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ORIGINAL RESEARCH

Efficacy and safety of use of dexmedetomidine with fentanyl vs dexmedetomidine for hypotensive anaesthesia in patients undergoing functional endoscopic sinus surgery

[1]Dr. Bandaru Mourya Chowdary, [2]Dr. Shashi Kumar T, [3]Dr. Jyoti Mantur, [4]Dr. Nayana R,[5]Dr. Sridevi Mulimani

[1]Final Year Post Graduate, [2]Assistant Professor, Department of ENT HNS, BLDE(DU) Shri BM Patil Medical College Hospital and Research Centre,Vijayapura, Karnataka, India
[3]Assistant Professor, [4]Senior Resident, [5]Professor, Department of Anaesthesiology, BLDE(DU) Shri BM Patil Medical College Hospital and Research Centre,Vijayapura, Karnataka, India

Corresponding Author
Dr.JyotiMantur
Assistant Professor, Department of Anaesthesia, BLDE(DU) Shri BM Ptail Medical College Hospital and Research Centre, Vijayapura, Karnataka, India
Emai:jotimantur23@gmail.com

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ABSTRACT

Background: Functional Endoscopic Sinus Surgery (FESS) requires a bloodless operative field for surgical precision. Controlled hypotension is a key anaesthetic technique. Dexmedetomidine offers sedative and sympatholytic benefits, while fentanyl attenuates the stress response. This study compares the efficacy and safety of dexmedetomidine alone versus its combination with fentanyl during FESS.**Aim:**To compare the efficacy and safety of intravenous infusion of dexmedetomidine with fentanyl versus dexmedetomidine alone in providing hypotensive anaesthesia in FESS.**Methods:**In this randomised prospective study, 106 ASA I/II patients aged 18–60 years undergoing elective FESS were divided into two groups: Group D (dexmedetomidine 0.5 μg/kg/hr) and Group DF (dexmedetomidine 0.5 μg/kg/hr + fentanyl 0.5 μg/kg/hr). Hemodynamic parameters, Boezaart's grading, surgeon satisfaction, adverse events, and postoperative analgesia were evaluated.**Results:**Group DF showed significantly lower mean HR (68.7 ± 5.1 bpm vs. 72.1 ± 5.9 bpm; $p = 0.001$) and MAP (62.9 ± 3.1 mmHg vs. 81.2 ± 3.1 mmHg; $p < 0.001$). Boezaart scores were better in Group DF (2.04 ± 0.6 vs. 2.42 ± 0.8; $p = 0.006$), with higher surgeon satisfaction (56.6% vs. 45.3%). Adverse events like bradycardia and hypotension were significantly fewer in Group DF. The postoperative analgesia requirement was lower (5.6% vs. 32%). **Conclusion:** Dexmedetomidine with fentanyl offers superior intraoperative hemodynamic control, better surgical field visibility, fewer adverse events, and reduced postoperative analgesia requirement compared to dexmedetomidine alone in FESS.

Keywords: Dexmedetomidine, Fentanyl, Hypotensive Anaesthesia, FESS, Boezaart Grading, Hemodynamic Stability

INTRODUCTION

Functional Endoscopic Sinus Surgery (FESS) is a cornerstone in the modern surgical management of chronic rhinosinusitis, nasal polyposis, and other sinonasal disorders refractory to medical therapy. The evolution of FESS has allowed for targeted removal of pathological tissue while preserving mucosal integrity, enhancing patient outcomes, and reducing morbidity. However, despite being minimally invasive, FESS is often complicated by bleeding from the richly vascularized nasal mucosa, which may obscure the operative field, prolong the duration of surgery, and increase the risk of complications such as cerebrospinal fluid leaks and orbital injury[1 2.]

A clear surgical field is imperative for precise dissection during FESS. Even minimal bleeding in the narrow confines of the nasal cavity can drastically impair endoscopic visualization. To address this, anesthesiologists routinely employ strategies to achieve controlled hypotension, a technique aimed at reducing mean arterial pressure (MAP) to a target range of 50–65 mmHg or by 30% from baseline. This practice significantly reduces intraoperative blood

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loss, improves visibility, and enhances surgeon satisfaction[3 4.]

Several pharmacological agents have been employed to induce controlled hypotension, including vasodilators (e.g., nitroglycerin, sodium nitroprusside), beta-blockers (e.g., esmolol, labetalol), and inhalational agents (e.g., isoflurane, sevoflurane). However, these agents come with limitations such as delayed emergence from anaesthesia, tachyphylaxis, cyanide toxicity (nitroprusside), and myocardial depression (inhalational agents)[5 -7]. Therefore, recent focus has shifted to drugs that can provide hypotensive effects with added benefits of sedation, analgesia, and reduced stress response.

Dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist, has garnered significant attention due to its unique pharmacodynamic profile. It induces dose-dependent sedation, analgesia, and sympatholysis, leading to reduced heart rate and systemic vascular resistance, thereby achieving a controlled hypotensive state. Unlike conventional vasodilators, dexmedetomidine provides hemodynamic stability with fewer fluctuations and has been associated with improved surgical field quality and reduced intraoperative bleeding in FESS[8-10].However, its side effects such as bradycardia and hypotension may limit its usage, particularly at higher doses.

Fentanyl, a potent synthetic opioid, is widely utilized for its strong analgesic properties and its ability to blunt the sympathetic response to surgical stimulation. While not primarily a hypotensive agent, fentanyl complements agents like dexmedetomidine by stabilizing cardiovascular parameters, especially during stressful events such as laryngoscopy, intubation, and surgical incision. Furthermore, it enhances postoperative analgesia and reduces anaesthetic requirements.

Despite the individual advantages of dexmedetomidine and fentanyl, limited clinical data exists comparing their combined administration to dexmedetomidine alone for hypotensive anaesthesia in FESS. It remains unclear whether the combination provides a synergistic benefit in terms of improved hemodynamic stability, better surgical field conditions, fewer adverse events, and enhanced surgeon satisfaction.

Therefore, the present study was undertaken to evaluate the **efficacy and safety of intravenous dexmedetomidine combined with fentanyl versus dexmedetomidine alone** in achieving controlled hypotension in patients undergoing FESS. The aim was to provide an evidence-based assessment of whether this combination could improve surgical outcomes and patient safety while minimizing the dose-dependent side effects of individual drugs.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomized, controlled, parallel-group study conducted in the Department of Anaesthesiology at Shri B.M. Patil Medical College Hospital and Research Centre, B.L.D.E. (Deemed to be University), Vijayapura, Karnataka. The study was carried out between 2023 and 2025 after obtaining approval from the Institutional Ethics Committee and written informed consent from all participating patients.

Participants

A total of 106 adult patients, aged between 18 and 60 years, scheduled for elective Functional Endoscopic Sinus Surgery (FESS) under general anaesthesia were included in the study. All participants were classified as American Society of Anesthesiologists (ASA) physical status grade I or II.

Inclusion Criteria

- Patients aged 18–60 years.
- ASA Grade I and II.
- Scheduled for elective FESS.
- Provided written informed consent.

Exclusion Criteria

- Pregnant or lactating women.
- Hemodynamically unstable patients.
- Pre-existing bradycardia (HR < 55 bpm).
- Patients on beta-blockers or with cardiac conduction abnormalities.
- History of hypersensitivity to study drugs.

Sample Size Calculation

Based on pilot data showing mean systolic blood pressure (SBP) values of 85.73 ± 13.85 mmHg in the dexmedetomidine group and 91.37 ± 10.21 mmHg in the combination group, a minimum sample size of 53 patients per group (total N = 106) was calculated to achieve 80% power and 5% level of significance (two-tailed), using the independent t-test for comparing means.

Randomization and Group Allocation

Patients were randomly assigned to two groups using a computer-generated random number table:

- **Group D (Dexmedetomidine group):** Received intravenous infusion of dexmedetomidine at 0.5 µg/kg/hr.
- **Group DF (Dexmedetomidine + Fentanyl group):** Received intravenous infusion of dexmedetomidine (0.5 µg/kg/hr) and fentanyl (0.5 µg/kg/hr).

Infusions were initiated 10 minutes before induction of anaesthesia and continued intraoperatively until 10 minutes before reversal.

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Pre-Anesthetic Evaluation

All patients underwent thorough preoperative evaluation, including medical history, general and systemic examination, airway assessment (Mallampati grading), and routine investigations such as complete blood count, blood sugar, liver and renal function tests, ECG, HIV, HBsAg, and chest radiography. Patients were appropriately counselled regarding anaesthesia, surgery, and the study protocol.

Anesthesia Protocol

All patients were premedicated with intravenous midazolam (0.02 mg/kg) and glycopyrrolate (0.004 mg/kg). General anaesthesia was induced using intravenous propofol (2 mg/kg) and succinylcholine (1.5 mg/kg) to facilitate endotracheal intubation. Maintenance was achieved with isoflurane in a 50:50 air-oxygen mixture, with vecuronium as the neuromuscular blocker.

The study drug infusion (as per group allocation) was initiated 10 minutes before induction and continued till 10 minutes before reversal of the muscle relaxant. Standard ASA monitoring was used throughout the procedure.

Monitoring Parameters

Hemodynamic parameters include:

- Heart Rate (HR),
- Systolic Blood Pressure (SBP),
- Diastolic Blood Pressure (DBP),
- Mean Arterial Pressure (MAP),

were recorded at baseline, after infusion initiation, after induction, post-intubation (1, 3, 5, 10 minutes), every 15 minutes intraoperatively, and postoperatively at 10, 15, 20, and 30 minutes in the PACU (Post-Anesthesia Care Unit).

