Original Article

DOI: 10.7860/JCDR/2024/65462.18980

# Efficacy of Dexmedetomidine and Labetalol for Induced Hypotension in Endoscopic Sinus Surgeries: A Randomised Clinical Study

Anaesthesia Section

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## ABSTRACT

**Introduction:** Functional Endoscopic Sinus Surgery (FESS) is one of the most commonly performed surgical procedures that requires minimal bleeding during the procedure. Dexmedetomidine, an alpha-agonist and labetalol, a beta-blocker, have been used to decrease intraoperative bleeding and provide optimal surgical conditions.

**Aim:** To evaluate the efficacy of labetalol and dexmedetomidine on intraoperative blood loss and surgical conditions during FESS.

**Materials and Methods:** The present randomised single-blinded clinical study was conducted in the Department of Anaesthesiology, Gandhi Medical College and associated Hamidia Hospital, Bhopal, India, from January 2020 to May 2021. Study was performed on 60 patients aged 18-60 years undergoing FESS. The patients were divided into two groups: Labetalol (L) or Dexmedetomidine (D). Heart rate and arterial blood pressure were measured after induction, during and at the end of the surgery. An assessment of bleeding was done by a blinded surgeon. Surgical field quality, surgeon satisfaction, emergence time, Aldrete score and any side effects were observed. Data were analysed using the Statistical Package of Social Sciences (SPSS) software version 17.0 for Windows and the unpaired student t-test.

**Results:** In the total study population, the mean age in group D was 42.96±11.52 years and in group L was 47.33±10.97 years. In both groups, female patients were more prevalent than males (Group L: 53.3%; Group D: 60%). There was a significant decrease in heart rate in group D compared to group L during and after the operation. Mean Arterial Pressure (MAP) after induction (106.63±6.094 mmHg vs 114.80±6.272 mmHg), at extubation and after extubation for six hours was significantly higher in group L than in group D. The emergence time of group D was higher than that of the labetalol group. The surgical field quality and surgeon satisfaction were significantly higher in group D. Time to reach Aldrete score ≥9 (15.67±1.788 vs 11.23±1.654), time for first analgesic requirement and Ramsay sedation score were found to be higher in group D and were statistically significant.

**Conclusion:** Both dexmedetomidine and labetalol can be used for controlled hypotension during FESS. Dexmedetomidine provides more haemodynamic stability and is ideal for creating a better surgical field during endoscopic surgeries.

**Keywords:** Controlled hypotension, Extubation, Functional endoscopic sinus surgery, Mean arterial pressure

## INTRODUCTION

The FESS is one of the most common surgeries in otolaryngology, primarily performed through endoscopy. Endoscopy is a minimally invasive procedure in which the success of the surgery largely depends on the surgical field. The nose, being rich in blood vessels, can obscure the vision and significant bleeding can compromise the surgeon's pace, leading to increased surgical duration. Bleeding in delicate areas such as the ear, nose and throat is a major concern for the anaesthesia and surgery teams. Slow oozing of blood can blur the vision, making anatomical landmarks difficult to identify, which becomes a significant problem in endoscopic sinus surgeries [1]. The choice of anaesthetic agents plays a crucial role during FESS surgeries and ideally, the procedure is performed under controlled hypotensive anaesthesia to minimise bleeding [2].

Bleeding during surgery can cause discomfort and prolong the hospital stay. Induced hypotension is a technique used to maintain the intraoperative mean arterial blood pressure at a level that facilitates surgery, reduces bleeding and provides the best possible field for the surgeon to operate [3]. Various approaches have been used to reduce bleeding, ranging from simple techniques like positioning the head higher than the level of the heart to decrease venous congestion of the upper body, to the application of vasoconstrictive agents on the nasal mucosa to decrease capillary bleeding, or the administration of intravenous anaesthetics [4].

Different agents such as inhalational agents like halothane and isoflurane, intravenous propofol infusion, vasodilators like sodium nitroprusside and nitroglycerine, as well as remifentanil, magnesium sulfate, beta-adrenergic blockers and alpha-adrenergic agonists have been used and compared in various studies [5-8].

