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Comparative evaluation of propofol versus dexmedetomidine infusion for hypotensive anesthesia during functional endoscopic sinus surgery: a prospective randomized trial

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Background: During functional endoscopic sinus surgery (FESS), intranasal bleeding affects operative field visibility and increases the frequency of complications. Therefore, hypotensive anesthesia is a widely used technique to improve surgical outcomes. This study aimed to compare the efficacy of propofol and dexmedetomidine infusion for hypotensive anesthesia in patients undergoing FESS.

Methods: This prospective randomized trial was conducted in 80 adult patients who were scheduled for FESS under general anesthesia. Patients were randomly divided into two groups: group P (n = 40) received propofol infusion of 100–200 μg/kg/min and group D (n = 40) received dexmedetomidine infusion with a loading dose of 1 μg/kg over 10 min after induction, followed by maintenance infusion of 0.4–0.8 μg/kg/h. Intraoperative blood loss, quality of the surgical field (Fromme- Boezaart scale), hemodynamic control, and patient recovery were recorded. Statistical analysis was performed using Student's t-test, chi-square test, and Mann–Whitney U test.

Results: The mean arterial pressure and heart rate were significantly lower in group D throughout the surgery than in group P. Blood loss was significantly higher in group P (100.73 ± 18.12 ml) than in group D (85.70 ± 18.56 ml). The average number of patients with Fromme's score 1/2/3 was comparable between the groups. Intraoperatively, only one incidence of bradycardia and hypotension was observed in group D (2.5%) compared to group P.

Conclusions: Both dexmedetomidine and propofol are efficacious and safe drugs for facilitating controlled hypotension during FESS; however, dexmedetomidine provides better hemodynamic control and is associated with lesser blood loss without any significant adverse effects.

Keywords: Dexmedetomidine; Functional endoscopic sinus surgery; Induced hypotension; Propofol.

INTRODUCTION

Functional endoscopic sinus surgery (FESS) is a highly sophisticated surgery that has reformed the surgical management of chronic sinusitis in the modern era. The term FESS was first coined by Kennedy [1] and introduced in the mid-1980s. Although it has been associated with a higher success rate in medically refractory chronic rhinosinusitis and chronic polypus rhinosinusitis for symptomatic improvement, the potential for serious complications, such as nasolacrimal duct damage, intraorbital or intracranial hemorrhage, optic nerve damage, and cerebrospinal fluid leak, has shadowed the efficiency of this surgical procedure [2]. The risk of complications associated with FESS mainly depends on the endoscopic visibility of the anatomical structures of the paranasal sinuses, extent of sino-nasal disease, and surgeon's experience. The main hindrance to clear endoscopic visibility is excessive bleeding during surgery [3]. Hence, it is essential to keep the surgical field as free of blood as possible, which can be achieved through the reverse Trendelenburg position, preoperative steroid administration, topical local anesthetics and vasoconstrictors such as phenylephrine, and controlled hypotension through various anesthetic techniques [4].

Progress in surgery is dependent upon advances in the field of anesthesia, and hypotensive anesthesia as an adjuvant to surgery is an excellent example of this interdependence. Controlled hypotension or hypotensive anesthesia is an anesthetic technique in which there is deliberate reduction in systemic blood pressure during anesthesia, which should be in accordance with the patient's baseline blood pressure rather than a specific target pressure. The mean arterial blood pressure (MAP) can be reduced by 30% below the patient's baseline MAP, with a minimum MAP of 60–70 mmHg in American Society of Anesthesiologists class 1 patients being clinically acceptable [5]. However, lowering the blood pressure carries its own risks, including insufficient blood flow to the brain, hypoxia, delayed awakening, permanent brain damage, and death. Various agents such as inhalational anesthetics, β-blockers, nitroglycerine, sodium nitroprusside, and magnesium sulfate have been routinely used for controlled hypotension but with limitations due to its reported disadvantages, including delayed recovery from inhaled anesthetics, resistance to vasodilators, and cyanide toxicity for nitroprusside [6]. To achieve controlled hypotension, certain agents must have desirable features, including ease of administration, faster onset time, quicker offset time

on termination, rapid elimination without toxic metabolites, negligible or no effects on vital organs, and predictable dose-dependent effects [7].

