Section: Anaesthesiology

Original Research Article

A PROSPECTIVE RANDOMIZED CONTROL STUDY BETWEEN INTRAVENOUS CLONIDINE AND DEXMEDETOMIDINE AS PREMEDICATION FOR INDUCED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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ABSTRACT

Background: Functional Endoscopic Sinus Surgery (FESS) often requires a bloodless field to optimise visibility. Controlled hypotension with alpha-2 agonists, such as clonidine and dexmedetomidine, is commonly used to achieve this. **Objective:** To compare the efficacy of intravenous clonidine and dexmedetomidine as premedication for induced hypotension in adult patients undergoing FESS, evaluating surgical field quality, surgeon satisfaction, patient recovery, and adverse effects. **Materials and Methods:** Sixty ASA I/II patients scheduled for FESS were randomly allocated to two groups. Group A received intravenous dexmedetomidine (1 µg/kg), and Group B received intravenous clonidine (2 µg/kg), both administered 15 min before induction. The intraoperative mean arterial pressure was maintained between 50 and 70 mmHg using isoflurane titration. The parameters assessed included the Fromme-Boezaart surgical field score, heart rate, blood pressure, isoflurane requirements, sedation scores, and awakening time. **Result:** Both groups were comparable in terms of demographic characteristics. Group A showed a significantly better Fromme-Boezaart score (1.8 ± 0.66 vs. 2.43 ± 0.68), shorter awakening time (5.23 ± 1.33 min vs. 8.6 ± 1.67 min), and reduced isoflurane requirement. Heart rates were similar during surgery, except for post-extubation, where Group A had higher rates. The mean arterial and diastolic pressures were significantly lower in Group A, whereas the systolic pressures were comparable. No adverse reactions were reported. **Conclusion:** Intravenous dexmedetomidine provided more effective hypotensive anaesthesia than clonidine, enhancing surgical field quality, reducing anaesthetic requirements, and improving recovery profile. Dexmedetomidine may be preferred as premedication for induced hypotension in FESS, with good safety and surgeon satisfaction.

INTRODUCTION

A minimally invasive technique called functional endoscopic sinus surgery (FESS) fixes damaged sinus structures to enhance drainage and ventilation. Successful surgery depends on having a clear view of the complicated anatomy of the sinuses and nose, but bleeding from the highly vascular nasal lining frequently makes this impossible.[1] To ensure sufficient lighting, magnification, and access during FESS, a surgical field that is almost bloodless is necessary.[2] For this reason, controlled hypotension—which entails purposefully lowering the mean arterial pressure (MAP) to between 50 and 70 mmHg—has emerged as a crucial anaesthetic technique to lessen bleeding during surgery.[3] Controlled hypotension reduces bleeding, enhances visibility, and allows the surgeon's work by lowering the blood flow pressure in the nasal lining. This shortens the duration of the procedure and minimises associated complications.[4] If the proper patients are selected and careful monitoring is maintained at all times, this approach is both safe and effective.

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Among the drugs that can cause controlled hypotension are beta-blockers, vasodilators, alpha-2 adrenergic agonists, and inhalational anaesthetics.[6] Of these, clonidine and dexmedetomidine received the most attention due to their interactions with central alpha-2 adrenergic receptors.[7] By reducing sympathetic nervous activity and peripheral resistance, these drugs lower systemic blood pressure.[8] They also have pain-relieving and sedative qualities that may facilitate a quicker recovery and stable vital signs.[9] When used as premedication, clonidine and dexmedetomidine can support a smooth induction of anaesthesia, reduce the stress response to laryngoscopy and intubation, and help maintain controlled hypotension during surgery, all of which could enhance the quality of the surgical field.[10]

Because clonidine and dexmedetomidine have similar mechanisms of action but differ in strength, selectivity, and side effects, there is ongoing discussion about which premedication is best for FESS.[7] Despite their widespread use, there is a lack of research directly comparing the use of these medications for controlled hypotension during FESS. Understanding how these drugs differ in their effects on the surgical field, surgeon satisfaction, recovery profile, and adverse events is essential for supporting four clinical decisions.[3]

A prospective randomised controlled study was carried out to compare intravenous clonidine and dexmedetomidine administered as premedication for controlled hypotension in patients undergoing FESS with endotracheal general anaesthesia. Assessing the quality of the bloodless surgical field was the main objective, with secondary objectives being the evaluation of surgeon satisfaction, recovery characteristics, and any adverse events related to each drug.

