Conscious sedation for middle ear surgeries: A comparison between fentanyl-propofol and fentanyl-midazolam infusion

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ABSTRACT

Introduction and Aim: Middle ear surgeries can be performed under local anesthesia and sedation and can be well tolerated by the patient with minimal discomfort. This study was undertaken to compare two techniques of conscious sedation, intravenous midazolam, and propofol infusion for tympanoplasty. **Materials and Methods:** Forty patients scheduled for right or left tympanoplasty. American Society of Anesthesiologists I or II in age group 18-75 years were included in the study. The patients were randomly allocated into one of the two groups to receive either propofol (group I) or midazolam (group II). **Results:** The mean duration of anesthesia was 116.00 ± 33.94 min in group I, while 97.50 ± 30.76 min in group II (P = 0.07). The modified Ramsay sedation scale was not statistically significant in both the groups. In group I, 70% of the patients and 95% of the patients in group II had amnesia during the surgery (P = 0.091). The mean visual analog scale (VAS) score for surgeons and patients was not statistically significant in both the groups. In group I there was a positive correlation between the total dose of fentanyl and VAS score for surgeons (P = 0.02). There was also a positive correlation between the total dose of propofol and VAS score for surgeons (P = 0.034) and patients (P = 0.039) in group I. **Conclusion:** Though propofol had shown a faster recovery and less nausea vomiting, we need a larger sample size to conclude, which of the technique is better. Both the techniques are safe, simple and versatile and provide excellent sedation with rapid trouble free recovery.

Key words: *Conscious sedation, midazolam, middle ear surgeries, propofol, tympanoplasty*

INTRODUCTION

Common middle ear surgery includes tympanoplasty, mastoidectomy, myringotomy, grommet insertion and cochlear implantation[1] can be performed under local anesthesia and sedation.[2] Special considerations taken during middle ear surgeries include: Provision of a bloodless surgical field, attention to patient's head positioning, airway management, facial nerve monitoring, the effect of nitrous oxide on the middle ear, a smooth and calm recovery, and prevention of postoperative nausea and vomiting (PONV).[1,3,4] Under local anesthesia may patients experience various discomforts like a sense of noise, anxiety, dizziness, backache, claustrophobia or earache.[5] Dislocation of the ossicular chain with and without opening of the labyrinth, injuries to the facial nerve, PONV and hemorrhage from large arteries and veins may occur.[3,4] Most-middle ear procedures can be performed as outpatient surgery; thus rapid recovery, good analgesia, and avoidance of nausea and vomiting are essential.[6] The properties that make midazolam suitable for use with local anesthesia are anxiolysis, sedation and antegrade amnesic action.[7]

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Propofol is an ultra-short acting sedative-hypnotic agent with a rapid onset of action, substantial potency, extremely short recovery time and high patient satisfaction because of its antiemetic and euphoric properties.[8]

This study was undertaken to compare two techniques of conscious sedation, intravenous midazolam and propofol infusion for tympanoplasty. We tried to ascertain whether any of these agents had any advantage over the other by comparing the incidence of complications due to the anesthetic technique and the satisfaction of the anesthetic technique from patients and the surgeons' point of view.

MATERIALS AND METHODS

After approval from the institutional ethics committee, informed consent was obtained from each of the 40 patients who were scheduled for right or left tympanoplasty. All the patients belonged to American Society of Anesthesiologists (ASA) I or II and were in the age group of 18-75 years were included in the study. Patients with a history of an allergic reaction to the study drugs, chronic opioid or sedative drug use and obesity (body mass index >30 kg/m^2) were excluded from the study. The patients were randomly allocated into one of the two groups to receive either propofol (group I) or midazolam (group II). All these patients were premedicated with injection atropine 0.6 mg intramuscularly half an hour before the surgery. After arriving in the operating room, the NBM status of the patient was confirmed, and intravenous access was established. All the patients were monitored with a pulse oximeter, electrocardiography, noninvasive blood pressure and capnometer (via nasal prong) and baseline parameters were recorded. Patients also received continuous supplemental oxygen with nasal prongs.

