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Original Article

Anaesthesia Section

Comparison between Bispectral Index-guided Propofol Induction and Clinically-guided Induction in Adult Hypertensive Patients undergoing Elective Laparoscopic Surgery: A Randomised Controlled Study

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ABSTRACT

Introduction: Traditional clinical endpoints for propofol induction often led to unintentional overdose, leading to haemodynamic instability, delayed recovery, and other complications. Bispectral Index monitoring could potentially prevent undesired haemodynamic changes like hypotension.

Aim: To compare BIS-guided propofol induction with clinically guided propofol induction.

Materials and Methods: A randomised controlled study was conducted in the Department of Anaesthesiology at Apollo Hospitals, Guwahati, Assam, India, between December 7, 2020 and December 6, 2021, on adult hypertensive patients undergoing elective laparoscopic surgeries. The Clinical Group (n=30) received propofol induction based on clinical guidance, and the Bispectral index group (n=30) underwent Bispectral Index (BIS) guided induction. Demographic variables, the dose of drug required for BIS 50, and the total amount of drug consumed were recorded. After the administration of each dose, Systolic BP (SBP), Diastolic BP (DBP), Mean Arterial BP (MAP), Heart Rate (HR), and SpO_2 were recorded. Frequencies and percentages were used to describe qualitative data, whereas the mean and standard deviation were used to express quantitative data. Parametric tests included unpaired t-tests for comparison between groups. A p-value of <0.05 was considered statistically significant.

Results: Total 60 patients with 30 in each group, were studied. There was a steady fall in SBP, DBP, and MAP with successive incremental doses of 0.5 mg in both groups. Mean SBP was comparable between the two groups at dosages of 1 mg/kg, 1.5 mg/kg, and 2 mg/kg. At 2.5 mg/kg, the clinical group had a significantly lower SBP (p=0.0001). Mean DBP was comparable in both groups at doses of 2 mg/kg and 2.5 mg/kg but significantly lower in the BIS group at 1 mg/kg and at 1.5 mg/kg (p=0.003, p=0.01). Mean MAP was comparable at doses of 2 and 2.5 mg/kg but significantly lower in the BIS group at doses of 1 mg/kg and 1.5 mg/kg (p=0.007, p=0.02). Mean HR was comparable between the two groups at doses of 1 and 1.5 mg/kg. HR showed an increase in group CL and a gradual drop in group BIS with incremental doses. Mean HR was significantly lower in the group BIS at doses of 2 mg/kg and 2.5 mg/kg (p=0.001, p=0.001). The BIS group required a substantially lower total dose of propofol compared to the CL group (158.63±30.57 mg vs. 118.23±28.53 mg, p=0.0001).

Conclusion: BIS-guided propofol induction leads to more stable haemodynamics during induction. It helps to titrate propofol administration, which, in turn, reduces the frequency of propofol overdose and its subsequent adverse effects on haemodynamic stability. The total dose of propofol consumed is also reduced.

Keywords: Anaesthesia, Arterial pressure, Awareness, Consciousness, General, sleep, Haemodynamics

INTRODUCTION

Propofol is a popular intravenous induction agent due to its rapid and smooth induction, comparatively brief context-sensitive time, fast terminal half-life, and speedy recovery. It also causes decreased postoperative nausea and vomiting and has minimal side effects [1]. A dose of 1.5-2.5 mg/kg body weight is recommended for the induction of general anaesthesia. However, one of its most noted side effects, namely arterial hypotension, has led to difficulty in titrating its dose in patients, especially in elderly or critical patients [2,3].

Traditionally, the loss of verbal response and eyelash reflex were taken to be the clinical endpoints for induction with intravenous agents such as propofol. The state of awareness of the patient could not be properly assessed by using this method in the absence of cerebral monitoring such as BIS.