Intravenous α-2 agonists have potentially favorable effects, such as hypotension, analgesia, and sedation, and also show better hemodynamic stability due to their central sympatholytic actions. Moreover, due to its analgesic and anesthetic sparing effects, clonidine and dexmedetomidine have been used in anesthetic practice to achieve controlled hypotension [8]. The use of propofol for induction and as part of total intravenous anesthesia (TIVA) has been popularized in the modern era, and it is one of the most common intravenous anesthetic agents [9,10]. Due to its rapid onset and offset time together with one of the useful side effects, that is, hypotension, the use of TIVA, including propofol and remifentanil, has become a common technique to provide hypotensive anesthesia in Western countries [10,11]. However, in India, due to the nonavailability of remifentanil, the use of propofol alone has been attempted for hypotensive anesthesia. Hence, this study aimed to compare the effectiveness and safety of propofol and dexmedetomidine infusion for hypotensive anesthesia in terms of intraoperative blood loss as the primary outcome and quality of the surgical field, hemodynamic stability, and postoperative recovery as secondary outcomes in patients undergoing FESS. Here, we hypothesized that the use of dexmedetomidine for hypotensive anesthesia during FESS would be more efficacious than the use of propofol.

MATERIALS AND METHODS

This prospective, randomized, double-blind, clinical trial was conducted from July 2018 to September 2019 as per the Indian Council of Medical Research guidelines for biomedical research in human subjects and in accordance with the principles of the Declaration of Helsinki (2013). After obtaining Institutional Ethical Committee (no. ECR/836/Inst/PB/2016) approval dated 13/02/18 and registering the trial with the Clinical Trial Registry of India (no. CTRI/2018/07/014746), this study was conducted on 80 adult patients with American Society of Anesthesiologists grade I or II, of either sex, and aged between 18 and 50 years who were scheduled for elective FESS. Written informed consent was obtained from all patients. Patients with a history of uncontrolled hypertension, autonomic neuropathy, American Society of Anesthesiologists physical status III or IV, hepatorenal dysfunction, coagulation disorders, recurrent sinus surgery, and hyper-

sensitivity to study drugs and pregnant patients were excluded from the study. A total of 80 patients were randomly allocated into two groups (40 patients each) using a computer-generated randomization program in a simple randomization manner (Fig. 1). Eighty sealed envelopes were prepared comprising two drug codes (40 each), that is, P and D, for concealment of randomization by a designated consultant (not included in the study protocol), who opened it just before the start of the study and prepared all the drugs in identical syringes as per the code in the envelope. Double blinding was performed in such a manner that the anesthesiologist who recorded the study variables was blinded, and a different anesthesiologist administered the anesthesia. The attending anesthesiologists kept a record of the patients along with the codes of the syringes given to them, which were divulged on completion of the study in all 80 cases. A routine preanesthetic checkup was performed a day before surgery, and all eligible patients were advised preoperative fasting for a minimum of 6 h and were premedicated with

0.25 mg alprazolam tablet and 150 mg ranitidine tablet orally at night and in the morning (2 h before) on the day of surgery.

