Section: Anesthesiology

Original Research Article

A COMPARATIVE STUDYOF MIDAZOLAM AND PROPOFOL FOR BISPECTRAL INDEX GUIDED SEDATION DURING ENT SURGERY UNDER LOCAL ANESTHESIA

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Abstract

Background: It has been widely recognized that most surgical procedures in the middle ear for adults can be carried out using local anesthesia. To compare Midazolam and Propofol for BIS-guided sedation during ENT surgery under local anesthesia. **Materials and Methods:** The current study was a Prospective randomized comparative study conducted at the Department of anesthesiology government Theni medical college hospital from April 2021 to September 2022. A total of 60 participants with were selected as the study population. Patients were allocated into 2 groups Group A and Group B by the investigators. Group I was of 30 Patients, receiving Inj. Midazolam infusion and Group II consisted of 30 Patients, receiving Propofol infusion. Categorical outcomes were compared between study groups using the Chi square test. Data were analysed by using coGuide software. **Result:** The mean bispectral index <80 with in group I was 19.6±1.07 and it was 13.53±1.25 in group II, the mean difference of time to obtain bispectral index <80 in study group was statistically significant with a P value <0.001. In bispectral index, the mean difference between study group was statistically significant at all time periods (P-value <0.05). The mean difference of time taken for recovery (Bispectral index >90) in study group was statistically significant with a P-value <0.001. **Conclusion:** The results of the current study show that as compared with Midazolam, Propofol appears to be more proper sedative agent for BIS guided sedation. Propofol has quicker onset of sedation, rapid recovery and less postoperative nausea and vomiting.

INTRODUCTION

It has long been known that the majority of middle ear operations in adults may be performed under local anaesthesia. The obvious advantages of local over general anaesthesia in middle ear surgery (MES) are faster recovery time and less bleeding during the operation. However, during MES under local anaesthesia, many patients experience various discomforts (a sensation of noise, anxiety, dizziness, backache, claustrophobia, or earache). To reduce these discomforts, careful patient selection, adequate preparation for anaesthesia, and appropriate sedation are necessary.[1]

Anaesthetic drugs are administered during procedures under Monitored Anesthesia Care (MAC) with the goal of providing analgesia, sedation, and anxiolysis and ensuring rapid recovery without side effects The addition of adjuvants (analgesic or sedative agent) can further reduce the dose of two agents to produce the desired level of deep sedation while minimizing the side effects.[2] MAC is specific anaesthesia modality during which the patient receives local anaesthesia with sedation and analgesia preserving the airway reflexes. Three components of MAC are conscious sedation, allaying patient's anxiety and effective pain control. It offers all the advantages of local anaesthesia and general anaesthesia and at the same time combating their side effects. MAC provides a comfortable, pain free, satisfied and easily arousable patient with rapid postoperative recovery and same day discharge. Patient's cooperation is also an important component of MAC.[3] The bispectral index (BIS) is an electroencephalogram (EEG) -derived parameter to monitor the hypnotic effects of anesthetics. BIS was shown to correlate well with the level of sedation produced by propofol and to accurately predict loss of consciousness.[4-6] The bispectral index (BIS) is a dimensionless numerical scale for measuring brain electrical activity. It is derived from cerebral electrical activity (an electroencephalogram (EEG))

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captured from the scalp surface at the forehead to reflect the sedative and hypnotic components of anaesthesia. Its value is a number within a range between 0 to 100, where 0 represents 'no detectable brain electrical activity' and 100 represents 'awake state'.[7,8]

Amongst the armamenterium of monitoring equipment available to the modern anaesthetist, BIS is perhaps the latest and the best suited tool. Besides providing an idea about the hypnotic state of the patient, it also enables titration of anaesthetic agents so as to avoid adverse effects as awareness due to inappropriate dosage as well as unwanted effects of overdosage.[9]

Propofol is a substituted isopropyl phenol. It is a selective modulator of Gamma-Aminobutyric Acid (GABA) A receptors. It is a sedative hypnotic agent with rapid onset of action with short and clear-headed recovery. If given in the doses of 25-100 mcgs/kg/min, it causes conscious sedation. It also has antiemetic properties. Few adverse effects are hypotension, bradycardia and pain on injection.[10]

Midazolam is a potent imidazobenzodiazepine which possesses typical benzodiazepine properties namely hypnotic, amnestic, anticonvulsant and anxiolytic activity.[11] Midazolam administration can be through oral, intranasal, buccal, intravenous, and intramuscular routes. For the perioperative use of midazolam, the induction dose is 0.15 to 0.40 mg/kg via the intravenous route. For the premedication, the dose is 0.07 to 0.10 mg/kg with the intramuscular route. For intravenous sedation, the dose is titrated at 0.05 to 0.15 mg/kg. For children 1 to 5 months old, the recommended intranasal dose is 0.2mg/kg. For children six months and older, 0.2 to 0.3 mg/kg intranasal dose is the recommendation.[12] Propofol and midazolam both are established sedative agents both intraoperatively and in an ICU.[13,14]

The current literature lacks the studies comparing the effects of propofol and midazolam using BIS under local anaesthesia during ENT surgeries. Hence the current study was performed to compare Midazolam and Propofol for BIS guided sedation during ENT surgery under local anaesthesia.

