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Comparison of Labetalol and Dexmedetomidine Infusions for Hypotensive Anaesthesia in Middle Ear Surgery: A Randomised Controlled Trial

Anaesthesia Section

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ABSTRACT

Introduction: Hypotensive anaesthesia has become an inevitable choice for patients undergoing microscopic middle ear surgeries under general anaesthesia, especially to decrease the intraoperative bleeding leading to improved visibility and reduced complications. Out of several agents, Dexmedetomidine and Labetalol have both been established as effective agents to cause controlled hypotension.

Aim: To compare the efficacy and safety of Dexmedetomidine and Labetalol for producing controlled hypotension in microscopic middle ear surgeries under general anaesthesia.

Materials and Methods: This parallel group randomised controlled trial was conducted at the Department of Anaesthesiology, Tertiary Medical College, Institute of Post Graduate Medical Education and Research, in Kolkata, West Bengal, India over a period of 15 months from April 2018 to June 2019. A total of 78 patients, aged 18 – 60 years, posted for microscopic middle ear surgeries under general anaesthesia, were randomly divided into two groups. Group D received Dexmedetomidine infusion with a loading dose of 1 µg/kg followed by a maintenance infusion of 0.4 µg/kg/h, whereas Group L received Labetalol 20 mg bolus followed by infusion at a rate of 0.5 mg/min. Intraoperative blood loss assessed by the Bleeding Score (BS) and Final Opinion on Bleeding Score (FOBS), haemodynamic parameters and awakening time were measured at designated time frames. Data were summarised and analysed by Student's Independent-samples t-test for numerical variables between groups, by Mann – Whitney U test when skewed and by Chi-square test or Fisher's exact test for categorical variables between groups.

Results: The groups were comparable demographically (p-values for age, body weight and duration of surgery were 0.679, 0.104, 0.893 respectively). BS and FOBS (2/2-3 for group D and 4/3-4 for group L) were both significantly lower in group D. Haemodynamically, both groups were equally stable, with better attenuation of intubation and extubation surge in group D. Awakening time was also less in group D in comparison to group L.

Conclusion: Dexmedetomidine is a better alternative than Labetalol in producing controlled hypotension in patients undergoing microscopic middle ear surgeries under general anaesthesia. The Dexmedetomidine group showed less bleeding and improved haemodynamics than the Labetalol group. Awakening was also found to be faster in the dexmedetomidine group.

Keywords: Awakening, Bleeding score, Controlled hypotension

INTRODUCTION

The practice of otorhinolaryngological surgery has evolved considerably with the advent of the operating microscope, as many such procedures are now performed using microscopic visualization [1]. Surgical bleeding during these procedures, however, can markedly reduce the visibility of the operative field, thereby posing a risk of undue complication as also prolonging its duration [2].

Although middle ear surgeries are often performed under local anaesthesia, this approach requires patient cooperation, as the patient must remain motionless with the head turned to one side throughout the procedure. Some patients, however, may not comply, requiring either a good amount of sedation or general anaesthesia [3]. On the other hand, the basic disadvantage of general anaesthesia is the surge of blood pressure, especially following laryngoscopy, intubation and extubation of the trachea, in a light plane of anaesthesia, surgical stimuli, and airway suctioning, which can cause inadvertent bleeding, thereby causing difficulties in performing the surgery [3].

To reduce bleeding during middle ear surgeries, controlled hypotension, or hypotensive anaesthesia, has been the most preferred technique in recent times [2]. In this approach, the systemic blood pressure is decreased intentionally, maintaining a Mean Arterial Pressure (MAP) in a range of 60 to 80 mmHg during surgery [4]. This helps to improve the visibility of the operative field, reduce blood loss, ensure greater ease of operation and reduce the operating time [1,5,6]. In hypotensive anaesthesia, the goal is to reduce the MAP by approximately 25-30% from the patient's baseline level. However, it is crucial to ensure that the MAP does not fall below 60 mmHg, as artificially lowering the arterial pressure to a very low level can predispose the patients to several hazards, such as prolonged awakening, cerebral thrombosis, extensive cerebral and cerebellar infarction, oliguria and anuria resulting from questionable perfusion to vital organs [4]. Therefore, achieving a balance between haemodynamic stability and an adequate depth of anaesthesia to avoid sudden surges in blood pressure throughout the intraoperative period is very important so as to reduce intraoperative blood loss and produce a relatively dry operative field. Several techniques have been advocated to achieve deliberate hypotension. Ranging from the use of inhalational agents such as sevoflurane and isoflurane, to intravenous (i.v.) propofol infusion, vasodilators like Glyceryl Trinitrate (GTN), remifentanil, magnesium sulphate, beta-adrenergic blockers like esmolol, labetalol, and metoprolol, to α-adrenergic agonists like clonidine and dexmedetomidine, the list becomes exhaustive, with each having its merits and demerits [7].