This study presented data on the relative efficacy and safety of these two medications to help anaesthesiologists choose the best premedication to achieve the best surgical conditions for FESS while ensuring patient safety and favourable recovery outcomes.

MATERIALS AND METHODS

A prospective, double-blind, randomised, controlled study included 60 patients. All patients gave their informed consent, and the ethical committee approved the procedure.

Inclusion Criteria

Patients with ASA I and II who were scheduled for FESS under general anaesthesia and were between the ages of 18 and 60 were included.

Exclusion Criteria

The study excluded patients with a BMI of more than 35 kg/m², substantial cardiovascular disease, severe hepatic or renal impairment, bleeding disorders, anticoagulant use, chronic sedative or opioid use, psychiatric illness, pregnant or lactating women, and hypersensitivity to clonidine or dexmedetomidine.

Methods

Two equal groups of 30 patients each were randomly selected from among 60 patients scheduled for Functional Endoscopic Sinus Surgery (FESS) under general anaesthesia. Group A received intravenous dexmedetomidine 1 mcg/kg diluted in 100 ml normal saline, and Group B received intravenous clonidine 2 mcg/kg diluted in 100 ml normal saline. Both medications were given ten to fifteen minutes before the induction.

Before surgery, measurements were made of blood urea, serum creatinine, haemoglobin, platelet count, bleeding time, and clotting time. The patients were brought to the operating room after an 8-hour fast, where monitors were connected and baseline vital signs like heart rate, blood pressure, oxygen saturation, and mean arterial pressure were noted.

An 18-G cannula was used for safe intravenous access, and Ringer's lactate (10 ml/kg) was preloaded into the patients. Premedication included glycopyrrolate (5 µg/kg) and fentanyl (2 µg/kg). Following the start of the study drug infusion, patients were preoxygenated with 100% oxygen and induced with vecuronium (0.1 mg/kg) and propofol (2 mg/kg). A saline-soaked throat pack was applied, and an endotracheal intubation tube of the proper size was used.

Intermittent vecuronium, titrated isoflurane, and nitrous oxide and oxygen in a 2:1 ratio were used to maintain anaesthesia. The mean arterial pressure was maintained between 50 and 70 mmHg by adjusting the isoflurane concentration, which was recorded every 5 min. The quality of the surgical field was assessed using a 6-point Fromme-Boezaart scale. After surgery, neuromuscular blockade was reversed using neostigmine (50 µg/kg and glycopyrrolate 10µg/kg. Postextubation vital signs and awakening times were recorded. In the recovery room, patients were monitored for sedation (Ramsay scale), nausea, vomiting, and vital signs. Both groups remained stable, without adverse effects.

Statistical Analysis

The Mann-Whitney U test or independent t-test was used to compare the continuous variables, which were summarised as mean ± SD. Fisher's exact test or the chi-square test was used to compare categorical variables. SPSS version 25.0 was used for the analyses; a $p < 0.05$ was considered statistically significant.

RESULTS

Groups A (37.93 ± 11.66 years) and B (38.4 ± 9.99 years) had similar mean ages, with no significant difference ($p = 0.868$). Compared to Group A (61.33 ± 7.95 kg, $p = 0.04$), Group B the mean weight was a significantly higher (65.6 ± 7.76 kg). Both groups sex distributions were comparable ($p = 0.796$). Group B Fromme-Boezaart score was

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2.43 ± 0.68, whereas Group A was 1.8 ± 0.66, which was significantly lower (better) ($p = 0.001$). Group A awakening time was significantly shorter (5.23 ± 1.33 min) than Group B's (8.6 ± 1.67 min, $p < 0.0001$) (Table 1).

