Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/n91j3n50

# INTRANASAL DEXMEDETOMIDINE IN OPTIMISING SURGICAL FIELD VISUALISATION DURING FUNCTIONAL ENDOSCOPIC SINUS SURGERY: RANDOMIZED CONTROLLED TRIAL

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## ABSTRACT

**Background:** FESS a common procedure in the field of ear, nose, throat medicine performed using fibreoptic endoscopy can cause serious adverse events if there is stress response to laryngoscopy and intubation and surgical site bleeding and can affect the postoperative outcome. This study compared the intranasally administered dexmedetomidine and normal saline alone on quality of the surgical field, bleeding and hemodynamic parameters during intubation, intraoperatively and postoperatively during FESS surgeries.

**Methods:** Eighty four patients undergoing FESS were randomly allocated to receive either intranasal dexmedetomidine (group D)(2 micro gram/kg) or 0.9% normal saline alone(group C) via dripping the drug into both nostrils in equal volume using 2ml syringe 15 mins before Induction. The primary objective was to study the quality of surgical field visualisation through endoscope and the blood loss that occurred. The secondary objective was to study the hemodynamic changes during laryngoscopy and intubation, side effects of intranasal Dexmedetomidine that is bradycardia and hypotension and the incidence of postoperative nausea, vomiting and sore throat.

**Results:** Surgical field visualisation, blood loss, hemodynamic profile during laryngoscopy and intubation and during surgery and postoperative outcome and satisfaction scores of patients and surgeons were significantly better ($p<0.05$) in dexmed group than control group.

**Conclusion:** Patients receiving intranasal dexmedetomidine for FESS had better surgical field and surgeon's satisfaction and minimal hemodynamic fluctuations with less bleeding with better postoperative outcome and analgesia.

**Key words:** Nasal dexmeditomedine, fess surgery, field visualization, haemodynamic stability.

## INTRODUCTION

Functional Endoscopic Sinus Surgery (FESS) is a minimally invasive technique aimed at restoring sinus ventilation, primarily used for patients with chronic or recurrent sinusitis unresponsive to medical treatment. Achieving optimal surgical conditions requires clear visualization, which can be compromised by intraoperative bleeding under general anaesthesia.[1,2,3,4] Controlled hypotension is

commonly employed to manage bleeding. Dexmedetomidine (DEX), a highly selective α2-adrenergic agonist, offers benefits including sedation, analgesia, and hemodynamic stability without respiratory depression and is more potent than clonidine. Intranasal administration of DEX provides rapid onset, high bioavailability, and fewer side effects than the intravenous route. Its peripheral effects are believed to be from local vasoconstriction or direct suppression of nerve impulse conduction in peripheral nerves.[4,5,6] It also blunts the stress response to laryngoscopy, reduces anaesthetic needs, and minimizes postoperative sore throat through its anti- inflammatory effects.[7] This study investigates the effectiveness of intranasal DEX in FESS under balanced anaesthesia, focusing on surgical field clarity, hemodynamic control, stress response, extubation time, postoperative nausea, sore throat, and any associated side effects, with the aim of improving surgical outcomes and surgeon's satisfaction.

## Aim & Objectives

### Aim

This study aims to evaluate the efficacy of intranasal Dexmedetomidine in optimisation of surgical field visualisation in functional endoscopic sinus surgery.

### Primary Objective

To study the optimisation of surgical field visualisation in functional endoscopic sinus surgery.

### Secondary Objective

- To study the hemodynamic changes following laryngoscopy and intubation.
- To study the side effects of intranasal Dexmedetomidine that is bradycardia and hypotension.
- To study the incidence of postoperative nausea, vomiting and sore throat.

## MATERIALS AND METHODS

The current Prospective Randomized control study was conducted in the department of anaesthesiology, Caritas Hospital, Thellakom, Kottayam for a period of one year from August 2022-February 2024, on Patients undergoing FESS under general anaesthesia at Caritas hospital, Thellakom, Kottayam, after getting ethical and scientific committee clearance and getting Informed consent.

