Comparison of the Effects of Dexmedetomidine and Remifentanil in Reducing Bleeding During Paranasal Sinus Surgery: A Double-Blind Randomized Clinical Trial

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Abstract

Background: Intraoperative bleeding is a challenge in functional endoscopic sinus surgery (FESS). This study aimed to compare the effects of Dexmedetomidine and Remifentanil on intraoperative bleeding, hemodynamic stability, and postoperative pain in patients undergoing paranasal sinus surgery.

Methods: In this randomized controlled trial, 100 adult patients undergoing paranasal sinus surgery were randomly assigned to receive either Dexmedetomidine (0.2 µg/kg/h) or Remifentanil (0.25 µg/kg/min) by continuous intravenous infusion during surgery. General anesthesia was administered in both groups. The primary outcome was intraoperative blood loss, assessed both by volume (in milliliters) and bleeding severity (on a 5-point Likert scale). Secondary outcomes included systolic and diastolic blood pressure, heart rate, Visual Analog Scale (VAS) pain scores, and surgery duration.

Results: There was no significant difference in mean intraoperative blood loss between groups (Dexmedetomidine: 114.76 ± 126.65 mL vs. Remifentanil: 119.20 ± 47.28 mL; p = 0.81). However, bleeding severity was significantly lower in the Dexmedetomidine group, with 76% experiencing mild bleeding compared to 56% in the Remifentanil group, and 16% in the latter experiencing severe bleeding (p = 0.008). Postoperative VAS pain scores were significantly lower in the Dexmedetomidine group (2.04 ± 0.53 vs. 3.12 ± 1.08; p < 0.001). Hemodynamic parameters decreased substantially over time in both groups, with no clinically significant intergroup differences, except at isolated time points.

Conclusions: While both Dexmedetomidine and Remifentanil effectively maintained hemodynamic stability during FESS, Dexmedetomidine resulted in milder bleeding severity and better postoperative analgesia, supporting its use as a preferred agent for controlled hypotension in sino-nasal surgery.

Keywords: Dexmedetomidine; Remifentanil; Controlled Hypotension; Functional Endoscopic Sinus Surgery; Intraoperative Bleeding; Postoperative Pain

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Introduction

Chronic rhinosinusitis (CRS) represents a persistent inflammatory condition of the paranasal sinuses that significantly impairs quality of life and frequently requires surgical intervention in cases refractory to medical therapy. Functional endoscopic sinus surgery (FESS) has emerged as a minimally invasive yet effective modality for restoring sinus ventilation and mucociliary function in patients with this condition. With a reported success rate of up to 90% in symptom improvement, FESS is now a

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mainstay treatment for CRS [1,2].

Despite its minimally invasive nature and generally favorable safety profile, FESS is not devoid of complications. Intraoperative bleeding remains one of the most prominent challenges, with the potential to obscure the surgical field, compromise surgical precision, prolong operative time, and increase the risk of postoperative complications [3–6]. Even minimal bleeding can significantly impair visualization due to the confined anatomical space, underscoring the necessity of optimal hemostasis during surgery [3]. Several hemodynamic and patient-related factors, such as arterial pressure, heart rate, and coagulation status, contribute to the extent of surgical bleeding [7,8].

To mitigate intraoperative bleeding, various strategies have been employed, including topical vasoconstrictors, electrocautery, and controlled hypotension using systemic agents [9–11]. Among these, controlled hypotension—defined as reducing systolic blood pressure to 80–90 mmHg, mean arterial pressure (MAP) to 50–65 mmHg, or decreasing MAP by 30% from baseline—is considered particularly effective [12]. However, this approach must be applied judiciously, as excessive hypotension may compromise perfusion to vital organs, especially in vulnerable patients [12,13].

Modern anesthetic agents and techniques have facilitated more precise hemodynamic modulation during surgery. Several pharmacologic agents, including inhalational anesthetics, sodium nitroprusside, nitroglycerin, beta-blockers, calcium channel blockers, and alpha-2 adrenergic agonists, have been evaluated for their capacity to induce controlled hypotension while preserving end-organ perfusion [12–14]. Ideally, an agent used for this purpose should exhibit rapid onset and offset, predictable pharmacodynamics, minimal adverse effects, and should not compromise tissue oxygenation [12,15].

Dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist, offers sedative, anxiolytic, and analgesic properties without significant respiratory depression. Through its central sympatholytic effects, Dexmedetomidine reduces norepinephrine release, leading to a decrease in blood pressure and heart rate. Its ability to blunt autonomic responses and facilitate a more hemodynamically stable profile has positioned it as a potential agent for intraoperative blood pressure control and reduction of bleeding [16].

Remifentanil, on the other hand, is an ultra-short-acting μ-opioid receptor agonist with a rapid onset and offset of action, as well as favorable cardiovascular stability. Its pharmacokinetic properties allow precise titration, making it well-suited for controlled hypotension during surgeries such as FESS. When administered with agents like propofol or volatile anesthetics, Remifentanil has been shown to improve surgical field visibility without compromising microcirculatory perfusion [17–20].

Despite the individual efficacy of both Dexmedetomidine and Remifentanil in reducing surgical bleeding and maintaining hemodynamic stability, direct comparative studies focusing on paranasal sinus surgeries remain limited. The existing literature presents variable findings regarding their relative effectiveness in reducing blood loss, improving surgical field quality, and enhancing postoperative outcomes [20–22].

Given the ongoing debate and clinical need for evidence-based anesthetic strategies that optimize both surgical conditions and patient safety, the present study was designed to compare the effects of Dexmedetomidine and Remifentanil on intraoperative bleeding and associated parameters in patients undergoing paranasal sinus surgery.

We hypothesized that Dexmedetomidine would offer superior surgical field clarity and hemodynamic stability compared to Remifentanil, without increasing adverse events. Specifically, this study aimed to assess the differences in intraoperative blood loss, hemodynamic parameters, surgical duration, and postoperative pain between the two drug regimens in a randomized, double-blind clinical trial setting.

Materials and Methods

Study Design and Setting

This study was designed as a double-blind, randomized controlled clinical trial conducted at Kosar Educational and Medical Center in Sanandaj, Iran. It was carried out over a 13-month period, from December 2021 to January 2023.

Eligibility Criteria

The study population consisted of patients scheduled for elective paranasal sinus surgery.

Inclusion criteria

- Age between 18 and 45 years
- Physical status I or II according to the American Society of Anesthesiologists (ASA)
- Eligibility for elective endoscopic paranasal sinus surgery

Exclusion criteria

- History of cardiovascular, renal, hepatic, or respiratory disease

• Coagulation disorders
• Psychiatric illness
• Current use of antihypertensive medications or NSAIDs
• BMI greater than 30

Sample Size and Randomization

The sample size was calculated using an online calculator (ClinCalc) [23], assuming a 22% difference in the primary outcome (intraoperative bleeding volume) between the groups. A minimum of 49 participants was required per group. To increase statistical power and account for possible dropouts, 100 patients were enrolled—50 in each group.

Participants were randomly assigned to one of two intervention groups using block randomization with randomly permuted blocks of size four (AABB, ABAB, ABBA, BBAA, BABA, BAAB). Allocation concealment was maintained throughout the study.

Interventions

All patients underwent a standardized anesthesia protocol. Premedication included intravenous fentanyl (2 µg/kg), midazolam (1 mg), dexamethasone (8 mg), and lidocaine (1 mg/kg). Induction was performed using propofol (1.5 mg/kg) and atracurium (0.5 mg/kg), followed by endotracheal intubation. Patients were positioned in a 15-degree reverse Trendelenburg position. Anesthesia maintenance consisted of 1.2% isoflurane with a gas mixture of oxygen and nitrous oxide (3 L/min each).

• Group D received intravenous dexmedetomidine at a continuous infusion of 0.2 µg/kg/h.
• Group R received intravenous remifentanil at a rate of 0.25 µg/kg/min.
• Both drugs were administered via infusion pump throughout the procedure.

