

BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY

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Abstract- BIS, used to assess the depth of anesthesia is a processed EEG in which electrodes are placed on the forehead, and BIS scores are continually presented. One of the aims of modern anaesthesia is to facilitate early recovery and home discharge. Hence, more emphasis is being given to make sure adequate depth of anaesthesia is maintained in order to prevent awareness during anaesthesia without unnecessarily overdosing patients with powerful medications often leading to extended ventilation and postoperative sedation. The present aim of the study is to compare the time and quality of recovery in the post-operative period with and without the use of BIS (Bispectral Index).

Keywords – Bispectral index monitor, anesthesia recovery period, general anesthesia, intraoperative awareness

I. INTRODUCTION

BIS monitoring has been demonstrated to be successful among all existing technologies for monitoring anaesthetic depth[1-4]. The bispectral index, a non-invasive approach where the EEG is recorded from 4 electrodes that are applied over the forehead, and after processing it with mathematic algorithms, it generates a number from 0 to 100. These BIS scores are shown continuously and objectively in the monitor, indicating the state of awareness. The patient when under profound anaesthesia the BIS value is less than 40 and when under mild sedation the value is greater than 80[3,5]. The use of BIS monitoring will most likely aid in the optimization of anaesthetic levels, ensuring that they are neither too light nor too deep.

BIS monitoring has been shown to help minimize drug usage and awareness, as well as speed up recovery time[6-9]. It offers various potential benefits over traditional intermittent patient evaluation procedures. Traditional evaluation is taking repeated readings of all vital signs to measure the level of anaesthesia and then adjusting the anaesthetic agent dosage accordingly.

One of modern anaesthesiology's accomplishments is the ability to determine anaesthetic depth[1]. Awareness during surgeries is a major condition that affects 0.1–0.2% of all surgical patients. Patients who have had an intra-operative awareness experience, regard it as the worst thing they have ever experienced, with such instances

accounting for 2% of all legal claims against anaesthetists and can cause the patient to experience postoperative psychosomatic disorder and should be strictly avoided[1,5].

Carlos Rogerio Degrandi Oliveira et. Al[10] have done research comparing the benefits of GA monitoring based on the BIS Index versus monitoring based only on clinical indicators. The study was shown benefits in reducing time to extubation, orientation in time and place, and discharge from operating room and post anaesthetic care unit.

Jasminka Persec et. Al[5] had studied that the use of BIS monitoring to guide anaesthesia will result in a much faster recovery time following anaesthesia.

As a result, titrating anaesthesia based on the BIS levels detected, facilitated to employ anaesthetic methods that allow early recovery while maintaining an appropriate depth of anaesthesia, avoiding all complications associated with extended postoperative ventilation.

In this present study, we evaluated the notion that BIS guided anaesthesia will result in earlier recovery time and improve quality of recovery when compared to conventional anaesthesia practice.