The BIS monitor is used to record brain activity, which reflects the sedative and hypnotic components of anaesthesia. It analyses one frontal Electroencephalographic (EEG) signal to compute a dimensionless number that expresses a patient's degree of consciousness. The BIS value ranges from 100 to 0, where 100 represents a fully awake patient and 0 stands for the absence of brain activity [4]. After alcohol cleaning, disposable BIS sensor electrodes are placed on the forehead of the patient. The sensor consists of four interconnected parts. Part 1 is applied in the middle of the forehead about 5 cm above the nasal bridge, part 4 is put directly above the eyebrow, part 2 is applied in the space between parts 1 and 4, and part 3 is applied on the temple area between the corner of the eye and the hairline [5]. BIS scores ranging from 40 to 60 are adequate to prevent anaesthesia awareness while permitting a decrease in the amount of anaesthetic agent administered [6].

When BIS is used for monitoring, undesired haemodynamic changes like hypotension after administering propofol could be potentially prevented. The total requirement of propofol could also be decreased [7-10].

However, there were some studies that could not find any significant difference between BIS-guided induction and the clinical method of induction [11-13].

There are plenty of studies on the use of BIS as a guide to propofol induction, as cited above [7-10,14], but recent literature regarding the superiority of BIS over traditional clinical methods is rare to find [15]. A recent 2023 study also did not find any overt advantage of the closed-loop method over the traditional method [16]. In addition, there is overall very scarce data on the use of BIS in the Indian population [12,14,17].

Keeping these facts in mind, the present study aimed to compare BIS-guided propofol induction with clinically guided propofol induction.

MATERIALS AND METHODS

A randomised controlled study was conducted at Apollo Hospitals, Guwahati, Assam, India between December 7, 2020, and December 6, 2021, after obtaining Institutional Ethical Committee approval (AHG/IEC/2020-50). The anaesthesia procedure, study protocol, and drug details were explained, and informed written consent was obtained from selected patients.

Sample size calculation: A pilot study served as the basis for calculating the sample size, where it was found that a sample of 52 (rounded to 60, i.e., 30 per group) would be sufficient in the present study with 95% confidence and 80% power, corresponding to a very small margin of error at 0.0259 lower than the reference group [18].

Inclusion criteria:

- Age >18 years to <60 years
- Consenting patients posted for elective laparoscopic surgeries
- American Society of Anesthesiologists physical status class 2
- Hypertensive patients with SBP <140 mmHg and DBP <90 mmHg

Exclusion criteria:

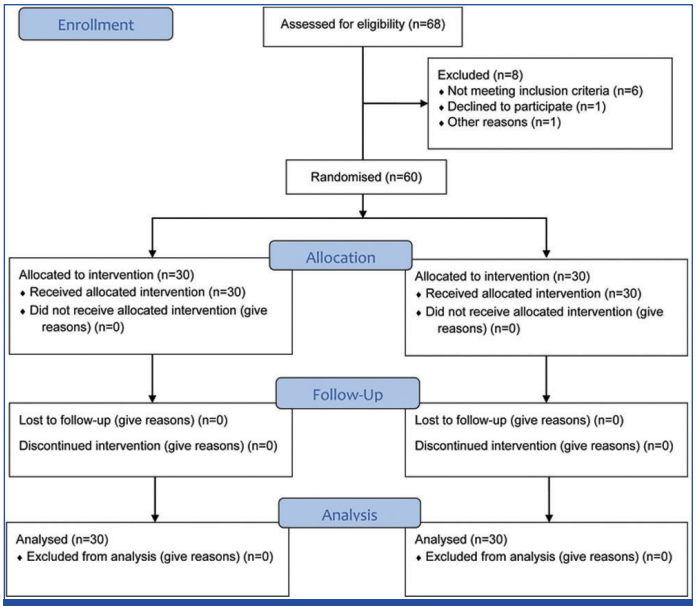
- Inability of the patient to provide consent for study participation
- Patients with difficulty in communication
- American Society of Anesthesiologists physical status class 1, class 3, or higher
- Emergency surgeries
- Pregnant patients
- Age <18 years and >60 years
- Patients with a history of uncontrolled hypertension, hypotension, or allergy to study drugs

