

Assessment of Efficacy of Nalbuphine and Dexmedetomidine versus Nalbuphine and Propofol in Middle Ear Surgeries under Monitored Anaesthesia Care: A Comparative Study

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ABSTRACT

Background: For middle ear surgery, familiarity with the interrelationships of the anatomical structures is as essential as knowledge of their individual morphology, as surgery is strongly influenced by the close spatial relations between the different components. In the present study, we assessed and compared the efficacy of nalbuphine and dexmedetomidine versus nalbuphine and propofol in middle ear surgeries under monitored anaesthesia care.

Materials & Methods: A total of 40 patients scheduled to undergo MESs were included in the present study and were broadly divided into two categories as follows: Group 1: Included patients who received injection dexmedetomidine along with nalbuphine (intravenously), Group 2: Included patients who received injection propofol along with nalbuphine (intravenously). Visual analogue score (VAS) was used for assessing the intraoperative and postoperative pain. Recovery to be assessed using Modified Aldrete scoring system (score ranging from 0 to 10) in the recovery room every 5 min, till score of 10 was achieved. Adverse events were recorded. Both patient satisfaction score (PSS) and surgeon satisfaction score (SSS) were recorded on a scale on 1 to 7; with 1 indicating extremely dissatisfied and 7 indicating extremely satisfied.

Results: Significant results were obtained while comparing the

mean VAS, number of patients with PSS of 5 to 7 and number of patients with SSS of 5 to 7 in between the two study groups. Non-significant results were obtained while comparing the incidence of complications between the two study groups.

Conclusion: In patients undergoing middle ear surgeries, Nalbuphine/ dexmedetomidine appeared to be significantly more effective combination in comparison to the nalbuphine/ propofol combination.

Keywords: Dexmedetomidine, Middle Ear Surgery, Propofol.

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INTRODUCTION

In many of the circumstances, the middle ear is a remarkable organ. Tympanic membrane (TM), ossicular chain and inner ear signify an extremely diverse sound pressure wave receiver, whose dynamics are matchless by any other sense organ. At the hearing threshold, the pressure and amplitude are a millionfold smaller than the loudest tolerable sound.^{1,2}

For middle ear surgery, familiarity with the interrelationships of the anatomical structures is as essential as knowledge of their individual morphology, as surgery is strongly influenced by the close spatial relations between the different components.³ Optimized and designed for sinus surgery, rigid zero degree and angled endoscopes are now the standard instrument for visualization of the paranasal sinuses.⁴

Dexmedetomidine, a potent and selective α_2 -adrenoceptor agonist, is used as adjuvant to general anaesthesia during surgery at pre-operative state (sedation), intra-operative state (analgesia and hemodynamic stability) and during post-operative period (no respiratory depression).⁵

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.^{6,7} Hence; under the light of above obtained data, we planned the present study to assess and compare the efficacy of nalbuphine and dexmedetomidine versus nalbuphine and propofol in middle ear surgeries under monitored anaesthesia care.

MATERIALS & METHODS

The present study was conducted in the department of general anaesthesia of the medical institute and it included assessment and comparison of efficacy of nalbuphine and dexmedetomidine versus nalbuphine and propofol in middle ear surgeries under monitored anaesthesia care. A total of 40 patients scheduled to undergo MESS were included in the present study and were broadly divided into two categories as follows:

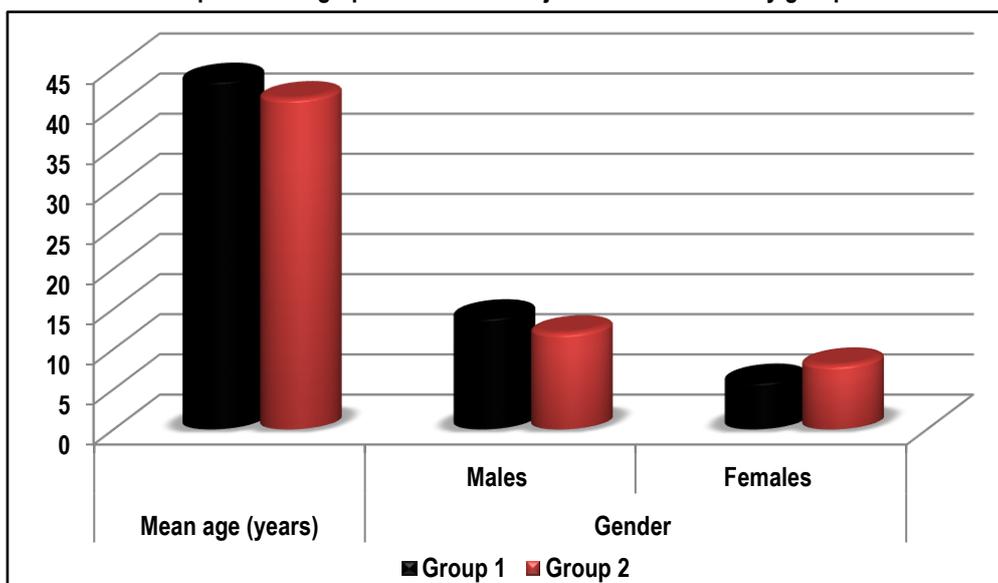
Group 1: Included patients who received injection dexmedetomidine along with nalbuphine (intravenously)

