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ORIGINAL RESEARCH ANESTHESIA FOR EYE / ENT SURGERY

Dexmedetomidine versus labetalol for induced hypotension during functional endoscopic sinus surgery: a randomized, double-blind study

Savita Gupta [1], Isha Yadav [2], Anupriya Saxena [3], Rahul Kumar Bagla [4], Nazia Nazir [5]

Author affiliations:

1. Savita Gupta, Department of Anaesthesia, Government Institute of MedicalSciences, Greater Noida, Uttar Pradesh, India; E-mail: dr.gsavita@gmail.com; {ORCID: 0000-0002-3104-7368}
2. Isha Yadav, Department of Anaesthesia, UCMS and GTB Hospital, Delhi, E-mail: ishayada@gmail.com; {ORCID: 0000-0001-7650-1248}
3. Anupriya Saxena, Department of Anaesthesia, Government Institute of MedicalSciences, Greater Noida, Uttar Pradesh, E-mail: anupriya.pmch@gmail.com; {ORCID: 0000-0001-8307-8628}
4. Rahul Kumar Bagla, Department of Otorhinolaryngology-Head & NeckSurgery, Government Institute of Medical Sciences, Greater Noida, Uttar Pradesh, E-mail: msrahulbagla@gmail.com; {ORCID: 0009-0002-6716-1813}
5. Nazia Nazir, Department of Anaesthesia, Government Institute of MedicalSciences, Greater Noida, Uttar Pradesh, E-mail: nazunazir@gmail.com; {ORCID: 0000-0001-6950-2111}

Correspondence: Dr. Savita Gupta, E-mail: dr.gsavita@gmail.com; Mobile: +91 8750657382

ABSTRACT

Background & Objective: Functional endoscopic sinus surgery (FESS) is a surgical procedure for treating sinus diseases. Bleeding is a common concern during FESS, so maintaining hemodynamic stability and ensuring quality surgical field visibility is crucial for achieving the best outcomes. The present study compared the time taken to achieve target mean arterial pressure (MAP) when using dexmedetomidine or labetalol during FESS and assessed the quality of the surgical field to establish the better choice of the two.

Methodology: The study was conducted as a prospective, randomized, double-blinded clinical study. Sixty patients classified as American Society of Anesthesiologists grade I or II, undergoing FESS under general anesthesia, were divided into two groups, each with 30 patients. Group D patients received dexmedetomidine and Group L received labetalol. The study aimed to maintain the mean arterial pressure (MAP) between 60-70 mmHg. The operative field visibility was assessed using the Fromme and Boezaart scoring system. Emergence time and postoperative first analgesic request time were also recorded.

Results: The time taken to achieve target MAP (60-70 mmHg) was less in Group D (15.1 ± 0.2 min) than in Group L (18.2 ± 0.5 min), and it was statistically significant ($P < 0.05$). Although insignificant, lower MAP were observed in the Group D than Group L. A significantly lower heart rate was observed at defined intervals in Group D than in Group L. The visibility of the surgical field in both groups has comparable results. The first analgesic request time was considerably longer in Group D (52.2 ± 1.9) compared to Group L (10.2 ± 2.1) ($P < 0.05$).

Conclusion: Dexmedetomidine provided better hemodynamic stability and operative field visibility than Labetalol during FESS.

Abbreviations: FESS - Functional endoscopic sinus surgery; MAP - Mean arterial pressure; $EtCO_2$ - end-tidal carbon dioxide

Keywords: Dexmedetomidine; Labetalol; Controlled Hypotension; Mean Arterial Pressure