After transporting the patient to the operating room, a multipara monitor with noninvasive blood pressure, five-lead electrocardiography, and pulse oximetry trackers was attached, and baseline parameters were recorded. Two intravenous lines with 18- or 20-gauze intravenous cannulas were secured at two different positions, one of which was used for infusion of the study drug and another for infusion of intravenous fluid or other anesthetic drugs. All patients were administered intravenous morphine 0.1 mg/kg for analgesia and glycopyrrolate 0.004 mg/kg as an antisecretory agent. After preoxygenation, induction was performed with intravenous propofol 1.5–2.5 mg/kg until loss of eyelash reflexes, and tracheal intubation was achieved under intravenous vecuronium 0.1 mg/kg. Anesthesia was maintained with one minimum alveolar concentration of isoflurane with nitrous oxide and oxygen mixture (60:40), and the top-up
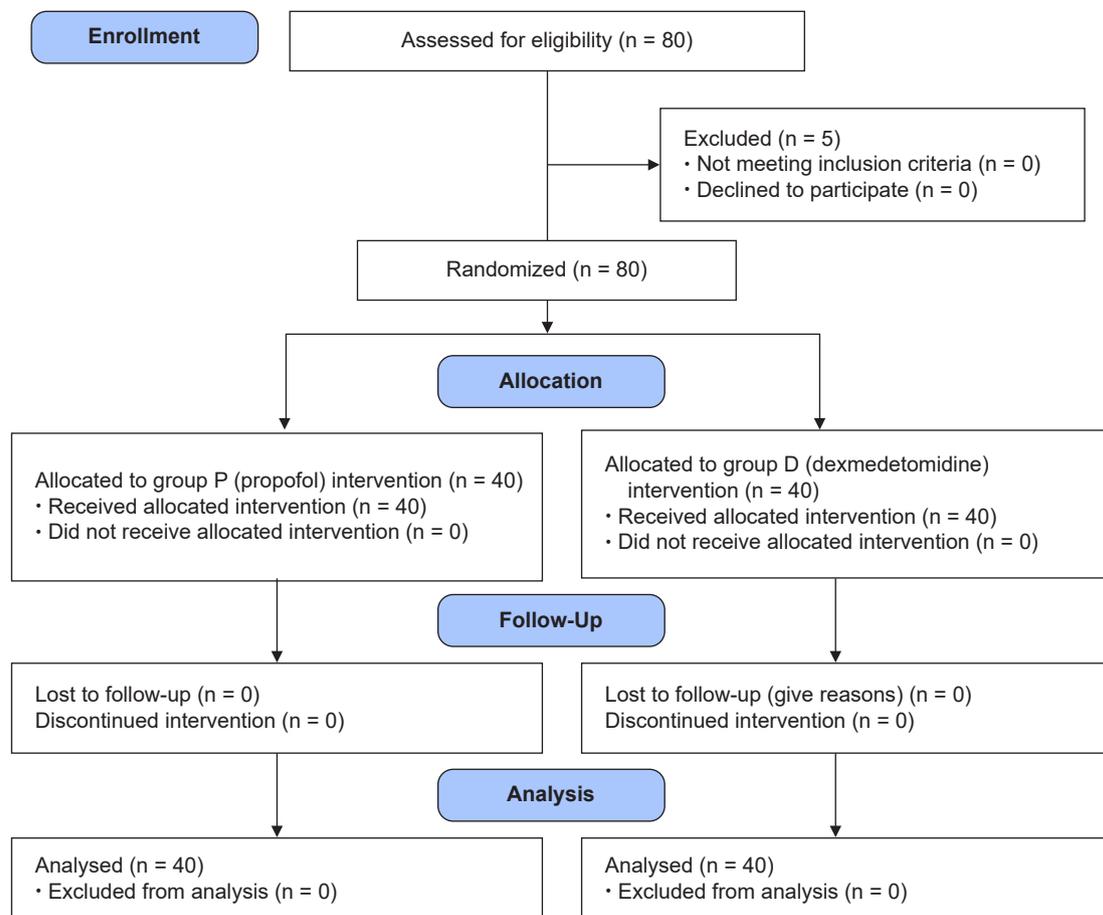

Fig. 1. CONSORT flow diagram. CONSORT: consolidated standards of reporting trials.

