Research article

Premedication with intranasal versus intravenous dexmedetomidine for hypotensive anesthesia during functional endoscopic sinus surgery in adults: A randomized triple-blind trial☆

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ABSTRACT

Functional Endoscopic Sinus Surgery (FESS) has been performed under controlled hypotension to increase operating field visibility. Intranasal (IN) dexmedetomidine is easy, noninvasive, and possesses lower C max, accompanied by lower pharmacodynamic action, including hypotension, bradycardia, and sedation. This trial aimed to compare IN and intravenous (IV) dexmedetomidine for hypotensive anesthesia during FESS.

This randomized, controlled, triple-blinded clinical trial involved sixty cases scheduled for FESS. Patients were divided into two equal groups by random manner. 45–60 min before anesthesia induction, group IN: received 1 μg/kg IN dexmedetomidine diluted in 10 ml of saline 0.9 % intranasally preoperative. Group IV: received 1 µg/kg dexmedetomidine diluted in 10 ml of saline 0.9 % infused over 10 min. The primary outcome was the total amount of administered atropine. The secondary outcomes included hemodynamic, through 1 h before surgery, intraoperatively and postoperatively at different time intervals. The quality of the operative field, sedation, adverse reactions and hemostatic stuffing after FESS were also assessed.

The total amount of consumed atropine decreased significantly in group IN compared to group IV. Preoperative Ramsay Sedation scores at T0, T5, T50 and T60 were comparable between the two groups, while at T10, T15, T20, T30, and T40 were lower significantly in the IN group compared with the IV group. Preoperative mean arterial blood pressure at T0, T5 and T60 had comparable differences across both groups while reduced at T10 to T 45 significantly in the IV group than IN group. Both groups had comparable satisfaction, postoperative Ramsey sedation, hemostatic suffering, quality of operative field and complications.

In conclusion, IN dexmedetomidine administration is relatively simple and appropriate; moreover, it decreases first-pass metabolism. Onset is prolonged relative to IV dosing; thus, it should be administered nearly 1 h before surgery and recommended in adult patients as they require minor sedation preoperatively.

Impact of research findings on patients.

- Utilization of intranasal dexmedetomidine for hypotensive anesthesia during functional endoscopic sinus in adults as it showed lower sedation.
- Intranasal dexmedetomidine possessed similar analgesic properties to IV with fewer adverse events during functional endoscopic sinus.
- Intranasal dexmedetomidine is a feasible, easy and noninvasive route with high bioavailability and reduced liver first-pass metabolism.

1. Introduction

Chronic rhinosinusitis (CRS) often needs therapy because of its detrimental influence on quality of life [1]. Functional Endoscopic Sinus Surgery (FESS) is the most appropriate potential management for persistent CRS and other conditions [2]. FESS is a slightly invasive treatment with hypotensive controlled anesthesia [3]. Significant bleeding resulted in increasing the likelihood of complications such as blindness, meningitis, leakage of cerebrospinal fluid [CSF], as well as prolongation of surgical duration [4,5]. Sometimes, increased bleeding causes procedures to be terminated early. Thus, enhancing intraoperative vision while minimizing blood loss is critical during FESS [6,7]. By decreasing the mean arterial pressure (MAP), controlled hypotension has been used during FESS to restrict blood loss and increase surgical field vision. In hypotensive anesthesia, the patient's initial MAP is decreased by 30 % or maintained between 65 and 70 mmHg. However, induced hypotension is associated with adverse events, including low cerebral perfusion and ischaemic injury of vital organs [8].

Several medicines have been utilized effectively to induce hypotension under general anesthesia, such as direct vasodilators and alpha blockers (clonidine and dexmedetomidine) [9].

Dexmedetomidine is primarily a sedative and antianxiety drug because it is a highly selective α 2 adreno-receptor agonist with a stronger affinity to α 2 adreno-receptor over clonidine [10]. Dexmedetomidine has an elimination half-life (t1/2 b) of 2 h and a redistribution half-life (t1/2a) of 6 min, making it an ultimate medication for intravenous (IV) titration [11]. Possibly favorable effects include a reduced need for additional anesthetics and analgesics. Disturbance of blood pressure, bradycardia, nausea, atrial fibrillation, and hypoxia are the most frequent adverse events of dexmedetomidine [12].

In addition to being appropriate, efficacious, and noninvasive, intranasal (IN) dexmedetomidine offers beneficial analgesia and sedative outcomes during surgeries [13]. The pharmacokinetic profile of IN dexmedetomidine provided lower C max than the IV route, which was accompanied by lower pharmacodynamic action, including hypotension, bradycardia and sedation [14].

The comparison between IN and IV routes of dexmedetomidine has been studied previously for various operations [15–17]. Still, the literature lacked this comparison during FESS, which is a crucial indication for controlled hypotensive anesthesia considering the evaluation of the operating field. Thus, this trial aimed to compare IN dexmedetomidine with intravenous (IV) dexmedetomidine for hypotensive anesthesia in FESS.

