

A prospective randomized comparative study of dexmedetomidine and propofol for conscious sedation in middle ear surgery under monitored anaesthesia care

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Abstract

Introduction: Monitored Anesthesia Care (MAC) is proposed to be a suitable technique for middle ear surgery.

Aim: In present study we compared the efficiency of dexmedetomidine and propofol as an adjunct to local anesthesia for in producing analgesia, sedation, variation in respiratory and hemodynamic responses, along with patients and surgeons satisfaction.

Materials and Methods: Fifty patients were enrolled in this prospective, single blinded, randomized study. The patients were allotted randomly into two groups: dexmedetomidine (Group D) or propofol (Group D). Sedation was assessed with Ramsay Sedation Scale (RSS) value of 3. Different parameters observed included changes in hemodynamic and respiratory values, post-surgical recovery time, sedation analgesia, surgeons' and patients' satisfaction about quality of anaesthesia.

Results: Both the drugs i.e. dexmedetomidine and propofol were found to be providing adequate sedation but propofol was related with increased need for rescue analgesia and less patient satisfaction. These results propose that dexmedetomidine provide sufficient sedation with analgesia with good surgeon and patient ease without any adverse effect for patients being operated for middle ear surgery under local anesthesia.

Keywords: Dexmedetomidine, Propofol, Fentanyl, Sedation, Middle ear surgery.

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Introduction

A common middle ear surgery (MES) includes tympanoplasty, stapedectomy and mastoidectomy. Tympanoplasty involves reconstruction of a tympanic membrane with permanent perforation with or without reconstruction of ossicles.¹ Most of these middle ear surgeries are usually undertaken under local anesthesia. Many advantages are reported when these surgeries are undertaken under local anesthesia such as reduced bleeding, cost effectiveness, early recovery and postoperative analgesia. Beside that improvement in hearing can be assessed in patients undergoing stapedectomy surgeries on the table itself. Still many of the MES are performed under general anesthesia due to patient anxiety, fear of sudden patient movement of patient while crucial operative step being performed and advantages associated with hypotensive general anesthetic techniques. The most common patient discomfort under local anesthesia is patient's anxiety caused by noise during surgery which may further increased if burr is used for drilling the bone along with dizziness and discomfort due to positioning of head and neck during surgery.^{2,3}

Pharmacologically Dexmedetomidine is a centrally acting α -2 adrenoceptor agonist. It has been increasingly used in monitored anesthesia care (MAC) as a sedative due to its analgesic property, "co-operative sedation" and lack of any respiratory depression.^{4,5} It is known to significantly reduce opioid requirements both intra and post operatively. Its sympatholytic action can attenuate the anxiety induced stress reaction to surgery (tachycardia and hypertension) while maintaining hemodynamic stability⁶. Although safe, bradycardia and hypotension are the most predictable and frequent side effects which are advantageous to provide less bleeding during surgery therefore provide blood free surgical field, essential for microsurgical procedures.

Propofol is also another widely used sedative-hypnotic having a rapid onset action, short recovery time with antiemetic and euphoric properties.⁷

This study was conducted to access the comparative safety and efficacy of dexmedetomidine and propofol in producing sedation and analgesia, bloodless surgical field, hemodynamic and respiratory variation along with patient and surgeon satisfaction in patients undergoing middle ear surgeries under local anaesthesia.

Materials and Methods

Approval was obtained from institutional ethics committee to conduct present study. Detailed written informed consent from the participants was taken. Fifty patients of both sexes were enrolled. Patients having American Society of Anesthesiologists Grade (ASA) 1 or 2, aged 18-60 years and undergoing middle ear

surgery under local anesthesia were included in the study. Exclusion criteria for this study were: Patients allergic to local anesthetic drug i.e. lignocaine, propofol or dexmedetomidine, pregnant and lactating women, contraindications to regional anesthesia such as patient's refusal of local anesthesia, clotting abnormalities, severe cardiac and pulmonary diseases. Patients having hepatic or renal insufficiency, endocrine and metabolic disorders were also excluded.

Patients having history of using any sedative medication in one week before the surgery were also excluded. All patients were rendered to a comprehensive pre-anesthetic evaluation comprising clinical history in detail, general and systemic examination with routine and special investigations.

Intravenous access was secured and Ringers Lactate solution was started. Oxygen was administered via nasal cannula at 2 L/min. Routine monitoring with electrocardiogram, SpO₂ and non-invasive blood pressure recordings were done. All patients received premedication with injection glycopyrrolate 2mg and injection fentanyl 1 ug/kg. The patients were randomly assigned into two groups in equal numbers.

Group D was the dexmedetomidine group. They received a loading dose of 1 ug/kg over 10 minutes and an infusion was continued during the operation at a rate of 0.4 ug/kg/hr (dexmedetomidine was diluted in 0.9% normal saline to a target concentration of 4 ug/ml)

Group P was the propofol group. They received a loading dose of injection propofol 75ug/kg/min intravenously over 10 min and an infusion was continued during operation at a rate of 50 ug/kg/min.