Out of all these, Labetalol, an amide with dual α and β adrenergic antagonist properties, can help in maintaining a sustained level of controlled hypotension [8]. Similarly, Dexmedetomidine, a highly selective α-2 agonist, reduces central sympathetic outflow leading to hypotension and bradycardia [1]. Labetalol and Dexmedetomidine

by infusion have been successfully used to produce hypotensive anaesthesia in middle ear surgeries independently to reduce intraoperative blood loss and improve visualisation of the surgical field in several studies [9,10]. Though their efficacies have been compared in a few previous studies [4,11] during functional endoscopic surgeries, a definite comparison in middle ear microscopic surgeries is lacking [4,7,11]. The present study aimed to compare the efficacy and safety of Dexmedetomidine and Labetalol for producing controlled hypotension in microscopic middle ear surgeries under general anaesthesia. The primary objective of the study was the evaluation of intraoperative blood loss, and the secondary objectives were the ability to improve visualisation of the surgical field and overall awakening time.

MATERIALS AND METHODS

This randomised controlled trial was conducted at the Department of Anaesthesiology, Tertiary Medical College, Institute of Post Graduate Medical Education and Research, in Kolkata, West Bengal, India, over a period of 15 months from April 2018 to June 2019. Institutional Ethics Committee clearance (Inst/IEC/2018/543, CTRI/2019/03/018088) and informed consent from each patient were obtained. It was a single-blinded study with only the participant being blinded; the randomisation being done by opening a concealed envelope.

Sample size calculation: The study sample size was estimated based on the Intraoperative Bleeding Score (IBS) as the primary outcome. The sample size was calculated to require 35 subjects in each group to detect a difference of 1 in the parameter with 80% power, a 5% probability of type I error, a Standard Deviation (SD) of 1.5, and a 10% allowance for dropout. Thus, the target was set at 39 subjects in each group and a total of 78 subjects overall.

Inclusion criteria: The study included 78 adult patients of either gender of American Society of Anaesthesiologists (ASA) Physical Status (ASA-PS) grade I and II aged 18 to 60 years who were posted for middle ear surgeries under general anaesthesia. Exclusion criteria: Patients who refused to give consent, had severe renal, cardiac or hepatic disorders, pregnant or lactating mothers and those allergic to the study drugs were excluded from the study.

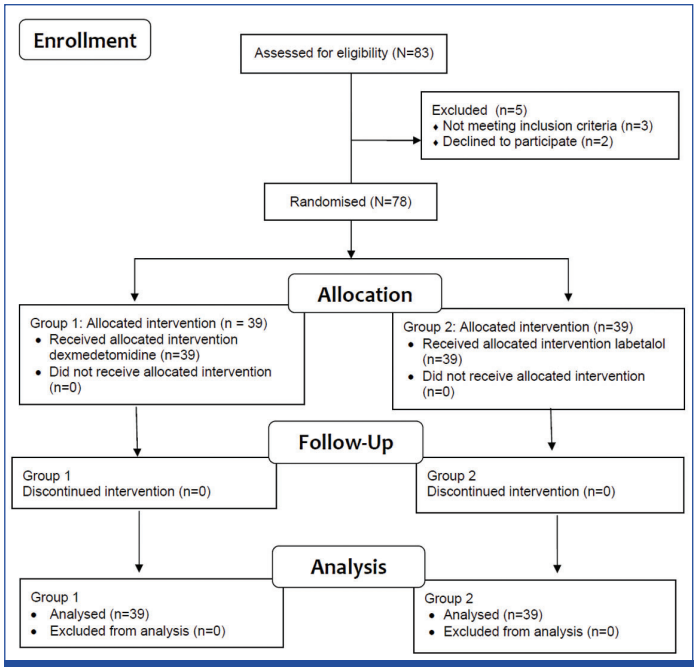
Study Procedure

Patients were assigned either to the Dexmedetomidine group (Group D, n=39) or the Labetalol group (Group L, n=39) by a computer-generated randomisation table (as shown in [Table/Fig-1]). After receiving the patients in the operating room, an intravenous line was established with an 18 G intravenous cannula and infusion of lactated Ringer's solution was started. Preoperative baseline haemodynamic parameters, including Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and MAP, were noted. Study drugs were prepared in identical-looking 100 mL syringes with 0.9% normal saline. A single consultant ENT surgeon operated on all the study patients to maintain uniformity of clinical assessment.