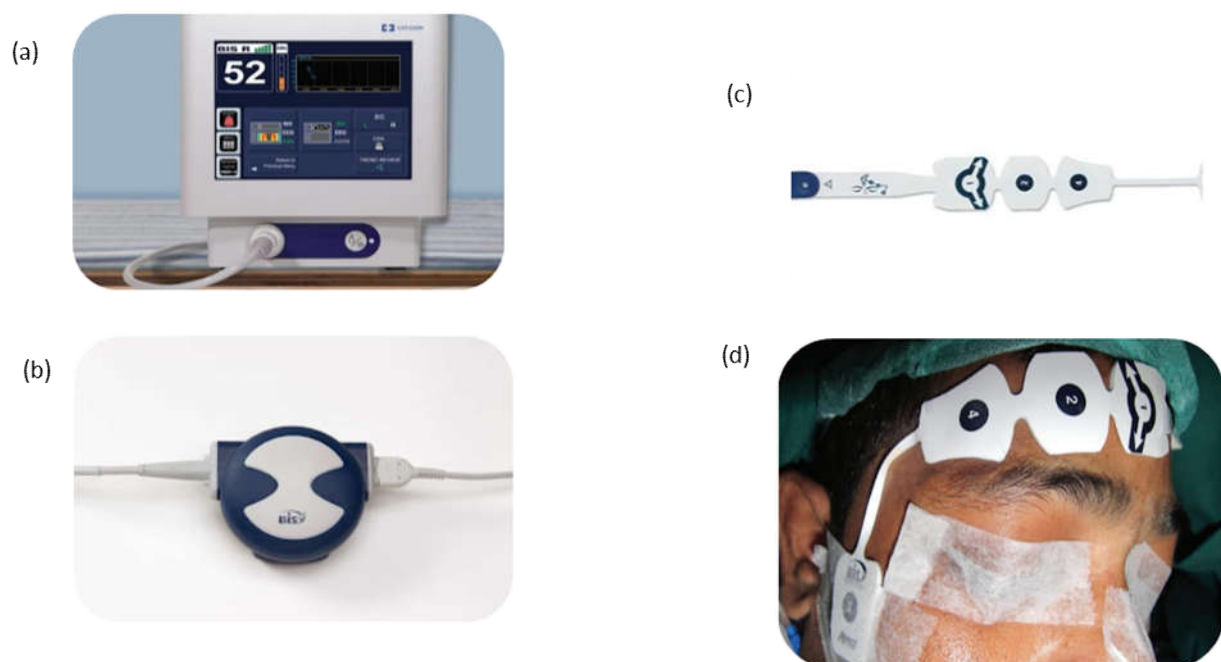


FIGURE 1: (a) Bispectral index monitor (b) BIS- X device (c) BIS strip (d) BIS strip placed on patient's forehead and temple region.

II. MATERIALS AND METHODS

The study was conducted from 22-11-2019 to 31-05- 2021 in the Department of Anesthesiology, Shri B M Patil medical college, hospital and research center after ethical committee approval. Written informed consent was obtained from each patient.

2.1. Inclusion Criteria–

- Patients of either gender, ages 18 to 60, who have been referred for elective laparoscopic surgical operations that will take at least one hour and will be performed under general anaesthesia.
- Patients of ASA grade I & II

2.2. Exclusion Criteria–

- Patient refusal for the procedure.
- Patients of III & IV ASA grade.

- Patients with established cardiac, renal, hepatic, neurological disorders, as well as any other major medical condition that would make response evaluation difficult.
- Anticonvulsants, benzodiazepines, opioids, alcohol, or other psychotropic medicines have been used (chronically or within 24 hours before the induction of anaesthesia).

2.3. Methods–

Seventy-two (72) patients undergoing elective Laparoscopic surgeries were randomly allocated into two groups as follows: 36 patients in the BIS group who received BIS monitoring in addition to standard monitoring were compared to 36 controls. Pre-anaesthetic evaluations were performed on all patients, and standard NPO protocols were observed. On arrival to the operating room, baseline measurements such as blood pressure, heart rate, ECG, and SpO₂ are recorded. Intravenous access was obtained, and a Ringer lactate IV infusion was commenced. After skin preparation, BIS electrodes strip was placed on the forehead and temples and connected to BIS monitor through BIS-X device. The EEG was constantly recorded from before anaesthetic induction until the patients were awake and responsive to vocal orders after extubation at the end of operation.

Patients were premedicated intravenously (IV) with Inj. Midazolam 0.08-0.1 mg/kg, Inj. Glycopyrrolate 0.008-0.15 mg/kg, Inj. Ondansetron 0.15 mg/kg half-an-hour before the procedure. Patients were pre-oxygenated for 3 min with 100% O₂. Inj. Fentanyl 2-4 mcg/kg IV was used as an analgesic. Induction was done using Inj. Propofol 2 mg/kg IV. After ensuring the adequacy of mask ventilation Inj. Succinylcholine 1-1.5 mg/kg IV was given as muscle relaxant to facilitate intubation of the trachea with appropriate size tube. Maintenance of anaesthesia: Oxygen (O₂): Nitrous oxide (N₂O) (33%:66%), controlled ventilation along with isoflurane 0.5- 1 %. Muscle relaxation was maintained using intermittent doses of Vecuronium 0.08-0.12 mg/kg IV. Mechanical ventilation has been used to keep ETCO₂ levels between 35 and 40mm Hg in all of the patients.

