

ORIGINAL RESEARCH

A comparative study of middle ear surgeries under sedation and local anaesthesia with midazolam plus dexmedetomidine versus midazolam plus nalbuphine

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ABSTRACT

Background: Monitored Anaesthesia Care (MAC) typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and/or analgesic drugs. Present study was aimed to compare middle ear surgeries under sedation and local anaesthesia with midazolam plus dexmed versus midazolam plus nalbuphine.

Material and Methods: Present study was a prospective, comparative study conducted in patients 18-60 years age, either gender, ASA Grade I /II, posted for middle ear surgery under Sedation & local anaesthesia. In first group MD, patients received intravenous inj. midazolam 1 mg plus inj. dexmedetomidine 1 ugm /kg bolus and 0.5 ugm kg added in 100 ml NS infusion, given at 0.3 to 0.4 ugm/ min. In second group MN, patients received intravenous inj. midazolam 1 mg plus inj nacphin 10 mg slowly.

Results: Patients were randomly divided in two groups of 30 each. In present study, age, gender, BMI, ASA grade, type of surgeries (Tympanoplasty, mastoidectomy, stapedectomy) & duration of surgery was comparable & difference was not statistically significant. Ramsay Sedation Score (RSS) at 30,40 & 90 minutes was better in MD group as compared to MN group, difference was statistically significant. Visual Analogue Score (VAS) at 20, 30,40, 60 & 90 minutes was better in MD group as compared to MN group, difference was statistically significant. Patient & Surgeon satisfaction score was better in group MD as compared to group MN, but difference was not statistically significant. **Conclusion:** Dexmedetomidine with midazolam was better than nalbuphine with midazolam, with respect to sedation, analgesic effect, patient & surgeon satisfaction.

Keywords: Dexmedetomidine, midazolam, nalbuphine, middle ear surgery

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INTRODUCTION

Monitored Anesthesia Care (MAC) has been defined by the American Society of Anesthesiologist (ASA), as a specific anesthesia service, meant for diagnostic or therapeutic procedure done under local anesthesia along with sedation and analgesia.¹ Monitored Anaesthesia Care (MAC) typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and/or analgesic drugs.²

Anaesthetic drugs are administered during procedures under MAC with the goal of providing analgesia, sedation, and anxiolysis and ensuring rapid recovery without side effects. The addition of adjuvants (analgesic or sedative agent) can further reduce the dose of two agents to produce the desired level of deep sedation while minimizing the side effects.

Midazolam is a potent imidazobenzodiazepine which possesses typical benzodiazepine properties namely hypnotic, amnesic, anticonvulsant and anxiolytic activity.¹ Dexmedetomidine is a centrally acting selective alpha 2-receptor agonist having property of analgesia, sympatholytic and sedation in the titrated dose without major respiratory depression.⁴

Nalbuphine is structurally related to oxymorphone. Nalbuphine has a short duration of action and rapid clearance compared with other opioids and is less likely to cause side effects such as pruritus, respiratory depression, urinary retention and excessive sedation.⁵ Present study was aimed to compare middle ear surgeries under sedation and local anaesthesia with midazolam plus dexmed versus midazolam plus nalbuphine.

MATERIAL AND METHODS

Present study was a prospective, comparative study conducted in Department of Anaesthesia, Vilasrao Deshmukh Government Medical College, India. Study period was from July 2020 to July 2021 (12 months). Approval of institutional medical ethics committee was obtained for present study.

Inclusion criteria

- Patients 18-60 years age, either gender, ASA Grade I /II, posted for middle ear surgery under Sedation & local anaesthesia willing to participate in study

Exclusion criteria

- Patients not fit for surgery under local anaesthesia
- Patients required intra-op or immediate post-op need of general anaesthesia

Study was explained to patients & written informed consent was taken for participation. All patients underwent history taking, physical examination, laboratory/radiological investigations & fitness for surgery.