### Inclusion Criteria

1. ASA 1&2
2. Patients of either sex
3. Age group 20-60
4. Patients undergoing FESS.

### Exclusion Criteria

1. Patient refusal
2. Patients undergoing emergency surgeries.
3. Obese individuals (BMI>30Kg/square metre).
4. Patients with known or anticipated difficult intubation.
5. Patients with heart rhythms other than sinus.
6. Patients with known allergy to Dexmedetomidine.
7. Patients on antihypertensive medications or preoperative drugs that could be Potential confounders (Clonidine, Gabapentin, Pregabalin, Steroids) or patients on Anticoagulants.
8. Patients on beta blockers, calcium channel blockers.
9. Patients with heart failure, cardiogenic shock, pulmonary hypertension, sick sinus Syndrome, Sinus bradycardia (HR<60), Systolic BP<100mmHg.
10. Renal disease, Hepatic disease.

11. Respiratory comorbities.
12. Patients with cardiovascular disease – ischemic heart disease, Sinus node Dysfunction, atrioventricular heart block.

**Sample Size**

Sample size was calculated as per formula

$$n = \frac{2S_p^2\left[Z_{1-\alpha/2} + Z_{1-\beta}\right]^2}{\mu_d^2}$$

$$= \frac{(12.0)^2 + (11)^2}{2}$$

$$= \frac{144 + 121}{2} \quad = 265 / 2 = 132.35$$

$$= \frac{2*132.35\ [1.96+0.84]^2}{52}$$

= 265.0 * 7.84 / (25.0) = 2077.6 / 25 = 83.10 = 84

Is the Minimum for one group so total for two group sample fix for this study is 76 minimum
$S^2p = [s12 + s22] / 2$
S1 =standard deviation of Group 1(SBP) = 12 S2=standard deviation of Group 2 = 11 Ud =Mean difference between ------5
α=significance level (0.05%)
1-β Power (80.0%)

**Materials Needed**

- Standard monitor to measure HR, NIBP, RR, SPO2, ECG
- DRUGS- Inj PANTOPRAZOLE, Inj METOCLOPROMIDE, Inj GLYCOPYRROLATE, Inj ONDANSETRON, Inj LIGNOCAINE, Inj FENTANYL, Inj PROPOFOL, Inj ATRACURIUM , Inj NEOSTIGMINE, SEVOFLURANE.
- All emergency drugs were kept ready.
- IV Fluids-Ringer lactate, isotonic normal saline.

**Methods**

After institutional ethical and scientific committee clearance, patients were evaluated during their preanaesthetic visit. Written informed consent were obtained from patients after explaining procedure to them. 84 patients with ASA Grade I and II electively posted for Functional Endoscopic Sinus Surgery under general anaesthesia by surgeon were allocated randomly into 2 groups, Group I and II as per randomisation method. Patients fasted as per standard Nil Per Oral (NPO) protocol and premedicated with Tab. PANTOPRAZOLE 40mg and Tab. PERINORM 10mg on previous night and morning of surgery with sips of water 2hrs prior to surgery.
The computed tomographic (CT) scans of all patients were reviewed before surgery by otorhinolaryngological surgeons. The Lund-Mackay (LM) CT score was obtained according to the degree of opacification of the involved sinus (0, no opacification; 1, partial opacification; or 2, obstruction) and the degree of obstruction of the osteomeatal complexes (0, no obstruction; 2, obstruction), which represented the severity of sinus disease. Patients with a total LM score greater than 12 are called high-LM score patients and those with a total LM score of 12 or less are called low-LM score patients.