Group 2: Included patients who received injection propofol along with nalbuphine (intravenously)

Both the study groups consisted of 20 patients each. Ethical approval was obtained from institutional ethical committee and written consent was obtained from all the patients after explaining in detail the entire research protocol. Operating surgeons performed the local infiltration procedure simultaneously. Ramsay sedation score (RSS) was used for assessing the level of

sedation. Patient's mean arterial pressure (MAP), heart rate, saturation peripheral pulse and need for intraoperative rescue sedation/analgesia were recorded. Visual analogue score (VAS) was used for assessing the intraoperative and postoperative pain. 0 score on VAS showed absence of pain, while 10 score on VAS showed maximum worse pain. For any value of VAS more than or equal to 3, IV (intravenous) paracetamol was given as intraoperative rescue analgesia. Recovery to be assessed using Modified Aldrete scoring system (score ranging from 0 to 10) in the recovery room every 5 min, till score of 10 was achieved. Adverse events were recorded. Both patient satisfaction score (PSS) and surgeon satisfaction score (SSS) were recorded on a scale on 1 to 7; with 1 indicating extremely dissatisfied and 7 indicating extremely satisfied. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software. Chi-square test was used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

Graph 1: Demographic details of subjects of both the study groups



Graph 2: Comparison of parameters between the two study groups

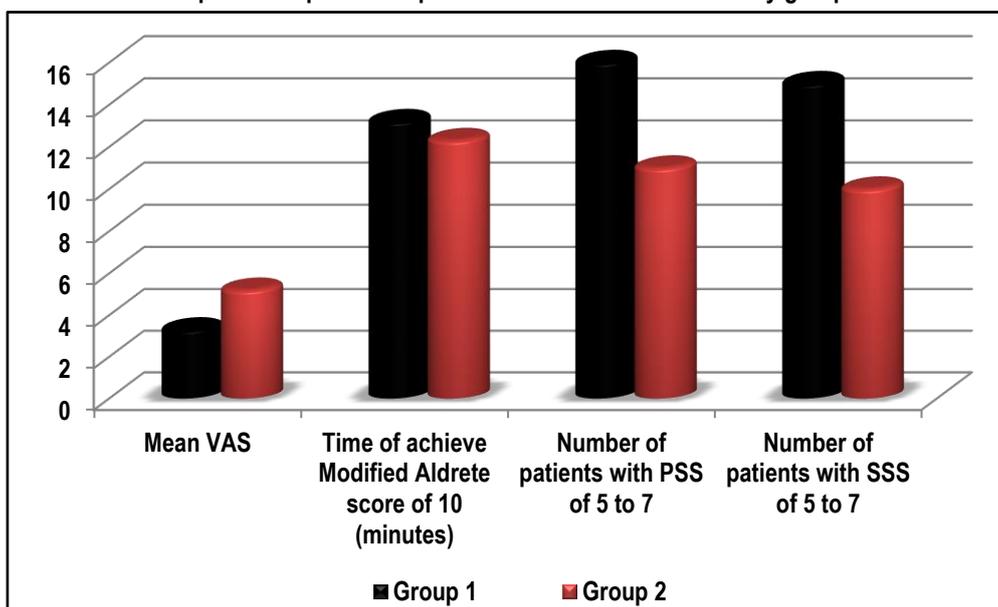


Table 1: Comparison of parameters between the two study groups

Parameter	Group 1	Group 2	p- value
Mean VAS	3.3	5.2	0.00*
Time of achieve Modified Aldrete score of 10 (minutes)	13.2	12.3	0.25
Number of patients with PSS of 5 to 7	16	11	0.02*
Number of patients with SSS of 5 to 7	15	10	0.01*