Patients in group D received Dexmedetomidine infusion, with a loading dose of 1 µg/kg dissolved in a 100 mL normal saline bottle and given over 10 minutes. This was followed by a maintenance infusion of 0.4 µg/kg/h, prepared by dissolving 100 µg of Dexmedetomidine in a 100 mL normal saline bottle and given as a continuous infusion via a micro drip infusion set [4].

Patients in group L received a Labetalol 20 mg bolus dose dissolved in 100 mL of normal saline solution over 10 minutes, then the infusion was started at a rate of 0.5 mg/min. Infusion of this drug was prepared by dissolving 60 mg of Labetalol in 100 mL of normal saline solution and similarly given with a micro drip set [1].

General anaesthesia, following standard protocol using Fentanyl (2 µg/kg) and Propofol (2 mg/kg) was commenced 5 minutes after the completion of the loading dose in each group. Tracheal intubation



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart of the participants.

was facilitated with atracurium at a dose of 0.5 mg/kg. Anaesthesia was subsequently maintained with oxygen:nitrous oxide (3:5), isoflurane 1% and appropriate top-up doses of atracurium (0.1 mg/kg/dose), under controlled mechanical ventilation with a tidal volume of 8 mL/kg and respiratory rate adjusted to maintain an end tidal Carbon dioxide ($etCO_2$) between 35-40 mmHg. Study drug infusion was stopped just before the end of surgery while suturing the incision. The surgeries were performed by the same surgeon. On conclusion of surgery, neostigmine 50 µg/kg and glycopyrrolate 10 µg/kg were given to antagonise residual neuromuscular blockade, and patients were extubated after meeting standard extubation criteria. Intraoperative analgesia was provided by infusion of Paracetamol (15 mg/kg body weight) and Tramadol (50 mg).

Blood loss was assessed intraoperatively by the BS and FOBS [1]. The BS was taken as the primary outcome of the study as the main determinant of the efficacy of the drugs along with FOBS. Haemodynamic parameters and any side effects related to the study drugs were considered as secondary outcomes as well as determinants of safety. BS - a four-point scale from

- 0=no bleeding (excellent surgical conditions),
- 1=minimum bleeding (sporadic suction),
- 2=diffuse bleeding (repeated suction),
- 3=abundant (troublesome) bleeding (continuous suction)

was assessed at ten minutes interval, starting from the time of incision and ending with closure of the wound.

FOBS-a five-point scale from

- 1=very low,
- 2=low,
- 3=average,
- 4=high,
- 5=very high

was assessed by the surgeon at the end of the operation. MAP and HR were recorded at different time points starting from baseline, followed by values just before induction, before intubation, at 1, 3,5 minutes after intubation, at the start of surgery and every 10 minutes intraoperatively, then at extubation and finally at 1 and 5 minutes after extubation.

The study-drug infusion were titrated according to HR and MAP. The rates were decreased by 0.1 µg/kg/h for group D and 0.1

mg/min for group L and was stopped immediately if the patient developed bradycardia (HR 30% from the preoperative baseline value. The lowest acceptable MAP threshold was therefore defined as 30% below the preoperative baseline value. The lowest threshold of MAP accepted was 30% below the preoperative value. Atropine and phenylephrine were used to counteract bradycardia and hypotension, respectively, and once the MAP exceeded the threshold, the study drug infusion started again.

STATISTICAL ANALYSIS

The data collected during the procedures were entered into a Microsoft Excel spreadsheet and analysed using Statistical Package for the Social Sciences (SPSS), version 18.0. Data were summarised by routine descriptive statistics, namely Mean and Standard deviation for normally distributed numerical variables, Median and Interquartile range for Skewed numerical variables and counts and percentages for categorical variables. Numerical variables were compared between groups by Student's Independent sample t test, when normally distributed and by Mann – Whitney U test when skewed. Categorical variables were compared between groups by Chi-square test or Fisher's-exact test as appropriate. All comparison was two-tailed and $p<0.05$ was considered statistically significant.