After shifting the patient to operational theatre, ECG, NIBP, Pulse oximeter were connected and baseline values noted. Intravenous line was secured with desired cannula. RL/NS infused based on body weight of patient. Group I received the study drug dexmedetomidine 2microgram/kg. Intranasal drug was dripped into both nostrils in equal volume using a 2 ml syringe in supine head down position about 15 minutes before induction. The equivalent volume of 0.9% normal saline was administered intranasal to group II. All the patients were instructed not to suck or sneeze after Intranasal drug administration. Patient was asked to lie down in supine position for 15 minutes. After 15 minutes, premedication was given with 4mg i/v ONDANSETRON, 1mg MIDAZOLAM and 2microgram/kg FENTANYL. Induction of anaesthesia with i/v PROPOFOL 2mg/kg. After achieving adequate bag and mask ventilation, the patient was paralysed with an intubating dose of ATRACURIUM 0.5mg/kg. Airway was secured with appropriate size endotracheal tube. Depth of anaesthesia was achieved with SEVOFLURANE (0.8 – 1.2MAC), and 50% Air O2 mixture. The patient received mechanical ventilation with a tidal volume of 6ml/kg at a frequency of 10-12 bpm to provide ETCO2 of 32-35 mmHg. ECG, SBP, DBP, MAP, SPO2 noted at baseline, every 5 minutes after dexmedetomidine drug administration before intubation, at intubation, every 5 minutes after intubation till 15 minutes and then every 15 minutes till extubation. Throat pack was kept. The target mean blood pressure was maintained at 55-65 mmHg by adjusting SEVOFLURANE. Additional fentanyl boluses (0.5microgram/kg) were given if there was hemodynamic changes after intubation. A bolus of PHENYLEPHRINE (40-80microgram) was used if hypotension occurs. An intravenous bolus of 0.6mg of ATROPINE administered if HR <50bpm. Two squeezed cotton balls soaked in Epinephrine in a concentration of 1:80000 was inserted into each nasal cavity. All patients were positioned in 15degree reverse trendelenburg position for entire procedure. Estimated blood loss was calculated by subtracting the total irrigation volume used for the procedure from total amount of fluid in suction canister at the end of surgery. Immediately after surgery, surgeons rated surgical visibility scale (NRS), ranging from 0 to 10, with 0 defined as best condition and 10 as worst. Boezaart grading scale was used to rapidly evaluate intraoperative bleeding. Boezaart grading ranged from 0 to 5 as follows: 0, no bleeding; 1, slight bleeding: no suction of blood required; 2, slight bleeding: occasional suctioning required, surgical field not threatened; 3, slight bleeding: frequent suctioning required, bleeding threatens surgical field a few seconds after suctioning is removed; 4, moderate bleeding, frequent suctioning required, 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. The anaesthesia time defined as the time from anaesthesia induction to end of all surgical manipulation and withdrawal of all operative instruments.

At the end of surgery throat pack was removed after proper suctioning. After discontinuing SEVOFLURANE, muscle relaxation was reversed with Inj. NEOSTIGMINE (0.05mg/kg) and Inj. GLYCOPYRROLATE (0.01mg/kg). Extubation was done once patient awake, breathing spontaneously. Patients were then shifted to PACU for postoperative monitoring. Postoperative analgesia was given with INJ.PARACETAMOL Q8H. Rescue analgesia was given with Inj. FENTANYL Boluses (0.5microgram/kg). Any event such as coughing, hypotension, agitation, and Hypoxemia during emergence from anaesthesia was also recorded. Patients was asked about recalling intraoperative events or any sign of awareness. A research assistant collected data, including postoperative pain created by visual analogue scale (VAS) 30mins for the first 4 hrs then hourly upto 6 hrs, postoperative nausea and vomiting, sore throat and other discomforts till 6hrs after surgery.

