

Monitored anaesthesia care - Comparison of nalbuphine/dexmedetomidine versus nalbuphine/propofol for middle ear surgeries: A double-blind randomised trial

Address for correspondence:

Dr. Srinivasa Rao Nallam,
Flat No. 105, Sri Krishna
Sai Apartments, Besides
Balireddy Hospital,
Co-Operative Colony,
Kadapa - 516 002,
Andhra Pradesh, India.
E-mail: drvaasu@gmail.com

Srinivasa Rao Nallam, Sunil Chiruvella, Anjineswar Reddy

Department of Anaesthesiology and Critical Care, RIMS, Kadapa, Andhra Pradesh, India

ABSTRACT

Background and Aims: Middle ear surgeries (MESs) are usually performed under sedation with local anaesthesia and can be well tolerated by the patient with minimal discomfort. In the present study, we compare the effect of nalbuphine/dexmedetomidine combination with nalbuphine/propofol on sedation and analgesia in monitored anaesthesia care. **Methods:** One hundred adult patients undergoing MESs under monitored anaesthesia care (MAC) were randomly allocated 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. **Conclusion:** 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. Haemodynamics need to be closely monitored.

Key words: Conscious sedation, dexmedetomidine, nalbuphine, propofol

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INTRODUCTION

The American Society of Anaesthesiologists (ASA), has defined the monitored anaesthesia care (MAC) as a planned anaesthesia procedure during which a diagnostic or therapeutic procedure is performed under local anaesthesia together with sedation and analgesia.^[1] The important essential elements and purposes of MAC include, safe sedation, control of the patient anxiety and analgesia.^[2]

Middle ear surgeries (MESs) can be performed under either local or general anaesthesia. Advantages with the local anaesthesia techniques are less bleeding,

early recovery, post-operative analgesia, inexpensive and most important one is the ability to test the hearing of the patient intraoperatively.^[3] Commonly performed MESs under MAC include tympanoplasty, stapedectomy or ossiculoplasty and mastoidectomy.

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Commonly used medications for sedation during surgery under local anaesthesia with MAC including opioids, benzodiazepines, propofol and $\alpha 2$ agonists.^[4] Practicing combination of two agents can provide better patient control and allows the use of smaller doses of each single agent avoiding its undesirable effects.

Nalbuphine is structurally related to oxymorphone. It is a highly lipid soluble agonist–antagonist opioid, with an agonist action at the kappa and an antagonist activity at the mu opioid receptors.^[5] 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.

Dexmedetomidine is an $\alpha 2$ agonist acting centrally with analgesic and conscious sedative effect without respiratory depression. Dexmedetomidine also acts as sympatholytic and can attenuate the stress response to surgery thereby maintaining haemodynamic stability.^[6,7]

Propofol is the commonly used drug for sedation during MAC. Propofol is an ultrashort-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]

Based on a previous study, we hypothesised that nalbuphine/dexmedetomidine combination provides better sedation and analgesia than nalbuphine/propofol combination in monitored anaesthesia care.^[9] In the present study, we compare the effect of nalbuphine/dexmedetomidine combination with nalbuphine/propofol on sedation and analgesia in monitored anaesthesia care.

METHODS

After Institutional Ethics Committee approval, written informed consent was taken from all patients who were included in the study. One hundred patients of either sex, aged between 20 and 60 years of ASA Grades I and II, undergoing MESs (tympanoplasty, myringoplasty and stapedectomies) under local anaesthesia were included. We compared the sedation and analgesia observed with nalbuphine/dexmedetomidine combination with nalbuphine/propofol combination as the primary outcome. The efficacy of these combinations of drugs to provide a near bloodless microscopic surgical field, hemodynamic and

respiratory effects, surgeon and patient satisfaction, and adverse effects, were secondary outcomes.

Patients with known sensitivity to local anaesthetics, allergy to study drugs, 2nd or 3rd degree heart block, renal and hepatic insufficiency, uncontrolled diabetes and hypertension, obesity (body mass index >30 kg/m²), pregnant and lactating females were excluded from the study. All patients were examined preoperatively and all routine investigations were done. Patients were explained about the concerned technique and were instructed to keep fasting for 6 h.