RESULTS

The comparisons of demographic statistics as well as the duration of surgeries between cases of the two groups (group D and group L), which shows that there was no statistically significant difference between the two groups [Table/Fig-2].

Parameters		Group D (Mean±SD)	Group L (Mean±SD)	p-value
Age (in years)		21.90±2.92	22.28±5.00	0.679
Body weight (in kg)		53.28±5.11	50.85±7.42	0.104
Duration of surgery (in minutes)		117.95±14.17	118.97±13.13	0.893
Gender	Male	19	22	0.616
	Female	20	17	
ASA status	I	21	19	0.712
	II	18	20	

[Table/Fig-2]: Demographic data of the participants.

Trends of IBS over time is shown in [Table/Fig-3]. There is a gradual reduction of IBS in group D from the 20th minute; significance was first achieved at 20 minutes and continued to be the same till 120 minutes. The gradual fall in IBS value, therefore, was noted in group D patients with the progress of surgery.

Time scale [in mins]	Group D [Median (I.Q.R)]	Group L [Median (I.Q.R)]	p-value
IBS 10	3 (3.00 - 3.00)	3 (3.00 - 3.00)	1.000
IBS 20	2 (2.00 - 3.00)	3 (3.00 - 3.00)	0.015
IBS 30	2 (2.00 - 2.00)	2 (2.00 - 3.00)	0.033
IBS 40	2 (1.00 - 2.00)	2 (2.00 - 2.00)	0.017
IBS 50	2 (1.00 - 2.00)	2 (2.00 - 2.00)	0.001
IBS 60	1 (1.00 - 2.00)	2 (2.00 - 2.00)	<0.001
IBS 70	1 (1.00 - 1.00)	2 (2.00 - 2.00)	<0.001
IBS 80	1 (1.00 - 1.00)	2 (1.00 - 2.00)	<0.001
IBS 90	1 (1.00 - 1.00)	2 (1.00 - 2.00)	<0.001
IBS 100	1 (1.00 - 1.00)	2 (1.00 - 2.00)	0.001
IBS 110	1 (1.00 - 1.00)	1 (1.00 - 2.00)	0.007
IBS 120	1 (1.00 - 1.00)	1 (1.00 - 2.00)	0.019
IBS 130	1 (1.00 - 1.00)	1 (1.00 - 2.00)	0.111

[Table/Fig-3]: Intraoperative bleeding Score (IBS).

The descriptive statistics for FOBS and awakening time between group D and group L, show a significant difference between group D and group L [Table/Fig-4].

Parameters	Group D [Median (I.Q.R)]	Group L [Median (I.Q.R)]	
Final opinion on bleeding score	2 (2.00 – 3.00)	4 (3.00 – 4.00)	<0.001
Awakening time in minutes	3 (2.00-5.00)	10 (7.00-15.00)	<0.001

[Table/Fig-4]: Final opinion on bleeding score and awakening time between the groups.

The intraoperative trend in HR in both the groups is compared [Table/Fig-5]. In both the groups, there was an increase in HR following laryngoscopy and intubation and during extubation, but this attenuation was much less in group D.