2. Patients and methods

This randomized, prospective, controlled, triple blinded clinical trial conducted on 60 cases aged> 21 years old, both sexes, American Society of Anesthesiologists (ASA) physical status classification I–III experienced FESS. The research was conducted between November 2022 and March 2023. Al-Azhar University (Damietta) Hospitals was the study's site.

Written informed consent was given by each patient. The research was performed after the approval of the Ethical Committee Al-Azhar University (Damietta) Hospitals (approval code: IRB 00012367-22-011-001), registration of clinicaltrials.gov (ID: NCT05604599) and March 11, 2022, was the first registration date.

Exclusion criteria included cases having a body mass index (BMI) of greater than 30 kg/m², current or recent serious illness, restrictions on the use of dexmedetomidine, existence or history of severe disease; major risk factors for cardiovascular illness; pronounced coronary heart disease if any identified genetic susceptibility; drug abuse, any prior history of drug allergies, mental or emotional difficulties, a systemic condition known to require the anticoagulants use, any nasal problems, such as recurrent nasal bleeding or nasal tumours, that may impede nasal administration of the medications and cases with a history of previous FESS.

2.1. Randomization and blindness

Using random numbers created by computers, sixty cases were divided evenly between two groups in a random manner. Group IN (intranasal dexmedetomidine group): received IN dexmedetomidine intranasally preoperative + infusion saline. Group IV (intravenous dexmedetomidine group): received dexmedetomidine infused over 10 min + IN saline. A chief nurse who was not involved in the trial used sealed, opaque, and sequentially numbered envelopes to guarantee random allocation. Observers, cases, and outcome evaluators were all unaware of the experimental medicine. An additional clinical pharmacist prepared the medications but did not participate in the subsequent rounds of the trial. All containers were identical in appearance.

2.2. Preoperative

In accordance with the cases, recording history, clinical assessment, and regular laboratory examinations were performed and distributed. During the preoperative consultation, the Visual Analog Scale (VAS) (0, no discomfort and no pain; 10, a high level of discomfort and maximum pain) was described to each patient. In a large forearm vein, a venous catheter was placed for dexmedetomidine administration and other medications potentially required to address side effects. A catheter was placed into the radial artery to collect blood samples and monitor blood pressure. A monitor comprising noninvasive blood pressure, pulse oximetry, a 5-lead electrocardiogram (ECG), capnography, and a temperature probe was attached to each case.

Forty-five to 1 h before the operation, cases received 1 μg/kg of dexmedetomidine in 10 ml of 0.9 % saline as drops to each naris in group IN and 10 ml of 10 ml 0.9 % saline directed to each naris as drops in group IV to ensure blindness. Cases in group IV received 1 µg/kg dexmedetomidine in 10 ml of saline 0.9 % infused over 10 min or infusion saline in the IN group before general anesthesia (GA) induction. Continuous invasive blood pressure monitoring, ECG, respiratory rate and peripheral arteriolar oxygen saturation (SpO$_2$) was performed. The preoperative sedation score was measured every 5 min, and the readings were recorded.

2.3. Intraoperative

Following this, the patients were brought to the operating room for surgical intervention. Infusion of 8–10 mL/kg Ringer's solution was started. Premedication did not include any additional sedatives.

In order to induce GA, 1 µg/kg fentanyl IV and 2 mg/kg propofol IV were delivered. IV CIS-atracurium 0.15 mg/kg given in order to facilitate endotracheal intubation. Maintenance of anesthesia was accomplished with a solution of isoflurane 1 %–1.5 % in oxygen 50 %. IV *cis*-atracurium dosage increases of 0.03 mg/kg were delivered as needed, and fentanyl dosage increments were administered as needed.

Parameters for mechanical ventilation were modified to maintain end-tidal carbon dioxide (ETCO$_2$) 30–35 mmHg. Whenever the heart rate (HR)or MAP exhibited a 20 % increase from their starting reading, further doses of 1 µg/kg fentanyl were administered IV. Fentanyl (with induction dosage) and isoflurane were noted as being administered intraoperatively.

Following induction and intubation, each patient was placed in a Trendelenburg position approximately 30° to the reverse. A typical amount of adrenaline (1:200,000 adrenaline) was administered in the nasal cavity.

The same physician conducted all surgeries to guarantee uniformity in operative field estimation. He was blinded for the hypotensive agent. 15 min before the completion of the surgery, and the study medicines were discontinued to allow for proper hemostasis. MAP and HR were documented at baseline and every 5 min till the end of the procedure.

Surgeons evaluated intraoperative surgical field quality throughout FESS by measuring the degree of bleeding according to a 6-point scale by Fromme-Boezaart scale: 0, no bleeding; 1, minimum bleeding and no suction needed; 2, mild bleeding and occasional suction required; 3, moderate bleeding and frequent suction required; 4, severe bleeding and compromised surgical field and continuous suction required; 5, massive bleeding - dissection cannot be performed [18].

Restoring the neuromuscular blockade were atropine and neostigmine at 0.05 mg/kg and 0.02 mg/kg, respectively. Patients were administered 1 g of paracetamol IV every 8 h. In the presence of a VAS greater than 3, rescue analgesic (50 mg pethidine IV) was provided. The onset of analgesic request and the cumulative amount of pethidine consumed within the first 24 h after surgery were recorded.