Study Procedure

Patients with controlled hypertension (SBP <140 mmHg and DBP <90 mmHg) posted for elective laparoscopic surgeries were selected. Hypertension is defined as a sustained elevation in office SBP ≥140 and/or DBP ≥90 mmHg, which corresponds to an average 24-hour ABPM of ≥130/80 mmHg or an HBPM average of ≥135/85 mmHg. This is supported by data from numerous Randomised Controlled Trials (RCTs) [19-23], which demonstrate the benefits of treating patients with these Blood Pressure (BP) values. The same classification is applied for younger, middle-aged, and elderly people (2018 ESC/ESH guidelines) [24].

The primary objective was to compare the total amount of propofol needed for the induction of anaesthesia between the Clinical group (CL) and the BIS group in hypertensive patients undergoing laparoscopic surgeries. The secondary objective was to compare the haemodynamic changes occurring during induction between the two groups.

A computer-generated randomisation chart was used to randomly divide the patients into two groups. The Clinical Group (CL) (n=30) received propofol induction based on clinical guidance, and the BIS group (n=30) underwent BIS-guided induction. The Consolidated Standards of Reporting Trails (CONSORT) diagram is provided in [Table/Fig-1].



[Table/Fig-1]: CONSORT 2010 flow diagram.

Standard monitors such as Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP), peripheral oxygen saturation (SpO_2), BIS, and End-tidal Carbon Dioxide ($EtCO_2$) were used in the Operating Room (OR), and an intravenous line was secured. Baseline parameters like Heart Rate (HR), BP, and peripheral arterial oxygen saturation (SpO_2) were noted.

Premedication was administered with inj. glycopyrrolate 0.004 mg/kg i.v., inj. midazolam 0.04 mg/kg i.v., inj. ondansetron 0.15 mg i.v., and inj. tramadol 2 mg/kg i.v.

Patients in the CL group received inj. propofol 1 mg/kg as a bolus dose followed by 0.5 mg/kg in 30-second intervals until the loss of eyelash reflex. Out of 30 patients, 26 needed a 2.5 mg/kg dose.

Patients in the BIS group were given inj. propofol 1 mg/kg as a bolus dose followed by 0.5 mg/kg every 30 seconds until the BIS value of 40-60 was obtained. Out of 30 patients, 19 needed a 2 mg/kg dose, and only three patients needed a 2.5 mg/kg dose.

After the administration of each dose, SBP, DBP, MAP, HR, and SpO_2 were recorded, and the demographic profile and total dose of drug consumed were noted.

Inj. atracurium 0.5 mg/kg i.v. was given to facilitate orotracheal intubation. Sevoflurane 1.5-2.5% in 66% Nitrous Oxide (N_2O) and 33% O_2 at a flow rate of 2L/min was used to maintain anaesthesia. Following surgery, any residual neuromuscular block was reversed with inj. neostigmine 0.05 mg/kg i.v. and inj. glycopyrrolate 0.01 mg/kg i.v., and patients were extubated.

Intraoperative hypotension (BP <20% of baseline), hypertension (BP >20% of baseline), bradycardia (HR <60/min), and tachycardia (HR >100/min) were recorded and treated appropriately.

STATISTICAL ANALYSIS

All data were gathered, and the analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 22.0. Frequencies and percentages were used to describe qualitative data, while the mean and standard deviation were used to express quantitative data. Parametric tests included unpaired t-tests for comparison between groups. A p-value of <0.05 was considered statistically significant.

RESULTS

The study included a total of 60 patients, with 30 cases in each of the CL and BIS groups. The demographic profiles of the two groups were similar [Table/Fig-2].

Regarding the type of surgery performed, no statistically significant differences were found between the two groups [Table/Fig-3].

