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TO STUDY THE CLINICAL EFFECTIVENESS OF THE BISPECTRAL INDEX (BIS) IN ELECTIVE SURGICAL PATIENTS UNDER GENERAL ANAESTHESIA- A PROSPECTIVE RANDOMIZED STUDY

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Abstract

Introduction: Anaesthesia is a drug-induced state of unconsciousness in which the patient is unable to feel or remember unpleasant stimuli. The ability to recollect events that occur during anaesthesia is referred to as awareness. Patients can perceive awareness while under general anaesthesia, as well as later remembrance of happenings during surgery, as terrifying episodes that cause permanent mental trauma and may develop posttraumatic stress disorder, which is characterized by complex psychopathological symptoms such as anxiety, insomnia, nightmares, irritability, and depression. BIS monitor determines the degree of anaesthesia and allows for anaesthetic titration to determine the patient's level of consciousness. The purpose of this study is to determine the clinical effectiveness of BIS monitoring in reducing awareness, as well as the effect on hemodynamic parameters, drug consumption, recovery times, and end-tidal volatile anaesthetic concentrations in adult patients undergoing various types of surgery under general anaesthesia.

Materials and Methods: 60 patients of ASA physical status I&II aged between 18 to 60 years old, receiving elective surgeries under general anaesthesia at SVMC, SVRRGGH, Tirupati were enrolled in this prospective, randomised study**.** The patients were randomly assigned to one of the two groups: Routine Care group or BIS guided anaesthesia group. All patients received standard general anaesthesia; outcome measures like BIS values and hemodynamic parameters were recorded every 5 minutes till extubation. At 24-36 hours after surgery, patients were interviewed to determine their awareness experience. Amount of anaesthetic agents used, intra operative physiological variables (signs of lacrimation, coughing, sweating, and movement) were measured throughout the duration of anaesthesia and surgery, and the time of discharge from PACU was recorded.

Results: Sixty patients were allocated randomly to BIS-steered anaesthesia (n=30) or routine care group (RC) (n=30). The difference in the inspired concentration of inhalational anaesthetic between the two groups under study is statistically significant ($P<0.05$). The Routine Care group's mean value was 0.028±0.007, while BIS group's mean value was 0.024±0.013 (P= 0.043). The end-tidal sevoflurane concentration difference is statistically significant: the mean value for Routine Care was 0.054±0.166 and for BIS was 0.018±0.012 (P=0.004). The difference in sevoflurane dosage between the two groups is statistically significant; the mean value for the Routine Care group was 0.029±0.008 while the mean value for the BIS group was 0.025±0.009 (P= 0. 023).

Conclusion: The present study demonstrated that, compared to routine care, BIS-guided anaesthesia (BIS kept at 40-60) lowered the risk of awareness. Furthermore, BIS monitoring decreases the need of inhaled anaesthetic agents and the time taken for Post anesthesia care unit (PACU) discharge.

Key Words: General anaesthesia, Awareness, BIS monitoring, PACU discharge.

INTRODUCTION

Anaesthesia is a drug-induced state of unconsciousness in which the patient is unable to feel or remember unpleasant stimuli[1]. The ability to recollect events that occur during anaesthesia is referred to as awareness. The amount of anaesthesia (GA) used must be optimal. If a patient receives more anaesthetic than needed may develop anaesthesia-related illnesses such as postoperative nausea, vomiting, and cognitive problems, which can result in a prolonged recovery period and increased health-care expenses.

Awareness is one of the problems that affect 0.1-0.2 percent of all surgical patients[2,3]. BIS monitor determines the degree of anaesthesia and allows for anaesthetic titration to determine the patient's level of consciousness[4]. Previously there is no enough data on the happening of awareness during various types of general anaesthesia. We believe that such a technology can help anaesthesiologists to determine the appropriate hypnotic dose and monitoring method ahead of time, reducing risks in regular medical practice[5,6]. This study will serve as a reference guide for anaesthesia teams, and the findings may have consequences for patient safety, mental health, medico-legal difficulties, and cost-effective results for patients and health-care systems.