Side effects were documented as vomiting, nausea, and hypotension (MAP <20 % of baseline readings and were treated with ephedrine 5 mg IV and normal saline IV) and bradycardia (HR < 60 beats/min and were managed by atropine 0.5 mg IV). The amount of atropine consumption was recorded.

The severity of adverse reactions to hemostatic stuffing following FESS was also assessed (1 = no swelling, can accept; 2 = swelling, can hardly bear; 3 = swelling, cannot accept).

Postoperative sedation using Ramasay sedation score (RSS). 1 = anxious, agitated, or restless; 2 = cooperative, oriented, and tranquil; 3 = responsive to commands; 4 = a sleep, but with brisk response to light, glabellar tap, or loud auditory stimulus; 5 = a sleep, sluggish response to glabellar tap, or auditory stimulus; and 6 = a sleep, no response 15, 30, 60mins after recovery was recorded.

Patients' satisfaction was measured immediately postoperative and after 24 h using a five-point Likert scale consisting of "very dissatisfied," "dissatisfied," "unsure," "satisfied," and "very satisfied."

The primary outcome was the total amount of administered atropine. The secondary outcomes included hemodynamic (HR, MAP), through 1 h before surgery, intraoperatively and postoperatively at different time intervals. The quality of the operative field, adverse reactions and hemostatic stuffing after FESS were also assessed.

2.4. Sample size calculation

The sample size determination was done by G*Power 3.1.9.2 (Universitat Kiel, Germany). We performed a pilot study (5 cases in each group), and we found that the mean ($\pm$SD) of the amount of atropine consumption (mg) (the primary outcome) was 0.3 $\pm$ 0.27in group IN and 0.6 $\pm$ 0.4 in group IV. When determining the sample size, the following factors were taken into account: an effect size of 0.87, a confidence limit of 95 %, a power of the trial of 90 %, and a 1:1 group ratio, with a minimum of 29 patients per group. We added one patient to each group to accommodate dropouts, thus we included 60 patients.

2.5. Statistical analysis

SPSS v 08 (IBM©, Armonk, NY, USA) was applied for statistical analysis. The data normality distribution was tested using the Shapiro-Wilks test and histograms. Quantitative parametric data were expressed as mean and standard deviation (SD). They were analyzed by unpaired student t-tests between the two groups and within-group comparisons tested by paired student t-tests. Quantitative non-parametric data were presented as the median and interquartile range (IQR). The Mann–Whitney U tested them between the two groups and within group comparison tested by Wilcoxon signed-rank test. When appropriate, qualitative variables were examined using Chi-square or Fisher's exact test and expressed as percentages or frequencies. Statistical significance was determined by a two-tailed P value less than 0.05.

3. Results

Eleven patients did not meet the requirements, and five cases declined to participate in the trial out of 76 that were considered eligible. In a parallel process, the remaining 60 cases were randomly divided into two groups with an allocation ratio of 1:1. (30 cases in each). A statistical analysis was performed on all cases that were assigned (Fig. 1).

Both groups were similar with respect to age, sex, BMI, ASA, and duration of operation (Table 1).

Preoperative RSS at T0, T5 and T60 were comparable between the two groups (p-value>0.05), while at T10, T15, T20, T30, and T40 elevated significantly in the IV group compared to the IN group (p-value <0.001). (Fig. 2).

Preoperative MAP at T0, T5 and T60 were comparable between both groups, while T10, T15, T20, T30 and T45 were significantly lower in the IV group than IN group. The intragroup comparison revealed that through the 60 min before surgery, MAP at T45 and T60 were lower significantly compared with baseline or T0 in group IN, while it started to decline significantly at T 10 till T60 compared to baseline in the IV group (Table 2).