Variables	Group CL (n=30) Mean±SD	Group BIS (n=30) Mean±SD	p-value
Age (years)	52.46±6.21	51.46±6.82	0.34
Gender M/F	15/15	13/17	0.60
Weight *(kg)	64.80±9.86	62.76±7.06	0.36
ASA grade II	30	30	1

[Table/Fig-2]: Demographic profile (*unpaired t-test).

Type of surgery	Group CL, n (%)	Group BIS, n (%)	Total
Lap cholecystectomy	15 (50)	20 (66.67)	35 (58.33)
Lap appendectomy	4 (13.33)	0 (0)	4 (6.67)
Lap cystectomy	3 (10)	4 (13.33)	7 (11.67)
Lap hernioplasty	4 (13.33)	3 (10)	7 (11.67)
Total lap hysterectomy	4 (13.33)	3 (10)	7 (11.67)

[Table/Fig-3]: Type of surgeries.
Chi-square test=5.18, p=0.39, Not statistically significant, Lap: Laproscopic

Preoperative vitals were comparable between the two groups [Table/Fig-4].

The mean SBP was comparable between the two groups at 1 mg/kg, 1.5 mg/kg, and 2 mg/kg body weight. There was a steady fall in SBP with successive incremental dosages of 0.5 mg/kg in both groups. At 2.5 mg/kg, the SBP of group CL was significantly lower when compared to group BIS (p=0.0001) [Table/Fig-5].

Variable	Group CL (n=30) Mean±SD	Group BIS (n=30) Mean±SD	p-value
SBP (mmHg)	150.43±20.47	141.20±12.87	0.04
DBP (mmHg)	94.03±13.88	88.86±10.75	0.113
MAP (mmHg)	112.43±15.19	110.06±10.26	0.496
HR (/min)	83.43±11.91	81.73±16.46	0.6
SpO_2	100.00	100.00	1

[Table/Fig-4]: Comparison of baseline vitals between two groups.

Cumulative dose	Group CL SBP (mmHg) N (Mean SD)	Group BIS SBP (mmHg) N (Mean SD)	Mean difference	p-value
1 mg/kg	30 (147.07±20.78)	30 (138.80±12.76)	8.27	0.06
1.5 mg/kg	30 (141.70±19.63)	30 (135.53±12.27)	6.17	0.14
2 mg/kg	30 (123.53±8.96)	19 (128.15±10.24)	4.62	0.10
2.5 mg/kg	26 (102.15±12.65)	3 (120.33±3.21)	22.67	0.0001*

[Table/Fig-5]: SBP changes during induction.

The mean DBP was significantly lower in group BIS at 1 mg/kg (p=0.003) and at 1.5 mg/kg (p=0.01). With subsequent incremental doses of 0.5 mg, there was a gradual fall in the DBP. Mean DBP was comparable in both groups at the cumulative doses of 2 mg/kg and 2.5 mg/kg [Table/Fig-6].

Cumulative dose	Group CL DBP (mmHg) N (Mean SD)	Group BIS DBP (mmHg) N (Mean SD)	Mean difference	p-value
1 mg/kg	30 (92.10±13.18)	30 (82.43±10.84)	9.67	0.003*
1.5 mg/kg	30 (89.67±11.41)	30 (82.10±10.72)	7.57	0.01*
2 mg/kg	30 (83.27±8.38)	19 (78.73±11.21)	4.54	0.11
2.5 mg/kg	26 (77.54±6.63)	3 (72.66±12.05)	4.88	0.27

[Table/Fig-6]: DBP changes during induction.

The mean MAP was significantly lower in group BIS at doses of 1 mg/kg (p=0.007) and at 1.5 mg/kg (p=0.02) but was comparable at doses of 2 and 2.5 mg/kg [Table/Fig-7].

Mean HR was comparable between the two groups at doses of 1 and 1.5 mg/kg. In group CL, the HR increased with incremental doses; however, in group BIS, HR gradually dropped with successive doses. Mean HR was significantly lower in the group BIS at a cumulative dose of 2 mg/kg (p=0.001) and of 2.5 mg/kg (p=0.001) [Table/Fig-8].