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1. INTRODUCTION

Surgical bleeding is dependent on tissue blood circulation. In the functional endoscopic sinus surgery (FESS), capillary oozing is a significant contributing factor in the operative field bleeding, which can be reduced by induced hypotension and topical vasoconstriction. Controlled hypotension, or hypotensive anesthesia, is an anesthetic approach where the systemic blood pressure is decreased intentionally during surgery. The technique can reduce blood loss in FESS, improving surgical field visibility.[1,2] In hypotensive anesthesia, the goal is to reduce the mean arterial pressure (MAP) by approximately 25-30% from the patient's baseline level. However, to ensure that the MAP does not fall below 60 mmHg is crucial to maintaining sufficient perfusion to vital organs.[3] Various pharmacological agents, such as nitroglycerine, sodium nitroprusside, tranexamic acid, alpha-1 blockers, beta-blockers, nicardipine, dexmedetomidine, and magnesium sulphate, have been used to induce hypotension.[4-6] An ideal hypotensive agent should be readily available and have a fast onset, rapid elimination, with nontoxic metabolites, and predictable effects

Dexmedetomidine affects central α2A and imidazoline-1 receptors, decreasing norepinephrine release. This reduces sympathetic outflow and lowers the blood pressure and the heart rate.[7]

Labetalol non-selectively antagonizes beta-adrenergic receptors and selectively antagonizes alpha-1-adrenergic receptors to decrease blood pressure.[8] The primary objective of this study was to compare the time required to reach the target MAP using different infusion doses of the study drugs. The secondary objectives included assessing the quality of the surgical field, adverse effects, and recovery characteristics.

2. METHODOLOGY

Upon securing approval from the institutional ethical committee (approval number GIMS/IEC/HR/01), the trial was registered with the Clinical Trial Registry of India under the registration number CTRI/2022/06/043087. This prospective randomized double-blind clinical study was conducted from June 2022 to July 2023. We included sixty patients, aged 18 to 60 y, ASA grade I or II, scheduled for FESS. Patients with hypertension, sinus bradycardia, hypotension, coagulation disorders, cerebrovascular insufficiency, ischemic heart disease, congestive cardiac failure, cardiac dysrhythmias, and hepatic and renal disorders were excluded.

A total of 60 patients were included in the study and were randomly assigned to one of the two groups, with 30 patients each based on a similar type of previous study.9 The study used a computer-generated randomization program to conduct the randomization process in a simple random manner. To ensure concealment of randomization, 60 sealed envelopes were prepared, each containing a drug code (30 envelopes for each drug, labelled as L and D). A designated anesthesiologist, who was not involved in the study protocol, opened the envelopes just before the start of the study and prepared the drugs in identical syringes according to the code inside each envelope.

Double-blinding was implemented in the study. The anesthesiologist responsible for recording the study variables was blinded, and another anesthesiologist administered the anesthesia and kept a record of the patients and the codes of the syringes assigned to them. The codes were revealed upon completion of the study for all 60 cases.

Before the surgery, a routine preanesthetic checkup was performed, and eligible patients were instructed to do overnight fasting. They were also premedicated with a 0.25 mg alprazolam tablet the night before the surgery.

On the day of surgery, two dedicated intravenous lines with 20 gauze cannulas were secured, one for infusion of dexmedetomidine or labetalol and the other for administering fluids and general anesthetic medications. Standard ASA monitors were connected upon arrival in the operating room. Ringer lactate (10 ml/kg) was initiated, and baseline vital signs, non-invasive blood pressure, pulse oximetry, and electrocardiogram were recorded.

Ten minutes before the start of the induction of the patient, Group D, patients received dexmedetomidine as a loading dose of 1 µg/kg diluted in 50 mL of 0.9% normal saline, which was followed by a maintenance infusion of 0.2-0.4 µg/kg/h. Group L patients received labetalol as a loading dose of 0.4 mg/kg intravenously, diluted in 50 mL of 0.9% normal saline, followed by a maintenance dose of 0.02-0.04 mg/kg/h.

All patients received fentanyl 2 µg/kg and glycopyrrolate 4 µg/kg IV. Induction was performed with propofol 2 mg/kg IV, and tracheal intubation was achieved with intravenous vecuronium 0.1 mg/kg IV.

Anesthesia was maintained using isoflurane with nitrous oxide and oxygen mixture. After tracheal intubation, a throat pack was inserted under full aseptic precaution with the help of a C-MAC video laryngoscope. In both study groups, the infusion rate of the experimental drugs was carefully adjusted to keep the mean arterial blood pressure from 60 to 70 mmHg. The aim was to ensure stable hemodynamics throughout the surgery. Additionally, the surgeon administered 3 ml of

lignocaine 1% with adrenaline 1:100,000 directly at the surgical site to minimize bleeding.