In operation theater, patients were randomly divided by computer generated numbers as group MD & group MN. The anaesthesiologists conducting the case, surgeons and patients were blinded to group assignment. All patients received antiemetic premedication drug inj glycopyrrolate & Inj. Ondansetron 0.15 mg/kg I.V. and I.V. Ringer Lactate solution 2ml/kg/hr. Patients were monitored using ECG, noninvasive BP and pulse oximetry. Baseline vitals were recorded. Local anaesthesia was given by ENT surgeons using 2% Lignocaine with Adrenaline (1:2,00000) in the postauricular area to block greater auricular & lesser occipital nerves in the incisura terminalis. Dose of Lignocaine with adrenaline should not exceed >5 mg/kg.

- In first group MD, patients received intravenous inj. midazolam 1 mg plus inj. dexmedetomidine 1 µg/kg bolus and 0.5 µg/kg added in 100 ml NS infusion, given at 0.3 to 0.4 µg/min.
- In second group MN, patients received intravenous inj. midazolam 1 mg plus inj. nacphin 10 mg slowly.

Post-operatively patients were given I.V. Inj Diclofenac sodium 1.5mg/kg for postoperative analgesia. After the loading dose of the drug, Ramsay Sedation Score (RSS) was assessed with target sedation of RSS 3 (Table-1). If patient complaint of pain, additional analgesic with inj. diclofenac or inj. Paracetamol or Inj. Tramadol was given. If patient, still not comfortable conversation to GA was done.

Variables studied were Ramsay sedation score (RSS), Visual analogue score (VAS). Analgesia was assessed by Visual Analogue Scale (VAS) as one to ten where one is minimum pain while ten is severe pain. A Numerical Rating Scale (NRS) with zero being least satisfied and 10 being most satisfied was used for grading of surgeon's satisfaction with respect to surgical conditions and sedation technique.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

Patients were randomly divided in two groups of 30 each. In present study, age, gender, BMI, ASA grade, type of surgeries (Tympanoplasty, myringoplasty, stapedectomy) & duration of surgery was comparable & difference was not statistically significant.

Table 1: General characteristics

Characteristics	Group MD	Group MN	P Value
Age (years)	33.1 ± 10.7	32.5 ± 11.1	0.78
Gender (Male/Female)	17/13	16/13	0.65
BMI (kg/m ²)	23.2 ± 2.8	23.6 ± 2.7	0.85
ASA (I/II)	25/5	24/6	0.81
Type of surgeries (%)			0.68
Tympanoplasty	18	16	
Myringoplasty	9	11	
Stapedectomy	3	3	
Duration of surgery (min)	68.2 ± 20.6	66.4 ± 23.8	0.74

Ramsay Sedation Score (RSS) at 30,40 & 90 minutes was better in MD group as compared to MN group, difference was statistically significant.

Table 2: Ramsay Sedation Score (RSS)

Interval	Group MD (Mean + SD)	Group MN (Mean + SD)	P Value
10 Min.	3.06 ± 0.44	3.00 ± 0.31	0.81
20 Min.	2.52 ± 0.87	2.56 ± 0.31	0.59
30 Min.	2.57 ± 0.36	2.76 ± 0.42	0.027
40 Min.	2.61 ± 0.65	2.85 ± 0.12	0.035
60 Min.	2.59 ± 0.67	2.67 ± 0.18	0.67
90 Min.	2.89 ± 0.53	3.06 ± 0.23	0.041

Visual Analogue Score (VAS) at 20, 30,40, 60 & 90 minutes was better in MD group as compared to MN group, difference was statistically significant.

Table 3: Visual Analogue Score (VAS)

Interval	Group MD (Mean ± SD)	Group MN (Mean ± SD)	P Value
10 Min.	0.56 ± 0.43	0.60 ± 0.41	0.68
20 Min.	3.53 ± 1.59	4.90 ± 1.51	0.001
30 Min.	2.97 ± 1.06	3.67 ± 0.92	0.012
40 Min.	3.43 ± 1.64	3.98 ± 0.45	0.032
60 Min.	2.56 ± 1.24	3.50 ± 0.80	0.031
90 Min.	2.79 ± 0.96	3.20 ± 0.91	0.013

Patient & Surgeon satisfaction score was better in group MD as compared to group MN, but difference was not statistically significant.