Cumulative dose	Group CL MAP N (Mean SD)	Group BIS N (Mean SD)	Mean difference	p-value
1 mg/kg	30 (110.03±14.92)	30 (100.80±10.19)	9.23	0.007*
1.5 mg/kg	30 (106.67±13.24)	30 (99.57±10.06)	7.10	0.02*
2 mg/kg	30 (96.17±7.19)	19 (95.22±9.74)	0.95	0.69
2.5 mg/kg	26 (85.46±6.82)	3 (88.0±9.0)	2.54	0.55

[Table/Fig-7]: MAP changes during induction.

SpO_2 was maintained at 100% throughout the duration of surgery in both groups [Table/Fig-9].

Compared to group CL, group BIS required a substantially smaller total dose of propofol (158.63±30.57 mg vs 118.23±28.53 mg, p=0.0001) [Table/Fig-10].

Cumulative dose	Group CL HR N (Mean SD)	Group BIS N (Mean SD)	Mean difference	p-value
1 mg/kg	30 (84.07±11.72)	30 (82.03±16.25)	2.04	0.57
1.5 mg/kg	30 (88.83±12.06)	30 (83.80±16.09)	5.03	0.17
2 mg/kg	30 (93.37±13.14)	19 (80.05±14.69)	13.32	0.001*
2.5 mg/kg	26 (101.77±13.10)	3 (73.66±2.08)	28.11	0.001*

[Table/Fig-8]: HR changes during induction.

Cumulative dose	Group CL N (Mean SD)	Group BIS N (Mean SD)	Mean difference	p-value
1 mg/kg	30 (100±0.00)	30 (100±0.00)	-	-
1.5 mg/kg	30 (100±0.00)	30 (100±0.00)	-	-
2 mg/kg	30 (100±0.00)	19 (100±0.00)	-	-
2.5 mg/kg	26 (100±0.00)	3 (100±0.00)	-	-

[Table/Fig-9]: SpO_2 changes during induction.

	Group CL	Group BIS	Mean difference	p-value
Total dose	158.63±30.57	118.23±28.53	40.40	0.0001*

[Table/Fig-10]: Total dose of propofol used.

DISCUSSION

Total 60 adult patients in total undergoing laparoscopic surgery were included in present randomised controlled prospective study. The demographic characteristics of the patients were comparable. The study was limited to controlled hypertensive patients only, so that both groups (CL, n=30, and BIS, n=30) were comparable regarding baseline parameters. Premedication and anaesthetic management were kept constant in both groups. The preoperative mean heart rate, saturation, and mean blood pressure were comparable in both groups. The type of laparoscopic surgery performed was comparable in both groups.

There was a statistically significant difference in the fall of SBP in the CL group when compared to the BIS group at cumulative doses of 2.5 mg/kg. DBP was comparable between the CL and BIS groups. The mean MAP was significantly lower in the BIS group at doses of 1 mg/kg (p=0.007) and at 1.5 mg/kg (p=0.02) but was comparable at doses of 2 and 2.5 mg/kg. Shangne S et al., found that there was a more significant fall in MAP from baseline immediately after induction in the non BIS group compared to the BIS group, with more rise after one minute in the BIS group, but it was insignificant [8]. However, Rüsch D et al., and Shajahan MS et al., found no significant difference between both study groups regarding hypotension and haemodynamic variables [11,12]. Chaparala C et al., found a minor decrease in DBP and rise in SBP similar in both groups [14]. Xie T et al., found similar changes in MAP in the two groups [16]. Saini S et al., found a significant reduction in MAP

in the propofol group following intubation and at one, three and five minutes later [25].

