or if required tracheal tube was available to manage the airway and breathing by the attending anaesthesiologist. After completion of the procedure, propofol infusion was terminated and awakening time and BIS at awakening (when the patient had spontaneous eye opening and appropriate verbal response) were recorded.

The patients were adequately sedated before initiation of the procedure and this state was defined as Ramsay sedation score three (Table 1). During this level, patients had sluggish response to verbal stimulation, spontaneous breathing, stable haemodynamic and could tolerate bronchoscope insertion without agitation, coughing, and irregular movement, yet the bronchoscopist was able to perform the procedure with no disturbance.

Table 1. Ramsay scale for assessment of sedation level

1-	Anxious, agitated, restless
2-	Cooperative, oriented, tranquil
3-	Responds to commands only
4-	Asleep, brisk response to stimulus
5-	Asleep, sluggish response to stimulus
6-	Unarousable

Demographic characteristics, indication for bronchoscopy and type of procedure were recorded for each patient.

Initial BIS value before anaesthesia (named as “primary BIS”) and thereafter, BIS values every five minutes were recorded. The lowest BIS value during which the bronchoscopy procedure could be feasibly performed was regarded as “stable BIS” and was categorized into three groups: > 60, ≥40 and ≤60, and <40. Time in minutes to reach this stable point was considered as “stable time”. Duration of procedure, time interval between the end of procedure and patient awakening (“awakening time”), and BIS value at awakening (awakening BIS) were also recorded (Table 2).

Table 2. The variables in this study

Variable name	Range	Description
Primary BIS	60-100	BIS level before initiation of sedation
Stable BIS	> 60, 40-60, and <40	The lowest BIS value during which the bronchoscopy procedure could be feasibly performed
Duration of the procedure	Minutes	
Awakening time	Minutes	Time interval between the end of the procedure and patient awakening
Awakening BIS	60-100	

Eventually total propofol dosage injected to each patient and all complications were documented.

Statistical analysis of the data was done using SPSS 16. The mean and standard deviation (SD) were used for describing quantitative variables and frequency and percentage were used for qualitative ones.

The correlation between different BIS values (primary, stable, and awakening), propofol dosage, duration of procedure, and “awakening time” was evaluated using the Pearson’s correlation coefficient. One-way analysis of variance (ANOVA) was used to determine the correlation between “stable BIS” and complications and also type of procedure. P-value <0.05 was considered to be significant.

RESULTS

A total of 70 patients were enrolled in this study. Their age ranged from 17 to 89 years with a mean of 50 ± 16 years, and 34 (48.6%) of them were males. The most common indication for fiberoptic bronchoscopy was diagnostic (35 patients, 50%) due to reasons like unexplained cough, haemoptysis, etc. Twenty-eight patients (40%) were suspected to have lung cancer and the number of patients with suspected tracheal stenosis, sarcoidosis and bronchiectasis was four (5.7%), two (2.9%), and one (1.4%), respectively.

Of the total participants, 24 patients (34.3%) underwent simple diagnostic bronchoscopy with or without bronchoalveolar lavage (BAL). Biopsy, including simple biopsy or transbronchial lung biopsy (TBLB), was done for 19 patients (27.1%) and the rest of the patients underwent interventional procedures including intralesional injection of chemotherapeutics in 13 (18.6%) and thermal therapies (electrocautery, laser and electrical knife) in 14 (20%).

The mean “primary BIS” was 96 ± 3.7, and the mean time to reach “stable BIS” (“stable time”) was 7.9 ± 6 minutes. The mean “stable BIS” was 52 ± 13.5. Frequencies of different levels of “stable BIS” among all the patients are demonstrated in Figure 1. The results of categorised stable BIS levels, total administrated propofol for each patient, the mean duration of procedure, the mean BIS level at the time of awakening, and the mean “awakening time” are shown in Table 3.

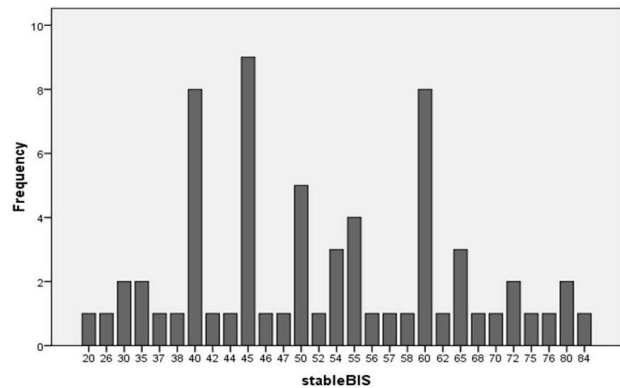


Figure 1. Frequency of different levels of Stable BIS among the patients

Table 3. Correlation of variables at different stages of procedure

Stage of procedure	Mean BIS level	Ramsay scale level	Duration	Propofol dose
Primary stage	96 ± 3.7	2	-	-
Stable stage	> 60 in 19.7% , ≥40 and ≤60 in 56.1%, < 40 in 24.2 %	5	18.6 ± 11.8 minutes	140 mg
Awakening stage	76.6 ± 7.6	2	8.4 ± 7.3 minutes	-

There was a significant negative correlation between "stable BIS" and "awakening time" ($r = -0.396$, $P = 0.001$). "Stable BIS" also showed significant negative correlation with propofol dosage ($r = 0.334$, $P = 0.006$). "Total propofol" dose showed a significant positive correlation with "awakening time" ($r = 0.321$, $p = 0.008$).

The frequency of complications during the procedure and also range and mean of "stable BIS" in each of them are demonstrated in Table 4. There was no significant relationship between "stable BIS" levels and occurrence of complications in general ($P = 0.68$). Three patients experienced mild hypoxia while spontaneously breathing, which were managed by assist of mask ventilation.

