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AN OBSERVATIONAL STUDY TO COMPARE INTRAOPERATIVE HEMODYNAMIC STABILITY AND RECOVERY CHARACTERISTICS OF BISPECTRAL INDEX GUIDED AND MINIMUM ALVEOLAR CONCENTRATION GUIDED ANAESTHETIC DEPTH IN LAPAROSCOPIC ABDOMINAL /PELVIC PROCEDURES.

Anaesthesiology

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ABSTRACT

Background and Aims: Monitoring the depth of anesthesia using Minimum Alveolar Concentration (MAC) or Bispectral Index (BIS) allows for individualized anesthesia management by adjusting drug administration based on the patient's level of arousal. This study aims to compare the effects of these two methods on hemodynamic stability and recovery outcomes during laparoscopic surgeries. **Methods:** Sixty patients undergoing elective laparoscopic surgeries under general anesthesia were enrolled in this double-blind observational prospective randomized study and allocated into two groups. Hemodynamic parameters and recovery characteristics were compared. The depth of anesthesia was monitored using BIS in group B (n = 30) and using MAC in group M (n = 30). **Results:** There was no significant difference in heart rate at all time points except at end of port placement (p=0.03) and at 10 minutes after extubation (p=0.005) HR was higher in group M then group B. There was no significant difference in mean arterial pressure at any time point except it was significantly lower in group M than group B at 15 minutes, 30 minutes and 60 minutes after port placement. MAC values were significantly lower in group B compared to group M. The BIS values were significantly lower in the group M compared with the group B. Time to eye-opening, time to extubation, discharge from PACU, sevoflurane consumption (4.40±2.06 minutes), (5.85±1.79 minutes), (1.68±0.27 hours), (15.83±7.97 ml) respectively in group B was significantly lower than that in group M for same parameters respectively (6.33±2.73 minutes), (8.10±2.52 minutes), (1.98±0.15 hours), (20.97±8.51 ml). **Conclusions:** Titration of inhalational anaesthetic agent to maintain a BIS value in the range of 40- 60 during general anesthesia for laparoscopic abdominal/pelvic surgeries provide better hemodynamic stability and reduction in the consumption of volatile anesthetic agent along with rapid emergence and shorter stay in PACU.

KEYWORDS

Depth of anesthesia, Haemodynamic parameters, Minimum alveolar concentration, Bispectral index.

INTRODUCTION-

Minimally invasive surgeries by laparoscopy with or without robotic assistance have replaced many open surgical procedures as the technique of choice.[1] With the creation of pneumoperitoneum and adverse patient positioning, increased intra-abdominal pressure (IAP) affects organ perfusion, causing cardiorespiratory compromise and initiating a systemic stress response.[2] In laparoscopic surgery, the standard anesthesia approach involves general anesthesia with endotracheal intubation. This includes administering inhalational anesthetic agents, a mixture of air and oxygen, as well as opioids and muscle relaxants to ensure adequate depth of anesthesia, prevent intraoperative awareness and to ensure a rapid, smooth recovery.[3] Monitoring depth of anesthesia during surgery either by minimum alveolar concentration (MAC) or by Bispectral Index (BIS) can enhance the precision of anesthesia management, leading to better patient outcomes and safety. Monitoring the end-tidal anesthetic concentration (ETAC) of anesthetic gases gives essential information about the minimum alveolar concentration (MAC) of the anesthetic agent. MAC has the advantage of simplicity and reproducibility but it correlates poorly with the degree of hypnosis as the values measured are from the alveolar concentration rather than the brain concentration, so the safe level of MAC to prevent intraoperative awareness is still controversial. BIS on the other hand is a processed electroencephalogram (EEG) parameter with extensive validation and demonstrated clinical utility. It is derived by EEG signal processing techniques including Bispectral analysis, power spectral analysis, and time domain analysis. BIS values range from 0 to 100; 0 signifies that there is no detectable brain activity, while a value of 100 signifies a fully awake state.[4] Both the above monitoring techniques are being used to titrate depth of anesthesia. However, the gold standard for monitoring of depth of anesthesia is still elusive. Our study was conceived to compare the hemodynamic behavior, recovery characteristics, and intra-operative awareness when two modes of anesthesia depth analysis and titration were used MAC and BIS during laparoscopic surgeries