A random number table for one hundred patients to be divided into two groups was generated using computer software and sequentially numbered opaque sealed envelopes were prepared [Figure 1]. To maintain the blinding, an anaesthesiologist not involved in the study opened the envelope just before the premedication and prepared the appropriate drug filled syringe according to the code (a fixed volume of 50 ml) and did not take part in management and observations. (Syringes and infusion lines were wrapped with an aluminium foil and an opaque sheet was used to separate the cannulated arm from the monitor). The anaesthesiologist who administered the study drugs and recorded the data was also blind to both groups assigned.

Patients were placed supine on the operating table with the head turned opposite to the ear to be operated. Routine non-invasive monitoring was applied to all patients with heart rate (HR), peripheral oxygen saturation (SpO₂), electrocardiogram and non-invasive blood pressure. Intravenous (IV) cannula 20-gauge was secured. Intraoperatively, all patients received 2 L/min oxygen through nasal catheters. All the patients were premedicated with IV injection glycopyrrolate.

All patients in both groups received injection nalbuphine 50 μ g/kg IV. Patients in Group D received a bolus dose of injection dexmedetomidine 1 μ g/kg IV over 10 min followed by an infusion started at 0.4 μ g/kg/h IV. Patients in 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. The level of sedation was assessed using Ramsay Sedation Score (RSS).^[10] Desired sedation level was defined as RSS ≥ 3 . (1 = anxious, agitated, restless; 2 = cooperative, oriented, tranquil; 3 = responds to commands only; 4 = brisk response to light glabellar tap or loud noise; 5 = sluggish response to light