Preoperative HR at T0, T5, T45 and T60 were matched between both groups, while T10, T15, and T30 were lower significantly in
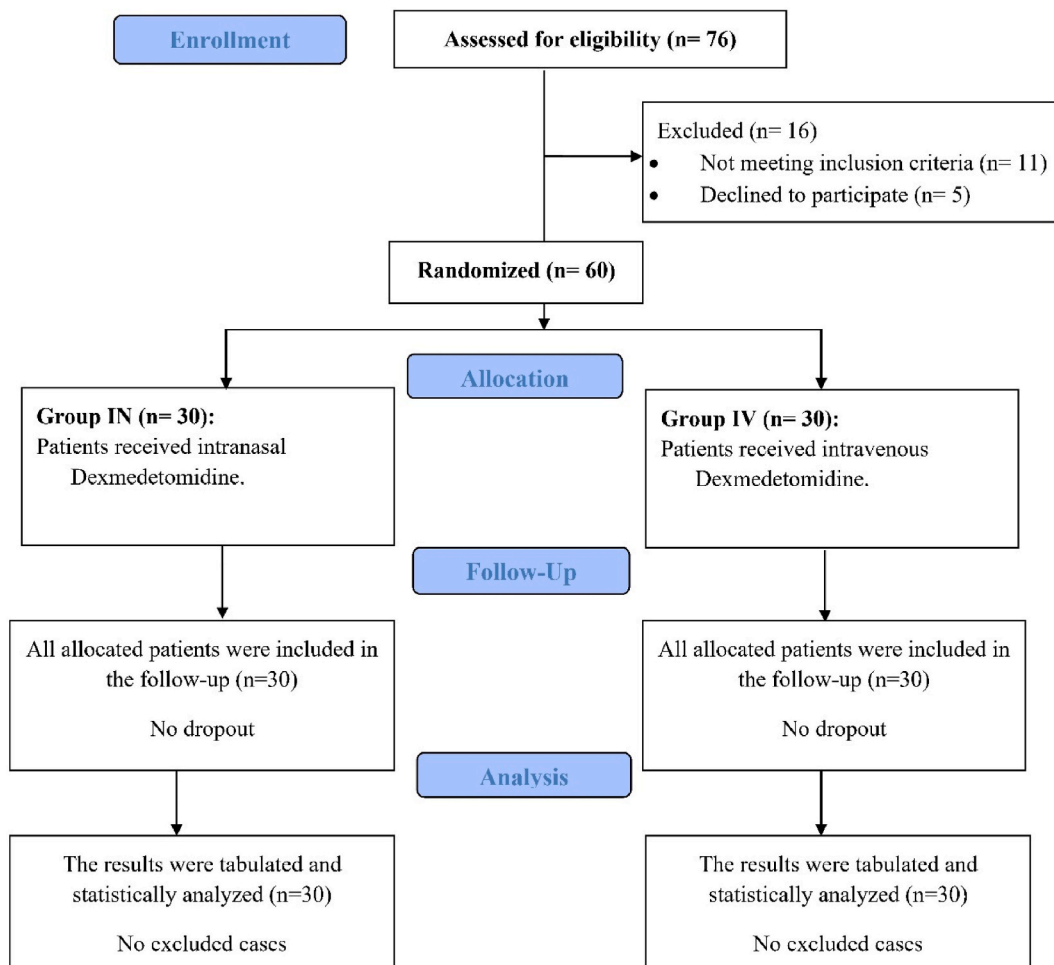

Fig. 1. CONSORT flowchart of the enrolled patients.

Table 1
Demographic data, ASA and duration of surgery of the studied groups.

		Group IN (n = 30)	Group IV (n = 30)	P value
Age (years)		43.9 ± 10.12	44.7 ± 11.96	0.781
Sex	**Male**	22 (73.33 %)	25 (83.33 %)	0.347
	Female	8 (26.67 %)	5 (16.67 %)	
BMI (kg/m^2)		26 ± 2.82	25.3 ± 2.55	0.317
ASA	ASA I	8 (26.67 %)	4 (20 %)	0.197
	ASA II	22 (73.33 %)	26 (86.67 %)	
Duration of surgery (min)		90.4 ± 8.97	86.8 ± 16.26	0.359

Data are presented as mean ± SD or frequency (%), BMI: body mass index, ASA: American Society of Anesthesiologists.
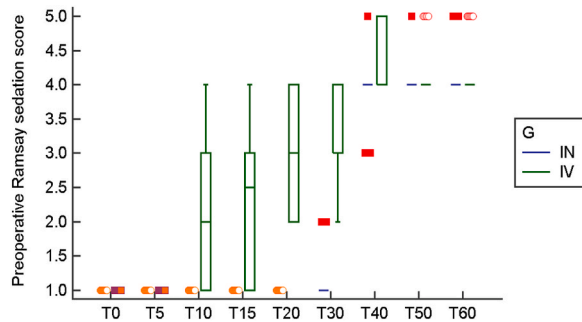

Fig. 2. Preoperative Ramsay Sedation score of the studied groups.

the IV group than in the IN group. The intragroup comparison revealed that through the 60 min before surgery, HR at T30 to T60 was significantly lower than baseline or T0 in group IN, while it started to decline significantly from T10 to T60 compared to baseline in the IV group (Table 3).

Intraoperative and recovery MAP and HR at all time intervals were insignificantly different between both groups (Figs. 3–6).

Both groups had comparable satisfaction, postoperative Ramsey sedation, hemostatic suffering, and complications (Table 4).

Preoperative and recovery respiratory rate and Spo$_2$ at all time points were insignificantly different between both groups without significant differences from baseline (Figs. 7–10).

Pethidine (mg), time to first rescue (hours), and quality field were matched between both groups, while the amount of atropine consumption was reduced significantly in group IN compared to group IV (Table 4).

4. Discussion

Due to significant bleeding, FESS performed under GA has been associated with serious consequences such as limited vision [19]. Controlled hypotension is a method to decrease intraoperative bleeding and create the optimal surgical field [3,20]. Prior research has demonstrated that IN delivery is an effective method for administering premedication [21–23]. Oral routes have been extensively examined [24], but data on IN are scant. IN delivery is a simple, noninvasive approach with great bioavailability [25]. Drug delivery and development are the most important translational research contributions to human health and well-being [26].