Table 4. Frequency of different complications, and range and mean of "stable BIS" in each group

Complications	Frequency (%)	"Stable BIS" mean ± SD	Range of "stable BIS"
Movement	6 (8.7%)	54.2 ± 11.7	42 - 72
Cough	15 (21.7%)	48.4 ± 16.4	26 - 84
Hypoxia	3 (4.3%)	53 ± 2.6	50 - 55
Bleeding	9 (13%)	54.3 ± 12.7	35 - 72
Others	5 (7.2%)	45 ± 8.7	40 - 60
No complication	31 (44.9%)	53.6 ± 13.8	20 - 80

Patients undergoing different procedures were categorized into three groups and the range of "stable BIS" in each group is demonstrated in Table 5. According to the results, 70% of the patients had a mean BIS level from 40 through 60. A statistically significant difference was detected between the second and third groups (mean BIS in group 2=55±4.61, mean BIS in group 3=50± 4.26; $P = 0.02$) and the first and third groups (mean BIS in group

1=55±8.16, mean BIS in group 3=50±4.26; $P = 0.005$). The difference between groups 1 and 2 was not significant ($P = 0.27$).

Table 5. Correlation between Bispectral index (BIS) level and type of procedure

Type of procedure	BIS Level			Total
	>60	≥ 40/ 60≤	<40	
Diagnostic FOB / BAL /	5	23	4	32
Bronchial Biopsy	(15.6%)	(71.9 %)	(12.5 %)	(45.7 %)
TBLB / Intra – lesional	8	13	2	23
injection	(34.8 %)	(56.5 %)	(8.7 %)	(32.9 %)
Tumor ablation with laser /	0	13	2	15
snare / knife	(0 %)	(86.7%)	(13.3%)	(21.4%)
Total	13	49	8	70
	(18.6%)	(70%)	(11.4 %)	(100 %)

DISCUSSION

This observational study demonstrated that although the suitable level of stable BIS for performing interventional bronchoscopy procedures varies according to the type of procedure, on average a BIS score of 52 ± 13.5 is required to reach an optimal status. This level of sedation state was required to ensure no patient movement during invasive procedures, which may result in airway damage.

As expected, lower levels of BIS were correlated with administration of higher doses of propofol and also longer awakening times.

Adjusting the level of anaesthesia to eliminate patient discomfort is an important issue. Anaesthesiologists always confront two main challenges: over-sedation, which results in respiratory problems and prolonged recovery, and inadequate sedation which is associated with intraoperative awareness, movement and pain sensation (4, 5). For several decades clinicians have assessed haemodynamic changes and/ or different responses to painful stimuli to determine the level of anaesthesia; however, these methods are case-dependent and also not applicable to unresponsive patients (6, 7).

As an objective tool, BIS has gained popularity for measuring the level of anaesthesia and sedation and therefore managing anaesthetic drug administration during the recent years. By combining different variables

with regard to the time and frequency domains of EEG, BIS produces a single index, which is independent of most hypnotic agents and also demographics of patients (5, 8, 9). In addition, a positive correlation has been demonstrated between BIS and other measures of sedation level such as Observer's Assessment of Awareness and Sedation (OAA/S) and Ramsay Sedation Score in several studies (6, 8).

Observing levels of BIS during interventional bronchoscopy in the current study showed that the lowest BIS level required for ease of procedure performance in most patients was 40 to 60. This range of BIS level has been indicated in many studies and also BIS guidelines as the suitable BIS value for patients undergoing general anaesthesia and also compatible with moderate hypnotic state and low probability of consciousness (5, 6, 8-14). Such a low level of BIS was not intended initially, but to reach a suitable condition for the procedure to be performed and to avoid complications, such a low level was gradually induced and consequently observed using BIS. One important point was that during the operation, use of Ramsay scale was highly limited and unreliable due to the harsh stimulation caused by bronchoscopy and that patient response was not interpretable.

In our experience, during interventional bronchoscopy with higher levels of BIS, patient awareness and their body movements or reactions to pain can interfere with the performance of bronchoscopist and therefore, result in complications, failure of the procedure or prolonged procedure time. In this study, three patients with "stable BIS" between 40 and 60 showed movements; this was surprising considering the low level of sedation. Furthermore, when BIS level decreases to deep hypnotic state, probability of anaesthesia-related complications such as apnoea, haemodynamic instability, and also prolonged awakening time increases. As mentioned earlier, three cases experienced hypoxia while their "stable BIS" was around 50 and were spontaneously breathing, which were managed with mask ventilation and no further instrumentation was required.

Considering the fact that our goal was to define the level of sedation, which is usually reached during our routine experience using an objective tool and to provide a satisfactory condition for patient, bronchoscopist and anaesthesiologist, and regarding the low incidence of complications, BIS range of 40-60 seems to be an appropriate level of sedation for performing interventional bronchoscopy procedures. But still it must be kept in mind that this level of consciousness is correlated with general anaesthesia and that in this state airway management is a major issue that must be taken care of meticulously. Therefore, it is logical and highly recommended to provide a safe and secure condition before any interventional bronchoscopy procedure, considering equipment and personnel experience to ensure patient safety altogether.

Yet, further investigations are recommended to clarify the correlation between BIS level and duration of procedure, success rate of procedure, and type of complication through prospectively designed case/control studies.

CONCLUSION

Interventional bronchoscopy procedures are usually performed under sedation for better patient tolerance. BIS is a useful objective tool, which can guide us through the process and according to our results, the mean BIS level of 52 ± 13.5 is recommended to ensure feasibility of the procedure.

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