The mean HR in the CL group was observed to be rising with cumulative doses. However, in the BIS group, the HR was constantly dropping with the subsequent doses. When observed across the groups, HR was significantly lower in the BIS group compared to the CL group at cumulative doses of 2 mg/kg and 2.5 mg/kg. Similarly, Shangne S et al., found that immediately after induction, HR decreased in the non BIS group and increased in the BIS group from the baseline ($p>0.05$) but was comparable at one, five and 10 minutes after intubation [8]. Rüsch D et al., found that the non BIS group had a more significant rise in HR than the BIS group after the injection of propofol [11]. Shajahan MS et al., and Morley A et al., found that haemodynamic variables such as HR, SBP, and DBP were similar over various time periods [12,13]. Chaparala C et al., had an insignificant decrease in HR in both groups [14]. Puri GD et al., found that the CLADS group utilising BIS had a more stable HR [15]. Xie T et al., found a change in HR with the deepening of anaesthesia, but the HR of the two groups did not differ significantly [16]. Saini S et al., found a decrease in HR in both groups after induction with an increase after intubation, but it was statistically insignificant [25]. SpO_2 remained unchanged in both groups.

The total dose of propofol required in group CL was 158.63±30.57 mg, and in group BIS, it was 118.23±28.53 mg, and it was observed that the dose of propofol requirement was significantly lower in group BIS when compared to group CL. Similarly, Pasin L et al., found that Closed-Loop Anaesthesia Delivery Systems (CLADS) using BIS was associated with a significant reduction in the dose of propofol required for induction but not the total propofol dose [7]. Shangne S et al., Shajahan MS et al., and Chaparala C et al., found significant differences in the mean dose of propofol for induction using BIS [8,12,14]. In a meta-analysis by Wang D et al., BIS-guided automated systems decreased the dosage of propofol compared to manual control [10]. Rüsch D et al., and Morley A et al., found no significant difference in the BIS group compared to the non BIS group regarding doses of propofol administered [11,13]. Xie T et al., found more propofol consumption in the closed-loop group using BIS than the open-loop group [16]. Saini S et al., found a higher induction dose of the drug required till BIS 50 with more total mean anaesthetic dose in the BIS group with propofol compared to etomidate [25].

Thus, various studies have concluded that there is a distinct advantage of using BIS guided induction of general anaesthesia using propofol [7,8,10,12,14,15]. Haemodynamic stability is an important goal that needs to be achieved in the management of patients on anaesthesia [6]. In present case, changes in the vital parameters among the patients given a titrated propofol dosage and evaluated by BIS and clinical index were studied. It was observed that haemodynamic parameters were more stable in the group assessed by BIS when compared with the group assessed clinically. The group assessed clinically was evaluated by taking into consideration the loss of verbal response or eye lash reflex. Although this is an extremely useful modality to assess the hypnotic effect of the drug, it is difficult to assess the overdose, which can only be accurately done by BIS index. Thus, BIS can potentially reduce the required propofol dose and hence its side-effects.

The combinations of the anaesthetic drugs administered do not seem to have an independent effect on BIS thresholds. Anaesthesia depth is not represented by comparable BIS values obtained with different agent combinations [26].

Limitation(s)

Only hypertensive patients were studied, and hence the values cannot be generalised within the normal population. The study is predominantly concerned with the haemodynamic changes during induction only. Future studies could include the study of haemodynamics after intubation, during maintenance, and recovery. Awareness during anaesthesia could also be assessed using some sedation awareness scales.

CONCLUSION(S)

The BIS-guided propofol induction is slightly better than clinically guided propofol induction in relation to haemodynamic stability. With increasing doses of propofol during induction, there is a lesser degree of fall in SBP. However, the DBP was lower in the BIS group at lower doses and equal in both groups with increasing doses. A rise in HR was seen more in the CL group at higher propofol doses. The total dose of propofol used was also less in the BIS group. Thus, BIS monitoring may help to titrate propofol administration, which in turn reduces the frequency of propofol overdose and its resultant side effects. In addition, BIS can help in the prevention of awareness during anaesthesia. Thus, authors conclude that BIS is a better modality for the assessment of the depth of anaesthesia compared to traditional clinical methods.

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