Intraoperative hypotension was described as a MAP less than 25% of baseline or an absolute value less than 60 mmHg, and it was treated with a fluid bolus and an IV bolus of mephentermine 6 mg. Bradycardia was defined as a heart rate of less than 50 beats per minute, and all patients with symptomatic bradycardia were given IV atropine 0.6 mg boluses. Tachycardia was defined as a heart rate more than 20% of baseline and intraoperative hypertension as a blood pressure greater than 25% of baseline (Orhon et al., 2013)[21]. During intraoperative hypertension episodes, the depth of anaesthesia was modified by raising the concentration of isoflurane or by boluses of fentanyl 25–50mcg with subsequent top-up doses of 0.02 mg/kg of vecuronium, as determined by the primary anaesthetist.

In both the groups, depth of anaesthesia was maintained by keeping BIS score between 40–60 in BIS group, while in the Control group, it was maintained by titrating isoflurane according to heart rate and mean arterial pressure (MAP).

Anaesthesia agents used for maintenance were discontinued towards the end of surgery to facilitate rapid recovery in both groups and to achieve a BIS score of 60-75 range in BIS group. Port site infiltration was done with 0.25% bupivacaine. Fresh gas flow rate was increased to 8–10 l/min with 60% N₂O in O₂. N₂O was discontinued after application of the last skin suture.

The neuromuscular block was restored by intravenous injections of glycopyrrolate 0.008 mg/kg and neostigmine 0.05 mg/kg IV. Once the patients meet the subjective and objective criteria for extubation, the endotracheal tube was removed. The patient's recovery profile was observed at this time in terms of the following:

- Recovery time is assessed in terms of
 - 1) time for eye opening (from time of discontinuation of inhalational agent to eye opening)
 - 2) responds to verbal commands (from time of discontinuation of inhalational agent to the time to respond and follow verbal commands)
- Quality of recovery is assessed by
 - 1) swallow reflex (whether patient is able to swallow freely and properly or having a poor swallow reflex)
 - 2) cough reflex (whether patient is able to breathe freely, cough freely or having a poor cough reflex) and
 - 3) orientation to time place and person (whether patient is conscious, oriented and able to tell his/her own name or not) noted.

Patients were shifted to post anaesthesia care unit (PACU). In PACU, Modified Aldrete score was noted. Modified Aldrete score comprise level of consciousness, physical activity, respiratory instability, oxygen saturation status, circulation (BP) with a total score of 10. Time of achieving score of ≥ 9 was considered sufficient for discharge from PACU to ward.

- To maintain the visual analogue scale score (VAS) below 3, all patients got appropriate post-operative analgesia with sufficient dosages of Inj. diclofenac, Inj. paracetamol, or Inj. tramadol, either given alone or administered together.

2.3. Statistical Analysis–

To do a comparative analysis for the time of recovery & quality of recovery with and without BIS guidance, 72 (36per group) patients are required to have a 90% chance of detecting, as significant at the 5% level, with anticipated SD as 1.55 to detect the expected difference between the two groups in accordance to previously published studies.

Calculation based on the formula: $n = f(\alpha/2, \beta) \times 2 \times \sigma^2 / (\mu_1 - \mu_2)^2$

Where μ_1 and μ_2 are the mean outcome in the study groups respectively, σ is the standard deviation.

For continuous variables, the summary statistics of N, mean, standard deviation (SD) was used. For categorical data, the number and percentage were used in the data summaries and data was analyzed by Chi square test for association, comparison of means unpaired t test, Mann-Whitney U test and diagrammatic presentation and a p-value < 0.05 is considered statistically significant.

Statistical software: Statistical Program for Social Science (SPSS) version 21.0 was used to analyse the data, while Microsoft Word and Excel were utilised to create graphs, tables, and other graphics etc.