When inhalational anaesthetics are used alone, they require higher concentrations to achieve the desired blood pressure, which can lead to delayed recovery and potential injury to the kidneys or liver. On the other hand, intravenous drugs are easier to administer, have a quicker onset of action, provide better control over blood pressure and bleeding and are rapidly eliminated without producing any toxic metabolites [1-5].

Dexmedetomidine is a highly selective $\alpha_2$-adrenoreceptor agonist (selectivity ratio $\alpha_2$: $\alpha_1$=1600:1) with favourable kinetics, a distribution half-life of six minutes and an elimination half-life of two hours [7]. It modestly reduces blood pressure and heart rate through centrally mediated action. As a sympatholytic drug, it decreases blood pressure, heart rate and cardiac output without the risk of respiratory depression. Consequently, it minimises bleeding during surgery, enhances surgeon satisfaction and improves patient safety. It also has sedative, anxiolytic, hypnotic, amnestic and analgesic properties [8]. Additionally, it reduces postoperative nausea and vomiting, decreases postoperative opioid requirement and alleviates pain severity [9].

Labetalol is a non selective alpha-beta adrenergic blocker. It selectively targets postsynaptic alpha-1-adrenergic receptors and is non selective for beta-adrenergic receptors [10]. The ratio of alpha to beta antagonism is 1:7 after intravenous administration. This drug is 5-10 times more specific for beta receptors than alpha receptors, preventing vasoconstriction induced by alpha receptors. Its overall

effects include a dose-dependent decrease in systemic resistance and blood pressure without causing reflex tachycardia [11].

The present study was aimed to observe the effects of two drugs, injection dexmedetomidine and injection labetalol, as hypotensive agents and evaluate their efficacy and impact on the surgical field among patients undergoing FESS.

## MATERIALS AND METHODS

The present study was a randomised, single-blinded clinical trial conducted in the Department of Anaesthesiology, Gandhi Medical College and associated Hamidia Hospital, Bhopal, India, from January 2020 to May 2021. The study received approval from the Institutional Ethics Committee on 4/01/2020 (ECR/1055/Inst/MP/2018).

**Sample size calculation:** A total of 60 patients were included, with the sample size calculated based on a confidence level of 70% and a margin of error of 6%. The minimum sample size for each group was determined to be 30 patients using a sampling formula.

**Inclusion criteria:** Male or female patients aged between 18-60 years, classified as American Society of Anaesthesiologists (ASA) I or II, scheduled for elective FESS.

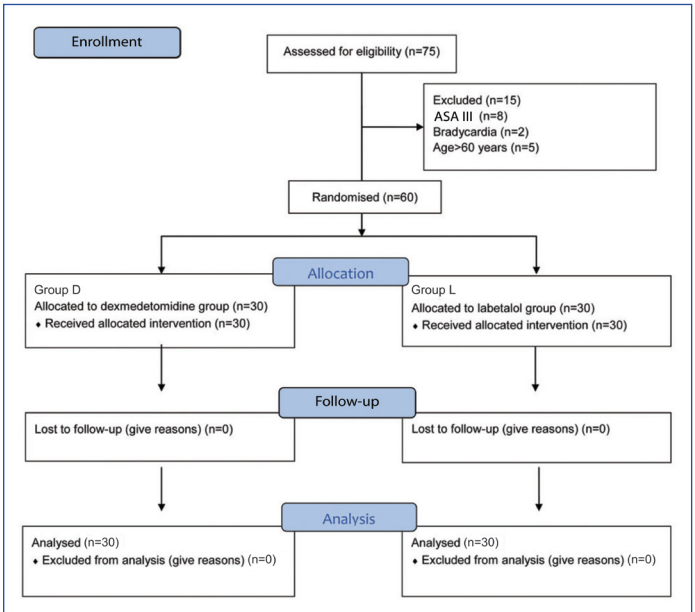
**Exclusion criteria:** Patient refusal, age above 60 years, ASA grade III/IV, patients with a history of allergy to either dexmedetomidine or labetalol, patients with uncontrolled hypertension, diabetes mellitus, asthma, or cardiovascular disease.