## RESULTS

The demographic variables such as age, sex, and BMI were comparable between both groups. However, the duration of surgery and anaesthesia was significantly longer in the normal saline group than in the dexmedetomidine group ($p < 0.001$). Baseline heart rate and MAP were similar across groups, but heart rate remained significantly lower in the dexmedetomidine group at nearly all time

points ($p < 0.001$), indicating better hemodynamic stability. Systolic, diastolic, and mean arterial pressures were consistently lower in the dexmedetomidine group, with significant differences at all intervals ($p < 0.001$).

| | Normal Saline | | | Dexmedetomidine | | |
|---|---|---|---|---|---|---|
| | **n** | **Mean** | **SD** | **n** | **Mean** | **SD** |
| Age (Years) | 42 | 38.5 | 10.5 | 42 | 43.7 | 7.9 |
| BMI (Kg/cm2) | 42 | 19.9 | 3.4 | 42 | 21.6 | 1.2 |
| Duration Of Surgery (Minutes) | 42 | 168.69 | 8.70 | 42 | 138.10 | 11.10 |
| Duration Of Anesthesia | 42 | 190.24 | 15.38 | 42 | 148.81 | 10.47 |
| Intraoperative Fluid Administration (Litre) | 42 | 1.81 | 0.40 | 42 | 1.44 | 0.50 |
| Blood Loss (ML) | 42 | 132.26 | 13.49 | 42 | 83.45 | 14.79 |
| NRS | 42 | 6.12 | 1.25 | 42 | 8.14 | 0.61 |
| LUND MACKAY SCORE | 42 | 1.95 | 0.70 | 42 | 2.50 | 0.51 |
| VAS for pain sensitivity | 42 | 5.69 | 1.24 | 42 | 3.38 | 0.85 |
| Boezaart Score | 42 | 4.12 | 0.83 | 42 | 2.48 | 0.51 |