Time point	Group D [Median (I.Q.R)]	Group L [Median (I.Q.R)]	p-value
Baseline	88 (75 – 98)	94 (78 – 104)	0.174
Just before induction	72 (69 – 81)	89 (76 – 92)	<0.001
Just after induction	77 (70 – 79)	94 (89 - 104)	<0.001
At Intubation	88 (83 – 92)	98 (91 - 109)	<0.001
Post-intubation 1 min	83 (78 – 89)	106 (98 - 112)	<0.001
Post-intubation 3 mins	77 (72 – 82)	100 (93 - 108)	<0.001
Post-intubation 5 mins	73 (69 – 76)	97 (81 – 102)	<0.001
Start of Surgery	70 (67 – 71)	90 (74 - 95)	<0.001
Intraoperative 10 mins	70 (64 – 73)	85 (77 - 94)	<0.001
Intraoperative 20 mins	68 (65 – 71)	78 (73 - 88)	<0.001
Intraoperative 30 mins	66 (63 – 71)	77 (68 – 89)	<0.001
Intraoperative 40 mins	67 (65 – 69)	78 (71 - 88)	<0.001
Intraoperative 50 mins	66 (63 – 71)	79 (71 - 89)	<0.001
Intraoperative 60 mins	67 (63 – 71)	78 (71 - 88)	<0.001
Intraoperative 70 mins	66 (62 – 69)	73 (68 - 87)	<0.001
Intraoperative 80 mins	68 (65 – 70)	74 (70 - 82)	<0.001
Intraoperative 90 mins	66 (63 – 71)	75 (68 - 83)	<0.001
Intraoperative 100 mins	65 (64 – 71)	73 (68 - 87)	<0.001
Intraoperative 110 mins	69 (63 – 73)	74 (65 - 87)	0.03
Intraoperative 120 mins	68 (64 – 71)	71 (63 - 86)	0.107
Intraoperative 130 mins	64 (62 – 66)	67 (62 - 73)	0.041
At extubation	94 (89 – 99)	112 (107 - 117)	<0.001
Post-extubation 1 min	101 (94 – 106)	115 (111 - 118)	<0.001
Post-extubation 5 mins	95 (92 – 99)	111 (103 - 115)	<0.001

[Table/Fig-5]: Comparison of HR in the perioperative period.

Time point	Group D [Median (I.Q.R)]	Group L [Median (I.Q.R)]	p-value
Baseline	89 (86 – 92)	90 (83 - 95)	0.805
Just before induction	84 (82 – 88)	83 (81 - 91)	0.785
Just after induction	87 (84 – 89)	85 (83 - 93)	0.293
At Intubation	89 (89 – 91)	89 (82 - 94)	0.001
Post-intubation 1 min	90 (78 – 93)	97 (81 - 99)	0.019
Post-intubation 3 mins	87 (79 – 91)	91 (81 - 97)	0.048
Post-intubation 5 mins	81 (77 – 83)	81 (77 - 92)	0.020
Start of surgery	79 (72 – 81)	82 (73 - 88)	0.010
Intraoperative 10 mins	75 (73 – 77)	84 (75 - 88)	<0.001
Intraoperative 20 mins	73 (70 – 75)	78 (73 - 82)	<0.001
Intraoperative 30 mins	74 (72 – 77)	79 (75 - 83)	<0.001
Intraoperative 40 mins	72 (71 – 74)	78 (74 - 83)	<0.001
Intraoperative 50 mins	73 (70 – 75)	79 (74 - 84)	<0.001
Intraoperative 60 mins	72 (71 – 77)	76 (73 - 81)	<0.001

Intraoperative 70 mins	73 (71 – 78)	79 (73 - 83)	<0.001
Intraoperative 80 mins	74 (71 – 75)	77 (74 - 82)	<0.001
Intraoperative 90 mins	72 (71 – 75)	78 (73 - 84)	<0.001
Intraoperative 100 mins	73 (72 – 77)	77 (75 - 81)	<0.001
Intraoperative 110 mins	73 (71 – 79)	78 (71 - 83)	0.004
Intraoperative 120 mins	72 (71 – 73)	77 (75 - 82)	<0.001
Intraoperative 130 mins	73 (72 – 79)	76 (73 - 81)	0.120
At extubation	92 (90 – 93)	98 (89 - 99)	0.225
Post-extubation 1 min	95 (91 – 99)	98 (92 - 103)	0.035
Post-extubation 5 mins	92 (89 – 98)	93 (85 - 105)	0.252

[Table/Fig-6]: Comparison of mean arterial pressure (MAP) in the perioperative period.

The comparison of mean arterial pressure measured at different points of time is summarised in [Table/Fig-6]. It was found to be significantly (statistically) lower in group D intraoperatively, though that was more or less insignificant clinically.

No study-drug-related adverse events were observed during the study period.

DISCUSSION

Middle ear surgeries encompass a very small operating field that necessitates minimal bleeding to prevent obscuration of the vision of the surgeon [1,7]. Therefore, the technique of anaesthesia for these surgeries needs to provide a relatively bloodless field, which can be accomplished by using hypotensive anaesthesia. Hypotensive anaesthesia or controlled hypotension has been traditionally and most successfully achieved by pharmacologic intervention. Different intravenous as well as inhalational agents are being commonly used to prevent intraoperative surges in blood pressure. The ideal hypotensive agent, though, should be specific, titrable, reversible, with no pharmacologically relevant interactions and with short duration of action [1,12,13].