III. RESULT AND DISCUSSION

3.1. Demographic Analysis–

Data are presented as mean±SD or numbers of patients. The patients in two groups were comparable with regard to all demographic data like age, weight, sex, Duration of anaesthesia and ASA grade (Table 1). The mean duration of anaesthesia in BIS group was 119.17± 20.891 in whom isoflurane was titrated as per BIS values (BIS group) and in Control group it was 124.17± 17.788 in whom anaesthesia was given as per the clinical parameters. There was no significant difference between groups

TABLE 1: Comparison of patients baseline characteristics.

VARIABLES	BIS GROUP	CONTROL GROUP	P VALUE
AGE	35.89±12.517	39.89±12.328	0.180
SEX (M/F)	11/25	16/20	0.4884
ASA GRADE (I/II)	24/12	20/16	0.4884
WEIGHT	61.22±7.672	63.56±7.385	0.193
DURATION OF ANAESTHESIA	119.17±20.891	124.17±17.788	0.278

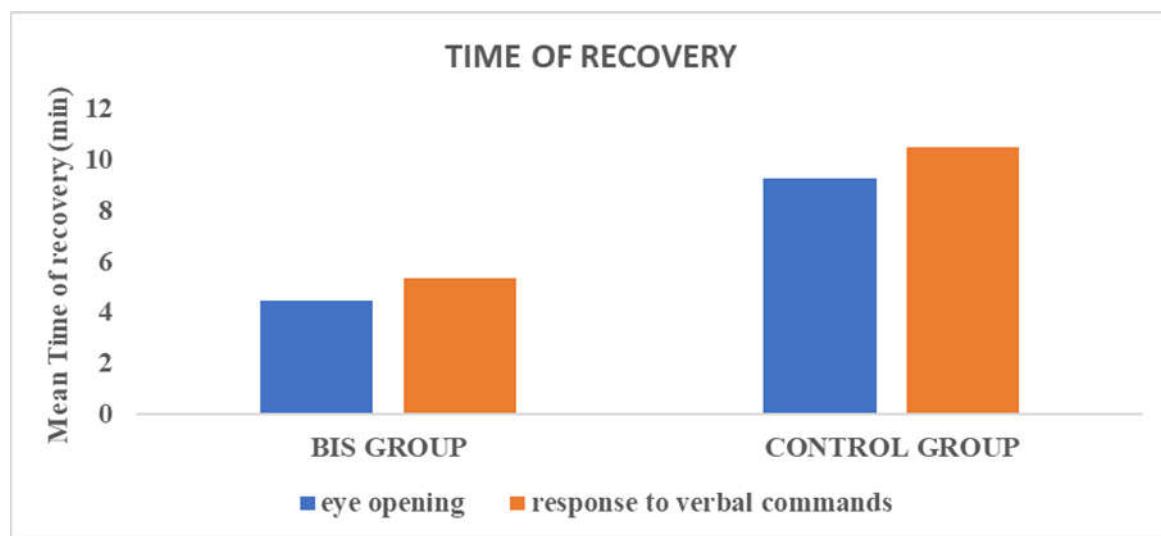
3.2. Recovery Parameters–

3.2.1. Time of recovery: The BIS patients recovered from anaesthesia faster than the Control patients. When it comes to comparing Mean time for eye opening and responds to verbal commands in patients of BIS group was 4.48 ± 0.89 min and 5.377 ±0.647 compared to the Control group where mean time for eye opening and responds to

verbal commands was 9.27 ± 0.668 min and 10.491 ± 0.775 with a significant p value ($P=0.0001$) (Table 2 & Figure 2).

TABLE 2: Comparison of Time of recovery in both groups.