doses of vecuronium were given as and when required to maintain muscle relaxation. All patients in group P received propofol infusion of 100– 200 µg/kg/min after induction of anesthesia, and those in group D received a loading dose of dexmedetomidine at 1 µg/kg over 10 min after induction of anesthesia, which was followed by a maintenance infusion of 0.4–0.8 µg/kg/h. The infusion rate of the study drugs was regulated in both groups to maintain a mean arterial blood pressure between 60 and 70 mmHg. To further reduce the amount of surgical bleeding, lignocaine (1%) with 1:100,000 adrenaline was infiltrated at the surgical site by the surgeon in all patients. The surgeon was allowed to start surgery only after 10 min of starting the infusion in both groups. Intraoperative hemodynamic parameters such as heart rate (HR), systolic blood pressure, diastolic blood pressure, MAP, and oxygen saturation (SpO_2) were recorded at baseline, during induction, 5 min after induction, and every 5 min thereafter until the end of surgery. HR < 50 beats/min was considered bradycardia and managed with 0.5 mg atropine intravenously. MAP < 60 mmHg (significant hypotension) was initially managed by titrating the dosage of infusion and further stoppage of infusion if no response was obtained, and then mephentermine 6 mg intravenously was administered to treat hypotension. The study drug was discontinued 5 min before the end of surgery. The residual neuromuscular blockade was reversed with intravenous neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg, and extubation was performed when the patient was fully awake and breathing regularly with adequate tidal volume. Recovery time, that is, time taken from cessation of anesthesia until the patient obeyed verbal commands, was noted at every 2-min interval. The duration of surgery was also recorded. The volume of intraoperative blood loss was estimated on the basis of the volume of blood in the suction bottle minus the irrigation fluid and the volume of the total blood-soaked patties (5 ml for each soaked patty). In the present study, one otorhinolaryngology surgeon consented to perform FESS in every patient, and he was informed about the grading of the surgical field preoperatively. The surgeon was blinded to the information on the anesthesia drug being investigated, and he provided numerical assessments of the operative conditions with respect to the amount of bleeding and its effect on visibility based on the scale described by Fromme et al. [12] and Boezaart et al. [13]. The visibility of the surgical field was scored as follows: 0 = no bleeding; 1 = slight bleeding, blood evacuation not necessary; 2 = mild bleeding, occasional suctioning without interference of the surgical field; 3

= moderate bleeding, suctioning usually used (bleeding threatens the surgical field but improves after suctioning); 4 = heavy bleeding, suctioning is frequently used (bleeding threatens the surgical field directly after suction is removed); and 5 = severe bleeding (bleeding appears faster than suctioning and is uncontrollable). Perioperative complications, such as hypotension, hypertension (MAP > 90), tachycardia (HR > 100/min), bradycardia, or hypoxemia (SpO_2 < 94%), and sedation were also noted.

Statistical analysis

Prior to the study, a power analysis was performed to calculate the necessary number of patients in each group based on intraoperative blood loss (primary outcome) where 10 pilot cases were conducted in each group (not included in the study), and it was found that intraoperative blood loss was 80 ± 15.25 ml and 103 ± 14.25 ml in groups D and P, respectively. Therefore, for better validity of the results, a maximum of 40 patients per group were enrolled, with a power of 80%, alpha error of 0.05, and beta error of 0.2. After completion of the study, data were compiled and analyzed usingthe Statistical Package of Social Sciences (version 17.0, SPSS Inc., USA). The Kolmogorov–Smirnov test was used to verify the normal distribution of continuous variables. Continuous variables are expressed as mean ± standard deviation. Normally distributed continuous variables were compared using Student's unpaired t-test. Categorical data were analyzed using the chi-square test or Fisher's exact test, as appropriate. Statistical significance was set at P < 0.05.

RESULTS

Regarding demographic parameters including age, sex, weight, American Society of Anesthesiologists I/II status, and duration of surgery, both groups were comparable without any statistically significant difference (Table 1). Intraoperatively, the estimated mean blood loss during FESS was 85.70 ± 18.56 ml in group D as compared to 100.73 ± 18.12 ml in group P, and this difference was highly significant (P = 0.001) (Fig. 2). The mean HR and MAP in group D were lower than those in group P at almost all-time intervals intraoperatively, and these differences were statistically significant except preoperatively and during induction (Figs. 3, 4). Moreover, both HR and MAP were significantly decreased (P < 0.05) in both groups after administering a loading dose of the study drugs as compared to baseline. Regarding visibility

Table 1. Demographic Data and Duration of Surgery

Variable	Group D (n = 40)	Group P (n = 40)	P value
Age (yr)	36.18 ± 2.54	38.30 ± 7.42	0.060
Weight (kg)	63.45 ± 8.16	66.57 ± 8.48	0.167
Duration of surgery (min)	109.50 ± 9.11	110.45 ± 10.02	0.179
Sex (M/F)	19/21	20/20	0.689
ASA physical status (I/II)	36/4	35/5	0.732