*: Significant

Table 2: Comparison of incidence of complications between the two study groups

Complications	Group 1	Group 2	p- value
Vomiting	2	1	0.36
Nausea	1	1	
Dry mouth	1	2	
Bradycardia	3	2	
Others	2	2	

RESULTS

In the present study, a total of 40 subjects were included in the present study, which were scheduled to undergo middle ear surgeries. All the subjects were divided randomly into two study groups; Group 1 and group 2. Subjects of group 1 and group 2 had mean age of 43.5 years and 41.2 years respectively. There were 14 males and 6 females in the group 1, while there were 12 males and 8 females in the group 2. Mean VAS of the subjects of group 1 and group 2 was 3.3 and 5.2 respectively. Mean Time of achieve Modified Aldrete score of 10 among the subjects of group 1 and group 2 was 13.2 minutes and 12.3 minutes respectively. Number of patients with PSS of 5 to 7 among group 1 and group 2 was 16 and 11 respectively. Number of patients with SSS of 5 to 7 among group 1 and group 2 was 15 and 10 respectively. Significant results were obtained while comparing the mean VAS, number of patients with PSS of 5 to 7 and number of patients with SSS of 5 to 7 in between the two study groups. Common complications observed among subjects of both the study groups were vomiting, nausea, dry mouth and bradycardia. Non-significant results were obtained while comparing the incidence of complications between the two study groups.

DISCUSSION

Middle ear surgery under general anaesthesia is revolutionised with the introduction of hypotensive anaesthesia that provides a relatively bloodless field while using an operating microscope.⁷ In the present study, subjects of group 1 and group 2 had mean age of 43.5 years and 41.2 years respectively. There were 14 males and 6 females in the group 1, while there were 12 males and 8 females in the group 2. Mean VAS of the subjects of group 1 and group 2 was 3.3 and 5.2 respectively. Starting in the 1990s, operative endoscopy was introduced in otologic surgery 1, and significantly changed not only surgical concepts 2 but also anatomic and physiologic concepts 3, and has become increasingly popular during the last 15 years. Since the introduction of this instrument, the concept of a minimally invasive approach in middle ear surgery is changing. Endoscopic middle ear surgery can offer some advantages compared to the traditional microscopic technique, guaranteeing excellent visualization of mesotympanic structures and direct visual control

of hidden areas such as anterior epitympanic spaces, retrotympanum and protympanum.⁷⁻⁹

In the present study, mean Time to achieve Modified Aldrete score of 10 among the subjects of group 1 and group 2 was 13.2 minutes and 12.3 minutes respectively. Number of patients with PSS of 5 to 7 among group 1 and group 2 was 16 and 11 respectively. Number of patients with SSS of 5 to 7 among group 1 and group 2 was 15 and 10 respectively. Nasreen F et al assessed the hypotensive effect of low dose dexmedetomidine (DEX) infusion during middle ear surgery. 42 ASA grades I and II patients of either sex aged 18–45 years undergoing elective middle ear surgery were randomly divided into two groups of 21 each. Group I received placebo bolus and infusion of saline at a rate similar to DEX in Group II. Group II received 10–15 min prior to induction of anesthesia 1 µg/kg IV bolus DEX diluted in 10 ml of normal saline over 10 min. Immediately thereafter an infusion of 0.4 µg/kg/hr of DEX commenced. Standard anesthetic technique was used. Halothane was titrated to achieve a mean arterial pressure 30% below the control value (value taken just after premedication). They observed that a statistically significant reduction in the percentage of halothane required to reduce MAP 30% below control value occurred in patients receiving DEX infusion in comparison to those receiving placebo (3.1 ± 0.3%). Patients receiving DEX infusion had a better surgical field. The mean awakening time was significantly reduced in patients of Group II when compared to patients of Group I.¹⁰

An extensive range of agents are available for providing sedation, anxiolysis and analgesia like midazolam, diazepam, propofol, thiopentone, ketamine, fentanyl, alfentanil, remifentanyl. Primary requisites for an ideal drug for sedation includes 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.¹¹ In the present study, significant results were obtained while comparing the mean VAS, number of patients with PSS of 5 to 7 and number of patients with SSS of 5 to 7 in between the two study groups. Common complications observed among subjects of both the study groups were vomiting, nausea, dry mouth and bradycardia.