MATERIAL AND METHODS:

This double-blind observational prospective randomized study was carried out in a tertiary care center after obtaining institutional ethical committee approval (vide approval number MICR-763/2017 dated 4th September 2017). The study was conducted from October 2017–to May 2018, in accordance with the principles of the World Medical Association Declaration of Helsinki, 1975. Sixty patients of age between 18 and 60 years, of American Society of Anesthesiologists (ASA) physical status I and II, undergoing elective laparoscopic/ robot-assisted abdominal/pelvic surgery requiring endotracheal intubation and surgery lasting between 90 to 150 minutes were included in the study. Patients with drug allergies, body mass index (BMI) >35 kg/m^2, history of obstructive sleep apnea, a history of cardiovascular diseases, history of alcohol intake, drug abuse, and pregnant patients were excluded from the study. A pre-anaesthetic check-up was done one day before surgery and written informed consent was obtained. A sequence of 60 numbers (30 per group) was allocated and consecutive alternate numbers were put into 2 groups (Group B and Group M).

In the operation theatre, intravenous fluid Ringers' Lactate was started with an 18 G IV cannula at the rate of 2 ml/kg/hr. Routine monitors i.e. electrocardiography, noninvasive blood pressure, and pulse-oximetry were applied. BIS™ Quatro (4 electrodes) sensor was applied to the forehead and connected to a BIS module (M1034A) compatible with the PHILIPS IntelliVue monitor, before induction to note a baseline value. MAC value of the inhalational agent was noted after induction of anesthesia. General anesthesia was commenced with standard anesthesia technique as per institutional protocol. Anesthesia was maintained with intermittent positive pressure ventilation with sevoflurane at a fresh gas flow of 1.0 -1.5 L/min (Air: Oxygen, 50:50 mixture), injection fentanyl 1 microgram/kg/hour and injection Atracurium at 0.25mg/kg/hour. Ventilation was adjusted to maintain end-tidal carbon dioxide between 30 to 35 mmHg. Infusion of atracurium and fentanyl was stopped after specimen extraction or at the start of port closure in case of no specimen. All patients received paracetamol 20 mg/kg at the start of port closure. The inhalational agent was stopped at the end of local anesthetic (Bupivacaine 0.25%) skin infiltration and fresh gas flow increased to 10L/min. All patients were reversed and extubated with an injection of neostigmine 0.05

mg/kg and an injection of glycopyrrolate 0.008 mg/kg.

Group B: BIS value of 40-60 was targeted with titration of MAC in the range of 0.6 to 1. MAC was not increased or decreased to counter hemodynamic changes if BIS was within the target range. If the BIS value breached the target in both directions along with hemodynamic changes, then only MAC was altered in the range of 0.6-1.0 MAC.

Group M: Intraoperative MAC was maintained between 0.7- 0.8 (range of 0.6-1.0 MAC). In case of hemodynamic instability MAC value was altered. A BIS monitor was also applied to these patients for uniformity and values were noted.

Management of intraoperative hypotension (Mean arterial pressure (MAP) < 60 mmHg or less than 20% of baseline) was treated with 6 mg boluses of ephedrine. After 3 such boluses if the hypotension persisted, then 300 ml of hydroxyethyl starch 130/0.4 was given over 10 minutes. Further episodes of hypotension were managed by phenylephrine infusion and titrated as per requirement. At no point in time MAC value was kept below 0.6.

Management of intraoperative hypertension (MAP>90 mmHg or more than 20% of baseline) was treated by changes in inhalational agent concentration within the target range (maximum MAC value 1.0 in M group), or according to BIS value (in patients with B Group). Apart from fentanyl infusion, patients were given intravenous clonidine once at 1 mcg/kg if required. If B.P. is not controlled 30 minutes after clonidine then the patient was excluded from the study.

Observations:
Hemodynamic parameters were recorded at different time points. Recovery characteristics noted were time to eye opening on verbal command, time to extubation from the time of stopping inhalational anesthetic agent, and time to achieve PACU discharge criteria from extubation (modified Aldrete score[5] of ≥ 9). The incidence of awareness (on the 1st, 2nd and 30th day postoperatively) was noted by Modified Brice interview[6] by an independent observer blinded by the technique. The amount of inhalational agent used[7] was also calculated. The total amount of clonidine, ephedrine, phenylephrine infusion, and/or colloid used was also noted.