Outcome Measuring Primary Outcome

Intraoperative blood loss, measured both quantitatively (in mL) and qualitatively using a 5-point Likert scale:

• Uncontrollable bleeding
• Severe bleeding, the field is immediately obscured
• Moderate bleeding, frequent suctioning needed
• Mild bleeding, occasional suctioning
• No bleeding, optimal field visibility

Blood volume was measured by subtracting the volume of irrigation fluid from the total suctioned volume and weighing blood-soaked gauze.

Secondary Outcomes

• Hemodynamic parameters (systolic and diastolic blood pressure, heart rate), recorded at baseline and every 15 minutes during surgery
• Duration of surgery (from first incision to closure)
• Postoperative pain using the Visual Analog Scale (VAS), 0–10 rating in the recovery room

Standardized postoperative analgesia included 1 g of intravenous Apotel (paracetamol) in 100 mL normal saline, infused over 20 minutes every 12 hours.

Data Collection and Personnel

Data collection was performed by a trained anesthesia resident, assisted by two operating room anesthesia nurses and two recovery room nurses. Demographic and clinical data were recorded on pre-designed forms.

Statistical Analysis

All data were analyzed using STATA version 14. Descriptive statistics (mean, standard deviation, frequency, and percentage) were used to summarize the data. Chi-square and Fisher's exact tests were applied to categorical variables. Independent samples t-tests and repeated measures ANOVA (RM-ANOVA) were used to compare continuous variables between groups. A p-value < 0.05 was considered statistically significant.

Results

Participant Characteristics

A total of 100 patients meeting the inclusion criteria were enrolled and randomized into two groups: Dexmedetomidine (n = 50) and Remifentanil (n = 50). There were no statistically significant differences in baseline demographic or clinical characteristics between the groups. The mean age was 40.04 ± 8.64 years in the Dexmedetomidine group and 38.88 ± 11.62 years in the Remifentanil group (p = 0.572). The gender distribution was comparable, with 44% males in the Dexmedetomidine group and 52% in the Remifentanil group (p = 0.420). The mean body mass index (BMI) was 25.68 ± 2.31 kg/m² in the Dexmedetomidine group and 25.86 ± 3.63 kg/m² in the Remifentanil group (p = 0.760). These data are summarized in Tables 1–3.

Intraoperative Bleeding

The mean estimated blood loss was 114.76 ±

Table 1: Mean (± SD) Age of Participants by Group

Variable	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Age (years)	38.88 ± 11.62	40.04 ± 8.64	0.572

Table 2: Gender Distribution of Participants by Group

Gender (n, %)	Remifentanil	Dexmedetomidine	P-value
Male	26 (52%)	22 (44%)	0.42
Female	24 (48%)	28 (56%)	

Table 3: Mean (± SD) Body Mass Index (BMI) of Participants by Group

Variable	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
BMI (kg/m²)	25.86 ± 3.63	25.68 ± 2.31	0.76

Table 4: Mean (± SD) Blood Loss Volume in Study Groups

Variable	Remifentanil	Dexmedetomidine	P-value
Blood Loss Volume (mL)	119.20 ± 47.28	114.76 ± 126.65	0.81
Weight of Blood Gauze (g)	39.24 ± 37.22	23.36 ± 21.66	0.01

Table 5: Bleeding Severity During Surgery Based on Likert Scale

Group	No Bleeding	Mild	Moderate	Severe	Uncontrollable
Remifentanil	4 (8%)	28 (56%)	10 (20%)	8 (16%)	0
Dexmedetomidine	0	38 (76%)	12 (24%)	0	0
P-value: 0.008					

Table 6: Mean (± SD) Systolic Blood Pressure at Different Times in Study Groups

Time	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Baseline	123.72 ± 10.90	123.54 ± 9.10	0.95
15 min	107.60 ± 11.15	116.67 ± 9.96	< 0.001
30 min	106.8 ± 12.26	102.62 ± 10.26	0.10
45 min	97.40 ± 11.15	97.85 ± 12.27	0.67
60 min	96.40 ± 11.27	96.81 ± 11.92	0.95

126.65 mL in the Dexmedetomidine group and 119.20 ± 47.28 mL in the Remifentanil group. No statistically significant difference was observed between the groups (p = 0.810). However, the mean weight of blood-soaked gauze was significantly lower in the Dexmedetomidine group (23.36 ± 21.66 g) compared to the Remifentanil group (39.24 ± 37.22 g; p = 0.010) (Table 4).