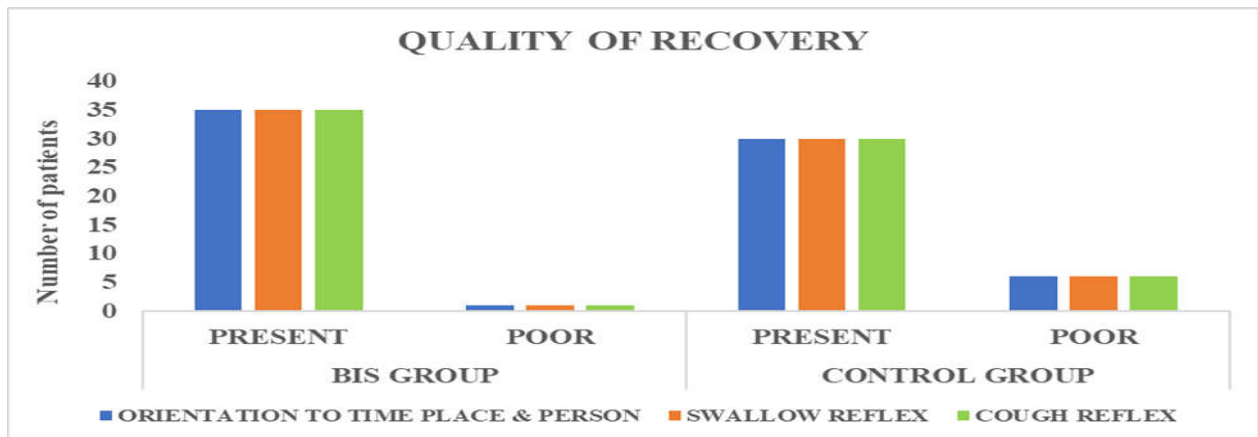
Time of recovery	BIS GROUP	CONTROL GROUP	P value
	Mean \pm SD	Mean \pm SD	
Opening of eye	4.48 \pm 0.89	9.27 \pm 0.668	0.0001*
Responds to commands	5.377 \pm 0.647	10.491 \pm 0.775	0.0001*



3.2.2. Quality of recovery: In our study, there were seven patients (one in BIS group and six in control group) who had poor swallow and cough reflex with minimal confusion and disorientation in post operative period. There was a significant difference between the two groups when the above said parameters were assessed for quality of recovery showing a p value <0.05 ($P=0.0467$). Only 83.3% of control group have achieved a good quality of recovery while 16.7% had failed to achieve good quality of recovery when anaesthesia was maintained based on clinical signs whereas 97.2% of patients had achieved a good quality of recovery when anaesthesia was maintained under BIS guidance. (Table 3 & Figure 3).

TABLE 3: Comparison of Quality of recovery in both groups.

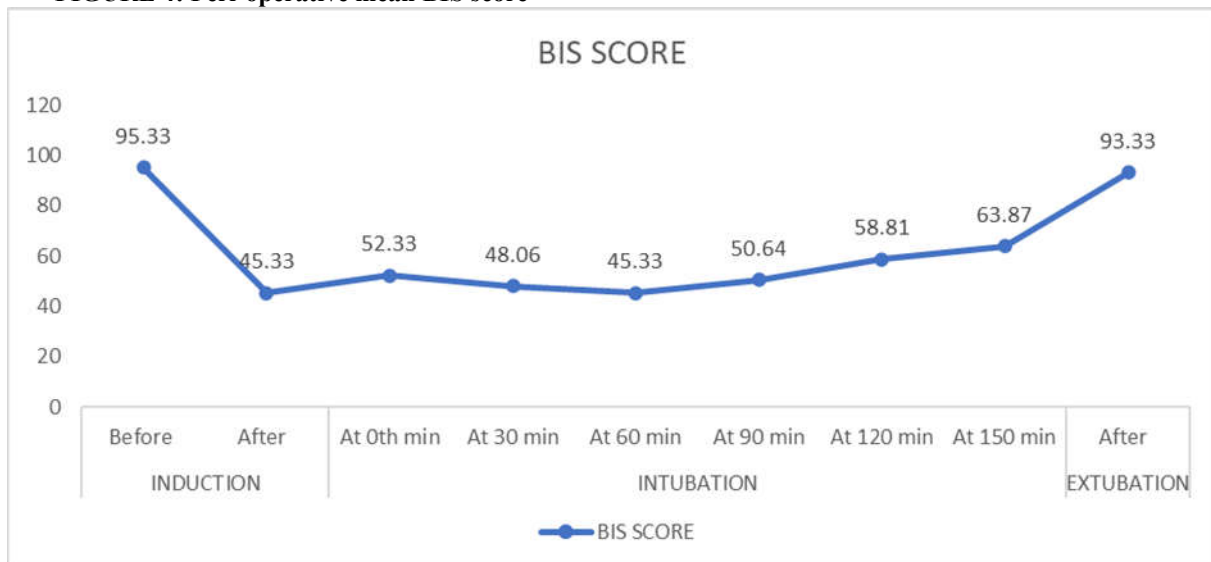
Quality of recovery	BIS GROUP		CONTROL GROUP		P value
	PRESENT	POOR	PRESENT	POOR	
ORIENTATION TO TIME PLACE & PERSON	35	1	30	6	P=0.0467
SWALLOW REFLEX	35	1	30	6	
COUGH REFLEX	35	1	30	6	