Values are presented as mean ± SD or number only. ASA, American Society of Anesthesiologists physical status. P > 0.05, not significant.
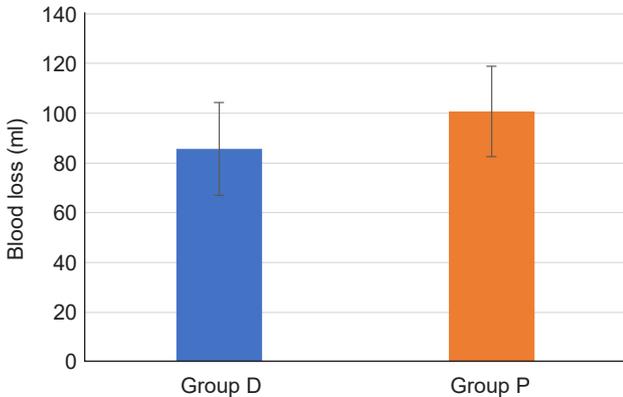
Fig. 2. Intraoperative mean blood loss (ml). Values are presented as mean ± SD.

of the surgical field, both groups were comparable with Fromme's score of 1 in 10% of patients, 2 in 65% of patients, and 3 in 25% of patients in group D and a score of 1 in 2.5% of patients, 2 in 70% of patients, and 3 in 27.5% of patients in group P with a mean Fromme–Boezaart score of 2.10 ± 0.44 and 2.28 ± 0.52 in groups D and P, respectively, and this difference was statistically insignificant (P > 0.05) (Table 2). The recovery time was comparable in both groups with duration of recovery of 29.90 ± 1.92 min in group D and 29.12 ± 2.52 min in group P (P > 0.05). Intraoperatively, only one incidence of bradycardia and hypotension was observed in group D (2.5%) compared to that in group P, which was managed successfully. Postoperatively, no significant adverse effects were observed in either group, except sedation in group D (2.5%), which was statistically and clinically insignificant.

DISCUSSION

For half a century, controlled hypotension has been used to provide a satisfactory surgical field and reduce bleeding with less need for blood transfusions in oromaxillofacial surgery, endoscopic sinus or middle ear microsurgery, spinal surgery, neurosurgery (aneurysm), and major orthopedic surgery (hip or knee replacement, spinal). Newer agents and techniques have recently been evaluated for their ability to induce effective hypotension without impairing the perfusion of vital organs. During FESS, bleeding from the sinuses is an important problem. Therefore, controlled hypotension has a definitive role in FESS, as it reduces bleeding during surgery and improves visibility of the surgical field. In the present study, a target range of MAP of 60–70 mmHg was used to achieve controlled hypotension in FESS, as performed by Aujla et al. [14] and Bajwa et al. [15], without any significant perioperative adverse effects.

Several studies have compared dexmedetomidine with other agents for hypotensive anesthesia, but very few have directly compared it with propofol, especially in FESS. Moreover, continuous infusion of dexmedetomidine or propofol was used in a specific dose range, whereas previous studies mainly used bolus doses or fixed-dose infusions. We have used a loading dose of dexmedetomidine of 1 µg/kg over 10 min, followed by a maintenance dose of 0.4–0.8 µg/kg/h, as similar doses were used by Shams et al. [16] for controlled hypotension in the FESS. In our study, a 100–200 µg/kg/min dose of propofol infusion was used, as Ankichetty et al. [9] also used propofol 200 µg/kg/min as loading dose and 133 µg/kg/min as maintenance dose in FESS patients to achieve controlled hypotension. In another study by Salama [17], propofol infusion was administered at a loading dose of 200 µg/kg/min followed by 100 µg/kg/min as the maintenance dose. Therefore, a range of doses was chosen for both drugs, so that infusion can be titrated according to the target MAP value and adequate surgical field exposure could be maintained.