After achieving a score of 3 on the Ramsay Sedation Scale, the operative field was infiltrated with

lignocaine with adrenaline (1:200,000). Surgery commenced after confirming satisfactory analgesia. Pain was measured on 10 point verbal scale.

Table 1: Ramsay Sedation Scale

Score	Response
1	Anxious and/or Restless
2	Cooperative, Oriented, Tranquil
3	Responds to verbal commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

The following measures were assessed:

- Heart Rate, Mean Arterial Pressure, Respiratory Rate, Oxygen Saturation(SpO₂) were recorded every 5 minutes during surgery and every 15 minutes in the immediate post operative period till the patient remained in PACU(Post Anesthesia Care Unit).
 - In the recovery room Aldrete score was assessed every 10 minutes till discharge. Patients were fit for discharge when they obtained an Aldrete score of 10.
 - The degree of pain was determined using a 0-10 cm Visual Analog Scale(VAS)for pain where:
 - 0=no pain
 - 10=intolerable pain
- At 1, 2, 3, 4, 5, and 6 hours after completion of surgery.
- Just before discharge from PACU patients were told to rate their approval with quality of sedation/analgesia on a seven point Likert like scale.

1	2	3	4	5	6	7
Extremely Dissatisfied	Dissatisfied	Somewhat Dissatisfied	Undecided	Somewhat Satisfied	Satisfied	Extremely Satisfied

- The surgeon was told to rate his approval with patient sedation using the same method (Seven Point Likert Like Verbal Rating Scale) after the completion of surgery.
- All adverse events including nausea, vomiting, dry mouth, hypotension (MAP<50 mm Hg sustained >10 min), bradycardia (Heart Rate<45 beats per minute) and oxygen desaturation (SpO₂<92%) were recorded.

If any patient was not adequately sedated and complained of pain, rescue fentanyl 1ug/kg was given. If any patient required more than one dose of rescue analgesic, he/she was removed from the study. All the patients were given 500 ml Ringer Lactate till completion of surgery.

On completion of surgery, the field was assessed in respect of bleeding by the surgeon blinded to the drugs under study using the scale developed by Boezaart.

On completion of surgery the drug under study was stopped and patients were shifted to the Post Anesthesia Care Unit (PACU) for at least one hour and discharged to the postoperative ward after ensuring that the patient attained an Aldrete score of 10.

All the qualitative data was analyzed using the Chi Square Test and the quantitative data using students unpaired t test. The results were expressed as mean±SD. P value<0.05 was considered statistically significant.

Results

Both groups were comparable with respect to age, sex, weight, ASA grade and duration of surgery (Table 2).

Table 2: Showing demographic parameters in two groups along with duration of surgery

	Group D	Group P	P value
Age(in years)	32.4±3.42	30.20±5.61	>0.05(NS)
Weight(kg)	62.01±4.6	64.33±6.5	>0.05(NS)
Sex(male, female)	14:11	13:12	>0.05(NS)
ASA 1,II (n)	15/15	14/16	>0.05(NS)
Duration of Surgery	86.12±23 minutes	92±35 minutes	>0.05(NS)

n = number of patients

Table 3: Showing time taken to achieve adequate sedation, degree of patient and surgeon satisfaction and time taken to achieve Aldrete Score of 10 in both groups

	Group D	Group P	P value
Time to achieve adequate sedation	16.56±2.3	10.34±2.6	<0.05(S)
Degree of patient satisfaction (7 point Likert Scale)	6.8+/-1.3	5.2+/-2.4	<0.05(S)
Degree of surgeon satisfaction (7 point Likert Scale)	6.7±3.6	6.2±0.21	>0.05(NS)
Time to achieve Aldrete Score of 10 (minutes)	42.32±5.67	39.46±5.63	>0.05(NS)