### Study Procedure

Sixty patients were randomly assigned to two groups using a computer-generated randomisation Consolidated Standards of Reporting Trials (CONSORT) flow diagram [Table/Fig-1].

**Group D:** Dexmedetomidine group (n=30): A loading dose of 1 mcg/kg diluted up to 10 mL with 0.9% normal saline was administered over 10 minutes before induction, followed by a continuous infusion of 0.4 to 0.8 ug/kg/hour.

**Group L:** Labetalol group (n=30): A bolus dose of labetalol 0.4 mg/kg diluted up to 10 mL with 0.9% NS was given over two minutes before induction, followed by a continuous infusion of 0.04 mg/kg/hour.




**[Table/Fig-1]:** Diagram for the flow of participants through each stage of the present study.

**Preanaesthetic evaluation:** The day before surgery, a preanaesthetic evaluation was conducted for all the patients. A thorough clinical examination and airway assessment were performed. The patients were informed about the procedure, its risks and benefits and written informed consent was obtained. They were also provided instructions to fast for six hours before the surgery.

All routine investigations were conducted. On the day of surgery, the anaesthesia machine, circuits, resuscitation equipment and drugs were checked. After confirming the nil per oral status and obtaining consent, patients were taken to the operating room and connected to the standard monitor. Intravenous lines were secured and preoperative baseline parameters, including heart rate, systolic blood pressure, diastolic blood pressure and mean blood pressure, were recorded after five minutes as baseline values in the operating room.

**Premedication:** All patients received intravenous glycopyrrolate at a dose of 0.01 mg/kg body weight, intravenous midazolam at a dose of 0.05 mg/kg body weight, intravenous fentanyl at a dose of 0.5 ug/kg body weight and intravenous ondansetron at a dose of 0.1 mg/kg body weight. Preloading was then performed with 5 mL/kg body weight of Ringer's lactate solution.

- Following this, group D was administered intravenous dexmedetomidine at a loading dose of 1 mcg/kg diluted up to 10 mL with 0.9% normal saline given over 10 minutes before induction, followed by a continuous infusion of 0.4 to 0.8 ug/kg/hour [9].
- Group L patients received a bolus dose of labetalol 0.4 mg/kg diluted up to 10 mL with 0.9% NS over two minutes before induction, followed by a continuous infusion of 0.04 mg/kg/hour [1].

All patients were induced with intravenous propofol (2 mg/kg) and after confirming mask ventilation, intravenous succinylcholine (2 mg/kg) was administered for laryngoscopy and intubation. Oxygenation was maintained through intermittent positive-pressure ventilation. Intubation was performed using an appropriately sised cuffed endotracheal tube and anaesthesia was maintained with oxygen, nitrous oxide, isoflurane and intermittent intravenous atracurium. All patients were placed in a 15-degree reverse Trendelenburg position and the throat was packed with a cotton pack mixed with epinephrine at a concentration of 1:10000.

- All surgeries were performed by the same surgeon, who was blinded to the drug used, to ensure consistency in the quality of the surgical field.
- Ten minutes before the procedure ended, the infusion of the study drugs was stopped. Patients were extubated after receiving intravenous neostigmine (0.05 mg/kg) and intravenous glycopyrrolate (0.01 mg/kg) and the throat pack was removed.

**Parameters monitored:**

- **Assessment of blood pressure, heart rate and the quality of the surgical field:** Blood pressure and heart rate were observed preoperatively, after induction, at 10-minute intervals during surgery, at extubation, 10 minutes after extubation and then every hour for the next six hours in the PACU. The interval between stopping the drug infusion and the response to verbal commands and eye opening was recorded as the emergence time.
- All patients were transferred to the Postanaesthesia Care Unit (PACU) after extubation and full recovery. The time of the first analgesia request was noted. Patients were monitored in the PACU and oxygen was administered via a face mask. Sedation levels were assessed using the Ramsay Sedation Scale and patients were transferred from the PACU once they achieved a modified Aldrete Score of 9 or higher.
- **Evaluation of the satisfaction level of the surgeon using Likert scale [12]:** This assessment was conducted by the surgeon during the surgery, in which satisfaction was given 1 to 5 scoring (5-excellent, 4-good, 3-satisfactory, 2-poor and 1-very poor).