**Table 1: Demographic variables**

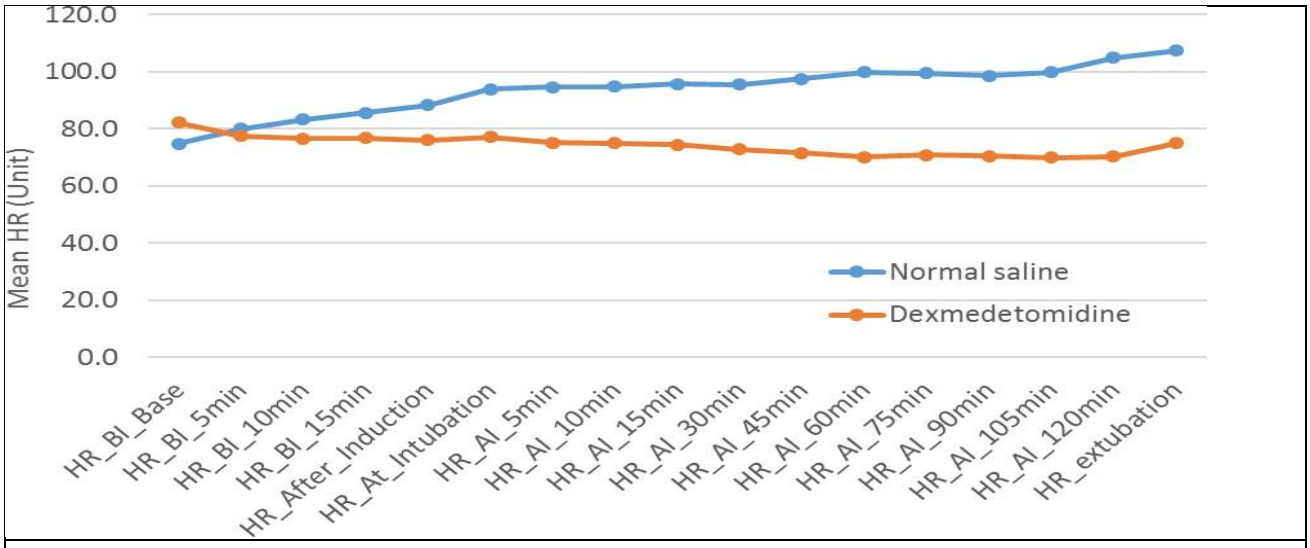


***Figure 1: Comparison of Heartrate between groups***

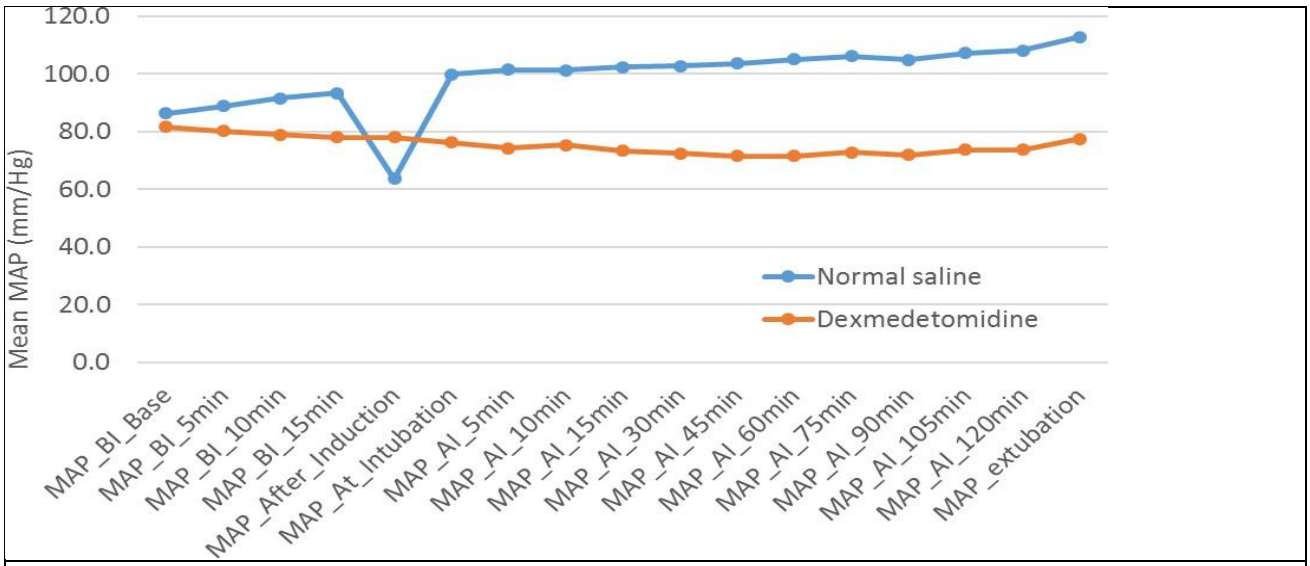


***Figure 2: Comparison of MAP between two groups***

Minimum alveolar concentration (MAC) values of sevoflurane were also significantly lower in the dexmedetomidine group across all time points, especially during intubation.
Only 21.4% of patients in the dexmedetomidine group required additional fentanyl, compared to 83.3% in the control group ($p < 0.001$), highlighting reduced intraoperative opioid needs.