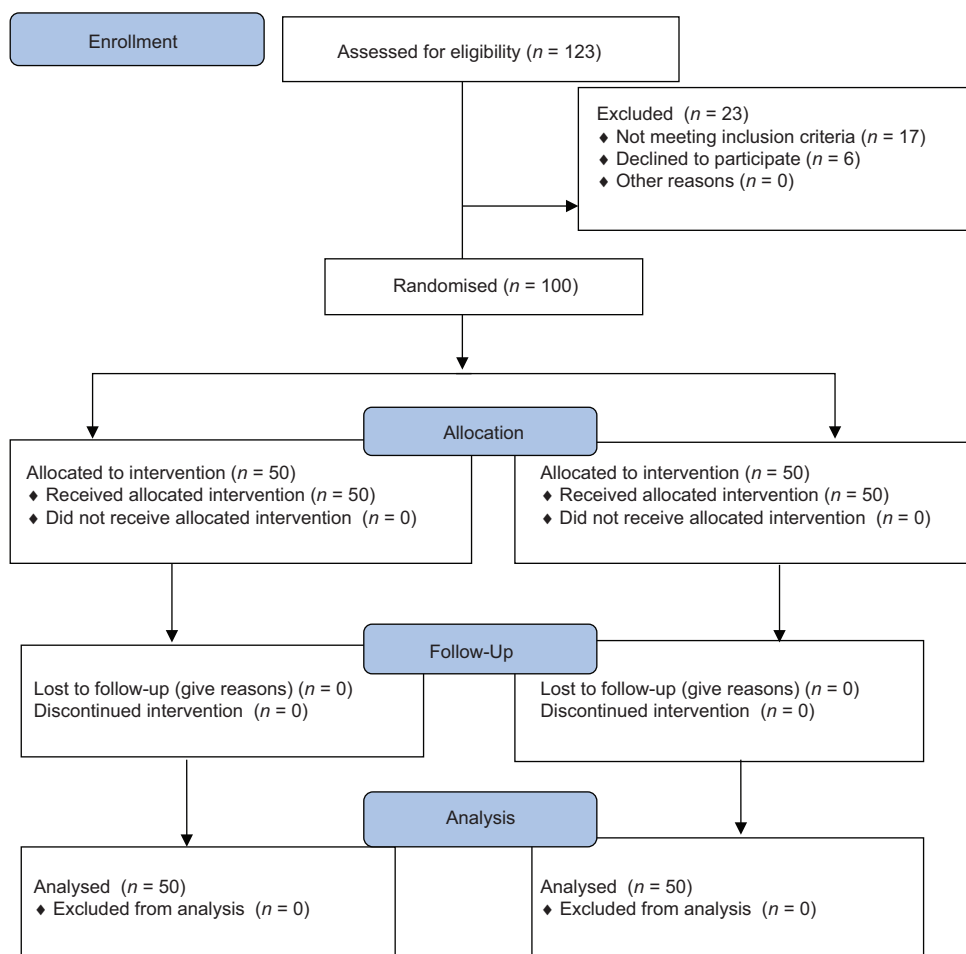


Figure 1: Consort diagram showing the number of patients included and analysed

glabellar tap or loud noise; 6 = no response). If RSS was <3, rescue sedation with a bolus of midazolam 0.01 mg/kg was given. Simultaneously, the operating area was prepared and draped. Local anaesthetic infiltration was performed by the operating surgeon who was unaware of the group randomisation, using lignocaine 2% with adrenaline 1:200,000 for blocking the tympanic branch of auriculotemporal nerve and great auricular nerve. Intraoperative pain was assessed using visual analogue scale (VAS). If the patient complained of pain (VAS ≥3) during the surgery, IV paracetamol infusion 1 g was given as intraoperative rescue analgesic and the surgeon used an additional dose of local anaesthetic.

HR, respiratory rate (RR), mean arterial pressure (MAP) and SpO₂ were recorded every 10 min till the end of surgery and then every 15 min while the patient remained in post-anaesthesia care unit (PACU) for 2 h. Intraoperative bleeding was assessed by Boezaart grading scale for scoring of surgical field bleeding, acceptable bleeding score being 0–2. (0 = no bleeding;

1 = slight bleeding, no suctioning of blood required; 2 = slight bleeding, occasional suctioning required, surgical field not threatened; 3 = slight bleeding, frequent suctioning required, bleeding threatened surgical field a few seconds after suction was removed; 4 = moderate bleeding, frequent suctioning required, bleeding threatened surgical field directly after suction was removed).

Adverse events such as bradycardia (HR <50 bpm or 20% decrease from the baseline value), hypotension (fall in blood pressure by 20% from the baseline or an absolute MAP <60 mmHg), bradypnoea (RR <8 breaths/min), desaturation (SpO₂ <94%), nausea, vomiting, dryness of mouth or any other events during or within 2 h after the procedure were noted. Bradycardia was treated with IV injection atropine 0.5 mg, hypotension was managed with a bolus of IV crystalloids or with increments of injection mephentermine 3 mg. Desaturation was treated with oxygen administration using face mask up to 6 L/min. Patients with RSS >5 was considered as oversedated

and was converted to standard general anaesthesia with appropriate sized endotracheal tube intubation.

After the completion of surgery patients were shifted to the PACU, where the following were done:

Post-operative pain was assessed using VAS (0–10 cm); if VAS was >3, post-operative rescue analgesia was provided with IV fentanyl 1 µg/kg. Recovery was assessed using Aldrete score in the recovery room every 5 min, till score of 10 was achieved.^[11] Time to achieve Aldrete recovery score of 10 was recorded.^[11] Patient's satisfaction was assessed by asking the patient to answer the question, 'How would you rate your experience during surgery?' using a 7-point Likert verbal rating scale. (1 = extremely dissatisfied; 2 = dissatisfied; 3 = somewhat dissatisfied; 4 = undecided; 5 = somewhat satisfied; 6 = satisfied; 7 = extremely satisfied). This assessment was done just before shifting to ward to minimise the effects of sedation on patient's judgement. Surgeon satisfaction was also recorded postoperatively as he was also asked to rate their satisfaction with operative conditions, using the 7-point Likert verbal rating scale at the end of surgery. Acceptable satisfaction score of both the patient and surgeon being 5–7.

