

A Randomized Comparative Study on Bispectral Index Monitoring on Early Postoperative Recovery In Morbidly Obese Patients Undergoing Laparoscopic Sleeve Gastrectomy

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Abstract

Introduction: Obesity has become a relatively common condition that has a tendency to profoundly affect morbidity and mortality. With an increase in the prevalence of obesity, the anaesthesiologists are challenged with these population of patients posted for surgery due to various medical and surgical pathologies.

Objective: The objective of this study was to evaluate the role of bispectral index (BIS) monitoring in recovery time in obese patients undergoing laparoscopic sleeve gastrectomy.

Materials and Methods: A total of 80 patients of both sex aged between 25 and 45 years, posted for laparoscopic sleeve gastrectomy were randomized into two groups of 40 each (Group 1 – BIS and Group 2 – non-BIS group) using computer randomization. Time taken for recovery from anesthesia as noted by the mean time taken for awakening and the mean time taken for extubation along with the mean time to achieve a modified Aldrete score of ≥ 9 were recorded in minutes.

Results: Between Groups 1 and Group 2, the mean awakening time (11.38 ± 2.807 and 14.92 ± 3.885 with $P = 0.000$), mean extubation time (15.90 ± 2.863 and 19.28 ± 4.120 with $P = 0.000$), and mean time to achieve modified Aldrete score ≥ 9 were (31.60 ± 3.862 and 40.80 ± 4.681 with $P = 0.000$), respectively. There was a statistically significant difference between the two groups in awakening time, extubation time, and modified Aldrete score.

Conclusion: The present study had revealed that using BIS monitoring lead to early postoperative recovery of morbidly obese patients undergoing laparoscopic sleeve gastrectomy.

Key words: Bispectral index, Modified aldrete score, Obesity, Sleeve gastrectomy

INTRODUCTION

The word obesity is derived from the Latin word *obesus* meaning fattened by eating. Obesity has been become a relatively common condition that has a tendency to

profoundly affect morbidity and mortality. According to the WHO, obesity is defined by calculating body mass index (BMI) or Quetelet Index. BMI of 18–24.9 is normal, 25–29.9 is overweight, 30–34.9 is Grade I obesity, 35–39.9 is Grade II Obesity, and >40 is morbid obesity (WHO 1997) [1,2]. Obesity is a major risk factor for many chronic diseases such as diabetes, hypertension, coronary artery disease, high triglycerides and cholesterol, sleep apnoea, strokes, gallbladder disease, and carcinomas.

With this increase in the incidence of obesity, there is an increased incidence of a wide range of medical and surgical pathologies and an anesthesia providers are challenged with

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these populations of obese indiv^[3,4] Obesity predisposes to several potential problems to the patient in the perioperative period such cardiovascular and respiratory events and also challenges anesthesiologists providing difficult mask ventilation and laryngoscopy.^[5,6] Conventionally, obesity has been seen as a physiologic state that magnifies the importance of the fat–blood solubility coefficient of the anesthetic in its relation to emergence and recovery; hence, early and uneventful postoperative recovery of morbidly obese patients remains a challenge for anesthesiologists. All volatile anesthetics accumulate over time in adipose tissue delaying recovery from anesthesia. Obesity magnifies the importance of the fat–blood solubility coefficient of the anesthetic in its relation to emergence and recovery.^[7]

In obese patients, factors such as decrease total body water, increase in adipose tissue, altered tissue protein binding, increase in renal blood flow, and glomerular filtration rate all lead to alteration in pharmacokinetics of the drug in comparison to nonobese patient. Hence, monitoring precise endpoint of anesthesia is important in preventing undue delay in recovery, reducing postoperative morbidity, and complications. Clinical studies involving electroencephalographic-based cerebral monitors have demonstrated titration of both intravenous^[8,9] and inhalational^[10,11] anesthetics during general anesthesia. Bispectral index (BIS) monitoring is a form of electroencephalography-based cerebral monitor that uses bispectral analysis and has been proven to be effective in preventing awareness [Figure 1]. Bispectral analysis is a statistical technique that allows the study of phenomena with nonlinear character, such as surf beats and wave breaking.^[12] Bispectral analysis provides a description to a continuous pseudorandomly varying signal (e.g., electroencephalogram [EEG]) that is an alternative to other conventional power spectral analysis techniques derived from fast Fourier transformation. The EEG information, from which the BIS value is derived, is obtained by placing the sensor on the patient's forehead connecting it to the patient interface cable. The sensor transmits EEG signal to the monitor where it is processed through a complex and sophisticated algorithm, resulting in a BIS value which provides information on patient's status. BIS is a dimensionless number scaled from 100–0, with 100 representing an awake EEG and zero representing complete electrical silence (cortical suppression) [Figure 2]. In nonobese patients, optimizing anesthesia level using BIS monitoring will probably help shorten recovery time and reduce total anesthetic drug consumption.^[10,11,13] However, it could be even more valuable to titrate the administration of some inhaled anesthetic, such as sevoflurane, in morbid obese patients, the hypothesis being to shorten emergence from anesthesia using BIS monitoring. It would be a great advantage if BIS permitted a more rapid recovery.