Throughout the surgical procedure, hemodynamic parameters, including heart rate (HR), mean arterial blood pressure (MAP), systolic and diastolic blood pressure, oxygen saturation (SpO_2), and end-tidal carbon dioxide ($EtCO_2$) levels, were monitored during induction, and after every 5 min until the completion of the surgery.

Bradycardia (heart rate below 50 beats/min) was managed with of atropine 0.01 mg/kg IV. In the case of significant hypotension (MAP < 60 mmHg), the initial approach involved adjusting the drug infusion rate. If there was no response, the infusion was stopped, and mephenteramine 6 mg was administered intravenously to treat the hypotension.

The study drugs were discontinued 5 min before the end of the surgery. The residual neuromuscular blockade was reversed and extubation was performed.

In this study, a single surgeon performed FESS in all patients. The surgeon received preoperative information regarding the grading of the surgical field. Notably, the surgeon was unaware of the specific anesthesia drugs being investigated. He provided numerical assessments of the operative conditions, including the amount of bleeding and its impact on visibility, using the Fromme and Boezaart grading scale (Box 1).[10,11]

Emergence time was recorded as the interval between the discontinuation of anesthetics and the eye-opening response to verbal commands. After extubation and complete recovery, the patients were transferred to the post-anesthetic care unit (PACU). The duration of surgery and total anesthesia time were recorded. The postoperative recovery was evaluated by implementing a modified Aldrete score,[12,13] and the duration required to achieve a score equivalent to or above nine was documented. The visual analogue score (VAS) was used to assess pain, and tramadol 50 mg IV was administered if the score was above four. The time to the first analgesic requirement was recorded. The sedation score was measured using the Ramsay sedation scale at 15, 30, and 60 min after tracheal extubation.[14] Perioperative complications, including hypotension, hypertension, tachycardia (heart rate > 100/min), bradycardia, nausea, vomiting, shivering, and sedation were observed and noted.

Box 1: Endoscopic surgical field grading system

Grade	Assessment
0	No bleeding (cadaveric conditions)
1	Slight bleeding, no suctioning required
2	Slight bleeding, occasional suctioning required
3	Slight bleeding, frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed
4	Moderate bleeding, frequent suctioning required, and bleeding threatens surgical field directly after suction is removed
5	Severe bleeding, constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible

Adapted from reference Fromme et al.[10] and Boezaart et al.[11]

Statistical analysis

Data were analyzed using SPSS version 28 (SPSS for Windows; SPSS Inc., Chicago, IL, USA). Microsoft Word and Excel were used to generate tables and graphs. All quantitative data were summarized in the form of mean ± standard deviation. Demographic data, fentanyl consumption, and time to first analgesic request were analyzed using the Student's t-test, while MAP and HR were analyzed using one-way analysis of variance (ANOVA).

3. RESULTS

A total of 60 patients were included in the study and were grouped into Group D and Group L. Both groups were comparable regarding patients' demographic characteristics, including age, sex, male-female ratio, and hemodynamic profile (blood pressure and heart rate) (P > 0.05). Duration of surgery and the total time of anesthesia were also equivalent in both groups, with no statistically significant differences (Table 1).

The time taken to achieve target MAP (< 70 mmHg) was significantly shorter in Group D than in Group L; e.g., 15.1 ± 0.2 vs. 18.2 ± 0.5 min (P < 0.0001).

The MAP in Group D was lower than in Group L throughout intraoperative period; the difference being statistically not significant except during the induction period and 5 min post-extubation (Table 2). Although both groups showed a decrease in HR after the loading doses of the study drugs as compared to baseline, the decrease in HR was more in Group D than in Group L, and it was statistically significant after induction of anesthesia till 5 min after extubation (P < 0.05).