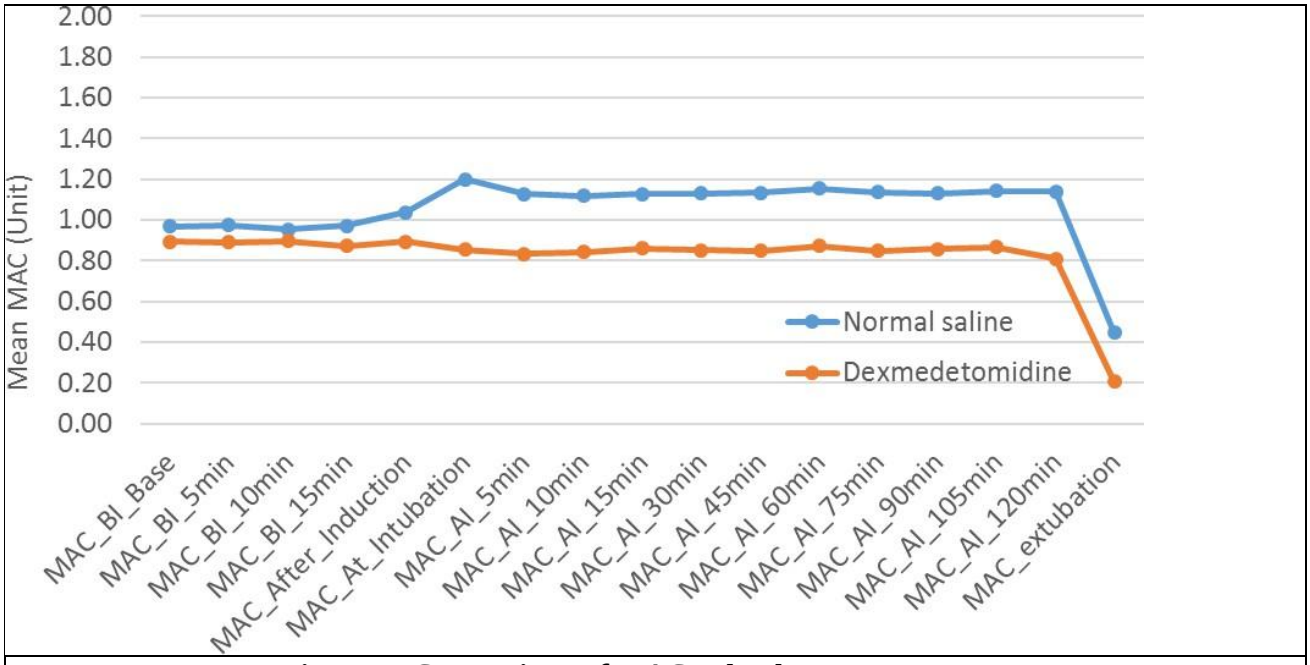


***Figure 3: Comparison of MAC value between two groups***

Blood loss was notably lower in the dexmedetomidine group (mean 83.45 ± 14.79 mL) than in the control group (132.26 ± 13.49 mL), which corresponded to a lower intraoperative fluid requirement (1.44 ± 0.5 L vs. 1.81 ± 0.4 L). Bleeding scores, assessed using NRS and Boezaart scores, were significantly better in the dexmedetomidine group (NRS: 8.14 ± 0.61, Boezaart: 2.48 ± 0.51) than in the control group (NRS: 6.12 ± 1.25, Boezaart: 4.12 ± 0.83). Interestingly, despite having a higher mean Lund-Mackay score (2.5 ± 0.51 vs. 1.95 ± 0.7), indicating more severe disease, the dexmedetomidine group still showed better surgical outcomes.
Postoperative pain, measured by the Visual Analogue Scale (VAS), was significantly lower in the dexmedetomidine group (3.38 ± 0.85) compared to the control group (5.69 ± 1.24). The incidence of intraoperative hypotension and bradycardia was lower in the dexmedetomidine group, and postoperative complications such as nausea, sore throat, coughing, and recall of intraoperative events were also significantly reduced ($p < 0.001$), indicating better overall patient comfort and recovery.

## DISCUSSION

This study aimed to evaluate the effectiveness of intranasal dexmedetomidine in improving surgical field visibility during Functional Endoscopic Sinus Surgery (FESS). It also assessed hemodynamic changes during laryngoscopy and intubation, as well as side effects like bradycardia, hypotension, postoperative nausea, vomiting, and sore throat. A total of 84 patients were divided into two groups: 42 received intranasal dexmedetomidine, and 42 received saline. Excessive bleeding in FESS can obscure the surgical field and increase complications. The study found that dexmedetomidine significantly reduced heart rate, mean arterial pressure, and the required minimum alveolar concentration of sevoflurane. It also improved surgical field quality, reduced the need for additional analgesics, and minimized emergence agitation. The findings support that intranasal dexmedetomidine effectively enhances surgical conditions in FESS by promoting hemodynamic stability and reducing bleeding.[1,8,9,10]