- **Quality of the surgical field:** Bleeding in the operative field was assessed by the surgeon and graded according to the scale proposed by Fromme GA et al., [13].
- **Sedation was assessed using the Ramsay Sedation Score [14]:** Sedation scores were recorded at 15, 30 and 60 minutes after extubation.
- **Postanaesthesia recovery score:** This score was assessed using the Modified Aldrete Score [15]. The time required to achieve a Modified Aldrete Score of 9 or higher was recorded.
- **Postoperative analgesia:** The time at which the patient requested analgesia or complained of pain was noted. Patients were also observed for any complications, including nausea, vomiting, bradycardia or tachycardia, hypotension or hypertension, or any other complications during the first 24 hours after surgery in the PACU.

## STATISTICAL ANALYSIS

All data were entered using Microsoft Excel software and analysed using SPSS software version 17.0 for Windows. An unpaired Student's t-test was used to compare the mean values of various parameters between the two groups. The p-values <0.05 were considered statistically significant.

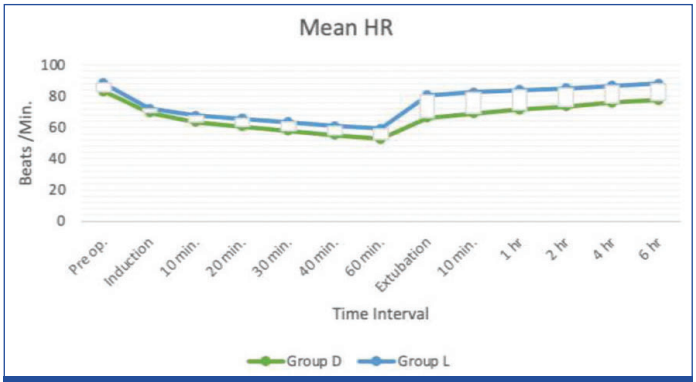
## RESULTS

The present study included 60 patients who were randomly allocated to either group L (labetalol) or group D (dexmedetomidine). Demographic data such as age, sex, weight and ASA physical status were compared between the groups [Table/Fig-2]. The mean age in group D was 42.96±11.52 years and in group L it was 47.33±10.97 years. In both groups (Group L: 53.3% and Group D: 60%), female patients were more prevalent than males, but the difference was not statistically significant (p-value >0.05). There was also no significant difference in weight and ASA grade between the two groups.

| Parameters | Group-D (n=30) | Group L (n=30) | p-value |
|---|---|---|---|
| Age (kg) (Mean±SD) | 42.96±11.52 | 47.33±10.97 | 0.596 |
| Weight (kg) (Mean±SD) | 59.12±8.01 | 57.33±10.97 | 0.677 |
| Gender (Male/Female) (n) | 12/18 | 14/16 | 0.679 |
| ASA status (I/II) (n) | 17/13 | 18/12 | 0.690 |
| Duration of surgery (min) (Mean±SD) | 98.58±5.55 | 111.30±7.23 | 0.773 |

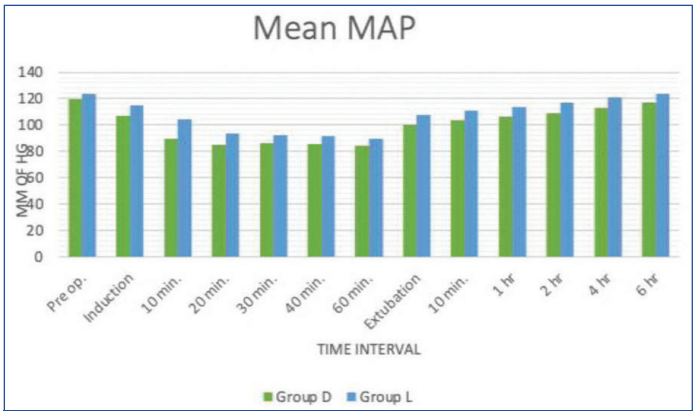
**[Table/Fig-2]:** Demographic characteristics.
Chi-square test, t-test

Heart rates were comparable between the two groups throughout the intraoperative period until the cessation of the drug (p-value=0.006). After intubation and 10 minutes later, the difference was not statistically significant. However, from 20 minutes to six hours postoperatively, the heart rate in the labetalol group was significantly higher than that in the dexmedetomidine group and this difference was statistically significant (p-value <0.0001) [Table/Fig-3].