The purpose of this study is to determine the clinical effectiveness of BIS monitoring in reducing awareness, as well as the effect on hemodynamic parameters, drug consumption, recovery times, and end-tidal volatile anaesthetic concentrations in adult patients undergoing various types of surgery under general anaesthesia.

MATERIALS AND METHODS

This prospective, randomized study was conducted in the department of Anaesthesiology, SV medical college, Tirupati. After receiving approval from institutional ethics committee, 60 patients with American Society of Anaesthesiologists physical status I&II, aged between 18-60 years of either sex scheduled for elective surgeries under general anaesthesia were randomly assigned to two groups of 30 each -Routine care group and BIS steered group. Patients on beta

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blockers, with H/O cognitive impairment, psychiatric disorders, EEG abnormalities, addicted to opioids were excluded from the study. After obtaining written informed consent from all patients, standard general anaesthesia was administered. In operating room, monitoring- electrocardiogram, blood pressure, heart rate, saturation, ETCO2 and BIS were connected. Patients were premedicated with Inj. Glycopyrrolate 0.2mgIV, Inj ondansetron 0.1mg/kg IV, inj Midazolam 0.03mg/kg IV,1-2mcg/kg fentanyl. After preoxygenation, patients were induced with 2-2.5mg/kg propofol, 0.1 mg/kg vecuronium and intubated with appropriate sized ET tube. Anesthesia was maintained with a mixture of Oxygen, Nitrous Oxide, and Sevoflurane (1-1.5 percent) and vecuronium 0.02mg/kg aliquots and connected to mechanical ventilator support.

Throughout surgery, the concentrations of end-tidal sevoflurane were monitored. If there were clinical indicators of a lack of depth of anaesthesia, such as an increase of > 20% of pre-anaesthetic values in HR and MAP, tears, coughing, sweating, and movement, patients were given fentanyl (1 mcg/ kg) intravenously. BIS, HR, and BP were assessed and recorded at specific points during anaesthesia: prior to induction; 30 secs after laryngoscopy and intubation; and every 5 mins until the patient was extubated.

When the skin closure started, sevoflurane and nitrous oxide were turned off. Neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg was used as reversal agent and extubated after regaining consciousness. The time from the end of the inhalational agents to the opening of the eyes was recorded. To determine consciousness, all patients were interviewed 24-36 hours after surgery. The primary outcome was awareness confirmation, as indicated by the memory of patient's intraoperative events as determined through a series of questions.[7]

BIS monitoring began before anaesthetic induction and continued throughout surgery. At the beginning of the procedure, value of BIS which was 100 dropped to 50 post induction. After it was maintained in the range of 40-60. Sevoflurane concentration increased if the patient had an increase in heart rate or blood pressure and if the BIS value was greater than 60. Fentanyl was given if the BIS values were in the target range of 50-60. Sevoflurane was lowered and the patient was observed for lack of pain alleviation if the BIS value was less than 50. In the control group, anaesthetist was free to adjust based on the needs of the patient.

Intra-operative inhalational anaesthetic consumption, Recovery outcomes (time to extubation), Time to eye opening (either voluntary or in response to request), Postoperative Nausea and vomiting (PONV), Pain, Time to PACU discharge were assessed.

Statistical analysis: Statistical analysis was done using SPSS version 21. Continuous variables were expressed as mean± standard deviation with students T test for comparison. Categorical variables a were expressed as percentages and comparison was by chi square analysis. A P value <0.05 was considered as statistically significant.

RESULTS

Sixty patients were allocated randomly to BIS-steered anaesthesia (n=30) or Routine care group (RC) (n=30). The groups were comparable in terms of clinical characteristics and demographic variables as shown in Table 1.

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Table 1: Clinical characteristics and demographic variables compared between study groups (Routine Care and BIS).