Power analysis was based on the results of a previous study.^[9] Sample size calculation was based on a population standard deviation of 1.1 with 80% power and 5% alpha error. To detect a difference in sedation score of one between groups, a sample size of 43 patients per group was required. We included fifty patients in each group for better validation of results. Data were checked, entered and analysed using SPSS version 19 for Windows (Armonk, NY, USA: IBM Corp.). Data are expressed as mean ± standard deviation for quantitative variables, and for categorical variables as number, and percentages. *Z* test and Chi-square tests were used for comparison in between groups. *P* < 0.05 was considered statistically significant.

RESULTS

The demographic characteristics such as age, gender, body mass index and ASA grade were comparable in both groups [*P* > 0.05, Table 1]. There was no difference in base line vital signs (HR, MAP, SpO₂) in both groups [*P* > 0.05, Table 1]. The surgical procedure performed in patients was either: myringoplasty, tympanoplasty, or stapedectomy. The distribution of

these procedures and mean duration of surgery between the two study groups were comparable [Table 1, *P* > 0.05].

Target sedation level (RSS ≥3) was achieved by significantly higher number of patients in Group D (88%, *n* = 44) as compared to Group P (56%, *n* = 28). Mean RSS was also significantly more in Group D (4.24 ± 1.54) as compared to Group P (2.58 ± 0.95) (*P* = 0.0001). Furthermore, rescue sedation with injection midazolam, to achieve target sedation score was required by significantly less number of patients in Group D (12%, *n* = 6) than in Group P (44%, *n* = 22) [*P* = 0.0004, Table 2]. No patient was oversedated in our study. Intraoperative rescue analgesic (paracetamol infusion) was required by significantly more number of patients in Group P (*n* = 8, 16%) than in Group D (*n* = 2, 4%) (*P* = 0.0455). Post-operative VAS score was also significantly less in Group D (3.5 ± 1.7) than in Group P (5.4 ± 1.8) (*P* = 0.0001). Postoperatively, rescue analgesia with injection fentanyl was required

Variables	Group P	Group D	<i>P</i>
Demographic data			
Age (years)	34.7±9.2	33.2±8.4	0.395
Gender (male/female)	32:18	30:20	0.560
BMI (kg/m ²)	21.8±2.3	22.6±2.1	0.069
ASA (I/II)	48/2	47/3	0.646
Baseline vital signs			
HR (bpm)	91.5±18.6	94.7±19.8	0.405
MAP (mmHg)	98.9±13.2	96.7±9.4	0.337
SpO ₂ (%)	99.7±1.8	99.7±1.7	0.999
Type of surgeries (%)			
Tympanoplasty	23 (46)	26 (52)	0.999
Myringoplasty	16 (32)	12 (24)	0.999
Stapedectomy	11 (22)	12 (24)	0.999
Duration of surgery (min)	67.6±12.4	69.4±11.8	0.457

Data are represented as mean±SD or percentage. SD – Standard deviation; BMI – Body mass index; ASA – American Society of Anaesthesiologists; SpO₂ – Peripheral oxygen saturation; HR – Heart rate; MAP – Mean arterial pressure

Variables	Group P (%)	Group D (%)	<i>P</i>
Sedation score	2.58±0.95	4.24±1.54	0.0001
Rescue midazolam (%)			
Yes/no	22/28 (44)	6/44 (12)	0.0004
Rescue LA infiltration (%)			
Yes/no	21/29 (42)	9/41 (18)	0.0088
Rescue paracetamol (%)			
Yes/no	8/42 (16)	2/48 (4)	0.045
Intraoperative bleeding score (0-2)	23 (46)	41 (82)	0.0002

Values are expressed as number (percentage Yes). LA – Local anaesthetic

by 31 (62%) patients in Group D and 43 (86%) patients in Group P [$P = 0.0062$, Table 3].