In healthy volunteers, IN administration of dexmedetomidine has been demonstrated to be effective and compliant by patients [27]; that may be an effective replacement for oral midazolam as a premedication for youngsters [14,28]. This research aimed to compare premedication with IN and IV dexmedetomidine for hypotensive anesthesia in FESS in adults.

Our results revealed that preoperative RSS at T0, T5, T50 and T60 were similar between both groups, while at T10, T15, T20, T30, and T40 were significantly lower in IN group than IV group. Anxiety before surgery might exacerbate stress-induced hemodynamic

Table 2
Preoperative MAP of the studied groups.

Time interval	Group IN (n = 30)	Within group comparison	Group IV (n = 30)	Within group comparison	Comparison between IN and IV groups
T0	89 ± 12.09	–	85.8 ± 13.59	–	0.339
T5	84.9 ± 4.56	0.094	82.9 ± 3.21	0.303	0.051
T10	85 ± 7.11	0.057	81.2 ± 6.33	0.02*	0.032*
T15	84.6 ± 4.33	0.061	80.6 ± 4.4	0.031*	0.0001*
T30	85.2 ± 6.33	0.073	80.8 ± 5.9	0.037*	0.006*
T45	84.2 ± 2.91	0.047*	81.2 ± 6.32	0.045*	0.022*
T60	82.7 ± 5.09	0.004*	78.8 ± 14.52	0.035*	0.177

Data are presented as mean ± SD, *: Significant when P value ≤ 0.05.

Table 3
Preoperative HR of the studied groups.

Time interval	Group IN (n = 30)	Within group comparison	Group IV (n = 30)	Within group comparison	Comparison between IN and IV groups
T5	81.4 ± 4.16	0.054	79.3 ± 5.66	0.103	0.118
T10	80.9 ± 6.39	0.067	69.5 ± 8.57	<0.001*	<0.001*
T15	81.2 ± 5.54	0.106	69.6 ± 8.14	<0.001*	<0.001*
T30	69.8 ± 7.54	<0.001*	63.5 ± 7.89	<0.001*	0.002*
T45	65 ± 9.75	<0.001*	60.3 ± 9.44	<0.001*	0.063
T60	57.6 ± 11.32	<0.001*	58.7 ± 10.09	<0.001*	0.702

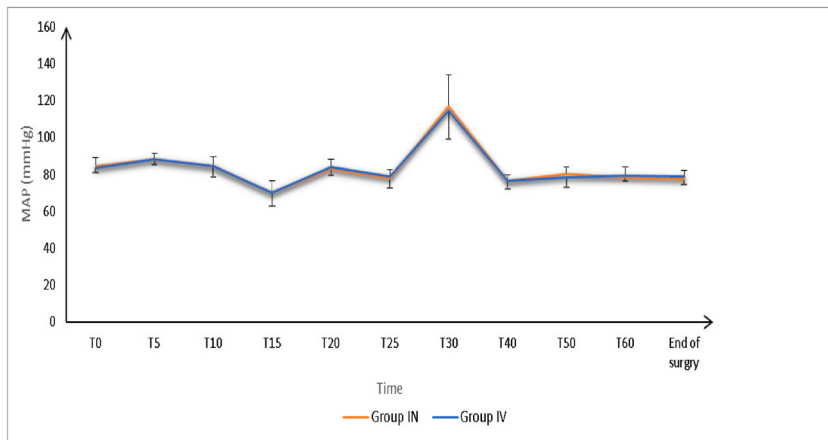Data are presented as mean ± SD, *: Significant when P value ≤ 0.05.

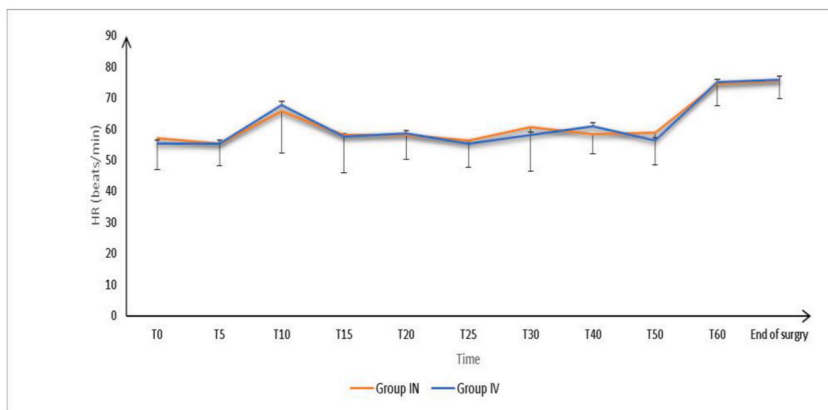**Fig. 3.** Intraoperative MAP of the studied groups.

Fig. 4. Intraoperative HR of the studied groups.

instability and complicate the induction of anesthetic [29]. Consequently, adequate premedication is essential. Dexmedetomidine has α2 receptor agonist selectivity and possesses hypnotic and sedative characteristics. It can induce analgesic effects by acting on the spinal cord, whereas its impact on the peripheral and central nervous systems can decrease sympathetic excitement [30].