3.2.3. Peri-operative mean BIS score –

Peri-operative mean BIS score at various time intervals is analysed and BIS values are well maintained between 40-60 during the procedure and values increased towards the end of procedure and reached a mean BIS score value of 93.33 after extubation in BIS group. (Figure 4)

FIGURE 4: Peri-operative mean BIS score

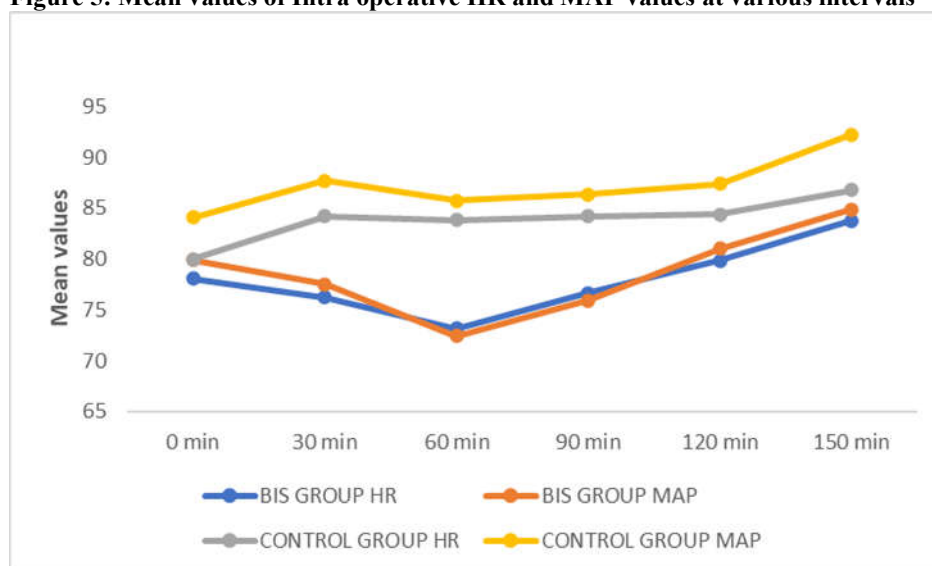


3.3. Intra-operative hemodynamic Parameters–

Inter-group, intra-operative HR and MAP was analysed and the variation in HR and MAP was statistically significant ($p < 0.05$): except at 0th and 150th min time interval where HR among two groups was insignificant ($p > 0.05$). (Table 4 & Figure 4)