Bleeding severity, assessed using a 5-point Likert scale, showed significant differences between the groups (p = 0.008). Mild bleeding was observed in 76% of patients in the Dexmedetomidine group versus 56% in the Remifentanil group. Notably, 16% of patients in the Remifentanil group experienced severe bleeding, while no cases of severe bleeding were reported in the Dexmedetomidine group (Table 5).

Hemodynamic Parameters

Systolic Blood Pressure

The mean systolic blood pressure (SBP) decreased over time in both groups. At 15 minutes post-induction, SBP was significantly higher in the Dexmedetomidine group (116.67 ± 9.96 mmHg) compared to the Remifentanil group (107.60 ± 11.15 mmHg; p = 0.001). No significant differences were found at baseline or at any other time point (p > 0.05). Repeated-measures analysis confirmed a significant time-related decrease in SBP in both groups (p < 0.001) (Table 6, Figure 1).

Diastolic Blood Pressure

Diastolic blood pressure (DBP) decreased during the procedure. At 30 minutes post-induction, DBP was significantly lower in the Dexmedetomidine group (63.65 ± 5.74 mmHg) compared to the Remifentanil group (67.08 ± 9.52 mmHg; p = 0.020). No other time points showed statistically significant differences. Time-related changes in DBP were substantial in both groups (p < 0.001) (Table 7, Figure 2).

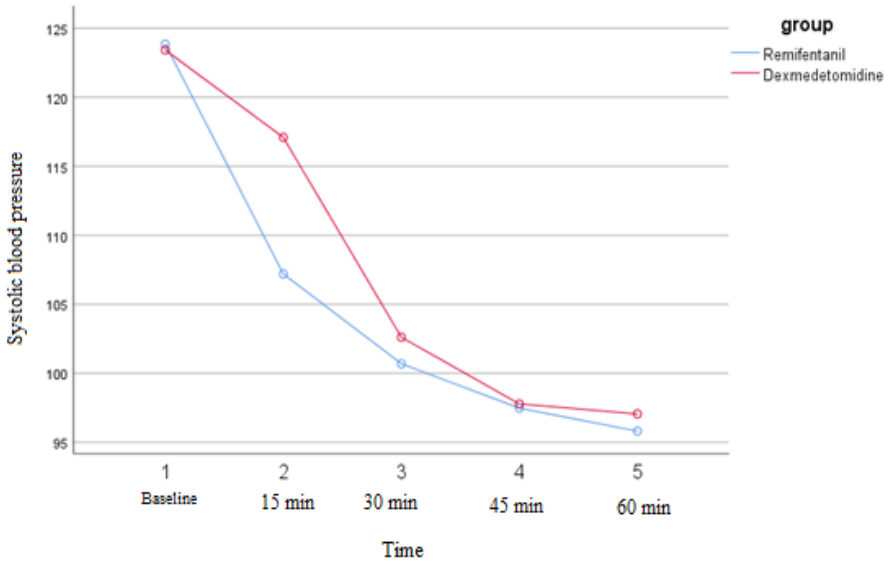

Figure 1: Systolic Blood Pressure Changes Over Time

Table 7: Mean (± SD) Diastolic Blood Pressure at Different Times in Study Groups

Time	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Baseline	75.88 ± 8.45	71.80 ± 5.15	0.06
15 min	67.10 ± 9.65	68.62 ± 6.41	0.54
30 min	67.08 ± 9.52	63.65 ± 5.74	0.02
45 min	62.28 ± 7.73	63.50 ± 5.74	0.21
60 min	62.16 ± 6.67	63.00 ± 5.92	0.32