Variable	Routine Care groupN=30	BIS groupN=30	P-value
Mean Age	42.11±19.892	43.34±16.363	0.571
Mean Weight	77.17±17.994	75.79±14.369	0.889
Mean Height	170.25±7.347	169.97±8.695	0.955
Patient Metabolic Index	26.62±4.70	26.14±4.00	0.690
Gender-male	21(70%)	21(70%)	0.931
Gender-female	9(30%)	9(30%)	
Previous surgery-Yes	20(66.7%)	18(62.1%)	0.862
Previous surgery-No	10(33.3%)	12(37.9%)	
Previous medication-Yes	6(20.0%)	5(16.7%)	0.639
Previous medication-No	24(80.0%)	25(85.3.%)	
Smoking-Yes	11(36.7%)	15(50.0%)	0.291
Smoking-No	19(63.3%)	15(50.0%)	
Chronic diseases-Yes	11(36.7%)	10(33.3%)	0.785
Chronic diseases-No	19(63.3%)	20(66.7%)	

Table 1 shows the clinical features and demographics of the patient for the two research groups. In terms of general patient characteristics, there are no notable differences between the two groups.

Table 2: Anesthetic drug doses (BIS and Routine Care)

DRUGS	Routine Care group N=30	BIS group N=30	P-value
Propofol mg	230±59.938	274.07±711.3	0.234
Midazolam mg	1.17±0.408	1.5±1	0.649
Fentanyl (mcg)	77.76±40.523	115.56±94.18	0.036*
Sevoflurane inspired concentration	0.028±0.007	0.024±0.013	

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	(0.011-0.04)	(0.0-0.07)	0.043*
IV anaesthetic agents mean dose (mg)	221.07±56.197	260.67±243.678	0.936
Mean dose of inhaled Anaesthetic agents	0.029±0.008 (0.012-0.04)	0.025±0.009 (0.01-0.035)	0.023*
Sevoflurane end tidal concentration %	0.054±0.166 (0.008-0.9)	0.018±0.012 (0.006-0.06)	0.004*

As shown in table 2, the difference in the inspired concentration of inhalational anaesthetic between the two groups under study is statistically significant (P<0.05). The Routine Care group's mean value was 0.028±0.007, while BIS group's mean value was 0.024±0.013 (P= 0.043). The end-tidal sevoflurane concentration difference is statistically significant: the mean value for Routine Care was 0.054±0.166 and for BIS was 0.018±0.012 (P=0.004). The difference in sevoflurane dosage between the two groups is statistically significant; the mean value for the Routine Care group was 0.029±0.008 while the mean value for the BIS group was 0.025±0.009 (P= 0. 023).The Routine Care group's mean value was 0.0282, which was reduced to 0.024 percent, while the P-value for the BIS group was 0.043. The statistics also show a statistically significant difference in the mean dose of inhaled anaesthetic agents between the two groups: With a P-value of 0.023, the mean value for the Routine Care group was 0.029 percent, which was reduced to 0.025 percent in the BIS group. The end-tidal sevoflurane concentration difference is statistically significant: the mean value for Routine Care was 0.054 and for BIS was 0.018, with a P-value of 0.004. The difference in sevoflurane dosage between the two groups is statistically significant: the mean value for the Routine Care group was 0.028, while the mean value for the BIS group was 0.023, with a P-value of 0. 023. The difference in fentanyl dosage between the two groups is statistically significant: the mean value for the BIS group was 115.56, while the mean value for the Routine Care group was 77.76, with a P- value of 0.035.

Table 3 Differences in Intraoperative Physiological Variables (BIS and Routine Care group)

Variable	Categories	Routine Care group N=30	BIS Group N=30	P-value
Intraoperative Sweating	No	30(100%)	26(86.7%)	0.296
	Yes	0(0%)	4(13.3%)	

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Intraoperative Lacrimation	No	25(83.3%)	25(83.3%)	0.686
	Yes	5(16.7%)	5(16.7%)	
Pupillary Dilatation	No	29(96.7%)	26(86.7%)	0.553
	Yes	1(3.3%)	3(13.3%)	
Intraoperative Coughing	No	29(96.7%)	29(96.7%)	0.313
	Yes	1(3.3%)	1(3.3%)	
Intraoperative Jerking	No	21(70.0%)	27(90.0%)	0.037*
	Yes	9(30.0%)	3(10.0%)	

The Intraoperative Jerking percentage decreased from 30.0 percent in the RC group to 10.0 percent within the BIS group, as shown in table 3, with a P-Value of 0.037. Statistical significance does not exist between the two groups as well as other variables under consideration.

