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Research Article

CLINICAL EFFECTIVENESS OF BISPECTRAL INDEX TO REDUCE THE RISK OF AWARENESS FOR ELECTIVE SURGICAL PATIENTS UNDER GENERAL ANESTHESIA: AN OBSERVATIONAL STUDY

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ABSTRACT

Objective: The objective of this study was to reduce the risk of intraoperative awareness (IA) for patients undergoing elective surgeries under general anesthesia.

Methods: A prospective, observational study was conducted on 98 adult patients undergoing elective surgeries under general anesthesia to assess IA using bispectral index (BIS) monitoring. The study was carried out from October 2019 to February 2021 after obtaining consent from the institutional ethics committee.

Results: In our study, using BIS monitoring percentage of patients remembering anything in between the operation is only 1.03% and percentage of patients not dreaming during the operation is about 98.97%. BIS monitoring is safe and has predictable values in the depth of anesthesia for reducing the IA in general anesthesia.

Conclusion: We conclude that BIS monitoring would be a helpful tool in reducing the risk of awareness for patients undergoing surgeries under general anesthesia.

Keywords: Bispectral index, Awareness, General anesthesia, Surgery.

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INTRODUCTION

Intraoperative awareness (IA), or the unexpected and explicit recall by patients of events that occurred intraoperatively, is a rare but serious event. Incidences of IA have been associated with extreme anxiety, psychological stress, and the development of post-traumatic stress disorder [1]. Anesthesia has debated the efficacy of brain monitoring devices, such as the Bispectral index (BIS) monitor, to reduce the incidence of IA [2]. By analyzing electroencephalography (EEG) waves, these monitors can be used to alert the anesthesia provider when the patient may not be under sufficient depth of anesthesia [3].

One of the objectives of modern anesthesia is to ensure adequate depth of anesthesia to prevent awareness without inadvertently overloading the patients with potent drugs [4]. One of the achievements of modern anesthesia is the ability to monitor the depth of anesthesia.

IA is a major medicolegal liability to the anesthesiologists and can lead to postoperative psychosomatic dysfunction in the patients, and therefore should be avoided at all costs [5]. Intraoperative monitoring of the anesthesia depth is important for the prevention of this problem [6]. From all the available devices, only the BIS monitoring has been proven effective for this purpose. However, the high cost per person and the low specificity in preventing awareness episodes do not allow its everyday use.

In the recent past, anesthesiologists lacked a generally accepted indicator of anesthetic adequacy. Part of the problem was related to the fact that there is no standard against which to assess indicators of anesthetic adequacy. While vital signs are used clinically to monitor patient status during anesthesia, hemodynamic responses alone are not adequate since many factors contribute to hemodynamic responses [7] which have poor predictive value for anesthetic depth. The use of clinical signs may not be reliable in measuring the hypnotic component of anesthesia. The use of BIS to guide the dose of anesthetic may have certain advantages over clinical signs [8].

Aim of the study

This study aimed to reduce the risk of IA for patients undergoing elective surgeries under general anesthesia.

Objectives of the study

1. To evaluate the effectiveness of BIS monitoring in clinical practice to reduce the risk of intraoperative awareness for patients undergoing elective surgeries under general anesthesia
2. To assess the correlation between BIS scores and hemodynamic parameters.

METHODS

A prospective, observational study was conducted on 98 adult patients undergoing elective surgeries under general anesthesia to assess IA using BIS monitoring at GITAM Institute of Medical Sciences and Research Hospital, Visakhapatnam, from October 2019 to February 2021 after approval from the Institutional Ethics Committee.

Inclusion criteria

1. Patients aged between 18 and 60 years of both sex
2. ASA Grade I, II
3. Patient scheduled for elective surgeries under general anesthesia
4. Duration of surgery between 1 and 4 h.

Exclusion criteria

1. Patients who refused to participate in the study
2. Patients <18 years and >60 years
3. ASA Grade III/IV
4. MAC, moderate sedation, regional + sedation
5. Emergency surgical procedures

6. Patients with neurological problems or undergoing neuro surgeries
7. Patients with hypotension and shock
8. Cardiothoracic surgeries and patients needing post-operative ventilation.