Dexmedetomidine prevented renal and myocardial harm, as indicated by decreased levels of pro-inflammatory cytokines, kidney-specific urine proteins, and myocardium-specific proteins [31]. Our findings came in line with Iirola et al. [14] who studied the bioavailability of dexmedetomidine after IN administration. They reported that the plasma concentrations of IN dexmedetomidine peaked at 38 (15–60) min and 65 % (35–93 %) absolute bioavailability. Similar pharmacological effects were observed with both IN and IV methods, but the onset of these effects was quicker with IV administration.

Also, Yuen et al. [27] highlighted that the sedation onset of IN dexmedetomidine began at 45 min, peaked at 90–150 min in healthy volunteers. The excessive sedation in the IV group may be justified as the Cmax values were 0.34 (0.23–0.70) and 3.48 (2.70–3.72) ng/ml after IN and IV routes, respectively [14]. At the same time, it has been reported that dexmedetomidine displays linear kinetics in the range between 0.2 and 0.7 (mcg)/kg/hr on IV infusion up to 24 h [32]. Therefore, IN administration may be a viable choice for
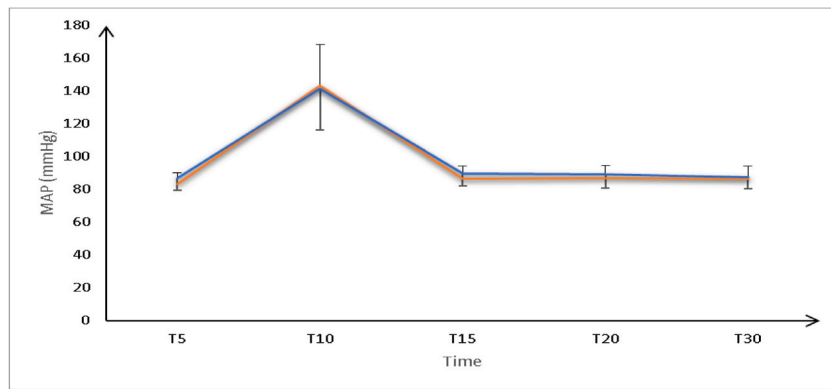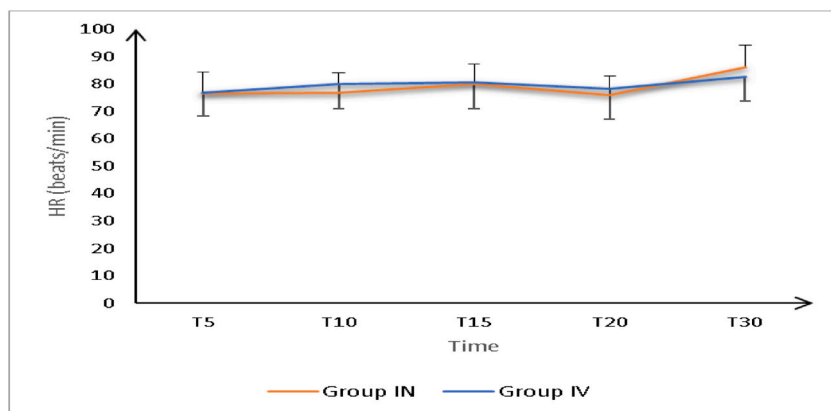
Fig. 5. Recovery MAP of the studied groups.

Fig. 6. Recovery HR of the studied groups.

Table 4

Satisfaction, postoperative Ramsey sedation, hemostatic suffering, analgesic effect, quality field, atropine consumption and complications of the studied groups.

		Group IN (n = 30)	Group IV (n = 30)	P value
Postoperative Satisfaction		4 (4–4)	4 (4–4)	0.646
Satisfaction post 24 h		4 (3–4)	4 (3–4)	0.775
Postoperative Ramsey sedation	Ramsey (1)	26 (86.67 %)	25 (83.33 %)	0.718
	Ramsey (2)	4 (13.33 %)	5 (16.67 %)	
Hemostatic suffering	No swelling, can tolerate	14 (46.67 %)	11 (55 %)	0.604
	Swelling, can barely tolerate	14 (46.67 %)	14 (70 %)	
	Swelling, cannot tolerate	2 (6.67 %)	4 (13.33 %)	
Pethidine (mg)		100 ± 50.85	106.7 ± 44.98	0.593
Time to first rescue (hours)		2 ± 1.1	2.3 ± 1.12	0.355
Quality field	**Quality field 1**	6 (20 %)	10 (50 %)	0.422
	Quality field 3	8 (26.67 %)	5 (16.67 %)	
Atropine (mg)		0.2 ± 0.34	0.7 ± 0.55	<0.001*
Complications	Vomiting	4 (13.33 %)		0.853
	Nausea	2 (6.67 %)		

Data are presented as frequency (%), or as median (IQR) or mean ± SD *: Significant when P value ≤ 0.05.

adults as they require modest sedation. At the same time, many preschool children feel severe anxiety during the preoperative phase, necessitating greater sedation [29].

