



Anaesthesiology

COMPARATIVE EVALUATION OF DEXMEDETOMIDINE AND PROPOFOL INFUSION FOR HYPOTENSIVE ANESTHESIA DURING MIDDLE EAR SURGERY: A PROSPECTIVE RANDOMIZED TRIAL

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ABSTRACT

Background: Intense bleeding during general anesthesia is the major limitation during middle ear surgery. It affects operative field visibility and increases complications. Hypotensive anesthesia is preferred to improve surgical outcomes. This study aimed to compare the efficacy of Propofol and Dexmedetomidine infusion for hypotensive anesthesia in patients undergoing middle ear surgery. **Objective:** To compare the efficacy and safety of Dexmedetomidine and Propofol for hypotensive anesthesia in middle ear surgeries. **Materials and Methods:** This prospective randomized trial was conducted in 60 adult patients who were scheduled for middle ear surgeries under general anesthesia. Patients were randomly divided into two groups: group P (n = 30) received Propofol infusion of 100-150mcg/kg/min and group D (n = 30) received Dexmedetomidine with a loading dose of 1 mcg/kg diluted in 10 ml 0.9% saline to be infused over 10 min after induction, followed by maintenance infusion of 0.4-0.8 mcg/kg/h. The infusions were titrated to maintain mean arterial pressure (MAP) between 60 and 70 mm Hg. Hemodynamic control, Intraoperative blood loss, Quality of the surgical field and patient recovery were recorded. **Results:** In our study, the mean arterial pressure and heart rate were significantly lower in group D throughout the surgery than in group P. Blood loss was significantly higher in group P (215.18 ± 18.15 ml) than in group D (180.50 ± 14.50 ml). The Surgical field visibility was comparable between the groups. The awakening time was significantly shorter in group D than group P. **Conclusion:** In our study, we observed that both Dexmedetomidine and Propofol are efficacious and safe for controlled hypotension during middle ear surgery; however, Dexmedetomidine provides better hemodynamic control and is associated with lesser degree of sedation without any significant adverse effects.

KEYWORDS : Dexmedetomidine, Hypotensive anesthesia, Propofol.

INTRODUCTION

Surgery with enhanced illumination and visualization dramatically improves surgical dissection. The main hindrance to visibility is excessive bleeding during surgery^[1]. Hence, it is essential to keep the surgical field as free of blood as possible, which can be achieved through the reverse Trendelenburg position, preoperative steroid administration, topical local anesthetics and vasoconstrictors such as phenylephrine, and controlled hypotension through various anesthetic techniques^[2].

Controlled hypotension or hypotensive anesthesia is an anesthetic technique in which there is deliberate reduction in systemic blood pressure during anesthesia, which should be in accordance with the patient's baseline blood pressure rather than a specific target pressure. Achieving optimum hypotension is a skill, as excess lowering of BP may be hazardous due to the reduced perfusion to essential organs such as brain, heart, and kidneys. The mean arterial blood pressure (MAP) can be reduced by 30% below the patient's baseline MAP, with a minimum MAP of 60-70 mmHg in ASA I patients being clinically acceptable^[1]. For achieving controlled hypotension, certain characteristics are desired in the agent used for the purpose. The ideal agent should have ease of administration, short onset time, an effect that disappears quickly on discontinuation, rapid elimination without toxic metabolites, negligible or no effects on vital organs, and predictable and dose-dependent effects.^[2] Various agents such as vasodilators, beta blockers, magnesium sulphate, inhalational agents, intravenous α -2 agonists and short-acting opioids are routinely used.

Dexmedetomidine is a highly selective α 2 agonist. It acts on α 2A and imidazoline type I receptors. Alpha-2 receptors regulate the autonomic nervous and cardiovascular systems. They are located in the blood vessels, where they cause vasoconstriction and in the sympathetic terminal where they inhibit nor-epinephrine release. This ultimately leads to fall in BP and heart rate (HR). It has got inherent analgesic, sedative, and anesthetic-sparing properties that avoid use of multiple drugs^[1,2]. It exerts sedative and analgesic-sparing effect through central locus ceruleus and in the dorsal horn of the spinal cord^[2,3].

