Original Article

DOI: 10.7860/JCDR/2022/56308.16618

Comparison of Nalbuphine and Dexmedetomidine versus Nalbuphine and Propofol for Monitored Anaesthesia Care in Tympanoplasty: A Randomised Double-blind Study

Anaesthesia Section

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ABSTRACT

Introduction: Tymanoplasty, a middle ear surgery, is done either under Local Anaesthesia (LA), General Anaesthesia (GA) or sedation with local anaesthesia. It is usually performed under Monitored Anesthesia Care (MAC) providing advantages of rapid onset, allowing hearing test intraoperatively and early mobilisation of the patient.

Aim: To study the effect of nalbuphine/dexmedetomidine with nalbuphine/propofol on sedation and analgesia in tympanoplasties performed under MAC.

Materials and Methods: This randomised, double-blind, clinical study was conducted from June 2020 to June 2021 in the Department of Anaesthesiology at Mahatma Gandhi Memorial Medical College and MY Hospital, Indore, Madhya Pradesh, India. Total 60 adult patients, of American Society of Anesthesiologists (ASA) grade I and II undergoing tympanoplasty under MAC, were randomly allocated into two groups. All patients received injection nalbuphine 50 µg/kg intravenously (i.v.). Group D received a bolus dose of injection dexmedetomidine 1 µg/kg i.v. over 10 min followed by an infusion at 0.3 µg/kg/h i.v. Group P received a bolus dose of injection propofol 0.75 mg/kg followed by an infusion at 0.025 mg/kg/min i.v. Sedation and analgesia were titrated to Ramsay Sedation Score (RSS) and Visual Analog Scale (VAS) of 3 each. The vital parameters and need for intraoperative rescue sedation/analgesia were recorded and compared.

Results: Mean RSS was significantly more in group D (3.11±0.055) than group P (2.80±0.350). Overall, VAS score was significantly less in group D (1.60±0.670) than group P (2.70±0.691). In group D, 2 (6%) patients and in group P, 4 (12%) patients required inj. midazolam. Similarly, the requirement of inj. paracetamol in group D was in 3 (10%) patients, and in group P, it was 10 (33%) patients. Bradycardia (23.3% in group D and 13.3% in group P) and hypotension (20% in group D and 13.3% in group P) were the major side effects seen in the study.

Conclusion: The present study concludes that, Nalbuphine/dexmedetomidine is superior to nalbuphine/propofol in producing sedation and decreasing VAS in patients undergoing tympanoplasty under MAC.

Keywords: Conscious sedation, Middle ear surgeries, Ramsay sedation score

INTRODUCTION

Middle ear surgeries form a major part of Ear, Nose and Throat (ENT) surgeries which include tympanoplasty, stapedotomy, myringoplasty, ossiculoplasty, mastoidectomy, grommet insertion. Tympanoplasty, the most common procedure in middle ear surgeries, is a surgical repair of tympanic membrane. It is commonly performed under local anaesthesia, general anaesthesia or monitored anaesthesia care. Each anesthesia technique has its own advantages and disadvantages. Tympanoplasty under local anaesthesia has an advantage of allowing hearing test intraoperatively and early mobilisation of the patient [1]. But it has the disadvantage of increased bleeding and is also associated with dizziness, claustrophobia, anxiety and earache which may cause movement of the head thus causing discomfort to the surgeon and the patient.

General anaesthesia when used for tympanoplasty surgeries gives completely quiet, immobile patient but usage of multiple drugs in general anaesthesia adds to various side effects, cost and also prolongs the hospital stay. Moreover, hearing cannot be tested intraoperatively. It is also associated with vomiting and postoperative pain. Hence, this mode of anaesthesia is mostly preserved for children and uncooperative adults.

Monitored Anaesthesia Care (MAC) is currently the most popular mode of anaesthesia for tympanoplasty. The MAC is specific anaesthesia modality during which the patient receives local anaesthesia with sedation and analgesia preserving the airway reflexes. Three components of MAC are conscious sedation, allaying patient's anxiety and effective pain control [2]. It offers all the advantages of local anaesthesia and general anaesthesia and at the same time combating their side effects. MAC provides a comfortable, pain free, satisfied and easily arousable patient with rapid postoperative recovery and same day discharge. Patient's cooperation is also an important component of MAC.