The visibility of the surgical field in both groups was comparable. Group D had a Fromme's score of 2 in 73.33% of patients and 3 in 26.67% of patients. But Group L scored 2 in 60% of patients and 3 in 40% of patients. A grade of 3 or less gives a highly acceptable surgical field to the surgeon. The mean Fromme-

Table 1: Demographic characteristics, duration of surgery, and the clinical characteristics of participants

Demographic Variables	Group D (n = 30)	Group L (n = 30)	P value
Age (y)	35.6 ± 6.3	32.8 ± 7.2	0.115
Male/Female	26/4	24/6	0.490
Duration of surgery (min)	110 ± 18.3	113 ± 17.3	0.516
Total anesthesia time (min)	130 ± 11.7	131 ± 11.3	0.737
Preoperative MAP (mmHg)	99 ± 3.3	100.3 ± 3.2	0.126
Preoperative HR (beats/h)	92.2 ± 3.2	93.8 ± 3.3	0.061

Values presented as mean ± SD or number only. P > 0.05, not significant. MAP = Mean arterial pressure, HR = Heart rate

Table 2: Comparison of mean MAP and HR (per minute)

Time of measurement	Group D	Group L	P- value
Mean MAP (mmHg)			
After loading dose of study drug	84.2 ± 4.2	82.4 ± 5.1	0.141
After induction of anesthesia	72.2 ± 5.2	75.9 ± 5.4	0.009
After intubation	76.7 ± 4.6	78.2 ± 4.8	0.221
Average intraoperatively	68.7 ± 3.9	70.1 ± 3.8	0.164
After extubation	74.5 ± 5.2	77.1 ± 5.8	0.072
5 min after extubation	70.7 ± 5.6	84.5 ± 5.2	< 0.0001
Mean HR (beats per min)			
After loading dose of study drug	72.6 ± 6.3	72.9 ± 5.2	0.841
After induction of anesthesia	68.1 ± 3.4	70.9 ± 2.2	0.0004
After intubation	72.7 ± 4.6	78.2 ± 4.8	< 0.0001
Average intraoperatively	64.0 ± 4.1	72.1 ± 4.6	< 0.0001
After extubation	70.5 ± 5.2	77.1 ± 5.8	< 0.0001
5 min after extubation	68.7 ± 5.6	84.5 ± 5.2	< 0.0001

Boezaart score was 2.26 ± 0.26 in Group D and 2.40 ± 0.32 in Group L, with no statistically significant difference observed (P = 0.068) (Table 3). The emergence time and recovery time assessed by the Modified Aldrete score and sedation score were greater in Group D due to its sedative effect. Group D had an average recovery time of 10.4 ± 0.8 min, while Group L had 7.2 ± 0.9 min (P < 0.05) (Table 4). During the surgery, one incident of bradycardia was observed in both groups, and one incidence of hypotension was observed in Group D. Two cases of shivering were noted in Group L compared to one case in Group D.

Table 3: Surgical field as graded by the surgeon according to the Fromme-Boezaart score

Fromme-Boezaart score	Group D (n = 30)	Group L (n = 30)	P value
0	0 (0)	0 (0)	0.068
1	0 (0)	0 (0)	
2	22 (73.3)	18 (60)	
3	8 (26.6)	12 (40)	

Data presented as n (%)

4. DISCUSSION

We compared the efficacy of dexmedetomidine versus labetalol in providing controlled hypotension in FESS. We also compared the hemodynamic response, quality of the surgical field, and time since the first analgesic request.

The two groups were comparable in age, gender, surgery duration, and anesthesia duration. In our study, the target MAP was < 70 mmHg, which was achieved earlier in Group D than in Group L, and it was clinically

Table 4: Recovery characteristics, sedation score, time to first analgesic request and side effects