Acceptable bleeding score (0, 1, 2) was achieved by a higher number of patients in Group D ($n = 41$, 82%) as compared to Group P ($n = 23$, 46%) ($P = 0.0002$). Time to achieve score 10 in Aldrete score was (12.4 ± 2.4) in Group D in comparison with (11.8 ± 1.8) in Group P [$P > 0.05$, Table 3]. Patient's satisfaction was significantly higher in Group D (82%) compared with Group P (56%) ($P < 0.05$). The same as regards surgeon's satisfaction where satisfaction was significantly higher in Group D (76%) than in Group P (44%) [$P < 0.05$, Table 3].

As regards intraoperative complications 38% of patients in Group D had bradycardia (HR < 50) in comparison with 6% of patients in Group P ($P < 0.05$). In mean arterial blood pressure, there was statistically significant difference between the two studied groups where 16 patients (32%) in Group D had hypotension (MAP < 60 mmHg) while 7 patients (14%) only in Group P had hypotension ($P < 0.05$). There was no significant difference between the two groups as regards nausea and vomiting ($P > 0.05$). No cases had RR < 8 /min or SpO₂ $< 94\%$ [Table 4]. HR and mean blood pressure were statistically significant lower in Group D than in Group P after 10 min from the start to the end of the procedure [$P < 0.05$, Table 5].

DISCUSSION

MESs are usually performed under MAC, in which an adequate sedation and analgesia without respiratory depression are desirable for comfort of both the surgeon and the patient.^[12] Administration of single anaesthetic agent for MAC, usually does not provide full control of the patient's status and almost always requires intraoperative intervention with rescue medications. Hence, combination of two anaesthetic agents from the beginning of the procedure, allows the use of lower dose of each agent and thereby decreasing its own undesired effects and gains the augmented desirable effects of each.

In this prospective study, we compared the safety and efficacy of nalbuphine/dexmedetomidine versus nalbuphine/propofol as IV administered agents for MAC during middle ear surgical procedures performed under local anaesthesia. We observed that mean RSS was significantly high in nalbuphine/dexmedetomidine group (Group D) than in nalbuphine/

Table 3: Post-operative variables

Variables	Group P (%)	Group D (%)	P
VAS	5.4±1.8	3.5±1.7	0.0001
Post-operative rescue analgesic (if VAS >4)	43 (86)	31 (62)	0.0062
Time to achieve to 10 in Aldrete score	11.8±1.8	12.4±2.4	0.157
Patient satisfaction score (5-7)	28 (56)	41 (82)	0.0049
Surgeon satisfaction score (5-7)	22 (44)	38 (76)	0.0011

Values are expressed as mean±SD, number (percentage). SD – Standard deviation; VAS – Visual analogue scale

Table 4: Intraoperative complications

Complication	Group P (%)	Group D (%)	P
Nausea	3 (6)	4 (8)	0.6951
Vomiting	1 (2)	3 (6)	0.3074
Dry mouth	6 (12)	8 (16)	0.5644
Hypotension	7 (14)	16 (32)	0.041
Bradycardia	3 (6)	19 (38)	0.0001

Values are expressed as number (percentage)

Table 5: Intraoperative haemodynamics

Variable	Time (min)	Group P	Group D	P
HR (bpm)	10	90.5±4.3	91.1±4.8	0.041
	20	76.4±3.5	65.1±4.2	0.024
	30	70.3±4.6	60.2±5.4	0.027
	40	68.4±4.4	60.4±3.6	0.036
	50	69.7±3.2	59.4±3.5	0.020
	60	68.7±3.8	61.1±4.5	0.037
	70	68.2±3.6	60.8±4.6	0.045
MAP (mmHg)	10	87.5±5.4	85.5±4.2	0.043
	20	87.3±3.7	73.5±3.7	0.018
	30	85.3±5.2	70.6±5.6	0.011
	40	80.6±4.7	70.1±4.8	0.027
	50	78.5±5.3	65.8±5.2	0.022
	60	75.5±4.2	60.5±4.1	0.038
	70	75.4±4.3	60.2±4.5	0.019

Values are expressed as mean±SD. SD – Standard deviation; HR – Heart rate; MAP – Mean arterial pressure

propofol group (Group P). Rescue sedation with a bolus of injection midazolam 0.01 mg/kg to attain target sedation level (Ramsay score of 3) was required by significantly higher number of patients in Group P (44%) as compared to Group D (12%).