Propofol is an intravenous anesthetic agent useful for controlled hypotension. It is associated with positive influence on the inhibitory function of the neurotransmitter γ -amino butyric acid (GABA) through GABA-A receptors.^[2,3] Propofol has negative inotropic effect through inhibition of sympathetic vasoconstrictor nerve activity. It has anti-emetic, anti-pruritic, and anticonvulsant activity. Complete awakening without residual central nervous system effects has made it popular for day care surgery. The use of Propofol infusion for controlled hypotension is associated with improved quality of surgical field in middle ear surgery.^[4,5]

Our study compared the efficacy of Dexmedetomidine and Propofol infusion when used for controlled hypotension during middle ear surgery.

MATERIALS AND METHODS

This study has been conducted after approval from institutional ethical committee and after obtaining informed written consents from all the patients. 60 patients with ASA I or II of either sex aged between 18 and 50 years, scheduled for elective middle ear surgery were enrolled in the study. Patients with history of uncontrolled hypertension, autonomic neuropathy, ASA III or IV, coagulation disorders, hypersensitivity and pregnant females were excluded from the study.

A routine pre-anaesthesia checkup was performed a day before surgery which included a detailed history, general physical and systemic examination. Basic investigations (complete blood count, fasting blood sugar, urea, creatinine, serum electrolytes, chest x-ray and 12 lead electrocardiogram) were done. All eligible patients were advised preoperative fasting for a period of 6 hours and premedication with 0.5mg Alprazolam tablet was given at night before the day of surgery.

A total of 60 patients were randomly divided into two groups (30 patients each); Group D (Dexmedetomidine) and Group P (Propofol).

In the operating room monitor with echocardiogram, pulse oximetry, noninvasive blood pressure and temperature probe was attached and base line vitals were recorded.

Two intravenous lines with 18 G intravenous cannula were secured, one for infusion of study drug and other for the infusion of intravenous fluids and other anaesthetic agents. All patients in both groups were started with Ringer's lactate in one intravenous line at 6 ml/kg/hr and received Inj. Ondansetron 0.15 mg/kg and Inj. Glycopyrolate 0.004 mg/kg intravenously as pre medication. After pre oxygenation, induction was performed with intravenous Propofol 2 mg/kg until loss of verbal contact followed by Injection Cis-atracurium 0.2 mg/kg intravenously to facilitate endotracheal intubation. Airway was secured with appropriate sized endotracheal tube. Anesthesia was maintained with O₂:AIR (50:50), one minimum alveolar concentration of Sevoflurane and the infusion of Cis-atracurium 0.1 mg/kg was started.

Group D (Dexmedetomidine): All patients received Inj. Dexmedetomidine with a loading dose of 1mcg/kg diluted in 10 mL 0.9% saline to be infused over 10 min after induction, followed by maintenance infusion of 0.4-0.8mcg/kg/h.

Group P (propofol): All patients received propofol infusion of 100-150mcg/kg/min after induction of anesthesia.

The infusion rate of the study drugs was regulated in both groups to maintain a mean arterial blood pressure between 60 and 70 mmHg. The surgeon was allowed to start surgery only after 10 min of starting the infusion in both groups. Intraoperative hemodynamic parameters such as heart rate (HR), systolic blood pressure, diastolic blood pressure, MAP, and oxygen saturation (SpO₂) were recorded at baseline, during induction, 5 min after induction, and every 5 min thereafter until the end of surgery. HR < 50 beats/min was considered bradycardia and managed with 0.5 mg atropine intravenously. MAP <60 mmHg (significant hypotension) was initially managed by titrating the dosage of infusion and further stoppage of infusion if no response was obtained, and then Inj. Ephedrine 6 mg intravenously was administered to treat hypotension.

The study drug was discontinued 5 min before the end of surgery.

The residual neuromuscular blockade was reversed with intravenous Neostigmine 0.05 mg/kg and Glycopyrrolate 0.008 mg/kg, and extubation was performed when the patient was fully awake and breathing regularly with adequate tidal volume. Recovery time, that is, time taken from cessation of anesthesia until the patient obeyed verbal commands, was noted at every 2-min interval. The duration of surgery was also recorded.

The surgeon estimated the quality of the surgical field using Fromme scale.

The total blood loss was measured on the basis of the volume of blood in the suction bottle minus the irrigation fluid and the volume of the total blood-soaked gauze pieces (10 ml for each).

Peri-operative complications such as hypotension (MAP<60), hypertension (MAP>90), tachycardia (HR>100), bradycardia (HR<50), hypoxemia (SpO₂<94%) and sedation were also noted.