In our study, both drugs for hypotensive anesthesia were compared with respect to blood loss during surgery, quality of the surgical field (Fromme's score), hemodynamic control, recovery time, and any other significant adverse effects. We found that although controlled hypotension was achieved
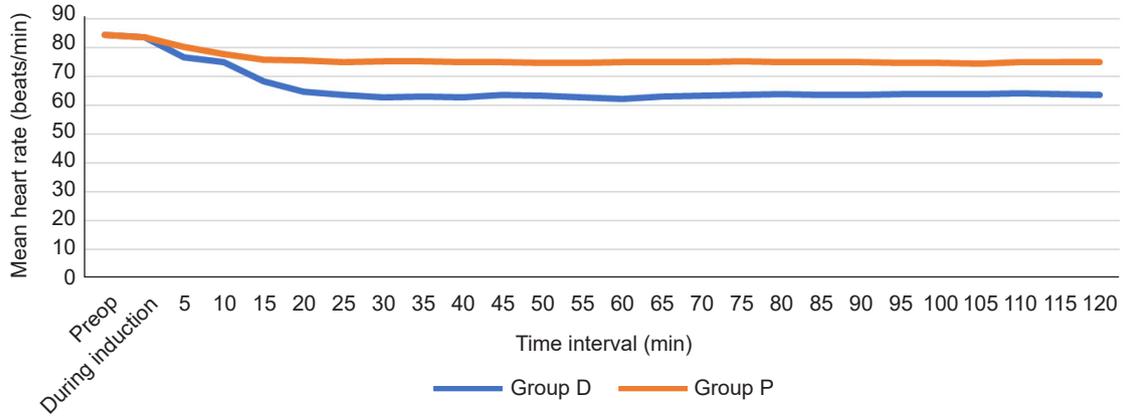
**Fig. 3.** Intraoperative heart rate (beats/min).
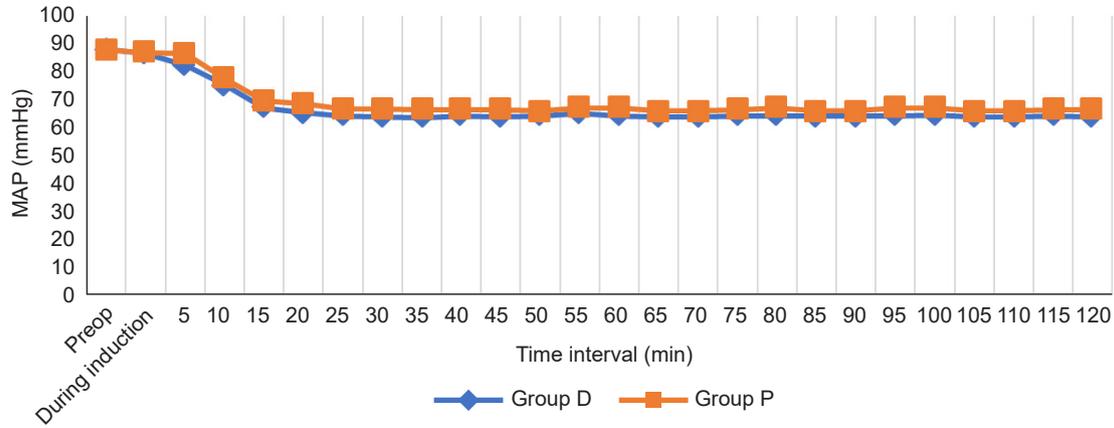
Fig. 4. Intraoperative mean arterial pressure (MAP) (mmHg).

Table 2. Surgical Site Visibility Scoring Using the Fromme–Boezaart Scale

Score	Group D (number of patients)	Group P (number of patients)	P value (Mann–Whitney U test)
0	0	0	0.103
1	4	1	
2	26	28	
3	10	11	
4	0	0	
5	0	0	

P > 0.05, not significant.

with both drugs, dexmedetomidine produced a more stable hemodynamic with lower readings of MAP and HR as compared to that of propofol; moreover, the target MAP range, i.e., 66.85 ± 1.63 mmHg in group D and 69.38 ± 1.69 mmHg in group P, was achieved after 15 min of infusion onwards. Similarly, a study conducted by Shah and Kulkarni [18] observing hemodynamic stability and operative field visibility in 60 patients undergoing FESS using dexmedetomidine and propofol infusion identified that the dexmedetomidine group

showed better hemodynamic control with a lower HR and MAP compared to that in the propofol group. Bajwa et al. [15] also compared the efficacy of infusion of three different drugs (nitroglycerine, esmolol, and dexmedetomidine) and found that the mean HR was significantly lower (P < 0.05) in the dexmedetomidine group than that in the other two groups.