MATERIALS AND METHODS

The current study was a Prospective randomized comparative study conducted at Department of anaesthesiology govt. Theni medical college hospital theni from April 2021 to September 2022. A total of 60 participants with were selected as study population. Inclusion criteria for participants in the study was inclusion of both genders, participants with age group between 20 to 60 years, those who were weighing between 40 to 70 kgs of body weight and patients identified with American Society of Anesthesiologists (ASA) physical status - I and II. Patients with ASA physical status - III or more, who were Allergic to local anesthetic, who were on Chronic sedative or analgesic, and those with Severe cardiac, hepatic, renal dysfunction, psychiatric illness was excluded from the study.

Patients were allocated into 2 groups

Group A and group B by the investigators

Group I: 30 Patients, receiving Inj Midazolam infusion

Group II: 30 Patients, receiving Propofol infusion

Ethical and informed consent: Ethical approval was obtained from the institutional review board [Ref: IHEC:1515/MEIII/21] of the centre concerned. Informed written consent was obtained before the study started and confidentiality was maintained throughout.

Procedure: After a thorough preanaesthetic evaluation, patient was assigned to any one of the two groups – group I and group II. All patients were kept fasting overnight and acid aspiration prophylaxis with T. Ranitidine150 mg and T.Metaclopromide 10 mg the night before surgery. Anaesthetic machine was checked before starting the procedure. All patients were premedicated with Inj. Glycopyrrolate 5mcg/kg IM 40min before procedure. Local anesthesia was given using lidocaine 2% with adrenaline 1:200,000. Group I patients received Inj. Midazolam 0.1% infusion at the dose of 0.15 mg/kg/h Group II patients received Inj.Propofol 1% infusion at the dose of 1.5mg/kg/h Maintenance was done with 0.1mg/kg/hr (If BIS <60) and 0.2mglkg/hr (If BIS >80) in Group I and 1mg/kg/hr (If BIS <60) and 2mg/kg/hr (If BIS >80) in Group II. Time for onset of sedation (BIS <80) was noted. To evaluate the level of sedation, the BIS index was used. Intraoperative BIS values noted at 10 minutes (BIS10), 20 minutes (BIS 20) and 30 minutes (BIS30) after starting infusion. The sedative infusion was stopped 5 minutes before surgery. The time taken to reach BIS> 90 as recovery time in immediate postoperative period.

Statistical methods: Time to obtain bispectral index <80 & Time taken for recovery (Bispectral index >90) were considered as outcome parameters. Study Group (Group I vs Group II) was considered as Primary explanatory variable. Age, gender, etc., were considered as study relevant variables. For normally distributed Quantitative parameters the mean values were compared between study groups using independent sample t-test (2 groups). Categorical outcomes were compared between study groups using Chi square test. P value < 0.05 was considered statistically significant. Data was analysed by using coGuide software.[15]

RESULTS

A total of 60 subjects were included in the final analysis.

The mean difference of age (years) in study group was statistically not significant (P value >0.05). The difference in the proportion of gender between study group was statistically not significant (P value >0.05). The difference in the proportion of ASA

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grade between the study group was statistically significant with a P- value of 0.003, with majority of 23 (76.67%) participants had ASA grade I in group I. In group I, the majority of 3 (10%) participants had awareness complication.

In heart rate (bpm), the mean difference between study group (group I and group II) was statistically not significant at Intra-op 10 mins whereas significant at baseline, Intra-op 20 and 30 mins. The mean of HR was high in group I at Intra-op 20 mins compared to group II whereas it was slightly high in group II compared to group I at baseline. The mean difference of Mean arterial pressure (mm Hg) at all time periods in study group was statistically not significant (P value >0.05). The mean difference of SPO2 (%) at Intra-op 20 and 30 mins in study group was statistically significant (P value <0.05).

The mean bispectral index <80 with in group I was 19.6 ± 1.07 and it was 13.53 ± 1.25 in group II, the mean difference of time to obtain bispectral index <80 in study group was statistically significant with a P value <0.001. In bispectral index, the mean difference between study group was statistically significant at all time periods (P value <0.05). The mean of bispectral index was high in group I at Intra-op 10 mins compared to group II whereas it was slightly high in group II compared to group I at baseline. The mean difference of time taken for recovery (Bispectral index >90) in study group was statistically significant with a P value <0.001.