The sample size was calculated based on a previous study by Song[8] et al, based on the following assumption: The mean value of MAP at incision was 65 and 78 in the group M and group B respectively with the difference in MAP in both groups of 13 with Standard deviation(SD) of (CV=80%) 10.4.

After 20 minutes of incision mean value of MAP was 88 and 95 in group M and group B respectively with the difference in MAP in both groups of 7 with SD (CV = 80 %) of 5.6.

With the above assumptions, the sample size for 95% confidence level and 80% power works out to 30 per group. The formula used is:

$$\mathbf{n = (\sigma_1^{\ 2} + \sigma_2^{\ 2})\,(Z_a + Z_B)^2/(\Delta_1 - \Delta_2)^2}$$

Where, Zα = Value of standard normal variate corresponding to α level of significance
Zβ = The standard normal deviate for the desired power
Δ = Average
σ = Standard deviation

Statistical Analysis Plan:
The analysis includes profiling of patients on different demographic and clinical parameters. Quantitative data were expressed as mean and standard deviation. Ordinal/categorical data are expressed as absolute numbers and percentage. Cross tables were generated and Chi Square test are used for testing of associations. Student t-test is used for comparison of individual quantitative parameters. P-value < 0.05 is considered statistically significant. SPSS software, version 24.0 is used for statistical analysis

RESULTS:
Both study groups were comparable concerning age, gender, weight, height, and ASA physical status.

There was no significant difference in heart rate at all time points except at the end of port placement (p=0.03) and at 10 minutes after extubation (p=0.005) it was higher in the group M than group B. (table 1) There was no significant difference (p>0.05) in MAP at any time points except it was significantly lower in MAC group than BIS at 15 minutes, 30 minutes, and 60 minutes after port placement. (table 1)

Table 1: Comparison of MAP and HR between the groups across the time periods

	MAP			HR		
Time period	BIS (n=30) Mean±SD	MAC (n=30) Mean±SD	p-value[1]	BIS (n=30) Mean±SD	MAC (n=30) Mean±SD	p-value[1]
Baseline/preoperative	95.85±10.45	96.49±11.39	0.82	75.13±9.30	80.10±11.72	0.07
Preinduction	98.87±8.35	99.36±13.50	0.87	78.13±12.38	85.20±16.15	0.06
10 min after induction	82.94±17.45	79.97±12.33	0.45	76.87±13.40	77.63±18.82	0.85
At skin incision	79.34±11.30	86.24±19.18	0.09	70.23±14.02	77.00±17.11	0.09
At end of port placement (IAP-20mmhg)	97.72±12.80	98.31±17.07	0.88	70.33±11.66	77.57±13.78	0.03*
15 minutes after port placement (IAP-15mmhg)	90.24±11.16	77.54±13.58	0.001*	71.00±10.95	73.40±10.79	0.39
30 minutes after port placement	90.04±9.21	79.07±16.14	0.003*	72.96±8.89	71.59±10.98	0.60
60 minutes after port placement	90.00±7.98	79.79±11.35	0.001*	79.12±8.95	75.96±9.79	0.23
120 minutes after port placement	92.18±14.83	87.74±10.39	0.36	85.47±6.35	80.67±11.98	0.14
At end of skin closure	85.91±9.30	87.97±10.90	0.43	80.97±11.42	82.57±10.59	0.57
10 minutes after extubation	88.88±10.32	93.43±14.23	0.16	82.33±11.38	91.20±11.89	0.005*

MAC values are significantly lower in BIS titrated group compared to MAC group at all time periods. (figure 1)

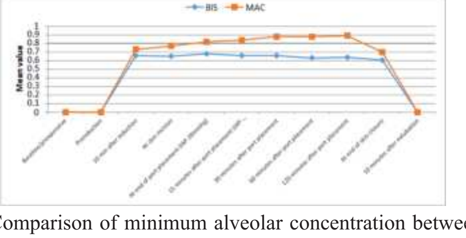

Fig.1: Comparison of minimum alveolar concentration between the groups across the time periods

The pre-induction BIS index values were more than 90 which decreased to a minimum mean value of 40.96 after induction of anesthesia. The BIS index values were significantly lower in the MAC group compared with the BIS-titrated group. The BIS index values on awakening (eye opening) were similar in both groups (figure 2).