Statistical Analysis

The entire statistical analysis was performed using SPSS version 11.5. Independent t- test was used for quantitative data.

Chi-square test was used for qualitative data.

The result was considered statistically significant if the p-value was < 0.05.

RESULTS

The demographic parameters including age, sex, weight, ASA I/II status and duration of surgery were comparable without any statistically significant difference in both the groups (Table 1). Intraoperatively, the estimated mean blood loss during middle ear surgery was 180.5 ± 14.50 ml in group D as compared to 215.18 ± 18.15 ml in group P, and this difference was highly significant (P = 0.001) (Fig. 1). The mean HR and MAP in group D were lower than those in group P at almost all-time intervals intra operatively, and these differences were statistically significant except preoperatively and during induction (Figs. 2, 3). Moreover, both HR and MAP were significantly decreased (P < 0.05) in both groups after administering a loading dose of the study drugs as compared to baseline. Both groups were comparable in visibility of the surgical field with Fromme's score of 1 in 20% of patients, 2 in 70% of patients, and 3 in 10% of patients in group D and a score of 1 in 6.3% of patients, 2 in 76.7% of patients, and 3 in 17% of patients in group P with a mean Fromme score of 2.22 ± 0.46 and 2.32 ± 0.54 in groups D and P, respectively, and this difference was statistically insignificant (P > 0.05) (Table 2). The recovery time was comparable in both groups with duration of recovery of 32.90 ± 1.82 min in group D and 33.12 ± 1.92 min in group P (P > 0.05). Only one incidence of bradycardia and hypotension was observed in group D (2.5%) compared to that in group P, which was managed successfully. Postoperatively, no significant adverse effects were observed in either group, except sedation in group D (2.5%), which was statistically and clinically insignificant.

Table 1: Demographic Data and Duration of Surgery.

Variable	Group D (n = 30)	Group P (n = 30)	P value
Age (years)	42.36 ± 7.04	39.24 ± 4.80	0.06
Weight (kg)	70.95 ± 6.20	69.20 ± 4.02	0.167
Duration of surgery	215.18 ± 6.34	116.32 ± 8.02	0.179
Sex (M/F)	17/13	16/14	0.689
ASA physical status (I/II)	24/6	27/3	0.732

Values are presented as mean ± SD. P > 0.05, not significant.

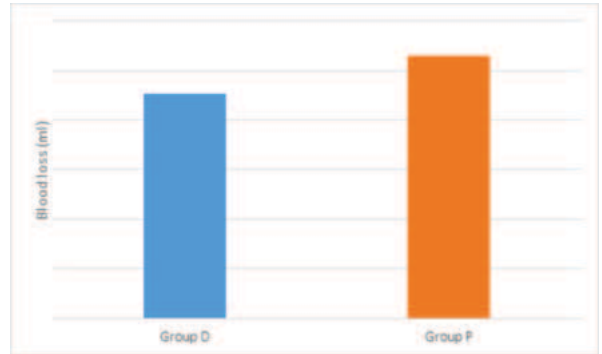


Fig 1: Intraoperative Mean Blood Loss (ml).

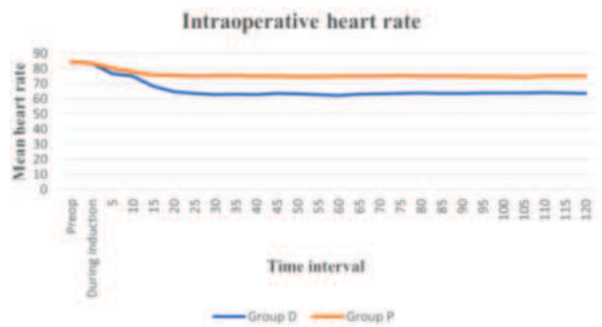


Fig 2: Intraoperative Heart Rate HR (Beats Per Min).

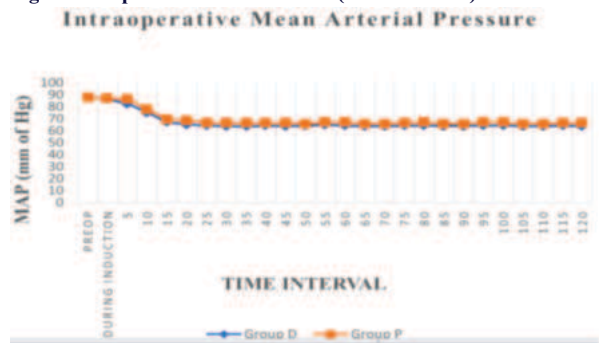


Fig 3: Intraoperative Mean Arterial Pressure MAP (mmHg).