The aim of this randomized comparative study was to investigate the effect of BIS monitoring on extubation and recovery times, in morbidly obese patients undergoing laparoscopic sleeve gastrectomy under general anesthesia using desflurane as maintenance anesthesia.

MATERIALS AND METHODS

This study was conducted in the Apollo Hospital, Chennai in December 2013–December 2014 after the ethics committee approval. A total of 80 morbidly obese patients (BMI >40 kg/m² and BMI >35 kg/m² or more and experiencing obesity-related health conditions, such as high blood pressure [BP] or diabetes) belonging to the American Society of Anesthesiologists (ASA) physical status 1 or 2 between the age groups of 25 and 45 years and scheduled for elective laparoscopic sleeve gastrectomy were included in the study. Informed and written consent



Figure 1: The bispectral index module

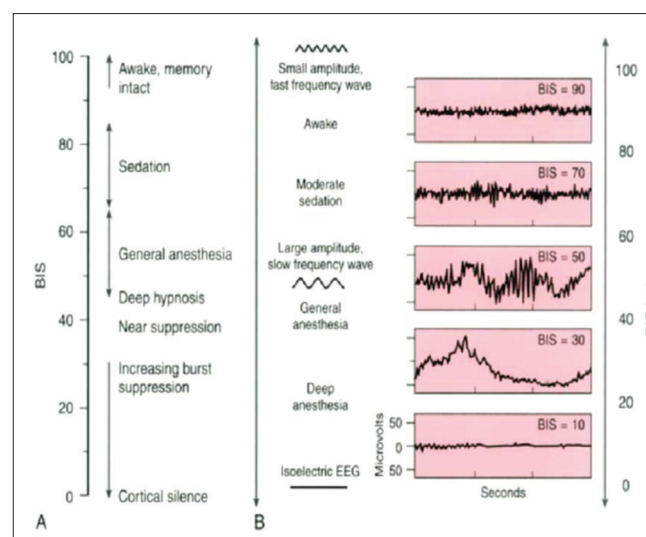


Figure 2: Clinical correlation of bispectral index

was obtained from each patient. Each patient underwent a preoperative evaluation and advised nil by mouth for 6 h.

Patients were randomly allocated into two groups (40 patients each) as follows: Group 1 (40 patients) were anesthetized with the use of BIS (BIS Group). Group 2 (40 patients) were anesthetized without the use of BIS (Non-BIS Group).

All the patients were premedicated with pantoprazole 40 mg orally at the night before surgery and metoclopramide 10 mg orally with sips of water 3 h before surgery. Basal vital parameters were recorded and patient preloaded with ringer's lactate solution. Following preoxygenation, intravenous induction was done with injection fentanyl 2 µ/kg and injection propofol 1.5–2 mg/kg. Intravenous rocuronium 0.9 mg/kg was administered to facilitates tracheal intubation and neuromuscular blockade. All patients were mechanically ventilated with 40% oxygen mixed with air to maintain an end-tidal carbon dioxide concentration of 35–40 mmHg and desflurane 6%. Intravenous paracetamol 1 g was given to all patients of both groups over 20 min after induction of anesthesia and local infiltration with bupivacaine 0.25% was given by the surgeon before all skin incisions. BIS monitoring (BISA-2000 software 2.21, Aspect Medical Systems, Newton, MA, USA) was initiated at induction, and smoothing time was 30 s (only in BIS group). Desflurane 6% in 2 L/min fresh gas flow, mixed in air and oxygen, was administered to all patients after endotracheal intubation until skin incision, then the concentration was changed every 5 min as follows:

In non-BIS group, the desflurane concentration was adjusted purely according to the clinical signs (heart rate [HR] and BP).