Methodology

Patients undergoing elective surgical procedures expected to last at least 1 h under general anesthesia were included in the study. A detailed pre-anesthetic evaluation was done, and standard NPO protocols were followed. On arrival in the operating room, pre-induction monitors – pulse oximeter, non-invasive blood pressure (NIBP), and electrocardiogram (ECG) were connected. The following parameters were noted – systolic blood pressure (SBP), diastolic blood pressure (SBP), mean arterial blood pressure, heart rate (HR), and oxygen saturation (SpO_2). Intravenous (IV) access was established with 18 G/20 G IV cannula and an infusion of crystalloid started. After skin preparations, BIS electrodes (Aspect® Adult BIS Quatro electrodes, USA) were placed on the forehead and temple using a frontal – temporal montage and connected through module (version 1.0) to Beneview T5® Multiparameter Patient Monitor (Shenzhen Mindray Bio-Medical electronics Co., LTD, China). BIS score was displayed on the monitor [9]. The EEG was recorded continuously beginning before the induction of anesthesia until patients were awake and responding to verbal commands after extubation. Patients were premedicated with injection of glycopyrrolate 0.005 mg/kg, injection of midazolam 0.05 mg/kg IV, and pre-oxygenated for 3 min with 100% O_2. IV induction was done with injection of propofol 2–2.5 mg/kg or injection of thiopentone 3–5 mg/kg, and paralyzed using Neuromuscular blocking agents (vecuronium/atracurium) in appropriate doses.

Anesthesia was maintained with oxygen and nitrous oxide/air and volatile agents under controlled ventilation. Dose adjustment of anesthetic agents to age, surgical and pathological condition of the patient was made accordingly, Multimodel analgesia was practiced. Post-induction monitoring included end-tidal carbon dioxide, NIBP, ECG, SPO_2, and temperature. Any obvious changes in HR and BP necessitating supplementation with analgesics, hypnotics, and antihypertensive medications were carried out and recorded. Descriptions of all intraoperative events, along with measures taken to rectify them, were recorded. The patient was reversed at the end of the surgical procedure with injection of neostigmine 0.05 mg/kg and injection of glycopyrrolate 0.005 mg/kg. Patients were extubated after adequate recovery from the neuromuscular blockade and were observed for 20 min following extubation.

All patients were interviewed for recall half an hour post-extubation and on the first post-operative day. The following questions were asked to enquire about awareness and recall in immediate postoperative period and on the first post-operative day:

1. What is the last thing you remember before you went to sleep for your operation?
2. What is the first thing you remember after your operation?
3. Can you remember anything in between?
4. Did you Dream during your Operation?
5. What was the worst thing about your Operation?

BIS along with hemodynamics parameters were recorded before induction after induction with propofol, laryngoscopy and intubation, BIS score and hemodynamics (HR, SBP, DBP, SPO_2) were noted for every 10, 30, 60, 90, 120, and 10 min before reversal. The primary objective of the study was to observe BIS value to assess the depth of anesthesia throughout balanced general anesthesia. The secondary objective was to simultaneously correlate the observed BIS scores with hemodynamic changes.

Statistical methods

Data were analyzed using MINITAB version 18.0, Statistical Package for the Social Sciences (SPSS) version 21.0 and Microsoft Excel. Mean and standard deviation were computed for quantitative variables and frequency and percentage were calculated for qualitative variables. Student's t-test is performed to check the significant difference between the mean of basal and mean of different time points of all hemodynamics parameters, whereas correlation coefficient is performed to check the impact of basal score on different time points of all hemodynamics parameters (HR, SBP, DBP, and SPO_2 (%)) using $p<0.05$ was considered statistically significant.

RESULTS

The average BIS value after 10 min is significantly dropped from the basal average and it is statistically significant at 5% level of significance (Table 1). From 10 to 120 min, the average score is slightly increasing and 10 min before reversal, the score is significantly increased but significantly lower than the basal average score at 95% confidence level as per the Student's t-test. The graphical representation is shown below, i.e., the bar represents the average BIS score whereas the symbol "I" represents as ±SD from the mean (Graph 1).

The average HR after 10–120 min after the operation is significantly dropped when compared with the average basal HR (Table 2); Whereas the average HR at 10 min before the reversal is significantly greater than the basal average score (Graph 2).

The average SBP after 10–120 min is significantly dropped from the average basal at 95% confidence level, whereas the average SBP at 10 min before the reversal is significantly greater than the basal average (Table 3 and Graph 3).

Patients remembered before going to sleep most frequently feeling mask on face (Table 4).

The first thing to remember most commonly after surgery was being in the ICU (Table 5).

Patients mostly did not remember anything (Table 6).

Most patients did not dream during the operation (Table 7):

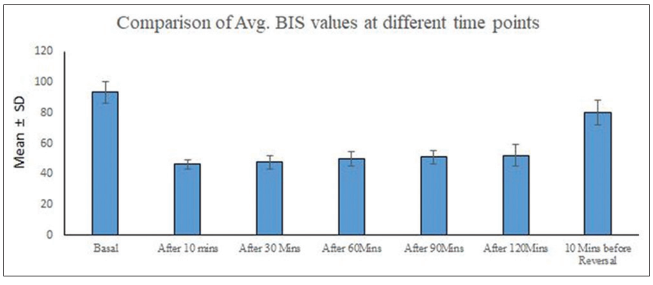
Most patients did not feel anything worse about their operation (Table 8).