Table 1: Comparison of demographic and clinical profiles between the groups

		Group A	Group B	P value
Age		37.93±11.66	38.4±9.99	0.868
Weight in kg		61.33±7.95	65.6±7.76	0.04
Sex	Male	15	16	0.796
	Female	15	14	
Fromme-boezaart scale		1.8±0.66	2.43±0.68	0.001
Awakening time		5.23±1.33	8.6±1.67	<0.0001

Regarding HR, both groups showed comparable values during most periods, except post-extubation, where Group A had a significantly higher heart rate (83.57 ± 5.76) than Group B (72.90 ± 17.06) with a p=0.002 (Figure 1).

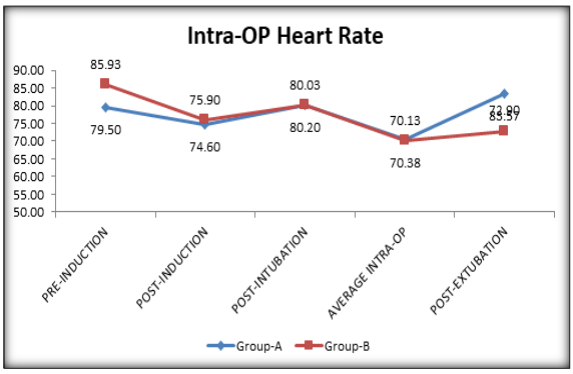

Figure 1: Intra OP heart rate

SBP was comparable between Groups A and B across all periods, with average intraoperative values of 100.09 mmHg in Group A and 101.15 mmHg in Group B and post-extubation values of 116.80 mmHg and 118.43 mmHg, respectively, with no significant differences (Figure 2).

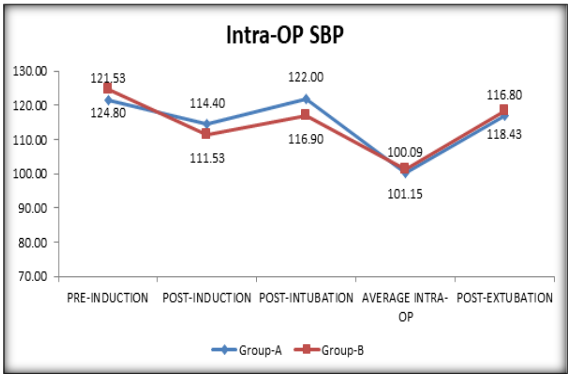

Figure 2: Intra-OP SBP

Group A showed lower average intraoperative diastolic pressure (58.06 mmHg) and post-extubation pressure (64.80 mmHg) than Group B (59.95 mmHg and 68.50 mmHg, respectively), indicating better diastolic control (Figure 3).

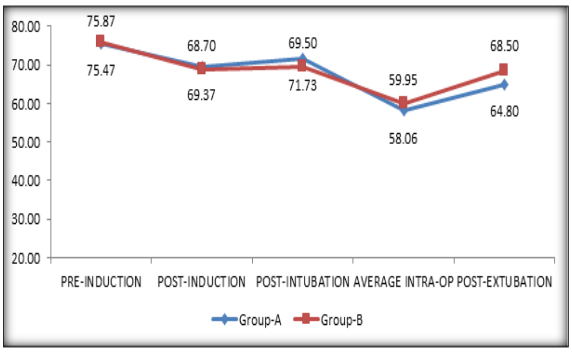

Figure 3: Intra OP DBP

Group A showed a lower average intraoperative mean arterial pressure (72.06 mmHg) than Group B (73.69 mmHg), with post-extubation values of 82.13 mmHg and 85.14 mmHg, respectively, indicating more effective MAP control in Group A (Figure 4).