In BIS Group, anesthesiologists adjust the desflurane concentration to achieve a target BIS in the range of 40–60. During the surgery, the patients in both groups were observed for signs of inadequate anesthesia (increased BP and HR 20% from baseline, lacrimation). Significant hypotension or bradycardia was defined as 20% reduction of vitals from their baseline. Any instances of inadequate anesthesia were managed by increasing the concentration of desflurane. Rocuronium 0.15 mg/kg neuromuscular blockade was maintained to a single twitch of train of four. During the past 15 min of surgery in the BIS group, desflurane was titrated to maintain BIS in the range of 60–70. Neuromuscular blockade was reversed with neostigmine 0.07 mg/kg and glycopyrrolate 0.015 mg/kg intravenously. A verbal command to open eyes was given every 30 s. After a train-of-four ratio higher than 0.9 and a 5 s, head lift was performed by the patients, patients were extubated.

Time from discontinuation of inhalational agent (Desflurane) to the eye opening and extubation and recovery times (eye opening on verbal commands and orientation to the time place and person) were assessed at 1 min interval and documented.

After extubation, when the patients were full awake, patients were transferred to post anesthetic care unit (PACU) with oxygen 4 L/min using oxygen mask. All patients were observed in PACU for 3 h. Postoperative pain was evaluated with five-point verbal rating scale for pain. Postoperative pain was treated with injection ketoprofen 100 mg intramuscularly. Time to attain modified Aldrete score ≥ 9 [Figure 3] was recorded by PACU nurse in minutes (min).

RESULTS

Based on the previous study, the sample size was calculated as 40 in each group. The sample size of 80 is enough to maintain the power of study at least 80%. All the continuous variables were assessed for the normality using Shapiro–Wilk's test. If the variables were normally distributed, they were expressed as the mean \pm standard deviation, otherwise median (interquartile range). All the categorical variables were expressed either as percentage or proportions. Comparison of normally distributed continuous variables was done by either independent sample *t*-test or ANOVA based on the number of groups. Comparison of non-normally distributed continuous variables was being done by Mann–Whitney U-test or Kruskal–Wallis H test. Comparison of categorical variables was done by either Chi-square test or Fishers exact test based on the number of observations. Data entry was done in MS-Excel spread sheet. Data validation and analysis were carried out using SPSS Version 11.0. All $P < 0.05$ were considered as statistically significant. Majority of patients in our study was female accounting 56.2% of the total. There were no

Parameter	Description of patient	Score
Activity level	Moves all extremities voluntarily/on command	2
	Moves 2 extremities	1
	Cannot move extremities	0
Respirations	Breathes deeply and coughs freely	2
	Is dyspneic, with shallow, limited breathing	1
	Is apneic	0
Circulation (blood pressure)	Is 20 mm Hg > preanesthetic level	2
	Is 20 to 50 mm Hg > preanesthetic level	1
	Is 50 mm Hg > preanesthetic level	0
Consciousness	Is fully awake	2
	Is arousable on calling	1
	Is not responding	0
Oxygen saturation as determined by pulse oximetry	Has level >90% when breathing room air	2
	Requires supplemental oxygen to maintain level >90%	1
	Has level <90% with oxygen supplementation	0
Maximum total score is 10; a score of ≥ 9 is required for discharge.		

Figure 3: Modified Aldrete score

significant differences between males and females in relation to BIS values at various stages of anesthesia. As mentioned in [Table 1 and 2], the mean age in BIS group was 34.3 ± 5.33 year, and the mean age group in non-BIS group was 35.5 ± 5.90 . There was no statistically significant difference ($P = 0.378$) when comparing age between BIS group and non-BIS group. The mean BMI in BIS group is 46.1 kg/m^2 and in non-BIS group is 44.9 kg/m^2 (P value of BMI-0.496). The mean BMI difference was not statistically significant between two groups. The mean HR was calculated for BIS and non-BIS group and was found to be 77.8 ± 3.39 and 79.1 ± 3.4 . There was no statistically significant difference between two groups ($P = 0.095$). The mean MAP was calculated for BIS and non-BIS group and was found to be 94.5 ± 3.5 and 95.8 ± 4.2 . There was no statistically significant difference between two groups ($P = 0.136$). The mean awakening time in minutes, extubation time in minutes, and time to achieve modified Aldrete score ≥ 9 were compared between two groups and were found to be mean awakening time (BIS 11.38 ± 2.807 and non-BIS 14.92 ± 3.885 with $P = 0.000$) [Graph 1], mean extubation time (BIS 15.90 ± 2.863 and non-BIS 19.28 ± 4.120 with $P = 0.000$) [Graph 2], and mean time to achieve modified Aldrete score (BIS 31.60 ± 3.862 and non-BIS 40.80 ± 4.681 with $P = 0.000$) [Graph 3]. There was a statistically significant difference between the two groups in awakening time ($P = 0.000$), extubation time ($P = 0.000$), and modified Aldrete score ($P = 0.000$).