**[Table/Fig-3]:** Mean heart rate among the study groups.

Mean arterial pressure was compared between the two groups preoperatively, after induction, at 10 minutes, 20 minutes, 30 minutes, 40 minutes and 60 minutes during surgery, at extubation, 10 minutes after extubation and then every hour for the next six hours. After induction, MAP was significantly higher in group L than in group D (106.63±6.094 vs 114.80±6.272). After extubation and for the next six hours, the MAP was significantly higher (p-value <0.0001) in the labetalol group compared to the dexmedetomidine group [Table/Fig-4].




**[Table/Fig-4]:** Mean arterial pressure among the study groups.

Surgeons experienced an ideal surgical field of grades 1 and 2 in 21 (84%) patients in group D, which was statistically significant between the two groups [Table/Fig-5].

| Grades of the surgical field | Group D, n | Group L n | p-value |
|---|---|---|---|
| **Quality of the field after 15 minutes of surgery** | | | |
| 0 | 0 | 0 | 1 |
| I | 2 | 1 | **0.006** |
| II | 19 | 11 | 0.064 |
| III | 9 | 18 | **0.0005** |
| IV and V | 0 | 0 | 1 |
| **Quality of the field after 30 minutes of surgery** | | | |
| 0 | 1 | 0 | 1 |
| I | 3 | 1 | **0.004** |
| II | 16 | 11 | 0.058 |
| III | 10 | 18 | **0.0001** |
| IV and V | 0 | 0 | 1 |

**[Table/Fig-5]:** Assessment of intraoperative bleeding by Boezaart score.
Chi-square test; The p-values in bold font indicates statistically significant values

During FESS, patients receiving dexmedetomidine infusion had a better surgical field compared to the labetalol group. The difference in bleeding at the surgical site was found to be statistically significant. In group D, nine patients had a very good score, 11 were good and 10 were moderate, while in group L, only one had a very good score and one had a bad score [Table/Fig-6]. The emergence time between the two groups (group D vs group L: 13.40±1.75 vs 7.97±1.56 minutes) and the time needed to achieve a modified Aldrete score of nine or more (15.67±1.788 vs 11.23±1.654 minutes) were significantly lower in the labetalol group. The comparison for emergence time showed statistical significance with higher values in group D than in group L. The time for rescue analgesia was significantly higher in group D than in group L (p-value <0.0001) [Table/Fig-7].

| Likert scale | | | | | |
|---|---|---|---|---|---|
| Groups | Very bad | Bad | Moderate | Good | Very good |
| Group D | 0 | 0 | 10 | 11 | 9 |
| Group L | 0 | 1 | 16 | 12 | 1 |

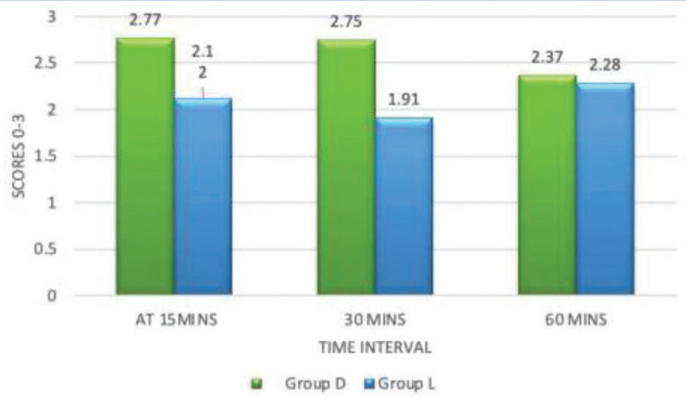
**[Table/Fig-6]:** Surgeon's satisfaction based on Likert scale.