**Method Analysis**

Several studies have demonstrated the effectiveness of dexmedetomidine in improving surgical outcomes during Functional Endoscopic Sinus Surgery (FESS). Qiao et al.[1] Found that intranasal dexmedetomidine (2 mcg/kg) administered 15 minutes before induction improved surgical field visibility and reduced bleeding. Saritha Fernandes et al.[8] Reported that an infusion of dexmedetomidine (0.5 mcg/kg/hr) provided hemodynamic stability and reduced sevoflurane requirements. Both intravenous and intranasal routes have shown benefits due to sedative, analgesic, and anaesthetic-sparing effects. The intravenous administration of dexmedetomidine is associated with adverse effects such as hypotension, bradycardia, and prolonged recovery due to its sedative properties. In comparison, intranasal delivery offers a non-invasive, convenient, and effective alternative with rapid absorption, quick onset of action, and high bioavailability of 100%. Owing to its high lipid solubility, dexmedetomidine is well absorbed systemically when administered via the transmucosal route.[1,7,11] Kohaf et al[12] Noted that intranasal administration is simple and effective, though it requires earlier dosing due to slower onset. Chaoling et al[13] Observed that combining intranasal dexmedetomidine with local anaesthesia reduced perioperative stress and inflammation, enhancing postoperative comfort.

**Demographic Variables**

The dexmedetomidine and control groups were comparable in demographic characteristics, including gender, age, BMI, and ASA grade. Statistical analysis using the Chi-square test showed no significant differences in sex ($p=0.513$) or ASA status ($p=0.629$). While there were differences in age (Group D: 43.7±7.9 vs. Group C: 38.5±10.5, $p=0.012$) and BMI (Group D: 21.6±1.2 vs. Group C: 19.9±3.4, $p=0.003$), overall, the groups were considered demographically comparable for the study.

**Baseline Hemodynamic Variables**

Both groups were comparable in baseline hemodynamic parameters. Although baseline MAP (Group D: 81.5 ± 5.6 vs. Group C: 86.3 ± 4.6, $p<0.001$) and HR (Group D: 82.2 ± 5.2vs. Group C: 74.9 ± 5.7, $p<0.001$) showed statistical differences, these were not clinically significant. The findings align with previous studies where intraoperative dexmedetomidine infusion use showed similar baseline hemodynamic profile. (Saurav Das et al[14] Mahendran K et al,[15] Bajwa et al,[16] Bayoumy et al,[2] Eghbal et al,[3] Parvizi et al,[4] Bayram et al.[17]

**Intraoperative Hemodynamic Variables**

Group D (dexmedetomidine) showed more stable heart rate (HR) and mean arterial pressure (MAP) compared to Group C. HR remained significantly lower and stable in Group D from 5 minutes after drug administration through extubation, while Group C showed consistently higher HR and MAP, especially during and after intubation. MAP was also significantly lower in Group D throughout the surgery. Hypotension incidence was lower in Group D (11.9%) than in Group C (23.8%). These findings, consistent with studies by Qiao et al.[1] and Saritha Fernandes et al,[8] indicate that dexmedetomidine provides superior hemodynamic stability, resulting in reduced blood loss, improved surgical field visibility, and greater surgeon satisfaction.

**Intraoperative Rescue Analgesic and Anaesthetic Requirement**

In Group D, only 21.4% of patients required additional fentanyl, compared to 83.3% in Group C-a statistically significant difference. Group C also needed higher concentrations and MAC of sevoflurane to maintain anesthesia depth. Additionally, the total fentanyl dose was significantly lower in Group D. These findings, consistent with studies by Shams et al(9). and Qiao et al(1)., highlight dexmedetomidine's anesthetic-sparing effect and reduced opioid requirement.