The sedative effect of IN dexmedetomidine was assessed recently by Bromfalk et al., and they highlighted that 60 min after administration, the dexmedetomidine groups had an elevated RSS score than the placebo group (placebo, 2.26 ± 0.45; dexmedetomidine, 4.03 ± 0.72; $p < 0.001$). During anesthetic preparation in the operating room, four (13 %) of the dexmedetomidine group experienced a drop in RSS score from 4 to 2 compared to the observations at 60 min [29].
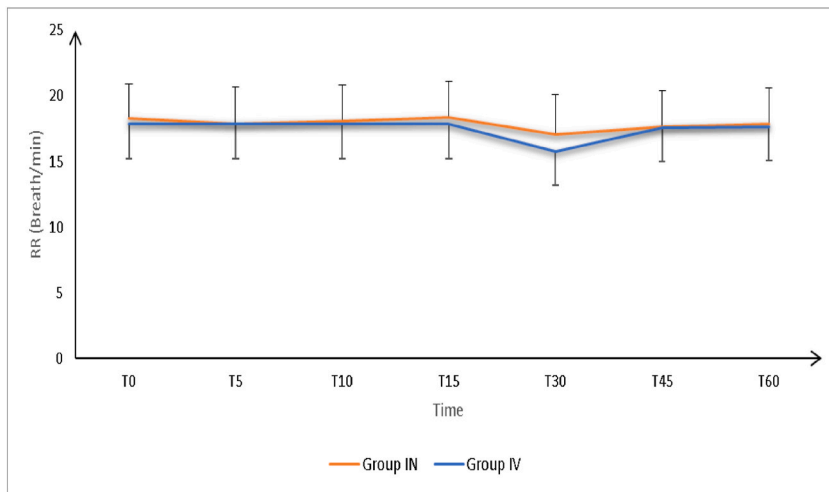
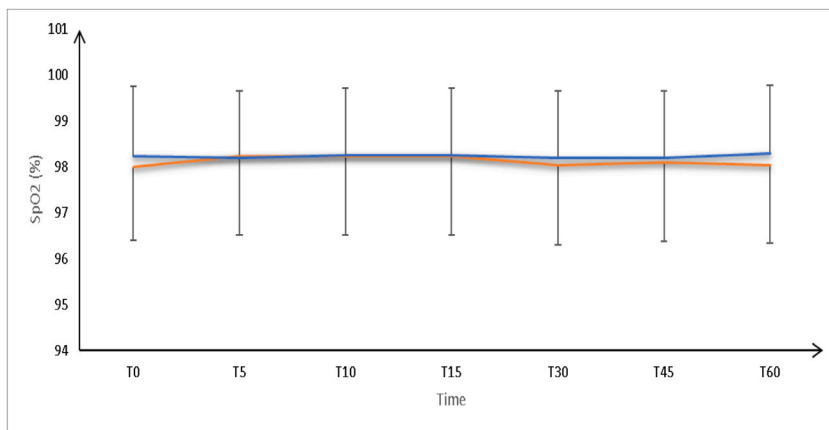**Fig. 7.** Preoperative respiratory rate of the studied groups.

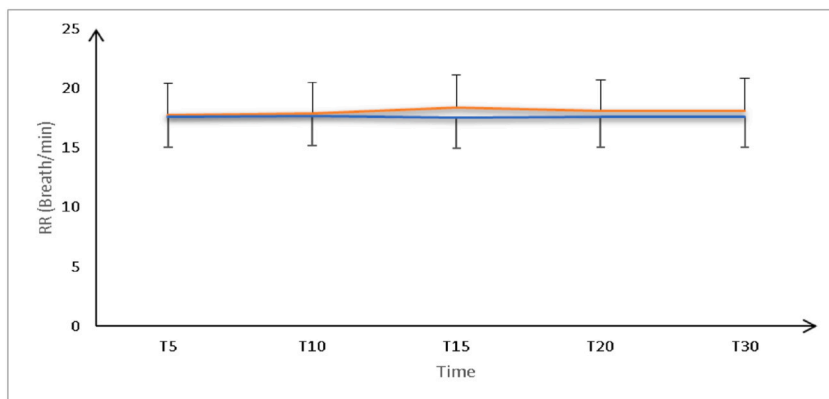**Fig. 8.** Preoperative oxygen saturation of the studied groups.

Fig. 9. Recovery respiratory rate of the studied groups.

According to our results, preoperative MAP at T0, T5 and T 60 were insignificantly different between both groups, while at T10 to T 45 were higher significantly in the IN group than in the IV group. Preoperative HR at T0, T5, T45 and T60 were comparable between both groups, while T10 to T30 were significantly higher in the IN group than in the IV group. Our findings are supported by Iirola et al.
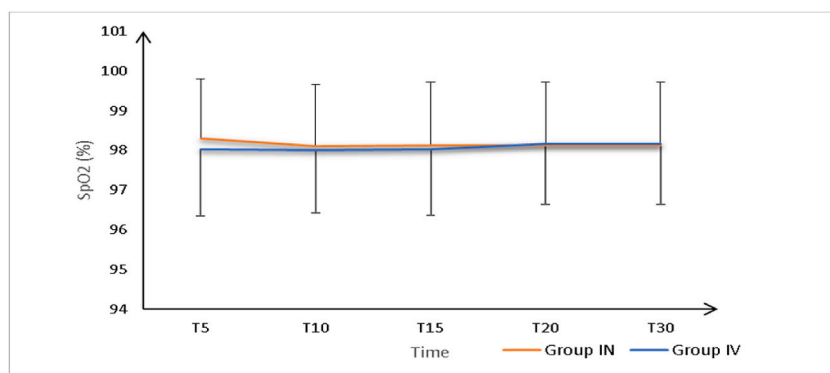
Fig. 10. Recovery oxygen saturation of the studied groups.