DISCUSSION

Anesthetic drug effects have traditionally been measured by the observation of HR, blood pressure, breathing pattern, and the presence or absence of movement. While these are useful measures,

Table 1: Changes in bispectral index throughout the procedure

Time	n	Mean	SD	T-value	p-value	Conclusion
Basal	98	93.47	7.20			
After 10 min	98	46.29	3.34	58.87	0.000	Significant
After 30 min	98	47.81	4.41	53.57	0.000	Significant
After 60 min	98	49.83	4.76	50.06	0.000	Significant
After 90 min	81	51.01	4.16	49.28	0.000	Significant
After 120 min	67	52.31	6.77	37.38	0.000	Significant
10 min before reversal	98	80.26	7.84	12.29	0.000	Significant



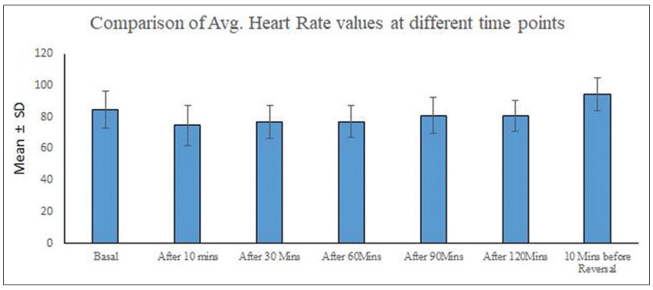
Graph 1: Changes in bispectral index throughout procedure

the cardiopulmonary effects of anesthetics are side effects rather than direct indicators of the sedative and hypnotic effects, which are the main reason that anesthetics are given in the first place. Clearly, patients can experience IA in the absence of clinical signs of light anesthesia, such as changes in HR, or blood pressure, or even movement. Therefore, a more direct and reliable method of measuring anesthetic drug effects on the brain is highly desirable and has been the object of research for many years. EEG is an obvious brain monitoring modality because it is the EEG, and these have been extensively studied. However, efforts to use EEG monitoring as a real-time clinical tool were not successful until relatively recently. The development of relatively inexpensive fast microcomputers was a critical prerequisite [10].

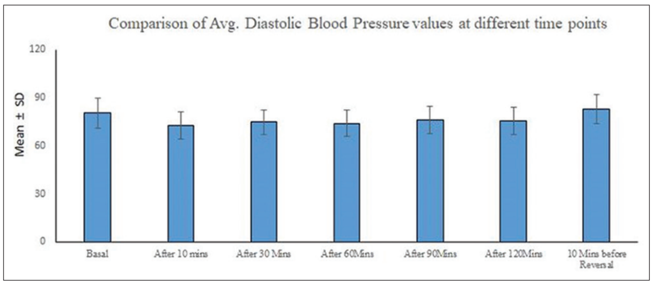
The results of this observational study show that BIS varies in various stages of general anesthesia in response to the anesthetic agents used. All patients who underwent elective surgeries under general anesthesia were included in the study. Moreover, there is no IA noted according to the questionnaire in all the patients and there is no significant difference in the BIS scores observed.

We selected in our study, the duration of surgery between a minimum of 60 min of duration to a maximum of 240 min of duration and conducted the study while evaluating the BIS scores at the basal level after 10 min, 30 min, 60 min, 90 min, 120 min, and 10 min before reversal. Most of the cases are completed beyond 120 min (68.37%) and the BIS scores are maintained at around 45–55 depending on the duration of the surgery. Despite maintaining the BIS scores, there is a significant increase in the BIS score is seen 10 min before reversal with a mean BIS score of 80.26±7.84 SD, which is statistically significant and in correlation with the observations of Mathur *et al.*, [11] Lewis *et al.,* [12] Spackman and Abel, [13] and Rosow and Manberg [14].

The mean basal BIS score was 93.47±7.2 SD and is observed. The average BIS value after 10 min of induction with injection propofol 2.2.5 mg/kg is significant and dropped from the basal average and it is statistically significant with a mean BIS of 46.29±3.34 with a T value of 58.87 and p<0.001. From 10 to 120 min, the average score is slightly increasing and after 10 min before reversal, the score is significantly increased but significantly lower than the basal average score at 95% confidence level as per the student t-test. These scores are in correlation with Spackman and Abel [13] and Rosow and Manberg [14].