Comparison between the two groups showed that sedation scores at 15 minutes (2.77±0.430 vs 2.12±0.490), p-value=0.002 and at

| Variables | Group D (n=30) | Group L (n=30) | p-value |
|---|---|---|---|
| Emergence time (min) (Mean±SD) | 13.40±1.75 | 7.97±1.56 | **<0.0001** |
| Aldrete's score (Time to achieve ≥9) (min) (Mean±SD) | 15.67±1.78 | 11.23 ±1.65 | **<0.0001** |
| Rescue analgesia (min) (Mean±SD) | 64.40±7.36 | 41.20±6.32 | **<0.0001** |

**[Table/Fig-7]:** Emergence time and Aldrete score, rescue analgesia among the study groups.
Student's t-test

30 minutes (2.75±0.45 vs 1.91±0.45), p-value <0.0001 after surgery were statistically significant in group D. At 60 minutes after surgery, the sedation score was 2.37 in group D and 2.28 in group L, which was not significant [Table/Fig-8].




**[Table/Fig-8]:** Ramsay sedation scores among the study groups.

During the study period, one patient experienced bradycardia in group D and two patients experienced hypotension in group L, but no medication was required for any of the patients. One patient experienced shivering and dryness of mouth in group D and none of the patients experienced nausea and vomiting [Table/Fig-9].

| Side-effects | Group D (n=30) | Group L (n=30) | Total % |
|---|---|---|---|
| Hypotension | 0 | 2 | 6.6 |
| Bradycardia | 1 | 1 | 3.3 |
| Nausea/Vomiting | 0 | 0 | 0 |
| Dryness of mouth | 1 | 1 | 3.3 |
| Shivering | 1 | 1 | 3.3 |

**[Table/Fig-9]:** Incidence of side-effects among study groups.

## DISCUSSION

Functional endoscopic sinus surgery is the most popular and frequently performed surgery in the Department of Ear, Nose and Throat (ENT). The most common complication of FESS surgery is bleeding, which is the main concern for anaesthesiologists. The technique of controlled anaesthesia used in endoscopic sinus surgery has greatly improved the quality of the surgical field and reduced blood loss and complications [14]. Several studies have been done concerning the efficacy of dexmedetomidine as a hypotensive agent, which is a highly specific alpha 2 adrenoreceptor. Dexmedetomidine has several advantages, including analgesic, sedative and anaesthetic-sparing effects [1,3,9,12,16].

In the present study, the demographic profile (age, gender and weight) and duration of surgery between the two groups were found to be statistically insignificant (p-value >0.05), as found in other studies [1,17]. Sujay JN et al., found no statistically significant difference between the two groups (dexmedetomidine and labetalol) in terms of demographic variables such as age, gender, duration of surgery and total anaesthesia time [1]. Malhotra SK et al., also found no statistically significant difference in age and sex between the dexmedetomidine and placebo groups in 72 patients 17.

In the present study, heart rate was found to be comparable between the two groups during the intraoperative period and until the cessation of the study drug (p-value=0.006). However, after 20 minutes, the heart rate in the labetalol group was significantly higher than in group D. Sujay JN et al., found a significantly lower heart rate in group D (70.8±4.2 beats/minute) compared to group L (73±4.4 beats/minute) intraoperatively and after two hours of discontinuation of the study drug [1]. On the other hand, Parvizi A et al., found no significant difference in heart rate between the dexmedetomidine and control groups in their study on 72 patients (p-value <0.05) [12].

In the present study, preoperative mean arterial pressure was statistically insignificant (p-value >0.05). However, after induction (106.63±6.094 vs 114.80±6.272) and during the intraoperative period, the mean arterial pressure was significantly higher in group L than in group D. At extubation (107.27±3.342 vs 100.47±3.350) and for the next six hours after extubation, the mean arterial pressure was significantly higher (p-value <0.0001) in the labetalol group compared to the dexmedetomidine group, which is highly statistically significant. Sajedi P et al., found that mean arterial pressure was higher in the labetalol group compared to the remifentanil group before and after induction and during the intraoperative period, but the difference was not statistically significant [11].

