

A Comparative Study of Midazolam and Propofol for BIS Guided Sedation during Middle Ear Surgery under Local Anesthesia

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Abstract: The study was conducted in 60, ASA grade I & II patients for BIS guided sedation during middle ear surgery under local anesthesia. All patients were Pre medicated with Inj. Fentanyl 2µg/kg and Glycopyrolate 5µg/kg, 10 minutes before surgery. Local anesthesia was given by the experienced ENT surgeon using lidocaine 2% with adrenaline 1:200,000. Patients were randomly divided into two groups. Group I (Inj. Midazolam 0.1% infusion, 0.15 mg/kg/h) and Group II (Inj. Propofol 1% infusion ,1.5mg/kg/h). Continuous infusion of study drug was given with manually controlled variable rate infusion pump. Maintenance was done with 0.1mg/kg/hr (If BIS <60) and 0.2mg/kg/hr (If BIS >80) in Group I and 1mg/kg/hr (If BIS <60) and 2mg/kg/hr (If BIS >80) in Group II. The infusion was titrated to the level of conscious sedation (BIS 60-80). Time for onset of sedation (BIS <80) was noted. The sedative infusion was stopped 5 minutes prior to end of surgery. In the immediate postoperative period, time taken to reach BIS >90 was noted as Recovery time. Conclusion: Both Propofol and Midazolam in equisedative infusions can be used safely for sedation in middle ear surgery under local anesthesia. Propofol has the advantage of providing faster onset of sedation, rapid clear headed recovery and lesser postoperative nausea/vomiting. We conclude that, Compared with Midazolam, Propofol appears to be more suitable sedative agent for BIS guided sedation.

Keywords: BIS, Sedation, Middle Ear Surgery, Local Anesthesia

1. Introduction

BIS MONITOR is perhaps the latest and the best suited tool for measurement of depth of anesthesia/ sedation. [1] Bispectral Index® allows clinicians to assess consciousness and sedation independent of cardiovascular reactivity. Majority of middle ear operations in adults may be performed under local anesthesia. [2], [3] The obvious advantages of local over general anesthesia in middle ear surgery are faster recovery time and less bleeding during the operation. However, during middle ear surgery under local anesthesia, many patients experience various discomforts (a sensation of noise, anxiety, dizziness, backache, claustrophobia, or earache). To reduce these discomforts appropriate sedation is necessary. Propofol and Midazolam both are established sedative agents both intra operatively and in an ICU [4],[5] We studied and compared the properties of Midazolam and Propofol for BIS guided sedation during middle ear surgery under local anesthesia. The aim of our study was to find out,

- 1) Time for onset of sedation (BIS <80)
- 2) Depth of sedation; BIS values
- 3) Changes in vital parameters
- 4) Time taken for recovery (BIS >90) and
- 5) Intraoperative & Postoperative side effects

2. Material and Methods

This prospective, randomized study was conducted in 60, ASA grade I & II patients, between 20 to 40 years of age, weighing 40 to 70kgs, of both genders, for BIS guided sedation during middle ear surgery under local anesthesia. Patients inc were informed about the procedure and a written

informed consent was taken. They were assessed on the preoperative day and kept NBM for 6 hours before surgery. Patient with a history of chronic use of analgesic or sedative agents, a history of alcohol abuse; mental disorder; allergy to medications; and those with cardiac, pulmonary, hepatic or renal dysfunction were excluded from the study. All patients were monitored with an electrocardiograph, noninvasive blood pressure, pulse oximeter and BIS monitor. Baseline readings were recorded. Pre medication (Inj. Glycopyrolate 5 µg/kg i.v. and Inj. Fentanyl 2 µg/kg i.v.) was given 10 min. before surgery. No preoperative prophylactic anti emetics were given. Local anesthesia was given by the experienced ENT surgeons using lidocaine 2% with adrenaline 1:200,000. Patients were randomly divided into two groups. Group I (Inj. Midazolam 0.1% infusion, 0.15 mg/kg/h) and Group II (Inj. Propofol 1% infusion, 1.5mg/kg/h). Continuous infusion of study drug was given with manually controlled variable rate infusion pump. Maintenance was done with 0.1mg/kg/hr (If BIS <60) and 0.2mg/kg/hr (If BIS >80) in Group I and 1mg/kg/hr (If BIS <60) and 2mg/kg/hr (If BIS >80) in Group II. The infusion was titrated to the level of conscious sedation (BIS 60-80). Time for onset of sedation (BIS <80) was noted. To evaluate the level of sedation, the BIS index was used. [6]

Blood pressure, heart rate, oxygen saturation, and BIS level were assessed every 2 min till BIS level reached 80 and then every 20 min till the end of surgery. During the intraoperative period, incidence of pain in arm, bradycardia, hypotension, apnea (>30 sec.) /bradypnea, involuntary movements, fall in oxygen saturation, confusion and appearance of rash was noted. O2 inhalation by vent mask was given when SpO2 came down below 90%.