Graph 2: Comparison of heart rate values at different time



Graph 3: Comparision of DBP values at different time points

Table 2: Heart rate changes during various stages

Time	n	Mean	SD	T-Value	p-value	Conclusion
Basal	98	84.6	11.8			
After 10 min	98	74.8	12.6	5.62	0.000	Significant
After 30 min	98	76.9	10.3	4.87	0.000	Significant
After 60 min	98	77.04	9.98	4.83	0.000	Significant
After 90 min	82	80.9	11.4	2.12	0.036	Significant
After 120 min	67	80.58	9.79	2.37	0.019	Significant
10 min before reversal	98	94.4	10.3	−6.20	0.000	Significant

Table 3: Systolic blood pressure during various stages

Time	n	Mean SBP	SD	T-value	p-value	Conclusion
Basal	98	135.1	14.4			
After 10 min	98	120.1	12.1	7.88	0.000	Significant
After 30 min	98	125	12.5	5.25	0.000	Significant
After 60 min	98	126.8	13	4.23	0.000	Significant
After 90 min	82	128.5	18.4	2.61	0.010	Significant
After 120 min	67	128.9	13.5	2.79	0.006	Significant
10 min before Reversal	98	143.4	12.2	-4.38	0.000	Significant

Table 4: Data of last thing to remember before going to sleep

Last thing to remember	Frequency	Percent
Being in preop area	18	18.4
Being with family	5	5.1
Burning sensation in IV line	22	22.4
Feeling mask on face	24	24.5
Seeing operating room	18	18.4
Smell of gas	8	8.2
Total	98	100.0

Table 5: Data of first thing to remember after surgery

First thing to remember	Frequency	Percent
Being in ICU	36	36.7
Being with family	28	28.6
Feeling mask on face	23	23.5
Seeing operating room	8	8.2
Total	98	100.0

Table 6: Data of patient remembers anything in between

Remember anything in between	Frequency	Percent
Hearing voices	1	1.02
Nothing	97	98.97

Table 7: Data of patient dream during operation

Patient dream during operation	Frequency	Percent
No	97	98.97
Yes	1	1.03

Table 8: Data of the worst thing of patient felt about his operation

Worst thing patient felt	Frequency	Percent
Anxiety	34	34.69
Fear of pain	18	18.37
Nothing	44	44.90
Pain during cannulation	2	2.04

The average basal HR of the study group is 84.6±11.8 SD and after induction at 10 min the mean HR is 74.8±12.6 SD with a significant p<0.001. The mean HR gradually increased at different time intervals and correlated with the increasing BIS scores. The highest HR is seen at 10 min before reversal with a mean HR of 94.4±10.3 SD, which is a significant in HR compared to the basal values and this increase in HR is correlated with increased awareness and increase in BIS scores. Similar observations in HR changes are made in all three age groups of the study. Our observations concurred with the average basal SBP of the study population is 135.1 mmhg±14.4 SD, there is a significant decrease in the mean SBP of the study population after 10 min of induction with a mean of 120.1±12.1 SD mmhg. The mean SBP gradually increased during the surgery and there is a significant rise in the mean SBP above the basal reading with a mean SBP of 143.4±12.2 mmhgSD with p<0.001 is observed.

Similar changes are also seen in DBP with a mean basal DBP of 80.44±9.47 SD mmhg with a decrease in the mean DBP of 72.54±8.59 SD mmhg at 10 min after induction with a significant p<0.001 and T value of 6.12. The mean DBP gradually increased during the surgery in correlation with BIS scores, with a maximum rise in the mean DBP at 10 min before reversal with a mean DBP of 83.11±9.09 SD mmhg with a significant p<0.05 and T value of −2.02.

An increase in BIS value, HR, SBP, and DBP values 10 min before reversal could be because of reducing the volatile agent concentrations. We observed that BIS fluctuation in the 50–60 years age group is not as much as the younger group.

In our study, we observed only one patient out of 98 patients we studied experienced awareness during surgery with hearing sounds and dreaming during the course of the surgery and is in correlation in the study conducted by Zhang *et al.* [15]. In this patient, there was an increase in the BIS value of 65 after 90 min of induction for a brief period, we intervened this with increasing the depth of anesthesia by giving 30 mg of IV thiopentone sodium and achieved a BIS value of <60 after 1 min.

CONCLUSION

BIS monitoring successfully reduces anesthetic use while preventing patient awareness resulting in quicker emergence from anesthesia decreased post-anesthesia care unit times. BIS monitoring reduces the complications like post-traumatic stress disorders.

We conclude that BIS monitoring would be a helpful tool in reducing the risk of awareness for patients undergoing surgeries under general anesthesia.

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AUTHOR'S CONTRIBUTION

Conceptualization and Data collection - Dr.Durgashekar Babu Dikkala Drafting&Editing - Vamshi Yaswanth K, Aman Sai G.

COMPETING INTERESTS

Nil.

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