S = Significant NS= Not significant

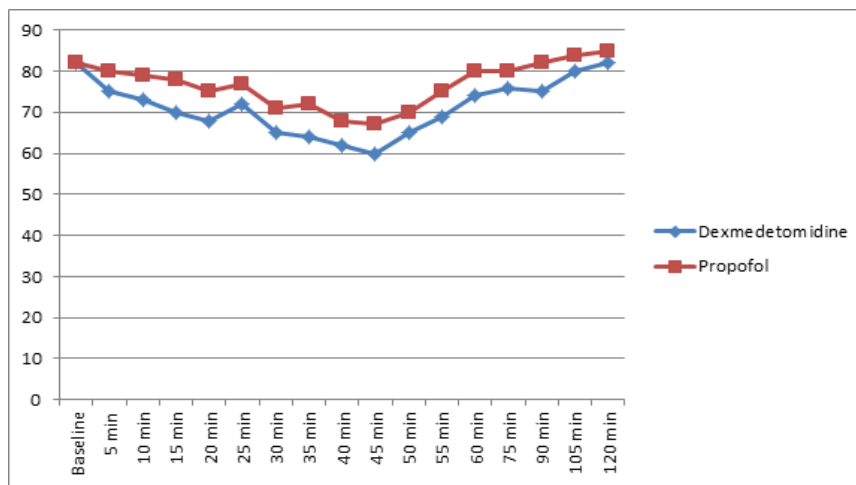


Fig. 1: Mean Heart Rate intraoperatively and postoperatively

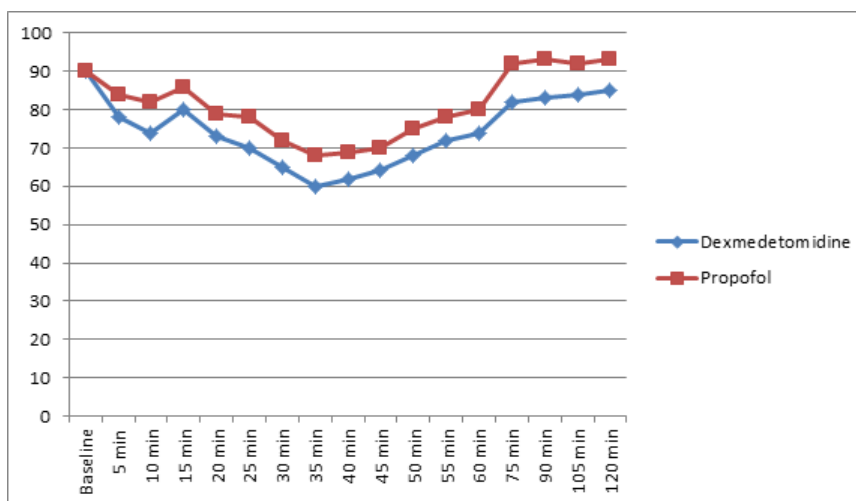


Fig. 2: Mean Arterial Pressure intraoperatively and postoperatively

The time taken from the onset of infusion of the drugs under study to the attainment of target level of sedation was significantly prolonged in the dexmedetomidine group (16.56 ± 2.3) than the propofol group (10.34 ± 2.6) as shown in table 3. P value was significant (<0.05). Respiratory Rate and SpO₂ were comparable and within normal limits in all the groups ($P > 0.05$).

Hemodynamically patients were stable throughout the surgery with lower heart rate and MAP observed in Group D in comparison to Group P. The mean decrease in heart rate and MAP was statistically significant in Group D was 15-20% in comparison to 5-10% in Group P ($p < 0.005$).

Rescue analgesia (Fentanyl 1 $\mu\text{g}/\text{kg}$) requirement is more in Group P (12) in comparison to group D and is statistically significant ($p < 0.05$). VAS Scores were lower in Group D in comparison to Group P. There was no nausea and vomiting, dry mouth, bradycardia or hypotension observed in either group.

Boezart Grading Scale for Surgical bleeding showed that in Group D 19,5 and 1 patient had Grade 1,2 and 3 bleeding respectively while in Group P 17,6 and 2 patients showed Grade 1,2 and 3 bleeding respectively. Surgeon satisfaction was observed equal in both groups (>0.05) while patient satisfaction was significantly better in dexmedetomidine group (<0.05). Time required to achieve an Aldrete Score of 10 was comparable in both groups (>0.05) as shown in Table 3.

Discussion

Monitored Anesthesia Care (MAC) is the terminology used for "sedation along with local anesthesia for short procedures".⁸ Dexmedetomidine is an extremely selective α_2 agonist inheriting both sedative and analgesic properties. By attenuating the sympathetic outflow, it prevents the release of norepinephrine and results a predictable, dose dependent decrease in arterial blood pressure and heart rate.⁹ Previous studies have also shown a dominant

inhibitory effect of propofol on sympathetic outflow.¹⁰ But Dexmedetomidine is unique in that it does not cause respiratory depression as its effects are not mediated by Gamma Amino Butyric Acid System.¹¹

Durums et al.¹² studied the effect of dexmedetomidine on operative bleeding in patients undergoing for tympanoplasty and nasal septal surgery and concluded that the use of dexmedetomidine was accompanied with decreased bleeding, less anesthetic requirements and less hemodynamic variations in response to both anesthesia and surgery. Dexmedetomidine has persistent analgesic action and conserve the patients' arousability in the post-operative period, resulting in significantly more analgesia and equivalent discharge times in comparison with short acting propofol. Surgeons' satisfaction with patient sedation was similar in both groups. However, in the dexmedetomidine group there was a higher patient satisfaction in comparison with the propofol group which can be because of the involvement of natural sleep pathway of dexmedetomidine sedation.¹³ The lower heart rate and mean arterial pressure with dexmedetomidine in comparison to propofol is result of its reduced sympathetic activity caused by its α_2 agonistic effect which was beneficial to provide comparatively blood less operative field for microscopic otological surgery.¹⁴ which is required for surgeon to carryout finer and important surgical steps meticulously in microscopic otological surgery.

Conclusion

Our study demonstrates that dexmedetomidine is a superior drug with minimal hemodynamic instability, better patient surgeon satisfaction with lower VAS score, lesser bleeding in operative field along with good sedation and analgesia in comparison to propofol for Monitored Anesthesia Care (MAC) for middle ear surgeries.

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