The quality of the surgical field was assessed using the Fromme and Boezaart scale and both labetalol and dexmedetomidine were effective in producing a good surgical field (average category scale=2) [13]. Surgeons experienced an ideal surgical field of grades 1 and 2 in 21 (84%) patients in group D, which was statistically significant between the two groups. Shams T et al., found no statistically significant difference in category score between the dexmedetomidine and esmolol groups in their study [18]. The mean scores at 15 minutes, 30 minutes, 45 minutes and 60 minutes in the dexmedetomidine and esmolol group were 2. In the study by Modir H et al., comparing labetalol and dexmedetomidine, labetalol (0.85±0.7) was found to be superior to dexmedetomidine (1.4±0.81) in terms of reducing intraoperative bleeding and improving the visualisation of the operative field [19].

In the present study, postanaesthesia recovery scores were assessed using a modified Aldrete score. The time to achieve a modified Aldrete score of ≥9 was significantly higher in the dexmedetomidine group (15.67±1.788) compared to the labetalol group (11.23±1.654) and this difference was statistically significant (p-value <0.0001). Similar results were obtained by Karabayirli S et al., who found that the time to reach an Aldrete score of 9-10 was higher in the dexmedetomidine group compared to the remifentanil group, although it was not statistically significant [20].

The sedation score was found to be statistically significant in group D and group L at 15 minutes (2.77±0.430 vs 2.12±0.490, p-value=0.002) and at 30 minutes (2.75±0.45 vs 1.91±0.45, p-value <0.0001) after surgery. However, there was no statistically significant difference at 60 minutes after surgery. Shams T et al., found that the sedation score at 15, 30 and 60 minutes postoperatively was significantly lower in the esmolol group (2.3±0.4) compared to the dexmedetomidine group (3.4±0.4) at 15 minutes and 30 minutes (2.2±0.5 vs 2.0±0.6) [18]. The time for rescue analgesia was significantly higher in group D compared to group L (64.40±7.36 vs 41.20±6.32, p-value <0.0001). Similar results were observed in Sujay JN et al., where the first analgesic request time was significantly longer in group D (50.20±9.15) compared to group L (24.87±5.13), which was highly significant (p-value <0.05) [1]. Side effects such as an undesirable decrease in heart rate, shivering and dryness of mouth were more common in group D compared to group L, but these differences were not statistically significant. In a study by Bayoumy AA et al., two cases of hypotension and five cases of bradycardia were seen in the dexmedetomidine group, but they were statistically insignificant [21].

## Limitation(s)

The limitations of the present study are that a quantitative assessment of blood loss could not be performed, invasive blood pressure monitoring was not conducted and the depth of anaesthesia and the effect of dexmedetomidine could not be assessed due to the unavailability of Bispectral (BIS) index monitoring.

# CONCLUSION(S)

Both labetalol and dexmedetomidine can be successfully used for induced hypotension in functional endoscopic sinus surgery. The present study demonstrates that dexmedetomidine is a safe and effective drug for achieving good surgical conditions when controlled hypotension is desired. Surgeons and anaesthetists are highly satisfied with the intraoperative use of dexmedetomidine as it reduces bleeding and maintains haemodynamic parameters. Additionally, it has the added advantage of providing sedation and analgesia while reducing the requirement for other anaesthetic agents compared to labetalol.

## Acknowledgement

The authors would like to express their gratitude to the ENT surgeons, Operation Theatre (OT) staff, patients and all the contributors to conduct the present study.

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**PLAGIARISM CHECKING METHODS:** [Jain H et al.]
- Plagiarism X-checker: May 20, 2023
- Manual Googling: Sep 22, 2023
- iThenticate Software: Nov 25, 2023 (18%)

**ETYMOLOGY:** Author Origin

**EMENDATIONS:** 10

**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: **May 19, 2023**
Date of Peer Review: **Aug 05, 2023**
Date of Acceptance: **Nov 28, 2023**
Date of Publishing: **Jan 01, 2024**