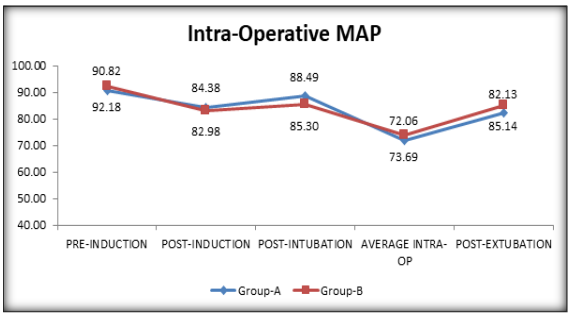

Figure 4: Intraoperative MAP

Group A demonstrated consistently lower intraoperative isoflurane requirements, ranging from 0.93% post-intubation to 0.20% at 80 min, compared with Group B, which ranged from 1.05% to 0.43%, indicating more effective anaesthetic sparing in Group A (Figure 5).

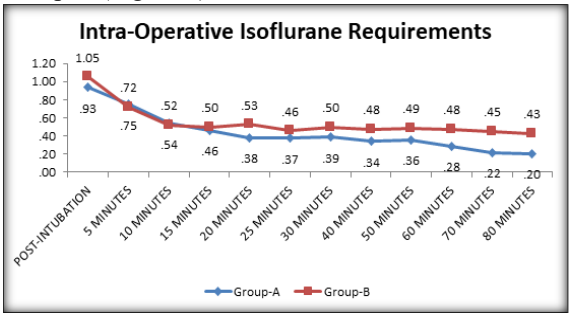

Figure 5: Intraoperative isoflurane requirements

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Group A demonstrated a slightly lower sedation score at 30 min (2.00 vs. 2.10) than Group B, while sedation scores were identical between groups at 60 min (1.97), indicating comparable recovery by the end of the observation period (Figure 6).

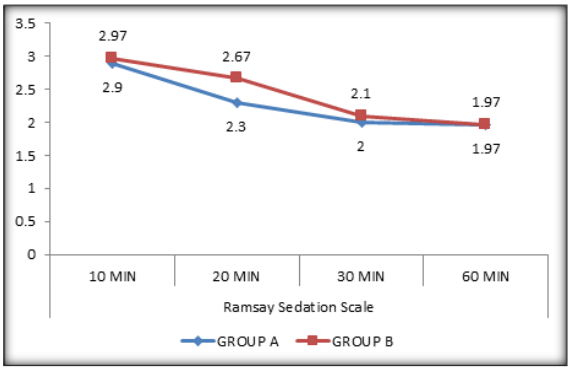

Figure 6: Sedation (Ramsay scale)

DISCUSSION

The dexmedetomidine (Group A) and clonidine (Group B) groups had similar mean ages and sexes. However, the Group A Fromme-Boezaart score was significantly higher (1.8 ± 0.66) than Group B (2.43 ± 0.68), and Group B mean weight was significantly higher (65.6 ± 7.76 kg) than Group A (61.33 ± 7.95 kg). Similarly, Suggala et al. found that the two groups demographic profiles were similar. Group C (36.10 ± 10.90 years, 151.02 ± 4.73 cm, 55.11 ± 3.54 kg) and Group D (35.92 ± 11.58 years, 149.56 ± 4.63 cm, 54.52 ± 3.54 kg) did not significantly differ in mean age, height, or weight. The sex distribution (male/female: 18/12 vs. 19/11, p = 0.98), as well as the ASA grade distribution, were comparable (p = 0.78). In comparison to Group C (clonidine), which had one patient with moderate bleeding, Group D (dexmedetomidine) had better surgical field quality, with more patients scoring 1 (14 vs. 10) and none scoring 3. Better operating conditions with dexmedetomidine are supported by these findings.[11]

In our study, Group A awakening time (5.23 ± 1.33 min) was significantly shorter than Group B (8.6 ± 1.67 min). Similarly, Bafna et al. discovered that the mean recovery time was 7.8 ± 2.6 minutes for the dexmedetomidine group and 11.2 ± 3.4 minutes for the clonidine group, indicating a significant difference ($p < 0.001$).[12] In contrast, Shruthi et al. discovered that Group D had a longer time to extubation and eye opening ($p < 0.001$).[13]