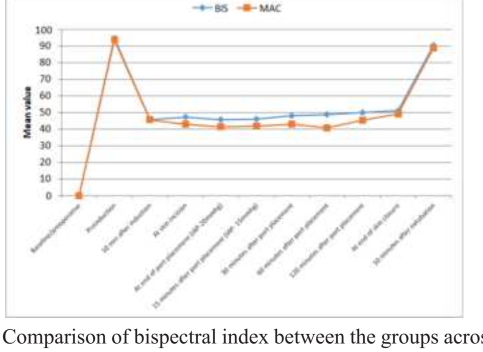

Fig. 2: Comparison of bispectral index between the groups across the time periods

Although statistically not significant, intraoperative fluid volume infused (ml) was found to be lower in the group B (846.67±476.14ml) than group M (973.33±366.65 ml).

No significant difference in consumption of intraoperative ephedrine, or clonidine.

The time of eye opening was significantly shorter in the B group (4.40±2.06 minute) compared with the M group (6.33±2.73 minutes). Time to extubation was significantly lower in group B (5.85±1.79 minutes) compared to group M (8.10±2.52 minutes).

Also, PACU stay was less in B group (1.68±0.27 hours) compared to group M (1.98±0.15 hours). Significantly less amount of inhalational agent was used in group B (15.83±7.97ml) compared to group M (20.97±8.51ml).

There was no awareness of intraoperative events on postoperative day 1, 2, and 30 in either group.

DISCUSSION:

BIS-guided depth of anesthesia monitoring in morbidly obese patients has shown a reduction in intraoperative desflurane requirement (cost) and early recovery times after laparoscopic sleeve gastrectomy, without compromising the hemodynamic stability, adequacy of anesthesia, or patient outcome in study conducted by Ibrahim et al.[9] In a study by Ramamurthy et al[10] cardiac surgeries under cardiopulmonary bypass, BIS guided depth of anesthesia helps maintain better hemodynamic stability as compared to MAC. Our study results also showed that BIS as compared to MAC gives better hemodynamic stability and early recovery in laparoscopic abdominal/pelvic surgeries. Shukla et al[11] also found that extubation times and mean sevoflurane concentration set on vaporizer was significantly less in the BIS group as compared to the ETAG group. In our study also, the results of time to eye opening to verbal command, time to extubation after inhalational anesthetic was switched off, discharge from PACU, and amount of sevoflurane consumed, were significantly lower in the group B than that in the group M.

Apart from the above-observed advantages of using BIS monitoring, the increased costs associated with BIS monitor and its disposable accessories are a concern. A cost-benefit analysis is important before using it in “routine” anesthesia practice.

Another concern when using a BIS monitor to titrate anesthesia depth is the possibility of intraoperative recall. Awareness during general anesthesia is an important adverse event because of its intraoperative physiological responses such as hypertension and tachycardia as well as postoperative psychological sequels such as sleep disturbances, nightmares, daytime anxiety, and patients' dissatisfaction.[12] In our study, none of the patients in any group experienced intraoperative recall when interviewed up to 30 days after surgery. Hence the lower concentrations of the volatile anesthetics administered in the group B appeared to provide an adequate hypnotic state with no awareness. In our study, the MAC value in group B was significantly on the lower side compared to group M at all the periods. Avidan et al[13] didn't find any superiority of the BIS protocol in their study. There was no difference between the groups concerning the amount of anesthesia administered or the rate of major postoperative adverse outcomes in their study.

There was no difference in intraoperative use of in intraoperative use of crystalloid/colloid, ephedrine, phenylephrine, and clonidine between the groups in our study.

Confidentiality:

Subject confidentiality was strictly held in trust by the participating investigators and the study staff. The study protocol, documentation, data, and all other information generated were held in strict confidence and the subject identification was not revealed to any unauthorized individual.

Limitations:

Small sample size, Power of study, availability and cost of single use BIS electrode. Prolonged duration of surgery, blood loss, temperature, and electrolyte imbalance can also affect recovery characteristics and were not included in this study.

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