Variable	Group D (n = 30)	Group L (n = 30)	P- value
Emergence time	8.92 ± 0.7	5.28 ± 0.9	< 0.0001
Time to achieve modified Aldrete score >9 (min)	10.4 ± 0.8	7.2 ± 0.9	< 0.0001
Sedation score 15 min after surgery	3.4 ± 1.4	2.1 ± 1.2	0.0003
Sedation score 30 min after surgery	2.4 ± 0.6	1.1 ± 0.8	< 0.0001
Sedation score 60 min after surgery	1.0 ± 0.1	1.0 ± 0.2	1.000
Time to first analgesic request	52.2 ± 1.9	10.2 ± 2.1	< 0.0001
Side- effects			
• Hypotension	1	0	
• Bradycardia	1	1	
• Nausea and vomiting	0	0	
• Shivering	1	2	

significant. This finding is consistent with those reported by Sujay et al., where target MAP was achieved earlier in dexmedetomidine than in the labetalol group.[9]

The MAP in Group D remained lower than in Group L throughout the operative period. However, the difference was statistically significant during the induction period and 5 min post-extubation only. The decrease in HR was more in Group D than in Group L and was statistically significant ($P < 0.05$) after induction of anesthesia till 5 min after extubation. A study conducted by Gupta et al. comparing dexmedetomidine with propofol found that dexmedetomidine produced more stable hemodynamics with lower MAP and HR readings compared to propofol.[15]

However, a study conducted by Chacko et al. who compared the efficacy of dexmedetomidine and labetalol for induced hypotensive anesthesia in ear, nose, and throat surgeries and showed no statistical difference in MAP and HR throughout the surgeries.[16]

We assessed surgical field visibility using the Fromme et al. scale. According to the findings, the surgical field visibility was better in the dexmedetomidine group compared to the labetalol group ($P > 0.05$), but the difference was not significant. The score was 2 or 3 in both groups. A study by Shams et al. also showed similar results when comparing dexmedetomidine with propofol.[17] However, few studies claim that dexmedetomidine provided a better operative field than other agents, including labetalol.[9,18]

The operative time was similar between the two groups ($P = 0.071$). This is also seen in other studies where dexmedetomidine is compared with other drugs for giving hypotensive anesthesia.[18,19]

The emergence time and sedation scores in Group D were found to be significantly higher than those in Group L, leading to late discharge from the PACU; similar results have been reported in other studies, where the recovery time was found to be higher with the use of dexmedetomidine than using esmolol, remifentanil or magnesium sulphate.[15,19,20] In our study, the time to first analgesic request was 52.2 ± 1.9 min in Group D compared to 10.2 ± 2.1 min in Group L, which was statistically significant ($P < 0.05$). These findings are similar to those reported by Sahu et al.[18] These characteristics can be explained as dexmedetomidine activates 2-adrenoceptors and causes the decrease of sympathetic tone, attenuating the neuroendocrine and hemodynamic responses to anesthesia and surgery; it reduces anesthetic requirements and causes sedation and analgesia.[15,21]

5. LIMITATIONS

Our study has limitations as a placebo-controlled group was absent, and the sample size was limited. Comparing labetalol and dexmedetomidine based on their known optimal and safe pre-medicating doses without knowledge of their equipotent doses is also a limitation. This limitation should be addressed in future studies with a larger sample size.

6. CONCLUSION

We conclude that dexmedetomidine and labetalol are safe agents for controlled hypotension. Both are effective in providing a more acceptable surgical field with minimal blood loss during FESS. However, compared to labetalol, dexmedetomidine offers the advantage of an inherent analgesic, sedative, and anesthetic sparing effect and achieves target mean arterial pressure earlier. However, it may prolong the sedation and the recovery during the postoperative period.

7. Data availability

The numerical data generated during this research is available with the authors and can be provided on a reasonable request.

8. Acknowledgement

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9. Conflict of interest

All authors declare no competing interest. No industry or external source funding was availed in this study.

10. Ethical considerations

The trial was approved by the institutional ethical committee (approval number GIMS/IEC/HR/01), and it was registered with the Clinical Trial Registry of India under the registration number CTRI/2022/06/043087.

11. Authors' contribution

SG: Concept, Literature search, conduction of the study work and manuscript editing;

IY,RKB, NN: Conduction of the study work;.

AS: Conduction of the study work, Literature search. All authors approve the manuscript for publishing.

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