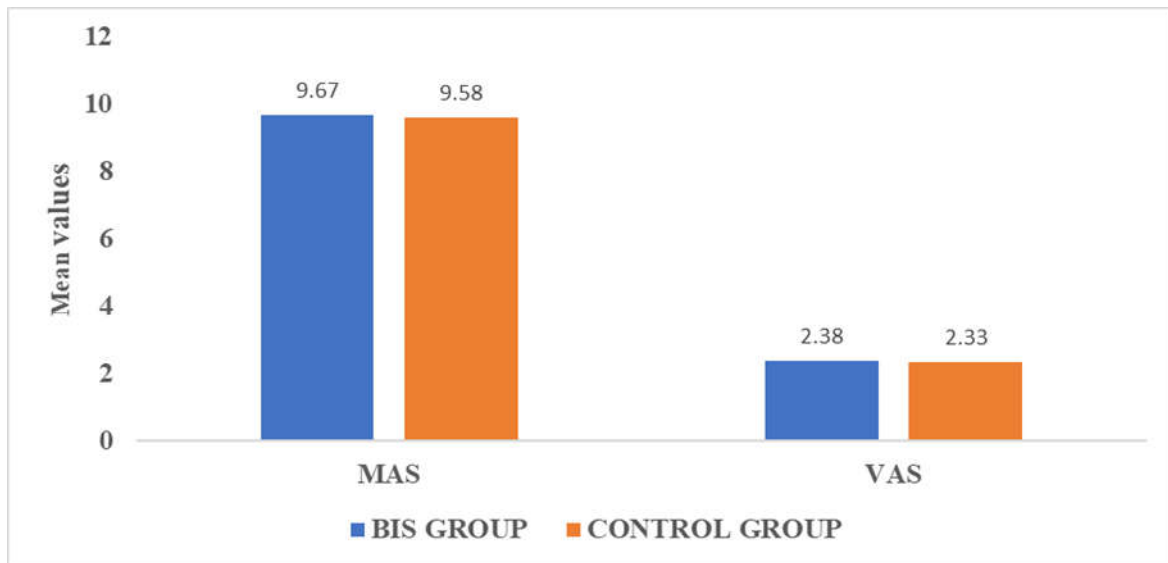
TABLE 4: Comparison of Intra operative HR and MAP in both groups

TIME	BIS GROUP	CONTROL GROUP	P VALUE	BIS GROUP	CONTROL GROUP	P VALUE
	HR	HR		MAP	MAP	
0 min	78.08±10.777	80.00±10.744	0.452	79.89±10.77	84.08±7.358	0.025
30 min	76.22±9.084	84.22±12.206	0.002	77.53±9.084	87.72±8.736	0.001
60 min	73.17±8.185	83.83±12.230	0.001	72.42±8.185	85.72±7.814	0.001
90 min	76.64±10.387	84.19±10.810	0.003	75.94±7.808	86.36±6.039	0.001
120 min	79.85±7.541	84.40±10.11	0.05	81.03±8.234	87.37±6.163	0.001
150 min	83.75±6.571	86.89±11.704	0.51	84.87±7.769	92.33±2.708	0.016

Figure 5: Mean values of Intra operative HR and MAP values at various intervals

3.4. Discharge Criteria–

Difference in modified Aldrete score ($P=0.468$) and visual analogue score ($P=0.626$) was not statistically significant between the two groups and both patients were eligible for discharge sooner (Figure 5).

Figure 6: Mean values of Modified Aldrete score (MAS) and Visual analogue score (VAS)

IV.CONCLUSION

Bispectral index is a simple, objective measure to assess depth of anaesthesia. The study concludes that Bispectral index monitoring is a very useful aid in General anaesthesia to ensure optimization of drug delivery to the needs of the individual patients in order to avoid adverse effects of the drugs. The amount of anesthetic required is optimized which translates into faster recovery and improves the Quality of recovery. This can lead to a better utilization of theatre time, decrease in PACU and hospital stay with reduction in costs. This can translate into an increased capacity to treat a greater number of patients which is especially useful in a day care set-up.

The information provided by the BIS monitor allows for improved anaesthetic management adjustments in addition to measuring consciousness during anaesthesia. Patients will be able to go home earlier with less leftover medication effects because of drugs, paired with enhanced recovery. As a result of our research, we proved that with BIS monitoring, recovery variables were shorter, which impacted the pace of recovery following Laparoscopic procedures under general anaesthesia.

In general, certain groups of patients who have increased risk of awareness (Critically ill patients, Caesarean section, trauma patients) due to decreased dosage of anesthetic drugs could be provided with better operative and post operative care. These patients could benefit with optimized anesthetic drug delivery to prevent awareness using this BIS monitor.

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