An ideal sedative agent for MAC should have rapid onset of action, high clearance, easy titration, less cardiovascular and respiratory depression [3]. Many agents like promethazine, midazolam, and ketamine were tried but none of them had all the properties, hence, a combination of agents were tried. Combination of drugs produce synergistic effects with the advantage of reduced doses of each drug and hence, reduced side effects of each. Since then, many combinations like promethazine and midazolam [4], midazolam and fentanyl [5,6], dexmedetomidine and midazolam [7], fortwin and phenergan and midazolam [8], dexmedetomidine and fentanyl versus dexmedetomidine and nalbuphine [9], were tried. Each one of them have their set of adverse effects.

Dexmedetomidine is a selective α-2 adrenoceptor agonist. These receptors are abundant in locus ceruleus which mediates arousal, algesia, memory and vigilance [10]. Dexmedetomidine, by blocking this nucleus, causes sedation and analgesia. The loading dose of dexmedetomidine is 1 mcg/kg given over 10 minutes, while the maintenance dose is 0.2-0.7 mcgs/kg/hr. It causes bradycardia, hypotension, dry mouth due to its sympatholytic action.

Nalbuphine, a phenanthrene opioid is μ receptor antagonist and κ, δ receptor agonist. It is given in the dose of 50-250 mcgs/kg i.v. Its onset of action is 2-3 minutes after an intravenous injection. It provides analgesia and sedation without respiratory depression (ceiling effect) [11].

Propofol is a substituted isopropyl phenol. It is a selective modulator of Gamma-Aminobutyric Acid (GABA) A receptors. It is a sedative hypnotic agent with rapid onset of action with short and clear-headed recovery. If given in the doses of 25-100 mcgs/kg/min, it causes conscious sedation. It also has antiemetic properties. Few adverse effects are hypotension, bradycardia and pain on injection [12].

Dexmedetomidine, propofol, and nalbuphine are commonly used as sedatives in Intensive Care Unit (ICU) and for MAC. In 2019 Kamal NM et al., used dexmedetomidine and nalbuphine for postoperative analgesia and concluded that the former could be used as a good adjuvant to nalbuphine, decreasing its consumption, improving its analgesic effect, providing good sedation and good patient satisfaction in patient controlled analgesia for postoperative pain in laparoscopic cholecystectomy [13].

The clinical trial aimed to compare the combination of these drugs (nalbuphine/dexmedetomidine and nalbuphine/propofol) in tympanoplasty surgeries scheduled under MAC. The primary objectives were intraoperative sedation (Ramsay Sedation score), and intraoperative analgesia (visual analogue scale). The secondary objectives were to record adverse events (bradycardia and hypotension).

MATERIALS AND METHODS

This randomised, double-blind, clinical study was conducted from June 2020 to June 2021 in the Department of Anaesthesiology at Mahatma Gandhi Memorial Medical College and MY Hospital, Indore, Madhya Pradesh, India. The study was started after approval by the Institutional Ethics and Scientific Review Committee (EC/MGM/FEB–20/48). A written informed consent was taken from all the patients after explaining the procedure, its associated risks and side effects.

Sample size calculation:

Formula for sample calculation=$2\times SD^2 (Z_{\alpha/2}+_{\alpha\beta})^2$

d^2 where,

$Z_{\alpha/2}$=coefficient of difference=1.96

αβ=0.84

d=margin of error=5%

SD=Standard Deviation=1.1

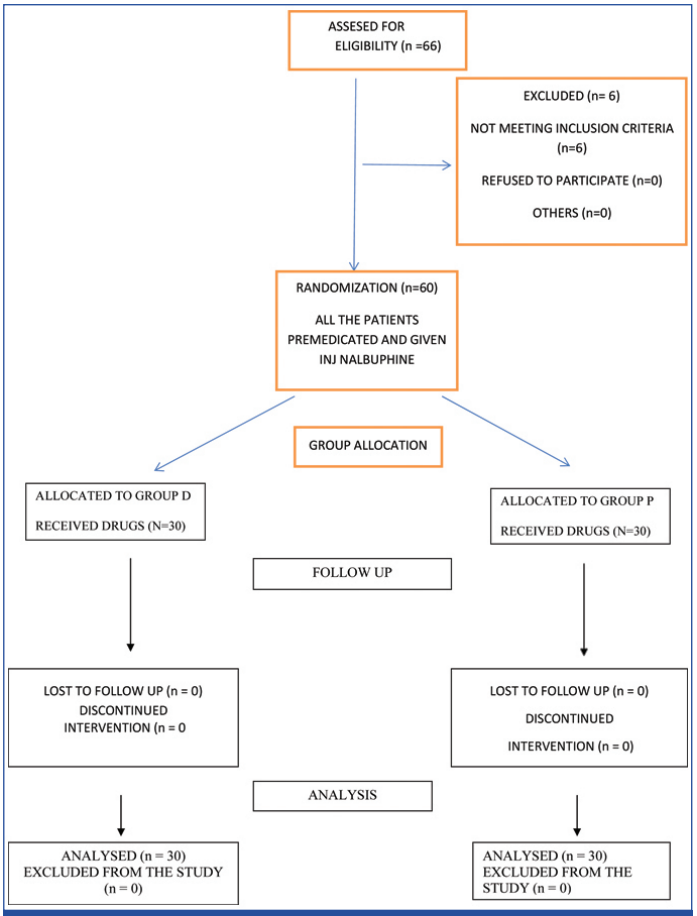
Sample size required was 59, and 66 were assessed for eligibility. Six subjects were later excluded for not meeting the inclusion criteria.

As shown in [Table/Fig-1], 66 patients were eligible for the study but six patients did not meet the inclusion criteria. Hence, 60 patients were included in the study.

Inclusion criteria: Patients of either sex, in the age group 18-60 years, belonging to American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective tympanoplasty under MAC were included in the study.

Exclusion criteria: Patients with hypersensitivity to study drug, patients with known allergy or hypersensitivity to local anaesthetics, patients with psychiatric illness and/or on any kind of sedative medication and pregnant patients were excluded from the study.

Patients were divided into two groups of 30 each. On the day of the surgery patient was asked to pick one chit from the bowl (bowl had 60 identical chits, with 30 for each group). The chit was handed to anaesthesiologist in the operation theatre. Both the groups were premedicated with Inj. Glycopyrrolate 0.2 mg i.m. and received Inj. nalbuphine at the dose of 50 mcgs/kg.



[Table/Fig-1]: CONSORT flow chart.

- Group D: Patients received inj dexmedetomidine 1 mcg/kg/min over 10 min, as Loading Dose (LD), followed by 0.3 mcgs/kg/hr as Maintenance Dose (MD).
- Group P: Patients received inj propofol 750 μg/kg as bolus dose, followed by maintenance infusion at the rate 25 μg/kg/min.

Preoperative evaluation: A thorough preoperative evaluation was done. History regarding previous anaesthesia, surgery, any significant medical illness, medications and allergy were noted. Complete physical examination and airway assessment was done. Following laboratory investigations were done i.e, complete blood count, blood sugar, urea, serum creatinine and coagulation profile. Patients were asked to remain nil orally a night before the surgery. In the preoperative room, patient's age, sex, weight, height, Body Mass Index (BMI), and baseline vital parameters like heart rate, blood pressure, oxygen saturation and respiratory rate were recorded.

Study Procedure

All the patients were premedicated with inj. glycopyrrolate 0.2 mg intramuscular (i.m.) 30 minutes prior to the start of the surgery. No sedative premedication was given. Patients were shifted to the operation theatre. All patients were connected to multipara monitors and baseline parameters like peripheral oxygen saturation (SpO_2), Heart Rate (HR), Non Invasive Blood Pressure (NIBP) were recorded {denoted as HR (0 min), SpO_2 (0 min), MAP (0 min)}. Zero (0) minutes denotes the time interval between patient taking in operation theater and before giving i.v. nalbuphine. A 18-gauge intravenous line was secured, and ringer lactate at 10 mL/kg was started. Oxygen at 2 L/min was administered to all the patients via nasal cannula. All the patients received inj. nalbuphine 50 mcgs/kg i.v. Infusion pumps and i.v. sets were covered with aluminum foils to blind to investigator. Drugs were given according to group allocation as described above.

Ramsay sedation score: Sedation was assessed by Ramsay Sedation Score (RSS) after 10 minutes of drug administered (RSS 10). Target sedation score was taken as 3 (responds to commands).