The present study also found that intraoperative blood loss was significantly lower in the dexmedetomidine group than that in the propofol group. Similarly, Vineela et al. [19]

and Somayaji and Raveendra [20] also found lesser blood loss with the use of dexmedetomidine during FESS. In another study, Ahn et al. [21], who used and compared target-controlled infusion of propofol versus sevoflurane (1–3%) with continuous remifentanil infusion at 0.2 μg/kg/min in endoscopic sinus surgery, observed significant reduction in blood loss with propofol compared with sevoflurane. Consequently, we observed that blood loss was decreased in both groups (dexmedetomidine and propofol) individually as well as in combination; therefore, we compared both drugs for their usefulness in reducing blood loss during FESS. A recent study by Bharathwaj and Kamath [22] also compared dexmedetomidine and propofol infusion for controlled hypotensive anesthesia in 80 patients undergoing FESS and found that blood loss was 83.75 ± 14.80 ml in the dexmedetomidine group compared to that in the propofol group where it was 96.25 ± 16.12 ml. These results are in concordance with the present study but differ in that they used fixed dosages for infusions (dexmedetomidine, loading dose 0.5 μg/kg for 20 min, maintenance dose 0.3 μg/kg/h, and propofol, started at 12 mg/kg/h for 10 min, then at 10 mg/kg/h for the next 10 min, and a maintenance dose of 8 mg/kg/h). Similarly in a study done by Shah and Kulkarni [18], blood loss was also significantly lower in the dexmedetomidine group (81.67 ± 27.95 ml) than in the propofol group (100.67 ± 32.47 ml). However, they used dexmedetomidine (0.5 μg/kg/h) and propofol (100 μg/kg/min) infusion for maintenance only without any loading dose of dexmedetomidine.

In this study, the quality of surgical field exposure was assessed using the Fromme–Boezaart scoring system and was found to be comparable in both groups. These results are in agreement with those of the study conducted by Bharathwaj and Kamath [22]. In another study of dexmedetomidine–isoflurane and propofol–fentanyl for FESS in 60 patients, a Fromme's score of 2 or 3 was found in both groups, with no statistically significant difference [23]. However, a study done by Shah and Kulkarni [18] observed a better Fromme's score in the dexmedetomidine group with a mean value of 1.7 compared to a mean value of 2.2 in the propofol group, and this difference in mean Fromme's score in the dexmedetomidine group from our study may be due to the no fixed target range of MAP. The recovery time in our study was comparable in both groups, similar to the study by Moshiri et al. [24]. Regarding adverse effects, a single episode of intraoperative bradycardia and hypotension was noted in the dexmedetomidine group (2.5%) than that in the propofol

group, which was statistically insignificant. This was similarly observed in a study by Shah and Kulkarni [18], in which 2 of 60 patients developed bradycardia in the dexmedetomidine group and managed successfully. No other incidences of hypotension, hypertension, or hypoxemia occurred in the present study.

This study has a few limitations. First, invasive monitoring for the MAP, which was not done in the present study, can be used as a sensitive marker for monitoring hypotensive anesthesia; however, a recent study concluded that it does not aid in achieving lower target blood pressures [25]. Second, the method of blood loss measurement could be improved in the present study by performing calculations based on hemoglobin values and total volume in the suction canister, as done by Ahn et al. [21]. Third, the present study used a target range of MAP (60–70 mmHg) to achieve controlled hypotension. However, it is sometimes recommended that hypotensive anesthesia needs to be adjusted in relation to the patient's preoperative blood pressure and be limited to the level necessary to reduce bleeding in the surgical field; however, how best to characterize controlled hypotension still remains unclear.

Both dexmedetomidine and propofol are efficacious and safe drugs for facilitating controlled hypotension during FESS in terms of improved surgical field, hemodynamic stability, and reduced blood loss; however, dexmedetomidine provides better hemodynamic control and is associated with lesser blood loss without any significant adverse effects.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analyzed during the current study are available from the corresponding author

on reasonable request.

AUTHOR CONTRIBUTIONS

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