Patients were placed supine on the operating table with the head turned opposite to the ear to be operated. All the patients received injection fentanyl 1.5 mcg/kg intravenously. The patients in group I received a bolus dose of injection propofol 0.75 mg/kg followed by an infusion started at 0.025 mg/kg/min intravenously. The patients in group II received a bolus dose of injection midazolam 0.03 mg/kg followed by infusion at 0.001 mg/kg/min intravenously. The infusion rates of both the drugs were increased or decreased to obtain the desired level of sedation. Simultaneously, the parts were painted and draped. Local anesthetic infiltration was performed with 2% lignocaine with 1:200,000 adrenaline for blocking the great auricular nerve and tympanic branch of auriculotemporal nerve. The infusion rates were adjusted so as to maintain a conscious sedation level corresponding to a modified Ramsay sedation scale of 2 where the patient is cooperative, easily arousable, oriented and alert to obey commands. Injection fentanyl bolus of 0.5 mcg/kg was administered if patient complained of excessive pain. All the patients were monitored, and their level of consciousness (modified Ramsay sedation scale), and respiratory (respiratory rate, SpO_2,) parameters were noted. Furthermore, undesirable events like desaturation (SpO_2 <90%), hypoventilation (respiratory rate <8), inappropriate movements, snoring, excessive pain, nausea and vomiting, loss of cooperation by the patient were recorded. At the end of the procedure, the surgeon was asked to express his degree of satisfaction regarding the sedation technique based on a visual analogue scale (VAS). They were asked to rate the sedation technique on a scale of 0-10 where 0 referred to cases where the procedure had to be abandoned or general anesthesia induced due to inappropriate sedation and 10 referred to cases where the patient was fully cooperative in all aspects. After 1 h of arrival in the recovery room, the patients were interviewed about their comfort level, painful or unpleasant experiences during the procedure. Their satisfaction was assessed using the VAS scale from 0 being the worst experience they ever had to 10 being a good experience. Depending on the interest of variables to be assessed like general complications, respiratory complications Chi-square test was used and two-tailed nonparametric correlation was used for individual groups. We actually did not do a sample size calculation and selected the sample size of 68 patients in total based on previous literature, but had to stop the study early.[5] All statistical analyses were performed with SPSS 11.5.1 (SPSS Inc., Chicago, IL, USA).

RESULTS

Of the 40 patients studied who were operated for tympanoplasty, males and females, as well as the site of tympanoplasty, were equally distributed in both the groups. The mean age in the group I was 29.10 ± 10.24 years and 33.00 ± 13.44 years in group II (P = 0.30). Two patients in group I were ASA PS II, while 3 patients from group II were ASA PS II. The mean duration of anesthesia was 116.00 ± 33.94 min in group I, while 97.50 ± 30.76 min in group II (P = 0.07). The modified Ramsay sedation scale was not statistically significant in both the groups [Table 1]. In group I, 70% of the patients and 95% of the patients

Table 1: Difference in various variables between group I and II

Variables	Group I mean ± SD	Group II mean ± SD
Age (years)	29.10±10.24	33.00±13.44
Weight (kg)	50.25±8.69	54.70±10.63
Duration of anesthesia (min)	116.00±33.94	97.50±30.76
Duration of anesthesia (h)	1.93±0.57	1.63±0.51
Fentanyl dose (mcg)	82.70±26.12	83.10±17.55
Total propofol dose (mg)	322.45±159.80	—
Total midazolam dose (mg)	—	6.82±2.21
VAS for surgeons	8.03±2.14	8.65±1.04
VAS for patients >1 h postsurgery	7.93±2.48	8.65±0.75
Modified Ramsay sedation scale	2.20±0.41	2.40±0.50