DISCUSSION

In this study, we compared the effects of BIS monitoring on early postoperative recovery in morbidly obese patients

undergoing laparoscopic sleeve gastrectomy. In this study, we found that there were no statistical differences in intraoperative mean arterial BP and mean HR in both groups. There were statistically significant differences in awakening time, extubation time, and time to achieve modified Aldrete score ≥ 9 .

Similarly, Punjasawadwong *et al.*^[14] results demonstrated that BIS reduced the recovery times; time for eye opening in 2557 patients was 1.93 min, response to verbal command in 777 patients was 2.73 min, time to extubation in 1501 patients was 2.62 min, and time to orientation in 373 patients was 3.06 min, and Song *et al.*^[10] have shown that titrating desflurane and sevoflurane using BIS monitor decreased the utilization of those volatile agents and contributed to a faster emergence from anesthesia in outpatients undergoing laparoscopic tubal ligation procedures.

Klopman *et al.*^[15] showed that BIS monitoring results in early recovery, shorter stays in the ICU, and reduced drug costs similar to our study. Results similar to our study were also observed by Boztug *et al.*^[16] who studied the effects of BIS monitoring in 50 ASA physical status I-II patients posted for craniotomy. At the end of the study, recovery times as defined as time for the first spontaneous breathing, eye opening, and extubation ($P = 0.035$, $P = 0.001$, and $P = 0.0001$) were significantly shorter in BIS group. Ekman *et al.*^[17] in their study, reported that the use of BIS monitoring during general anesthesia requiring endotracheal intubation and/or muscle relaxants was associated with a significantly reduced incidence of

Table 1: Demographic data and intraoperative, postanesthetic data for the BIS group and non-BIS group

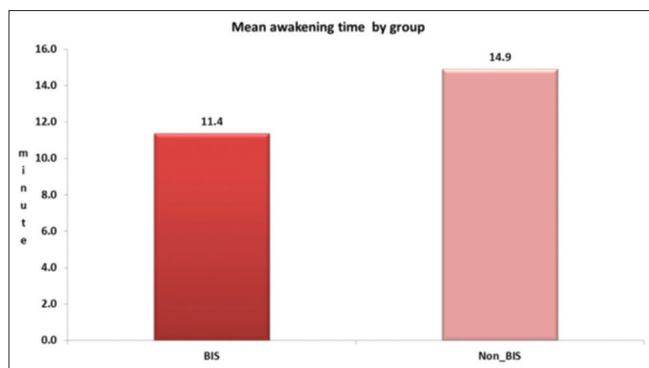
Data	BIS group <i>n</i> =40	Non-BIS group <i>n</i> =40	<i>P</i> value
Gender M/F	19/21	16/24	0.652
Age in year	34.3 ± 5.33	35.5 ± 5.90	0.378
ASA I and II	19/21	16/24	0.652
BMI kg/m^2	46.115 ± 7.35	44.917 ± 8.28	0.4906
Mean intraoperative HR	77.8 ± 3.39	79.1 ± 3.4	0.095
Mean intraoperative blood pressure (mm Hg)	94.5 ± 3.5	95.8 ± 4.2	0.136

BIS: Bispectral index, ASA: American Society of Anesthesiologists, BMI: Body mass index, HR: Heart rate