Non-significant results were obtained while comparing the incidence of complications between the two study groups.

Nallam SR et al, in their study, randomly allocated 100 adult patients undergoing MESs under monitored anaesthesia care (MAC) into two groups. All patients in both groups received injection nalbuphine 50 µg/kg intravenously (IV). Group D received a bolus dose of injection dexmedetomidine 1 µg/kg IV over 10 min followed by an infusion started at 0.4 µg/kg/h IV. Group P received a bolus dose of injection propofol 0.75 mg/kg followed by an infusion started at 0.025 mg/kg/min IV. Sedation was titrated to Ramsay Sedation Score (RSS) of 3. Patient's mean arterial pressure, heart rate, saturation peripheral pulse and need for intraoperative rescue sedation/analgesia were recorded and compared. The data analysis was carried out with Z test and Chi-square test. Results: Mean RSS was significantly more in Group D (4.24 ± 1.54) as compared to Group P (2.58 ± 0.95). Overall VAS score was also significantly less in Group D (3.5 ± 1.7) than in Group P (5.4 ± 1.8). In total, 16 patients (32%) in Group D had hypotension whereas 7 patients (14%) only in Group P had hypotension. Nalbuphine/ dexmedetomidine combination is superior to nalbuphine/ propofol in producing sedation and decreasing VAS in patients undergoing MESs under MAC.¹²

CONCLUSION

Under the light of above obtained results, the authors conclude that in patients undergoing middle ear surgeries, Nalbuphine/ dexmedetomidine appeared to be significantly more effective combination in comparison to the nalbuphine/ propofol combination. However; further studies are recommended.

REFERENCES

1. Luers JC, Hüttenbrink KB. Surgical anatomy and pathology of the middle ear. *J Anat.* 2015; 228(2): 338- 53.
2. Aggarwal R, Saeed SR, Green KJM. Myringoplasty. *J Laryngol Otol* 2006; 120: 429–432.
3. Ghisi D, Fanelli A, Tosi M, Nuzzi M, Fanelli G. Monitored anesthesia care. *Minerva anesthesiologica.* 2005 Sep;71(9):533-8.
4. Gupta K, Bansal M et al. Dexmedetomidine infusion during middle ear surgery under general anaesthesia to provide oligoemic surgical field: a prospective study. *Indian journal of anaesthesia.* 2015 Jan;59(1):26.
5. Abdellatif AA, Elkabarity RH, Hamdy TA. Dexmedetomidine vs midazolam sedation in middle ear surgery under local anesthesia: effect on surgical field and patient satisfaction. *Egyptian Journal of Anaesthesia.* 2012 Apr 1;28(2):117-23.

6. Gupta KL, Gupta A. Efficiency of nalbuphine as an adjuvant to bupivacaine in lower limb orthopaedic surgery-a prospective study. *International Journal of Research in Medical Sciences.* 2017 Jan 23;5(2):623-6.
7. Thomassin JM, Duchon-Doris JM, Emram B, et al. Endoscopic ear surgery. Initial evaluation. *Ann Otolaryngol Chir Cervicofac.* 1990;107:564–570.
8. Marchioni D, Alicandri-Ciufelli M, Molteni G, et al. Ossicular chain preservation after exclusive endoscopic transcanal tympanoplasty: preliminary experience. *Otol Neurotol.* 2011;32:626–631.
9. Marchioni D, Alicandri-Ciufelli M, Molteni G, et al. Selective epitympanic dysventilation syndrome. *Laryngoscope.* 2010;120:1028–1033
10. Nasreen F, Bano S, Khan RM, Hasan SA. Dexmedetomidine used to provide hypotensive anesthesia during middle ear surgery. *Indian J Otolaryngol Head Neck Surg.* 2009;61(3):205-7.
11. Monica MS, Paul FW. Monitored anesthesia care. In: Miller RD, editor. *Text Book of Anesthesia.* 5th ed. Philadelphia: Elsevier Saunders; 2000. pp. 1452–69.
12. Nallam SR, Chiruvella S, Reddy A. Monitored anaesthesia care – Comparison of nalbuphine/dexmedetomidine versus nalbuphine/propofol for middle ear surgeries: A double-blind randomised trial. *Indian J Anaesth* 2017;61:61-7.

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