Visual analog scale: Pain was assessed by Visual Analog Scale (VAS) after 10 minutes of drug administered (VAS 10). Target pain score was taken as 3 or less than 3 (no pain to mild pain). When the target scores were achieved patient was handed over to surgeon. The surgeon infiltrated the operating site by 6-8 mL of inj. lignocaine 2% with adrenaline 1: 200,000 concentration. The surgeon was unaware of the group allocation.

Vitals: Patient vitals (HR, MAP, SpO_2), sedation scores and pain scores were recorded at regular time intervals i.e. every 10 minutes for first 30 minutes then every 15 minutes till 1 hour followed by every 30 minutes till the end of the surgery.

Rescue sedative: At any point of the surgery if RSS was <3, rescue sedative Inj. midazolam at the dose of 10 mcgs/kg was given, and excluded from the study. If RSS was > 4, the patient was immediately intubated via appropriate size cuffed endotracheal tube via standard general anaesthesia protocols. However, none of the patients were excluded due to conversion into general anaesthesia. If VAS was >3 at any point of the surgery inj. paracetamol 1 gm was given as rescue analgesic.

Adverse effects: Any adverse event such as:

1) Bradycardia (HR <50 bpm or 20% decrease from the baseline value) were recorded. Inj. atropine 0.3 mg was given, if heart rate went below 50 bpm.
2) Hypotension (fall in mean arterial pressure by 20% from the baseline or an absolute MAP <60 mmHg) was recorded. Crystalloids and inj. mephentermine 3 mg in the incremental doses was used to treat hypotension.
3) Desaturation or fall in peripheral oxygen saturation <94%. Oxygen flow was increased from 2 L/min to 6 L/min to treat the desaturation.
4) Nausea, vomiting, dryness of mouth during the surgery were recorded. Inj. ondansetron 4 mg was given to treat nausea and vomiting.

STATISTICAL ANALYSIS

The data was initially entered into Microsoft excel from the customised proforma for analysis. Statistical Package for Social Sciences (SPSS) version 28.0 IBM software was used for calculating the p-values. To test the normality Unpaired t-test was applied, Unpaired t-test and Chi-square test used for categorical values as data expressed in number of patients or ratio (age, sex, weight, height, BMI, heart rate, MAP, SPO_2, and adverse effects), Mann Whitney U-test, Freidman test used for numerical values as data expressed in mean and standard deviation (sedation scores at various intervals intraoperatively, pain score at various interval intraoperatively, postoperative sedation and pain scores). A p-value of <0.05 was taken as statistically significant.

RESULTS

Both the groups were comparable in terms of age, gender, BMI, ASA grades, and duration of surgery [Table/Fig-2].

Mean RSS [Table/Fig-3] at start of the induction i.e. at 10 minutes was comparable in both the groups. RSS scores were on higher side in group D than group P at 30 minute, 60 minute, 90 minute and 120 minute (p-value was 0.007, 0.038, 0.016 and 0.041, respectively).

Mean VAS [Table/Fig-4] at start of the induction i.e. at 10 minutes was comparable in both the groups. The VAS scores were significantly lower in group D at 30 minute, 60 minute, 90 minute and 120 minute (p-value <0.001 at 30 ,60, 90 and 120 minute). Mean RSS in group D was (3.11±0.055) and in group P was (2.80±0.350). Mean VAS in group D was (1.60± 0.670) and in group P was (2.70±0.691).

Inj. midazolam was required by more patients in group P than the group D. Similarly, the requirement of inj. paracetamol was demanded by more patients in group P [Table/Fig-5].

Parameters	Group D	Group P	p-value (Chi-square test)
Age (years)	37.27±12.809	37.77±11.131	0.872
Gender			
Female	17	16	0.795
Male	13	14	
ASA grades			
Grades I	13	14	0.898
Grade II	17	16	
Weight (kg)	60.27±12.774	64.30±14.449	0.258
Height (cm)	160.10±12.361	160.23±12.367	0.967
BMI (kg/m^2)	22.150±2.230	22.1230±2.377	0.963
Duration of surgery (mins)	71.33±15.619	73.23±15.409	0.854

[Table/Fig-2]: Demographic details.
p-value <0.05 was considered as statistically significant

Ramsay sedation score	Number of cases in group	Group D (Mean±SD)	Group P (Mean±SD)	p-value (Mann Whitney U-test)
At 10 min	30	3.11±0.971	3.01±0.507	0.617
At 30 min	30	3.13±0.507	2.77±0.504	0.007
At 60 min	30	3.14±0.666	2.79±0.610	0.038
At 90 min	13 (Group D)*	3.15±0.376	2.85±0.555	0.016
	14 (Group P)*			
At 120 min	2 (Group D)*	3.05±0.701	2.67±0.707	0.041
	3 (Group P)*			