The sedative infusion was stopped 5 minutes prior to end of

surgery. In the immediate postoperative period, time taken to reach BIS >90 was noted as Recovery time. At the same time patient was asked to open the eyes and give his/her full name. Postoperative complications, if any such as nausea/vomiting, awareness, confusion, delirium, etc. were noted and if required, treated. Patients and surgeon were asked to rate their level of satisfaction, each on a three-point scale (1=very poor, 2=good, 3=excellent). The results were analyzed using Student's paired & unpaired t test and chi square test. A 'p' value of <0.05 was considered as statistically significant, whereas 'p' value of <0.001 was taken as highly significant.

3. Observation and Results

The study included 60 ASA I and II patients, between 20 to 40 years of age. There was no significant difference in mean age or weight among patients in two groups. Female patients were more than male patients in both groups.

Table 1: Time for onset of sedation (BIS<80)

Induction of sedation (Minute)	Group I	Group II	p value
	20.5±1.74	13.1±2.39	< 0.0001

The onset of sedation was faster in group II as compared to group I (p< 0.0001), which was statistically highly significant.

Table 2: Depth of sedation, BIS value

Time	Group I	Group II
Pre induction	98.87±0.35	98.83±0.37
2 min	97.3±0.79	97±0.83
4 min	96.33±0.95	95.43±1.56
6 min	95±1.14	92.56±2.27
8 min	93.87±1.35	90.37±3.50
10 min	91.17±1.80	84.83±3.63
20 min	80.07±2.21	76.06±1.43
40 min	72.93±2.61	72.26±2.33
60 min	75.2±3.97	76.6±3.37

BIS values were comparable in both groups preoperatively. Patients in Propofol group had lower BIS values at specific time points throughout the surgery. During the period of sedation, vital parameters (Pulse rate and Mean arterial pressure) were comparable in the two groups up to 30 minutes. Mean values for heart rate and mean arterial pressure were significantly lower in the Propofol group (p<0.05) after 30 minutes. ECG remains stable throughout the surgery in both the groups. Apnea (>30 sec.) / Bradypnea was none in group I as compared to 2 (10%) in group II (SpO2<90), requiring oxygen by venti mask. Pain in Arm due to infusion of sedative agent was found in 4 (13.33%) patients in Group II as against none in Group I. Bradycardia, Hypotension (>20% of preoperative value), Involuntary movements and Rash was not seen in any group.

Table 3: Time taken for recovery (BIS>90)

Recovery Time (Minute)	Group I	Group II	p value
	19.8±2.11	10.13±1.98	< 0.0001

Time taken for recovery (BIS>90) in group I (Midazolam group) was more than in group II (Propofol group) (p< 0.0001) and it was highly significant.

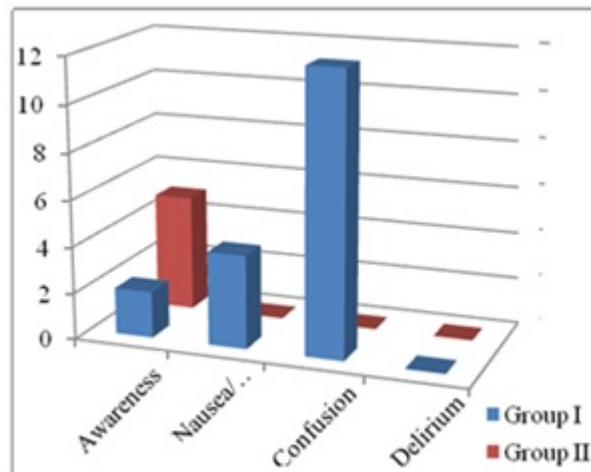


Figure 1: Postoperative complications

Patient and surgeon satisfaction was higher in the Propofol group than Midazolam group.

4. Discussion

The main benefit of conscious sedation with higher BIS values (60-80) during middle ear surgery under local anesthesia is to enable the surgeon to communicate with the patient throughout the procedure and to test the patient's hearing after restoration procedure.

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. [7]

Sandler NA et al, 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. [8]

Technique for administrating sedation with continuous infusion has been proved to produce lesser side effects, faster recovery, easy titratability and controllability over the desired depth of sedation. The mean time for onset of sedation was faster in group II as compared to group I, (p< 0.0001), which was statistically highly significant. This observation was Comparable with the AbhiruchiPatki et al. They concluded the desired level of sedation was achieved much faster by Propofol infusion as compared to Midazolam, (6.62 vs. 10.1minutes) and was highly significant (p<0.001).[9]

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) [10]. Patient and surgeon satisfaction was higher in the Propofol group than Midazolam group. Similar results were observed by JanezBenedik et al study. Compared to Midazolam, Propofol is more suitable for sedation in patients undergoing MES-LA. [11]

5. Summary and Conclusion

Both Propofol and Midazolam in equisedative infusions can be used safely for sedation in middle ear surgery under local anesthesia. Propofol has the advantage of providing faster onset of sedation, rapid clear headed recovery and lesser postoperative nausea/vomiting. We conclude that, our results bring to light some new aspects of sedation in the practice of middle ear surgery under local anesthesia. Compared with Midazolam, Propofol appears to be more suitable sedative agent for BIS guided sedation. Improvements possible are comparing this two study drugs with conventional drugs (fortwin and Phenergan) which are used routinely in middle ear surgery to provide sedation.

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