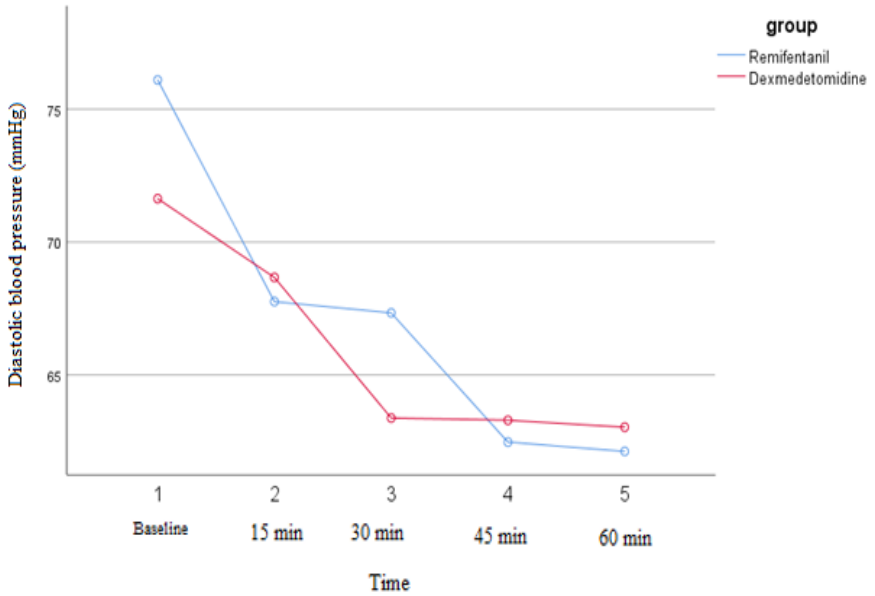

Figure 2: Diastolic Blood Pressure Changes Over Time (mmHg) in Both Groups

Heart Rate

Heart rate (HR) declined over time in both groups. Although the Remifentanil group had a slightly higher baseline mean HR (78.76 ± 4.76 bpm) compared to the Dexmedetomidine group (80.48 ± 7.33 bpm), this difference was not statistically significant ($p = 0.300$). No significant intergroup differences were observed at any time point (all $p > 0.05$). Repeated-measures analysis indicated significant within-group changes over time ($p < 0.001$) (Table 8, Figure 3).

Table 8: Mean (± SD) Heart Rate at Different Time Points in Study Groups

Time	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Baseline	78.76 ± 4.76	80.48 ± 7.33	0.30
15 min after induction	78.88 ± 10.25	76.74 ± 7.01	0.42
30 minutes after induction	74.56 ± 10.09	75.09 ± 8.01	0.52
45 minutes after induction	75.08 ± 7.46	74.39 ± 8.61	0.71
60 minutes after induction	73.60 ± 8.05	72.91 ± 7.17	0.56

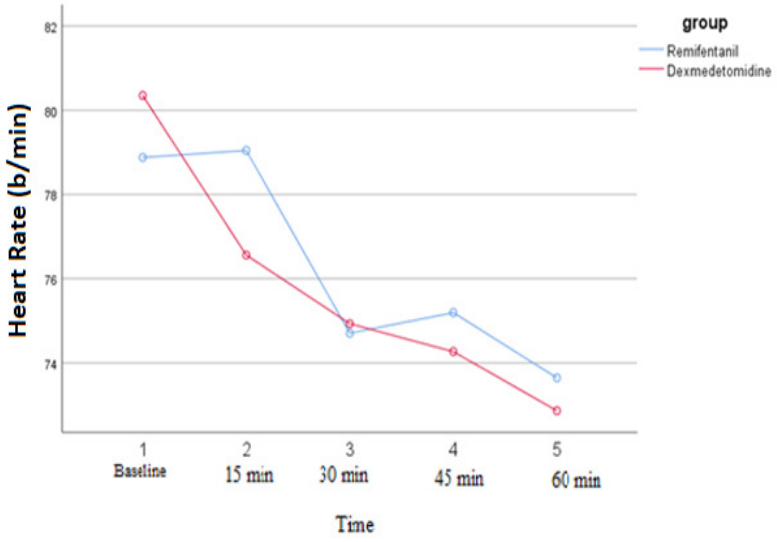

Figure 3: Heart Rate Changes Over Time in Both Groups

Table 9: Mean (± SD) Pain Intensity Based on VAS in Study Groups

Variable	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Pain Intensity	3.12 ± 1.08	2.04 ± 0.53	< 0.001