[Table/Fig-3]: Comparison of intraoperative mean sedation score at various time intervals.
*The surgery extended for 90 minutes (13 patients in group D and 14 patients in group P) and for 120 minutes (2 patients in group D and 3 patients in group P). In rest of the patients the duration of surgery was earlier than 90 and 120 minutes; p-value <0.05 was considered as statistically significant

Visual analogue scale	Number of cases in group	Group D (Mean±SD)	Group P (Mean±SD)	p-value (Friedman test)
At 10 min	30	2.15±0.695	2.37±0.858	0.279
At 30 min	30	1.53±0.681	3.17±0.531	<0.0001
At 60 min	30	1.60±0.675	2.97±0.490	<0.0001
At 90 min	13 (Group D)	1.50±0.522	2.50±0.674	<0.0001
	14 (Group P)			
At 120 min	2 (Group D)	1.51±0.601	2.52±0.343	<0.001
	3 (Group P)			

[Table/Fig-4]: Comparison of intraoperative mean vas score at various time intervals.
p-value <0.05 was considered as statistically significant

Parameters	Group	n (%)	p-value
Rescue sedative	D	2 (6%)	<0.05
	P	4 (12%)	
Rescue analgesic	D	3 (10%)	<0.05
	P	10 (33%)	

[Table/Fig-5]: Showing comparison between requirement of intraoperative rescue sedation and analgesia.
p-value <0.05 was considered as statistically significant

As shown in [Table/Fig-6,7] a dip was observed in heart rate and mean arterial blood pressure at 10 and 20 minute (HR: 60.22±10.23, 68.73±11.32 beats/minute and MAP: 62.23±8.76, 67.22±3.66 mmHg respectively) in group D soon after administration of bolus dose of dexmedetomidine. This dip was transient and may be attributed to sympatholytic effect of dexmedetomidine. After that dip group D was more haemodynamically stable than group P with respect to HR and MAP.

As shown in [Table/Fig-8] mean SpO_2 was comparable throughout the surgery.

Heart rate	Number of cases in group	Group D (Mean±SD)	Group P (Mean±SD)	p-value
At 0 min (baseline)	30	90.73±12.61	87.47±12.40	0.316
At 10 min	30	60.22±10.23	80.76±11.21	<0.0001
At 20 min	30	68.73±11.32	81.63±10.92	<0.0001
At 30 min	30	79.33±11.3	85.44±12.43	0.0511
At 45 min	30	81.87±11.65	82.76±12.78	0.779
At 60 min	30	82.76±11.22	81.15±9.35	0.548
At 90 min	13 (Group D)	83.73±11.32	82.63±10.92	0.703
	14 (Group P)			
At 120 min	2 (Group D)	83.87±11.65	83.76±12.78	0.726
	3 (Group P)			

[Table/Fig-6]: Comparison of heart rates between both the groups at various intraoperative intervals.
p-value <0.05 was considered as statistically significant

Mean arterial pressure	Number of cases in group	Group D (Mean±SD)	Group P (Mean±SD)	p-value
At 0 min (baseline)	30	91.77±14.59	91.31±13.21	0.903
At 10 min	30	62.23±8.76	82.65±9.01	<0.0001
At 20 min	30	67.22±3.66	78.66±8.84	<0.0001
At 30 min	30	72.73±11.42	77.64±10.81	0.092
At 45 min	30	74.86±11.66	78.76±12.78	0.221
At 60 min	30	79.76±10.22	80.15±9.35	0.878
At 90 min	13 (Group D)	80.74±12.32	82.65±10.92	0.527
	14 (Group P)			
At 120 min	2 (Group D)	85.89±10.67	86.76±12.45	0.772
	3 (Group P)			

[Table/Fig-7]: Comparison of Mean Arterial Pressure (MAP) (mmHg) between both the groups at various intraoperative intervals.
p-value <0.05 was considered as statistically significant