Table 4: Study Group Differences in recovery parameters (BIS and Routine Care.

Variable	Routine Care group N=30	BIS group N=30	P-value
Time of surgery(minutes)	73.8±85.8	116.4±106.2	0.194
Duration of eye opening from stoppage of inhalational agents (minutes)	7.32±4.643	5.19±3.462	0.086
Time taken for responding to commands(minutes)	10.03±5.335	8.11±4.516	0.205
Time taken for opening eye (either for command or spontaneous) (minutes)	10.81±5.955	8.24±4.833	0.086
Time taken for first movement response (minutes)	7.69±6.03	5.31±3.878	0.174
Time taken for phonation (minutes)	12.80±6.11	10.20±5.117	0.027*

Between the two study groups, the difference in time taken for phonation is statistically significant, as shown in table 4, with an average time taken for phonation in the Routine Care group being 12.80 minutes and the mean time for the BIS group being 10.21 minutes, and the Mann-Whitney test P-value being 0.026. There are no statistically significant variations in any of the variables between two groups.

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Table 5: Differences in Recovery Time, Discharge Criteria Score, and Time to Discharge from the PACU

Variables	Routine Care Group N=30 Mean±S.D	BIS group N=30 Mean±S.D	P-value
Time taken for recovery (minutes)	11.64±5.09	9.94±4.262	0.200
Score for discharge Aldrets Score	9.72±0.75	9.6±1.66	0.184
Time taken for Discharge from the PACU (minutes)	12.37±4.989 (6-26)	9.24±3.818 (4-20)	0.006

The time taken for discharge from the PACU within the two groups is statistically significant ($P<0.05$), as shown in table 5. The average time taken for discharge from the PACU was 12.37±4.989 minutes for the RC group and 9.24±3.818 minutes for the BIS group, with P-value-0.006. All the other variables under investigation have no statistically significant differences.

No statistically significant difference noted between 2 groups (BIS group and Routine Care) with regard to SpO_2, ET CO_2, Heart Rate, Systolic BP, Diastolic BP, Mean arterial pressure, RR ($P > 0.05$)except at a few points of time as shown in Table 6.

Table 6: Hemodynamic Parameters between Study Groups at specified time intervals

Parameters at SpecificTime Points-Minutes	RC Group N=30	BIS Group N=30	P-value
SBP -50min	109±28.08	128.45±25.482	0.016*
SBP-55min	103.75±20.722	122.25±27.34	0.028*
SBP-60min	100.08±28.268	126.29±32.031	0.034*
DBP-50min	60.18±16.693	75±15.822	0.007*
DBP-55min	61.33±15.556	72.67±16.612	0.038*
MAP-50min	76.56±17.594	92.56±19.736	0.013*

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The difference in SBP levels between the study groups does not change during intraoperative period, but only at specified time intervals (50, 55, and 60 min) were the differences significant in favour of the BIS group(P<0.05). There was statistically significant difference with regard to DBP noted only at specified intervals (50, 55 min) in BIS group (P<0.05). Statistically significant difference for MAP noted at 50min (P<0.05)

Table 7 Incidence of awareness in study population (RC and BIS).

PARAMETERS		Group		P-value
		Routine Care(,n=30) F(%)	BIS (n=30) F(%)	
Incidence of Awareness	No(n=55)	25(83.3%)	30(100%)	0.0.035
	Yes(n=5)	5(16.7%)	0(0%)	

There was statistically significant difference observed regarding incidence of awareness between two study groups (P<0.05) as shown in Table 7.

DISCUSSION

Anaesthesia-induced awareness is a significant condition with long-term psychological implications. Intra-operative awareness occurs in 0.1 percent of low-risk procedures (Jones & Aggarwal[8] 2001; Myles et al[3] 2004;) and 4% of high-risk procedures. However, there has been an increased focus in recent years on the issue of unexpected recall when under general anaesthesia The Bispectral index (BIS), which is calculated from a processed electroencephalogram, may help patients have less anaesthetic awareness. Consciousness during surgery is a difficult issue for both the anaesthesiologist and the patient, according to Kotsovolis & Komninos[9] (2009). Intraoperative awareness has been described by patients as the scariest they have ever experienced and may lead to post traumatic stress disorder which is typically caused by pain, worry, and were unable to react due to muscle paralysis, necessitating mental attention. The prevention of this condition necessitates intra-operative monitoring of the anaesthetic depth. Only the Bispectral Index monitoring (BIS) is a reliable option to monitor the depth of anaesthesia[10].