We found that intraoperative rescue analgesia was required by less number of patients in Group D (4%) compared to Group P (16%) ($P < 0.05$), which is consistent with the observations of Arain and Ebert.^[13] We also observed that more number of patients in Group P required injection fentanyl as post-operative rescue analgesia in comparison to Group D that explains the analgesic property of dexmedetomidine.

In this study, we selected a loading dose of 1 µg/kg of dexmedetomidine based on previous literature.^[14,15] Because of its shorter half-life of only 5 min, it is necessary to administer a maintenance infusion for dexmedetomidine. We choose a maintenance dose of 0.4 µg/kg/h, because the surgery was essentially done under local anaesthesia. The dose of propofol 0.75 mg/kg was chosen based on a recent study by Verma R *et al.*, that this dose is comparable to dexmedetomidine 1 µg/kg in terms of sedation.^[16] We aimed to compare equivalent doses of both the drugs to avoid any bias in our results. In addition, drugs in both the study groups were targeted to a predefined end point (Ramsay score of 3).

The mean HR and MAP in Group D were significantly lower in comparison to Group P [Table 5]. This can be explained by the decreased sympathetic activity caused by dexmedetomidine by virtue of its α₂ agonist effect.^[17] These results suggest that dexmedetomidine has clinical advantage over propofol in providing a better operative field for microscopic surgery. Our findings are similar to other studies where lower HR and MAP were observed in the dexmedetomidine group.^[18] Durmus *et al.* have evaluated this property of dexmedetomidine for providing controlled hypotension in general anaesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required.^[19]

Intraoperative bleeding was significantly lower in Group D as compared to Group P. Dexmedetomidine by producing controlled intraoperative hypotension can effectively decrease surgical blood loss and thereby improves surgical field exposure as compared to propofol, which is essential for otology surgeries.^[20]

In this randomised study, the patient and surgeon satisfaction scores were significantly higher in Group D than in Group P ($P < 0.05$) suggesting a difference in the quality of sedation of both the drugs. The lower HR and MAP in these patients could have probably resulted in a better surgical field thus attributing to better surgeon satisfaction. Moreover, surgeons are satisfied if there is no patient movement during surgery.

When dexmedetomidine and propofol were compared, no difference had been reported regarding time from the end of surgery to discharge readiness and actual discharge as supported by the present study, in which

all the patients in both groups had modified Aldrete score of 10 immediately after surgery. Contrary to our study, delayed readiness for recovery room discharge with dexmedetomidine compared to midazolam have been found by Alhashemi.^[21] This was explained by the possible presence of sustained therapeutic plasma concentration of dexmedetomidine on arrival in the recovery room, as it has an elimination half-life of about 2 h and drug infusion was continued up to the end of surgery in that study.

Dry mouth is a known side effect of α₂ agonist. We also observed that more patients (16%) in D Group complained of dry mouth post-operatively as compared to those in P Group (12%) but this difference was not significant statistically. This may be because of use of glycopyrrolate injection in premedication.

A possible limitation of this study could be that amnesia scoring and cognitive function testing for psychomotor impairment was not done as early discharge of the patients was not a concern of this study. Safety is the cardinal concern for MAC technique. However, a poorly controlled technique may result in deep sedation and respiratory failure or general anaesthesia with all its attendant risks. Therefore, using more than one agent may allow the anaesthetist to use reduced doses of individual agents, thereby decreasing the harmful effects of each agent and allows augmenting the beneficial effects of each drug used.

CONCLUSION

On the basis of the findings of the present study, nalbuphine/dexmedetomidine seems to be a better combination for MAC when compared to nalbuphine/propofol combination. Nalbuphine/dexmedetomidine provides a calm patient with better intra and post-operative analgesia, and a bloodless surgical field leading to increased satisfaction of both patient and surgeon.

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Conflicts of interest

There are no conflicts of interest.

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