Peripheral oxygen saturation	Number of cases in group	Group D (Mean±SD)	Group P (Mean±SD)	p-value
At 0 min (baseline)	30	99.3±0.44	99.1±0.41	0.173
At 10 min	30	99.2±0.54	99.4±0.69	0.182
At 20 min	30	99±0.64	99.1±0.57	0.502
At 30 min	30	99.1±0.62	98.9±0.15	0.182
At 45 min	30	99.2±0.27	99.1±0.31	0.176
At 60 min	30	99.4±0.33	99.23±0.46	0.165
At 90 min	13 (Group D)	99.4±0.54	99.52±0.86	0.421
	14 (Group P)			
At 120 min	2 (Group D)	99.5±0.42	99.5±0.11	1.000
	3 (Group P)			

[Table/Fig-8]: Comparison of intraoperative mean peripheral oxygen saturation at various intervals in both the groups.

Bradycardia (<20% of the basal heart rate) occurred in 7 patients (23.3%) in group D and out of these two patients required inj. atropine (heart rate <50 bpm). Four patients (13.3%) in group P had bradycardia and none required inj. atropine. Hypotension (MAP <20% from the baseline) occurred in 6 patients (20%) in group D and in 4 patients (13.3%) in group P. None of them required any intervention.

DISCUSSION

In this randomised double-blind clinical study, the safety and efficacy of nalbuphine/dexmedetomidine versus nalbuphine/propofol as intravenous administered agents for MAC during middle ear surgical procedures performed under local anaesthesia were compared. It was observed that mean RSS was significantly high in nalbuphine/dexmedetomidine group (group D) than in nalbuphine/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 (12%) as compared to group D (6%).

Dexmedetomidine 1 mcg/kg was used as loading dose based on previous literature 5,14 and maintenence dose at 0.3 mcgs/kg/hr. The dose of propofol 0.75 mg/kg was chosen based on the studies by Verma R et al., and Sokhal N et al., this dose is comparable to Dexmedetomidine 1 µg/kg in terms of sedation [14,15]. Authors aimed to compare equivalent doses of both the drugs to avoid any bias in the results. Results of the present study were similar to those by Sokhal N et al., [14]. They studied nalbuphine/dexmedetomidine versus nalbuphine/propofol for sedation and analgesia in middle ear surgeries on 100 patients. It was found that nalbuphine/dexmedetomidine combination had higher RSS than nalbuphine/propofol. Overall VAS score was also significantly less in this group. A lesser number of patients required inj midazolam in group D, which is in accordance with the finding of Sokhal N et al., they reported that 12% in group D and 44% in group P required rescue sedation [14].

The requirement of intraoperative rescue analgesia was significantly more in group P. The results are in accordance with Verma R et al., [15], they compared dexmedetomidine and propofol for analgesia in middle ear surgeries. It was found that four out of 40 patients required analgesic in dexmedetomidine group, and 15 out of 40 patients required analgesic in propofol group [15].

The mean HR and MAP in group D were significantly lower in comparison to group P. This can be explained by the decreased sympathetic activity caused by dexmedetomidine by virtue of its α-2 agonist effect. The fall in MAP was transient and did not require active intervention. These results suggest that dexmedetomidine has clinical advantage over propofol in providing a better operative field for microscopic surgery. Similarly, Durmus MA et al., evaluated this property of dexmedetomidine for providing controlled hypotension in general anaesthesia for tympanoplasty cases. They concluded that, it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required [16].

Dry mouth is a known side effect of α-2 agonist. In the present study, none of the patient had dry mouth. While Sokhal N et al., found that more patients (16%) in group D (nalbuphine/dexmedetomidine) complained of dry mouth postoperatively as compared to those in group P (nalbuphine/propofol) (12%) but this difference was not significant statistically. This may be because of use of glycopyrrolate injection in premedication [14].

Limitation(s)

A possible limitation of the study was that the Ramsay Sedation score was used to assess sedation while Bispectral Index (BIS) monitoring is ideal.

CONCLUSION(S)

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 intraoperative analgesia even with low maintenance doses. Also, nalbuphine/dexmedetomidine combination reduces the need for intraoperative sedation and analgesia. The use of BIS over the routinely practiced sleep guided dose of propofol and dexmedetomidine in terms of haemodynamics 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.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 25, 2022
- Manual Googling: May 30, 2022
- iThenticate Software: Jun 01, 2022 (24%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Mar 12, 2022**
Date of Peer Review: **Apr 15, 2022**
Date of Acceptance: **Jun 03, 2022**
Date of Publishing: **Jul 01, 2022**