VAS: Visual analogue scale; SD: Standard deviation in group II [Figure 1] had amnesia during the surgery (P = 0.091). General complications like inappropriate movements, excessive pain and nausea and vomiting are shown in Table 2. In group I, 35% of the patients and in group II 30% had some movements during the surgery (P = 1.00), and the dose of propofol and midazolam were increased in groups I and II respectively so that the patients did not move during the procedure. Similarly, 35% of the patients in group I and 30% of the patients in group II had excessive pain during the surgery (P = 1.00) and required small doses of fentanyl and local anesthetic infiltration. One patient in group II had vomiting, but none of the patients in group II had any nausea or vomiting (P = 1.00). None of the patients in both the groups had any desaturation or hypoventilation, while 1 patient in group I had snoring during the surgery. The average total dose of fentanyl was 82.70 ± 26.12 μg in group I and 83.10 ± 17.55 μg in group II (P = 0.07). The mean VAS score for surgeons and for patients was not statistically significant in both the groups [Table 1]. In group I, there was a positive correlation between the total dose of fentanyl and VAS score for surgeons (P = 0.02). There was also a positive correlation between the total dose of propofol and VAS score for surgeons (P = 0.034) and patients (P = 0.039) in group I.

DISCUSSION

Although it has been known that majority of ear surgeries can be carried out under local anesthesia, only a small number of surgeons feel comfortable using this technique for tympanoplasty. Drilling and manipulation of instruments with long duration of the surgery raises the concern that the patient may not tolerate the noise and discomfort. Most of the patients prefer to have no memory of the surgical procedure, and some form of sedation is necessary. The ideal sedative medication for use during surgery would provide for an easily titratable level of sleepiness, predictable amnesia, and decreased anxiety (anxiolysis), while providing for a rapid recovery with minimal side-effects. Sarmento and Tomita reported that the Retroauricular tympanoplasty under local anesthesia and sedation can be well tolerated by the patient with minimum discomfort.[9]

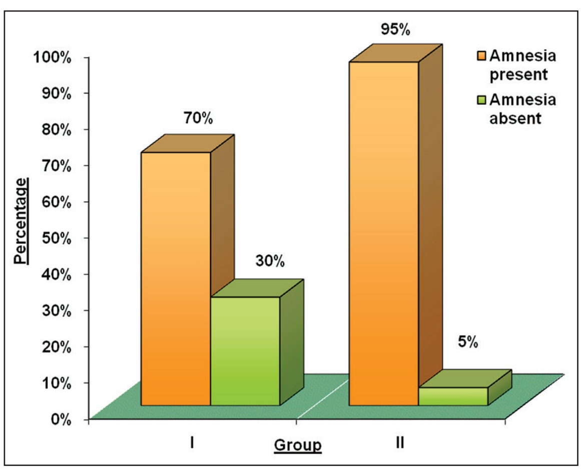

Figure 1: Amnesia in group I and group II

Table 2: List of general complications

Adverse events	Group I (n = 20)	Group II (n = 20)
Inappropriate movements	7	6
Excessive pain	7	6
Nausea vomiting	0	1
Snoring	1	0

With the resurgence of interest in regional anesthesia, the provision of good sedation becomes increasingly important if the advantages of the regional technique are to be fully exploited.[10] The advantages of local anesthesia are less bleeding, cost effectiveness, postoperative analgesia, faster mobilization and ability to test hearing and facial nerve integrity intraoperatively. In ear surgeries, excellent analgesia is achieved by blocking the branches of the great auricular nerve (retroauricular infiltration) and tympanic branch of auriculotemporal nerve (V-shaped infiltration). The mastoid cells are devoid of sensations, so drilling is not painful for the patient. Pain sensation depends not only on the extent of surgical trauma and infiltration technique, but also on the patients' emotional status and previous experiences. Careful explanation of the procedure in the preoperative visit reduces the anxiety.

Patients should understand that local anesthetics provide analgesia, but does not eliminate tactile sensation in the infiltrated area, which means one can feel the manipulation of tissues and noise of instruments, but not pain. It is important to ask the patients whether they are feeling any pain or discomfort and allow for some change in position as long as it doesn't compromise the surgical field (if the surgery goes on for a longer duration).