**Incidence of Hypotension and Bradycardia**

Intraoperative hypotension was less frequent in Group D (11.9%) than in Group C (23.8%), though not statistically significant (p=0.154). Fewer patients in Group D required phenylephrine, and those who did responded well. No cases of bradycardia were observed in the dexmedetomidine group, indicating it maintained a stable heart rate at the given dose. These findings align with studies by Qiao et al[(1)]. and Saritha Fernandes et al[(8)]., supporting dexmedetomidine's role in maintaining hemodynamic stability and reducing blood loss during FESS.

**Duration of Surgery and Anaesthesia**

Duration of surgery was less in group D (138.1±11.1) compared to group C (168.7±8.7), p<0.001 similarly duration of anaesthesia was prolonged in group C (190.24±15.38) compared to group D (148.8±10.4, p<0.001. It was mainly due to decreased bleeding with improved surgical field visibility Lund-Mackay score has an association with difficulty in surgery and hence in duration of surgery and anaesthesia. Group D has a mean score of (2.5±0.51) compared to group C (1.95±0.7).Similar results were obtained in studies by Qiao et al[1] Saritha Fernandes et al,[2] Guven et al,[18] Das et al[19] where either intranasal or intravenous dexmedetomidine were used.

**Blood Loss and Intraoperative Fluid Requirement**

Reduced bleeding was seen in group D (83.5±14.8) compared to group C (132.3±13.5). p<0.001, which was statistically significant. It was mainly due to decreased heart rate in patients using dexmedetomidine. Similar results were obtained in a study conducted by Qiao Et al[(1)] where they used intranasal atomised dexmedetomidine for optimisation of the surgical field during FESS. Intravenous fluid requirement was more in group C (1.81±0.4) as compared to group D (1.44±0.5). More the blood loss more IV fluid boluses required. Similar results were obtained in studies by Qiao Et al[(1)], Saritha Fernandes et al.[8] Thus dexmedetomidine group has reduced bleeding due to vasoconstriction and reduced heart rate compared to the control group.

**Bleeding Scores**

Bleeding was assessed by the surgeon using numerical rating scale (NRS) and BOEZAART score. NRS was better in group D (8.14±0.61) compared to group C (6.12±1.25). Similarly Boezaart score was better in group D (2.48±0.5) compared to the control group (4.12 ±0.83). Similar results were obtained in other studies by Qiao et al, Kim et al[11] Gupta et al[6] Bajwa et al[16] Parvizi et al,[4] Kale et al,[20] Saurav et al,[14] Saritha Fernandes et al.[8]

**Effect on Post-Operative Events**

Post-Operative events like nausea, vomiting, coughing sore throat and recalling intraoperative events were less in group D as compared to group C.Postoperative coughing was found in 6 patients (14.3%) in Group D and 11 patients (26.2%) in Group C. Postoperative nausea was found in 7 patients (16.7%) in group D and in 18 patients (42.9%) in Group C. Postoperative sore throat was found in 6 patients (14.3%) in Group D and in 19 patients (45.2%) in Group C. Recalling intraoperative events was found in 5 patients (11.9%) in Group D and 12 patients (28.2%) in Group C. Liang et al[21] and Watcha M F et al[22] conducted similar studies and found that dexmedetomidine has reduced postoperative adverse events. It was mainly due to decreased consumption of intraoperative opioids.

**Effect on Post-Operative Pain**

VAS scores were better in dexmedetomidine group D (3.38±0.85) compared to group C (5.7±1.24). Hence it is a better one for postoperative analgesia. Bafna et al[5] conducted similar study and found that intraoperative use of dexmedetomidine can be used for postoperative analgesia.

## CONCLUSION

Intranasal dexmedetomidine significantly improves surgical field clarity and hemodynamic stability in patients undergoing FESS. Its safety, ease of administration, and ancillary benefits such as reduced postoperative complications make it a valuable premedication option in sinus surgeries.

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