[14] who investigated that, as determined by the AUEC, the results of IN dexmedetomidine were comparable to those of IV; however, the initiation of the actin was more rapid after IV delivery. In accordance with the examined Cmax of IN dexmedetomidine and earlier experience in clinical pediatrics [33] and adult volunteers [27], the onset of action of IN dexmedetomidine was 30–45 min after delivery. Thus, IN dexmedetomidine should be delivered 45–60 min before the beginning of surgery. The lower hemodynamics data observed in the IV group may be explained by higher Cmax (ng/ml) of IV dexmedetomidine compared to IN (3.72 vs. 0.70 at 60 min, respectively).

According to the values for AUEC, Iirola et al. [14] documented that IV injection resulted in a significantly lower (P = 0.046) HR in the first 0–30 min compared to IN delivery. However, there was an insignificant change from 0 to 10 h, as systolic and diastolic blood pressure were comparable, irrespective of the route of administration.

That what occurred intraoperatively and postoperatively in our trial as MAP and HR at all time intervals were insignificantly different between both groups. This may be explained as both routes have nearly similar $t_{1/2}$ (114 (107–151) vs 115 (99–145) min in IN vs IV respectively) [14]. Yuen et al. [28] also stated that the HR of IN dexmedetomidine was lower in reference to the control group 60–75 min after drug administration.

According to our findings, pethidine (mg), time to first rescue (hours), and quality field were comparable between both groups. At the same time, the amount of atropine consumption reduced significantly in group IN than in IV. Activation of α2 receptors stimulates a central suppression of sympathetic activation, resulting in bradycardia and hypotension, reduced opioid requirements, and more hemodynamics stability in postsurgical recovery. Dexmedetomidine causes less respiratory depression and enables safe recovery [34].

The higher atropine consumption in the IV group may be justified by the higher Cmax of IV resulting in bradycardia treated with atropine. In postoperative cases who were under mechanical ventilation in an intensive care unit, sedation with IV dexmedetomidine was linked with a considerably higher hypotension frequency (30 % vs. 10 %; p < 0.005) and bradycardia (9 % vs 2 %; p < 0.005) in reference to placebo [35]. Bradycardia and hypotension usually occur either during or after the infusion of loading dose dexmedetomidine. Generally, hypotension is managed either without therapy or with adjustments in position and/or fluid intake. Bradycardia was managed either spontaneously or with medical intervention (e.g. atropine). Dexmedetomidine did not influence respiration rate or oxygen saturation [36], which is comparable to our findings. It has been reported that there was a higher incidence of bradycardia (7.3 % vs 0 %) in dexmedetomidine compared to placebo recipients [37].

In this study has some limitations including, there was just one site for the trial, and the duration of follow-up was brief. To generalize our findings, larger-scale investigations including many centres and longer periods of monitoring are required.

5. Conclusions

Intranasal administration of dexmedetomidine is relatively easy and appropriate; moreover, it decreases first-pass metabolism with decreased side effects, including significant hypotension and bradycardia evidenced by less atropine consumption. Onset is delayed compared with IV dosing; thus, it should be administered nearly 1 h before surgery and recommended in adult patients as they require minor sedation before surgery.

Author contributions

Neveen Kohaf: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Salama A. Harby: Writing – original draft, Validation, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. Ahmed F. Abd-Ellatief: Writing – original draft, Visualization, Resources, Funding acquisition, Data curation. Tamer F. Abd Elsalam: Writing – original draft, Supervision, Software, Funding acquisition. Mohamed A. Elsaid: Software, Resources, Funding acquisition, Data curation. Neazy A. Abdelmottaleb: Software, Resources, Funding acquisition

Data availability statement

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

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Ethics approval and consent to participate

The research was conducted in adherence to the principles outlined in the Declaration of Helsinki. Each patient gave informed consent in writing. The study was conducted subsequent to receiving approval from the Ethical Committee of Al-Azhar University (Damietta) Hospitals (approval code: IRB 00012367-22-011-001) and registration of clinicaltrials.gov (ID: NCT05604599).

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There are none to be declared.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

List of abbreviation

FESS   Functional Endoscopic Sinus Surgery
IN   Intranasal
IV   Intravenous
CRS   Chronic rhinosinusitis
CSF   Cerebrospinal fluid
MAP   Mean arterial pressure
ASA   American Society of Anesthesiologists
VAS   Visual Analog Scale
GA   General anesthesia
SpO_2 Peripheral arteriolar oxygen saturation
$ETCO_2$ End-tidal carbon dioxide
HR   Heart rate
RSS   Ramasay sedation score
BMI   Body mass index

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