A wide variety of drugs are available for providing sedation, anxiolysis and analgesia like midazolam, diazepam, propofol, thiopentone, ketamine, fentanyl, alfentanyl, remifentanyl. An ideal drug for sedation should have a rapid onset of action, predictable dose effect relationship, minimum excitatory effects and minimal cardiorespiratory depression. It should produce anxiolysis, amnesia and should have a rapid recovery following discontinuation of its administration.[4] In our study, we compared two drugs propofol and midazolam given as a bolus followed by continuous infusion. These were supplemented with fentanyl. We tried to maintain a level of sedation where the patient was cooperative, oriented, tranquil and easily arousable corresponding to a modified Ramsay sedation scale[11] of 2. Propofol has a short effect site equilibration time, rapid onset of action and complete, clear headed recovery without any residual effects,[8] has a prompt recovery without residual sedation and low incidence of nausea and vomiting making it particularly well suited for ambulatory conscious sedation. On the other hand, midazolam is used as a premedication, sedative and an anesthetic induction agent which also has anxiolytic, hypnotic, anticonvulsant, and antegrade amnestic effects.[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.[12] Mackenzie and Grant used propofol as an intravenous sedative agent along with regional anesthesia for orthopedic surgeries and reported it to be a safe, simple and versatile technique with a mean overall infusion ate of 3.8 mg/kg/h providing excellent sedation with no delays in surgery and relatively free from side-effects.[13]

In our study, all 40 patients received injection fentanyl 1.5 mcg/kg intravenously. The patients in group I 2 patients needed a top up dose of injection fentanyl 1 μg/kg intravenously in view of pain during the procedure, especially when it lasted for more than an hour. Two patients had a recall of intraoperative events and could hear the drilling noise, but it was not associated with pain or any unpleasant events. None of the patients were sedated at the end of the surgery, and a mean VAS score of 8 was recorded at the end of 1 h in the recovery room and they would undergo it again if the need be. Similarly, VAS score was noted for the surgeons as well with a mean VAS score of 8. The average duration of surgery was 116 min in group I and 97 min in group II. The overall mean infusion rate of propofol was between 3 and 4 mg/kg/h. The infusion was stopped on average, 5 min before the end of surgery, and most patients regained full consciousness within this period. Ninety percent of the patient in group II had amnesia of the surgery when compared to 70% in group I. None of the patients had any respiratory complications, and the postoperative recovery was good. The frequency of side-effects was low, and only 1 patient reported to have vomiting in the postoperative period. Since the sample size of our study was very less, a very large sample size may help us to clearly define the better of the two techniques. Thus, the intravenous route with the appropriate drug in low doses offers a controllable means of sedation with rapid onset and recovery. Both propofol and midazolam provided good sedation with fentanyl. Onset of sedation was smooth, and the depth was controlled easily. Sedation occurs without loss of airway reflexes or any cardiovascular changes. Amnesia for the immediate postoperative period was greater for midazolam, but it was not statistically significant. In a similar survey, Yung[14] found the most common discomforts reported were noise during surgery and anxiety, followed by dizziness, backache, claustrophobia, and earache. Despite these discomforts, however, 89% of patients said they would prefer local anesthesia for similar operations in the future. In our study, all patients in the propofol group were satisfied with their anesthetic and would choose the same technique again. Two patients in the midazolam group would prefer an alternative technique in the future, because of PONV. Patients who received midazolam were more somnolent at the end of the procedure. Recovery was significantly faster following propofol, about both return of consciousness and restoration of higher functions and were free from minor postoperative sequelae. There was also a positive correlation between the total dose of propofol and VAS score for surgeons.

CONCLUSION

Though propofol had shown a faster recovery and less nausea vomiting, we need a larger sample size to conclude, which of the technique is better. Both the techniques are safe, simple and versatile and provide excellent sedation with rapid trouble free recovery.

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