Table 10: Mean (± SD) Duration of Surgery in Two Study Groups

Variable	Remifentanil (Mean ± SD)	Dexmedetomidine (Mean ± SD)	P-value
Surgery Duration (min)	46.56 ± 13.89	46.76 ± 10.64	0.93

Postoperative Pain

Postoperative pain was assessed using the Visual Analog Scale (VAS). The mean VAS score in the Dexmedetomidine group was significantly lower (2.04 ± 0.53) than in the Remifentanil group (3.12 ± 1.08; $p < 0.001$), indicating better pain control in the former group (Table 9).

Duration of Surgery

The mean duration of surgery was 46.76 ± 10.64 minutes in the Dexmedetomidine group and 46.56 ± 13.89 minutes in the Remifentanil group. No significant difference was observed between the groups ($p = 0.930$) (Table 10).

Discussion

This study was designed to compare the effects of Dexmedetomidine and Remifentanil on intraoperative bleeding, hemodynamic stability, and postoperative pain in patients undergoing paranasal sinus surgery. While the primary outcome—total intraoperative blood loss—did not differ significantly between groups, Dexmedetomidine was associated with substantially milder bleeding severity and improved surgical field visibility.

Although the mean volume of blood loss was slightly lower in the Dexmedetomidine group, the difference was not statistically significant. However, when bleeding severity was evaluated using a standardized Likert scale, 76% of patients

in the Dexmedetomidine group experienced only mild bleeding compared to 56% in the Remifentanil group, with 16% of patients in the latter experiencing severe bleeding. These findings align with those of Karabayirli et al. [23], who also observed better bleeding control with Dexmedetomidine despite no significant differences in total blood loss. Importantly, our study achieved similar clinical outcomes using lower doses of both agents, which may have implications for cost-effectiveness and drug safety.

Our findings are consistent with those of Somayaji et al. [24], who demonstrated improved surgical field quality and reduced blood loss with Dexmedetomidine compared to placebo, and Kosucu et al. [15], who reported superior hemostatic effects of Remifentanil over placebo in rhinoplasty. Together, these results reinforce the utility of both agents in facilitating controlled hypotension during endoscopic sinus procedures. Regarding hemodynamic parameters, both Dexmedetomidine and Remifentanil effectively maintained blood pressure and heart rate within clinically acceptable ranges. Our study showed a statistically significant difference in systolic blood pressure at 15 minutes and in diastolic pressure at 30 minutes post-induction, with higher values observed in the Dexmedetomidine group. These findings may reflect the biphasic hemodynamic profile of Dexmedetomidine, which initially increases blood pressure via peripheral α2B receptor stimulation before lowering it through central α2A receptor effects [25, 26]. Repeated-measures analysis confirmed significant within-group declines in blood pressure and heart rate over time, consistent with previous reports [1, 23].

Postoperative pain scores, as measured by the Visual Analog Scale (VAS), were significantly lower in the Dexmedetomidine group. This finding is consistent with the known analgesic and sedative properties of Dexmedetomidine and supports the observations of Huh et al. [21], who reported reduced pain at 30 and 60 minutes postoperatively in patients receiving Dexmedetomidine. In contrast, Karabayirli et al. [23] did not identify a statistically significant difference in postoperative pain between the two drugs; this discrepancy may be explained by variations in pain assessment timing or patient characteristics.

Ethical Considerations

This study was approved by the Ethics Committee of Kurdistan University of Medical Sciences (IR.MUK.REC.1400.281) and registered in the Iranian Registry of Clinical Trials (IRCT ID: IRCT20220222054094N1). Written informed consent was obtained from all participants. Patient confidentiality was maintained, and standard care was not withheld from any participant.

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Declaration of Interest Statement

The authors declare that there are no conflicts of interest.

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