Dexmedetomidine and Labetalol have also been tested in several previous studies [7,11,14]. However, studies comparing these two drugs to produce controlled hypotension for middle ear surgeries are minimal [7]. So, the present study was performed to compare their relative efficacies, about intraoperative blood loss, ability to improve visualisation of the surgical field and awakening time while performing middle ear surgeries under general anaesthesia.

In the present study, group D receiving Dexmedetomidine infusion had a significantly lesser amount of bleeding. In a study by Durmus M et al., where they compared Dexmedetomidine with Propofol, bleeding was found to be less in the Dexmedetomidine group with a p-value <0.05 [5]. Similar results were also found in studies performed by Sarkar C et al., in 2016, where Dexmedetomidine was found to have better control over the blood loss [1]. In two different studies performed by Gupta N et al., and Sajedi P et al., where they compared desflurane with Labetalol and Remifentanil with Labetalol, respectively, Labetalol was found to produce less bleeding [15,16]. While comparing Dexmedetomidine with Labetalol directly for getting an oligemic surgical field in middle ear microsurgeries, Navya CN et al., in 2016, found that patients in the Dexmedetomidine group had significantly less bleeding with improved surgeon's satisfaction than the Labetalol group [7]. Similarly, when Sujay JN et al., in 2021, compared the efficacy of the two study drugs for getting controlled hypotension in FESS, they found scores for blood loss were significantly lower in the Dexmedetomidine group in comparison to the Labetalol group [11]. However, in 2024, when Gupta S et al., conducted a prospective, randomised, double-blinded clinical study with 60 patients for induced hypotension during FESS, they found the visibility of the surgical field was comparable in both groups [4]. In another similar study done by Kattishettar D et al., comparing perioperative Dexmedetomidine infusion with infusion Labetalol for Controlled Hypotension in FESS, they found that controlled hypotension and optimal surgical field were maintained equally in both the groups [14]. In another recent study, Radman M et al., however, found Labetalol to be the better option for controlling hypotension, thus providing a better surgical field visibility compared to dexmedetomidine in rhinoplasty surgery [17].

In the present study, patients in group D had significantly lower MAP from the 10th to almost the 120th minute in the intraoperative period, which definitely helped in maintaining a relatively bloodless surgical field. The HR was also lower in group D than group L in the majority of the perioperative period. The study by Gupta S et al., had a similar finding where they found significantly lower heart rate and a lower, though insignificant, MAP in group D in comparison to group L [4]. Studies by Navya CN et al., and Sujay JN et al., however, found comparable haemodynamics between the two groups [7,11].

Another important finding of the present study is the awakening time. It has been shown that awakening time was significantly shorter in patients who had received Dexmedetomidine. This finding corroborates with a study conducted by Nasreen et al., to assess the hypotensive effect of low-dose Dexmedetomidine infusion in middle ear surgery [18]. But the study done by Kattishettar D et al., showed that the Labetalol group had early recovery in comparison to the Dexmedetomidine group [14]. However, the reason for an early recovery in the present study might be that Dexmedetomidine produces conscious sedation; hence, patients remain easily arousable.

In the current study, the same surgeon operated on all the study patients to maintain uniformity in clinical assessment and eliminate bias. The same principle was followed by Ayaglu et al., who showed Dexmedetomidine to be an effective hypotensive agent in septoplasty and tympanoplasty operations [19].

Limitation(s)

The study relied on a subjective bleeding assessment and did not include objective blood-loss measurement. It was conducted at a single centre with a relatively small sample size, and the blinding procedure was unclear. The analysis used a repeated-measures statistical approach with multiple comparisons. No adverse events were reported, but drug plasma concentrations were not measured, which may limit generalisability.

CONCLUSION(S)

Dexmedetomidine infusion produces a more significant reduction in intraoperative bleeding, improving the operative field visibility and increasing surgeons' satisfaction than Labetalol infusion. The awakening time in the Dexmedetomidine group is however, early. There was no significant side effect in either of the groups. Thus, with these findings, it can be well concluded that Dexmedetomidine is a better alternative for providing controlled hypotension than Labetalol in patients undergoing middle ear surgery under general anaesthesia.

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