Table 4: Patient & Surgeon satisfaction score

	Group D	Group N	P Value
Post-operative rescue analgesic	15	17	0.54
Patient satisfaction score (more than 7)	24	21	0.43
Surgeon satisfaction score (more than 7)	22	19	0.35

DISCUSSION

ENT surgeries like tympanoplasty and modified radical mastoidectomy are usually done under local anaesthesia or local anaesthesia with sedation under monitored anaesthesia care (MAC) in adult patients.⁶ MAC may be applied for various ENT surgeries in which an adequate sedation and analgesia without respiratory depression are desirable for comfort of both the patient and the surgeon.⁷

There are many advantages of local anesthesia supplemented with intravenous sedation, such as less bleeding, cost-effectiveness, postoperative analgesia, faster mobilization of the patient, and the ability to test hearing intraoperatively.⁸

Alka C et al.,⁹ studied addition of dexmedetomidine and nalbuphine as an adjuvant to ketofol, The dose of ketofol at the time of induction was significantly high in Group N as compared to Group D ($P < 0.05$). Supplemental dose of ketofol at the time of insertion of endoscope was equivalent in both the groups ($P > 0.05$) but significantly a greater number of patients in Group D ($n = 19$ vs. $n = 11$, $P < 0.05$) received supplement for facial pain score >5 compared to patients in Group N, where more patients received supplement for Ramsay Sedation Score <3 ($n = 20$ vs. $n = 11$ $P < 0.05$). Significant decrease in heart rate (HR) and mean arterial pressure from baseline values was found in Group D as compared to Group N ($P < 0.001$). Group N patients achieved post anesthesia recovery score >12 earlier than Group D ($P < 0.001$).

Mohamed MH¹⁰ noted that the combination of dexmedetomidine/nalbuphine is a better alternative to midazolam/nalbuphine in MAC since it provides analgesia, amnesia and sedation with better intraoperative and postoperative patient satisfaction with better surgical field exposure. Nallam SR et al., noted that nalbuphine/dexmedetomidine combination is superior to nalbuphine/propofol in producing sedation and decreasing VAS in patients undergoing MESs under MAC. Better surgeon and patient satisfaction were observed with nalbuphine/dexmedetomidine.

Dexmedetomidine has also been found to provide qualitatively better sedation profile as compared to Midazolam-Fentanyl combination in patients for tympanoplasty under MAC.¹¹

Vyas DA et al., had also reported better surgeon and patient satisfaction with Dexmedetomidine than Midazolam in patients under MAC in ENT surgeries.¹²

Dexmedetomidine is a novel selective α_2 receptor agonist that produces sedation and analgesia without causing respiratory depression.¹³ It also allows patients to respond to verbal

commands during the sedation; easy conversion from sleeping to awakening is possible.¹⁴ Therefore, dexmedetomidine has been used in various clinical fields, such as sedation in the intensive care unit, radiologic examination of pediatric patients, awake intubation, shockwave lithotripsy, endoscopic examination and as an adjuvant to anesthetics.^{15,16}

Limitation of present study were small sample size, only ASA grade I/II included & Ramsay sedation score was used to assess sedation while Bispectral Index (BIS) monitoring is ideal. The use of BIS over the routinely practiced sleep guided dose of propofol and dexmedetomidine in terms of hemodynamics need further trials with inclusion of geriatric age group, multicentric studies with a larger sample and on patients with existing co morbidities should be conducted.

CONCLUSION

Dexmedetomidine with midazolam was better than nalbuphine with midazolam, with respect to sedation, analgesic effect, patient & surgeon satisfaction.

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