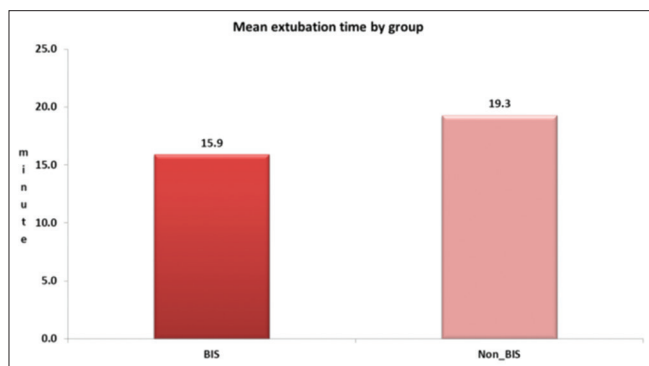
Table 2: Awakening time, extubation time, and time to achieve

Data	Group	Number	Mean (min)	Std. deviation	<i>P</i> value
Awake time	BIS	40	11.38	2.807	0.000
	Non BIS	40	14.92	3.885	
Extubation time	BIS	40	15.90	2.863	0.000
	Non BIS	40	19.28	4.120	
Time to achieve modified Aldrete score ≥ 9	BIS	40	31.60	3.862	0.000
	Non BIS	40	40.80	4.681	

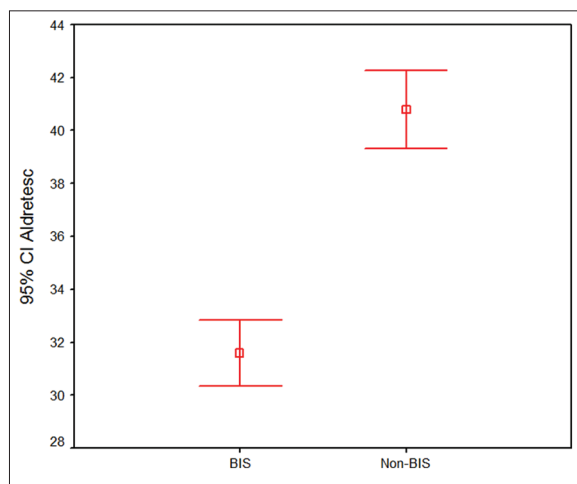
Aldrete score ≥ 9 in min expressed as mean \pm SD in minutes. SD: Standard deviation, BIS: Bispectral index



Graph 1: Bar diagram showing the difference in awakening time in min between the two groups



Graph 2: Bar diagram showing the difference in extubation time in min between the two groups



Graph 3: Error bar diagram showing the difference in attaining the modified Aldrete score ≥ 9 in min between the two groups

awareness. Heavner *et al.*^[18] had demonstrated that the use of BIS monitoring had improved recovery profiles in elderly patients anesthetized by desflurane and nitrous oxide. White *et al.*^[19] found that AEP and BIS monitoring can decrease the end-tidal desflurane concentration during maintenance of anesthesia and discharge times after the end of anesthesia.

The present study had demonstrated that using BIS monitoring lead to early postoperative recovery of morbidly obese patients undergoing laparoscopic sleeve gastrectomy. There was a significant difference in recovery times when comparing BIS-guided and non-BIS-guided anesthesia. The results were compared to those reported in other studies that assessed titration of propofol,^[20] desflurane, or sevoflurane^[10,21] by using BIS monitoring, but not in morbidly obese patients. Song *et al.*^[9] had concluded that BIS monitoring allows reduction in the total amount of intraoperative anesthetic consumption and appears to decrease emergency and recovery times. In this study, there were significant differences in the times of eye opening to verbal commands, extubation time, and orientation to time, place, and person between BIS and non-BIS groups. However, there were no statistically significant differences between mean HR and mean arterial blood pressure between two groups.

The use of cerebral monitors to minimize the intraoperative anesthetic drug consumption and improve the recovery process had raised concerns regarding the potentially deleterious effects of increased autonomic activity (e.g., myocardial ischemia) as well as the possibility of intraoperative awareness. However, in this study, intraoperative hemodynamic variables were not statistically significant.

CONCLUSIONS

The use of BIS monitoring was effective in reducing the recovery times in morbidly obese patients posted for elective laparoscopic sleeve gastrectomy. The difficult recovery and extubation in morbidly obese patients will be made ease with the use of BIS intraoperatively without compromising the hemodynamics and patient outcome. BIS monitoring clearly has a function in improving safety during sedation; however, anesthesiologists need to be proactive in providing rational guidelines for conscious sedation with or without BIS and improving patient safety. Depending on the specific patient characteristics, surgical procedure, and planned anesthetic technique, utilization of BIS monitoring may be a very appropriate decision.

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