In our study, except for Group A higher heart rate after extubation and their lower intraoperative and post-extubation diastolic pressures in comparison to Group B, HR and SBP were essentially comparable across the groups. Similarly, Hussain et al. showed that following drug infusion, Group D HR was significantly lower (77.6 ± 9.6) than Group C (75.9 ± 17.0).[14] While HR, SBP, DBP, and MAP were lower than baseline after extubation and comparable to basal values in group D at extubation, Shruthi et al. observed a significant increase in group C ($p < 0.001$).[13] Jan et al. discovered that the mean heart rate in the dexmedetomidine and clonidine groups was 74.07 ± 5.66 beats/min and 76.10 ± 6.08 beats/min, respectively, 10 minutes after extubation, and that the difference was not significant. However, compared to the clonidine group, the dexmedetomidine treated patients had lower blood pressure.[15]

In our study, MAP was lower in Group A, with an average intraoperative MAP of 72.06 mmHg and post-extubation MAP of 82.13 mmHg, while Group B MAP was 73.69 mmHg and 85.14 mmHg. Similarly, Mugabo et al. found that when compared to baseline, both groups' mean arterial pressure and heart rate were significantly lower than the desired levels ($p < 0.001$). However, compared to clonidine, dexmedetomidine caused more hypotension, and this difference was significant.[16] Das et al. found that there was a significant similarity in MAP and HR between the two groups ($p > 0.05$).[17]

Our study shows that Group A isoflurane demands were consistently lower than Group B (0.93% post-intubation to 0.20% at 80 minutes) compared to Group B (1.05% to 0.43%), indicating better anaesthetic sparing with dexmedetomidine. Similarly, Bhagat et al. found that patients given dexmedetomidine required significantly less isoflurane ($p < 0.0001$), indicating a definite anaesthetic-sparing effect.[18] Mariappan et al. showed that dexmedetomidine had a greater anaesthetic sparing effect than clonidine by significantly lowering end tidal isoflurane concentrations at one and two hours after prone positioning ($p = 0.001$ and $p = 0.039$, respectively).[19] In a double-blind RCT, Muniyappa et al. found that pre-induction dexmedetomidine (1 µg/kg) decreased end-tidal isoflurane to 0.56 ± 0.11% compared to 0.76 ± 0.14% in controls ($p < 0.001$).[20]

In our study, Group A sedation scores were lower at 30 minutes and comparable to both groups at 60 minutes, suggesting a similar level of recovery. Similarly, Srivastava et al. in a randomized intensive care unit sedation trial, showed that 86% of patients on dexmedetomidine reached the target Ramsay Sedation Score by 30 minutes, while 62% of patients on clonidine performed thus ($p = 0.04$), sedation scores later balanced, suggesting a comparable recovery of 60 minutes.[21] Reddy et al. found intravenous dexmedetomidine during bupivacaine spinal anaesthesia resulted in a higher maximum sensory level (T4 ± 1) than either clonidine (T6 ± 1) or a placebo (T6 ± 2), and it produced a faster onset of sensory block to T10 (2.91 ± 1.16 min) than clonidine (3.58 ± 1.06 min).[22]

Limitations

This single-centre study had a limited sample size and brief follow-up, which may restrict generalisability. The exclusion of patients with higher ASA grades and comorbidities reduced

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external validity. Potential observer bias, limited blinding checks, and unmeasured confounders may have influenced the findings.

CONCLUSION

Dexmedetomidine provided more effective controlled hypotension than clonidine, improving surgical field visibility, reducing isoflurane requirements, and allowing faster recovery without any adverse effects. Both agents were safe and well tolerated; however, dexmedetomidine offered superior haemodynamic control and surgeon satisfaction. It may be preferred as a premedication for inducing hypotension during functional endoscopic sinus surgery.

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