Table 2: Surgical Site Visibility Scoring Using the Fromme Scale

Score	Group D (number of patients)	Group P (number of patients)	P value (Mann–Whitney U test)
1	6	6	0.103
2	21	23	
3	3	1	

DISCUSSION

A lot of efforts have been done to optimize the surgical conditions for middle ear surgery. Induced hypotension has been widely advocated to control bleeding during middle ear surgery to improve the quality of surgical field. In our study, we chose a target MAP of 60–70 mmHg to provide the best quality of surgical field without any adverse effects. Both drugs were effective in achieving MAP of 60 to 70 mmHg and lowering the heart rate ensured good surgical condition and providing dry surgical field during middle ear surgery.

Similar studies have been done comparing Dexmedetomidine–Isoflurane and Propofol–Fentanyl based anesthesia using Dexmedetomidine at a loading dose of 1mcg/kg over 10 minutes and continuous infusion of a 0.5mcg/kg/hour dose. The Propofol infusion dose was also similar to our study but they started Fentanyl infusion at 0.5mcg/kg/hour. Both groups were able to achieve the target MAP within 5 minutes and were able to maintain this intra operatively. However, they chose a target MAP of 60 to 75 mmHg, which is in the higher range as compared to our study.

In our study, we have used a loading dose of Dexmedetomidine of 1 mcg/kg over 10 min, followed by a maintenance dose of 0.4–0.8 mcg/kg/h. Propofol infusion 100–150mcg/kg/min dose was used in

our study. We compared the study groups with respect to blood loss during surgery, quality of the surgical field, hemodynamic control, recovery time, and any other significant adverse effects. We found that although controlled hypotension was achieved with both drugs, Dexmedetomidine produced a more stable hemodynamic with lower readings of MAP and HR as compared to that of propofol. Moreover, the target MAP range, i.e., 62.48 ± 2.15 mmHg in group D and 67.46 ± 3.02 mmHg in group P, was achieved after 15 min of infusion onwards. Our study also found that intraoperative blood loss was significantly lower in the Dexmedetomidine group than that in the Propofol group. Consequently, we observed that blood loss was decreased in both groups (Dexmedetomidine and Propofol) individually as well as in combination; therefore, we compared both drugs for their usefulness in reducing blood loss during middle ear surgery. A recent study compared dexmedetomidine and propofol infusion for controlled hypotensive anesthesia in 80 patients undergoing middle ear surgery and found that blood loss was 183.75 ± 14.80 ml in the dexmedetomidine group compared to that in the propofol group where it was 196.25 ± 16.12 ml. These results are in concordance with the present study but differ in that they used fixed dosages for infusions (Dexmedetomidine, loading dose 0.5 mcg/kg for 20 min, maintenance dose 0.3 mcg/kg/h, and Propofol, started at 12 mg/kg/h for 10 min, then at 10 mg/kg/h for the next 10 min, and a maintenance dose of 8 mg/kg/h).

The recovery time in our study was comparable in both groups. Regarding adverse effects, a single episode of intraoperative bradycardia and hypotension was noted in the Dexmedetomidine group (2.5%) and none in the Propofol group, which was statistically insignificant. No other incidences of hypotension, hypertension, or hypoxemia occurred in the present study.

Limitations

- 1) Invasive monitoring for the MAP, which was not done in the present study, can be used as a sensitive marker for monitoring hypotensive anesthesia.
- 2) The method of blood loss measurement could be improved in the present study by performing calculations based on hemoglobin values and total volume in the suction canister.
- 3) Study used a target range of MAP (60–70 mmHg) to achieve controlled hypotension. However, it is recommended that hypotensive anesthesia needs to be adjusted in relation to the patient's preoperative blood pressure.

CONCLUSIONS

From the observations in our clinical study, we conclude that both Dexmedetomidine and Propofol infusion are efficacious and safe drugs for facilitating controlled hypotension. Both drugs can provide haemodynamic stability, an ideal surgical field and reduce blood loss throughout the middle ear surgery. However, Dexmedetomidine is comparatively better than Propofol in controlling heart rate and mean arterial pressure and in reducing blood loss.

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