According to this study, understanding the reason for awareness during anaesthesia necessitates examining the anaesthetic technique. RC group received less propofol, which induces hypnosis, and less fentanyl, which relieves pain, than those in the BIS group. This could explain why patients in the standard care group were aware than the BIS group in the current trial. When anaesthesia is administered too lightly, it might cause patients to remember events or discussions that occur in OT. Hence depth of anaesthesia monitoring is crucial to prevent intra operative awareness and titrate dose of anaesthetic agents. Our findings are likewise consistent with those of the Punjasawadwong trial, that found adequate proof to warrant the use of BIS-monitoring to guide

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anaesthetic dosing and prevent intraoperative awareness (Punjasawadwong, et al.[11] 2014). Our findings were corroborated by Sandin et al.[12], who found that monitoring of BIS during general anaesthesia decreased the occurrence of awareness by 13%in comparison with control group (Sandin et al.[12] 2000). Our findings are similarly consistent with those of Ekman et al.[10] (2004), who found a 77 percent decrease in awareness during BIS monitoring.

Assessment of anaesthetic depth by clinical variables (BP, HR) throughout anaesthesia is unreliable for determining anaesthesia depth (Weber F, et al[13]). When comparing routine care and BIS guided anesthesia care groups, we found a statistically significant reduction in the mean dose of inhaled anaesthetics in BIS guided group. Our findings are consistent with those of Punjasawadwong et al[11]. (2014), who found that BIS-guided anaesthesia can significantly reduce anaesthetic consumption, as well as those of Ibraheem et al[14] (2013), who found that using BIS monitoring reduced intraoperative desflurane requirements in patients undergoing laparoscopic sleeve gastrectomy. A failure of somatic response to noxious stimulus is defined as a lack of purposeful movement (twitching or grimacing, twisting or jerking of the head). In our study, we showed no difference in perspiration, tears, dilation of pupil, or coughing with both BIS group and R C group. There was a significant reduction in intraoperative jerking between BIS monitored and normal care patients. In other words, BIS is extremely helpful in avoiding noxious stimuli while maintaining complete lack of somatic response to a nociceptive stimulus.

There was no variation in time to extubation between the BIS group and RC group, according to the findings of this study. This finding contradicts prior research, which concluded monitoring of BIS was linked to a short extubation time. Extubation time was substantially shorter in the BIS group, according to Akcali et al.[15] (2008). Other studies came up with similar findings (Boztug, et al.,[16] 2006, Burrow, et al[17] 2001, Gan et al[18] 1997, Yili-Hankala, et al.[19], 1999. and Recart, et al.[20] 2003). Punjasawadwong, et al.[11] (2014) found that BIS-guided anaesthesia decreased all the elements of recovery duration, including the time for eye opening, response to voice, extubation, &orientation, regardless of the anaesthetic used. By using BIS- guided anaesthesia, we were able to shorten the time it took to open the eyes and extubate the patient, although the differences were not substantial except for thetime it took for phonation .In our study, compared to patients of usual care group, BIS monitored patients had a significantly shorter time to discharge from the PACU. These findings correlate with Punjasawadwong, et al[11] study. In our study**,** BIS group and the standard care group had substantial disparities in SBP, DBP, and MAP at specified tie intervals during surgery. Our findings backup those of Mozafari et al[21] (2014), who discovered that changes in hemodynamic parameters during abdominal surgery were unaffected by the type of monitoring system used.

CONCLUSION

From the above study it was concluded that, compared to Routine care, BIS-guided anaesthesia (BIS kept at 40-60) lowered the risk of awareness. Furthermore, BIS monitoring decreases the need of inhaled anaesthetic agents and the time taken for PACU discharge.

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