Table 1: Comparison of demographic parameters with study group

Parameter	Study Group (Mean± SD)		P value
	Group I (N=30)	Group II (N=30)	
Age (years)	38.37 ± 11.10	41.63 ± 9.84	0.233*
Gender			
Male	14 (46.67%)	25 (83.33%)	0.766 †
Female	16 (53.33%)	5 (16.67%)	
ASA Grade			
I	23 (76.67%)	22 (73.33%)	0.003 †
II	7 (23.33%)	8 (26.67%)	
Complications			
Awareness	3 (10%)	2 (6.67%)	‡
Confusion	2 (6.67%)	0 (0%)	
Nausea	2 (6.67%)	0 (0%)	
Nil	23 (76.67%)	28 (93.33%)	

*= Independent T Test P value; †=Chi square test; ‡= No test was applicable due to zero cell value

Table 2: Comparison of heart rate (bpm), MAP, SPO2 (%) at different time periods with study group

Parameter	Study Group (Mean± SD)		P value (IST)
	Group I (N=30)	Group II (N=30)	
Heart rate (bpm)			
Baseline	83.37 ± 13.64	89.6 ± 10.21	0.050
Intra-op 10 mins	86.17 ± 9.96	89.67 ± 10.25	0.185
Intra-op 20 mins	85.7 ± 10.75	76.27 ± 11	0.001
Intra-op 30 mins	87.63 ± 10.93	75.7 ± 10.88	<0.001
Mean arterial pressure (mm Hg)			
Baseline	81.97 ± 9.21	83.43 ± 12.75	0.611
Intra-op 10 mins	83.27 ± 9.87	83.33 ± 12.75	0.982
Intra-op 20 mins	81.97 ± 10.76	78.8 ± 9.43	0.230
Intra-op 30 mins	84.77 ± 9.68	80.1 ± 8.72	0.055
SPO2 (%)			
Baseline	99.43 ± 0.57	99.2 ± 0.81	0.200
Intra-op 10 mins	99.1 ± 0.8	99.2 ± 0.81	0.632
Intra-op 20 mins	99.1 ± 0.8	99.73 ± 0.45	<0.001
Intra-op 30 mins	99.03 ± 0.81	99.73 ± 0.45	<0.001

Table 3: Comparison of Bispectral index at different time periods with study group

Parameter	Study Group (Mean± SD)		P value (IST)
	Group I (N=30)	Group II (N=30)	
Time to obtain bispectral index <80	19.6 ± 1.07	13.53 ± 1.25	<0.001
Bispectral index			
Baseline	95.23 ± 1.04	96.47 ± 1.66	0.001
Intra-op 10 mins	76.53 ± 1.14	72.9 ± 8.4	0.022
Intra-op 20 mins	71.33 ± 1.65	68.03 ± 8.1	0.033
Intra-op 30 mins	67.33 ± 3.64	65.7 ± 0.75	0.019
Time taken for recovery (Bispectral index >90)	20.07 ± 0.78	10.07 ± 0.83	<0.001

DISCUSSION

The results of the present study bring us significant outcomes. It was observed that patients in group II which was of propofol showed significantly lower heart rates than those in the midazolam group. The major findings of the current study also showed that Time to obtain bispectral index <80 and Time taken

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for recovery (Bispectral index >90) was less in Propofol group than Midazolam group. Our findings were similar to many other studies from the past.

Glass, Peter S. MD, et al, 1997 studied BIS guided sedation for Propofol, Midazolam and isoflurane. They concluded that BIS may be a valuable monitor of the level of sedation and loss of consciousness for Propofol, Midazolam, and isoflurane. Sandler NA et al,[16] 2001 in their study concluded that the BIS provides additional information for standard monitoring techniques. It appears that use of the BIS monitor can help to titrate the level of sedation so that less drugs are used to maintain the desired level.[17] Similar results were observed by JanezBenedik et al study. Compared to Midazolam, Propofol is more suitable for sedation in patients undergoing MESLA.[1] Time taken for recovery (BIS>90) in group I (Midazolam group) was more than in group II (Propofol group) (19.8±2.11vs 13.17±2.41 min) ($p< 0.0001$) and it was highly significant. Similar recovery times were observed by Wilson et al., (9.2±1.5 vs. 2.1±0.3 min).[7] In study by Khurana P et al., the mean recovery time (as defined by BIS >90) was significantly lower in the propofol group than the midazolam group (10.1 ±3.6 vs 18.6±6.5 min) ($p=0.00$).[18] Similarly recovery times were observed by Wilson et al (9.2±1.5 vs 2.1±0.3 min).[7] Fanard et al. compared midazolam and propofol as sedative agents for surgeries under regional anesthesia. They found the quality of sedation as desirable in 88% of patients in the propofol group and 76% in the midazolam group. Furthermore, patients in the propofol group had a more rapid recovery as compared to the midazolam group.[13]

Limitation of present study were small sample size, only ASA grade I/II included. The use of BIS over the routinely practiced sleep guided dose of propofol and dexmedetomidine in terms of hemodynamics need further trials with multicentric studies with a larger sample and on patients with existing co morbidities should be conducted.

CONCLUSION

The results of the current study show that as compared with Midazolam, Propofol appears to be more proper sedative agent for BIS guided sedation. Propofol has quicker onset of sedation, rapid recovery and less postoperative nausea and vomiting.

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