Assessment Criteria

- **Surgical field visibility** was graded using the **Boezaart Grading Scale** (0–5).
- **Surgeon satisfaction** was recorded as Excellent, Good, Fair, or Poor.
- **Adverse events** such as bradycardia (HR < 50 bpm), hypotension (MAP < 60 mmHg), PONV, and respiratory depression were noted.
- **Postoperative analgesia requirement** was assessed based on patient demand for rescue analgesia (IV Paracetamol 1g) and Visual Analog Scale (VAS) score > 4.

Statistical Analysis

Data were analyzed using SPSS version 20. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were presented as frequencies and percentages. Inter-group comparisons were made using the independent t-test or Mann–Whitney U test for continuous variables, and the chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 106 patients were enrolled and randomized equally into two groups: Group D (Dexmedetomidine alone, n = 53) and Group DF (Dexmedetomidine + Fentanyl, n = 53). The demographic parameters such as age, gender distribution, and ASA physical status were comparable between the two groups. The mean age in Group D was 42.32 ± 14.13 years, while in Group DF it was 40.73 ± 14.53 years (p = 0.569). The gender distribution was similar, with Group D having 56.6% males and Group DF 52.8% males (p = 0.856). ASA Grade I patients accounted for 58.5% in Group D and 54.7% in Group DF, without significant intergroup variation (Table 1).

Table 1: Baseline Demographics

Parameter	Group D (n=53)	Group DF (n=53)	p-value
Mean Age (years)	42.32 ± 14.13	40.73 ± 14.53	0.569
Gender (M/F)	30/23	28/25	0.856
ASA Grade I (%)	58.5	54.7	0.783
ASA Grade II (%)	41.5	45.3	—

Following initiation of the study drug infusion, a significant reduction in heart rate (HR) was observed in both groups. However, Group DF consistently demonstrated better control, with significantly lower HR values recorded at 10 minutes after infusion (68.7 ± 5.1 bpm vs 72.1 ± 5.9 bpm in Group D; p = 0.001). This trend remained consistent at key intraoperative intervals such as post-induction, intubation, and during surgical dissection. At 70 minutes intraoperatively, Group DF had a mean HR of 63.1 ± 3.6 bpm compared to 66.2 ± 4.1 bpm in Group D (p < 0.001), indicating better sympatholytic control with the combination therapy.

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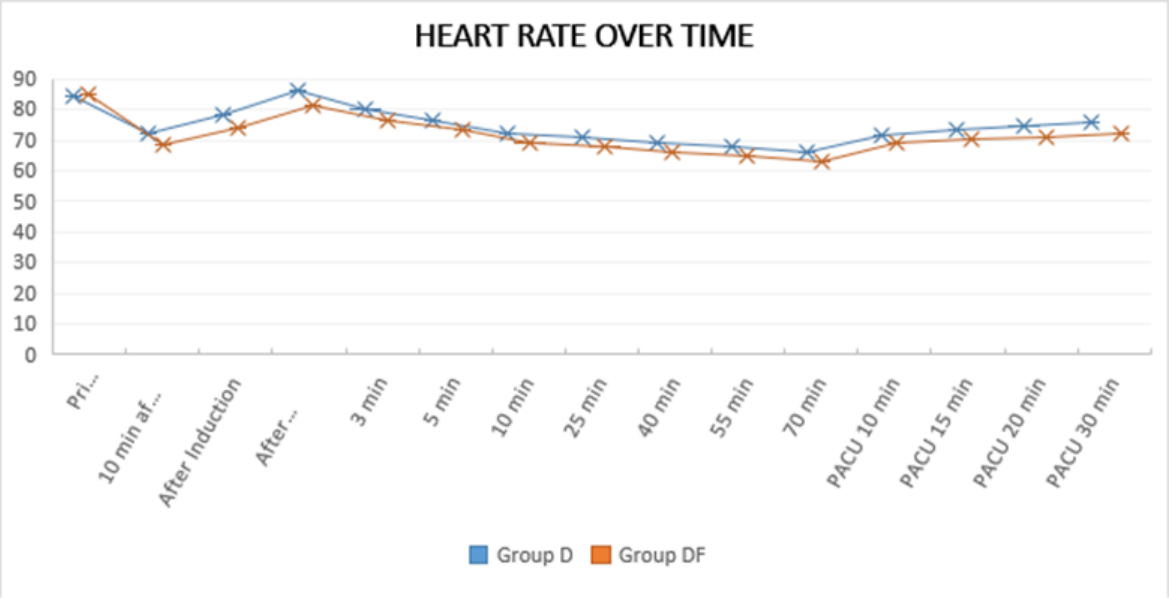
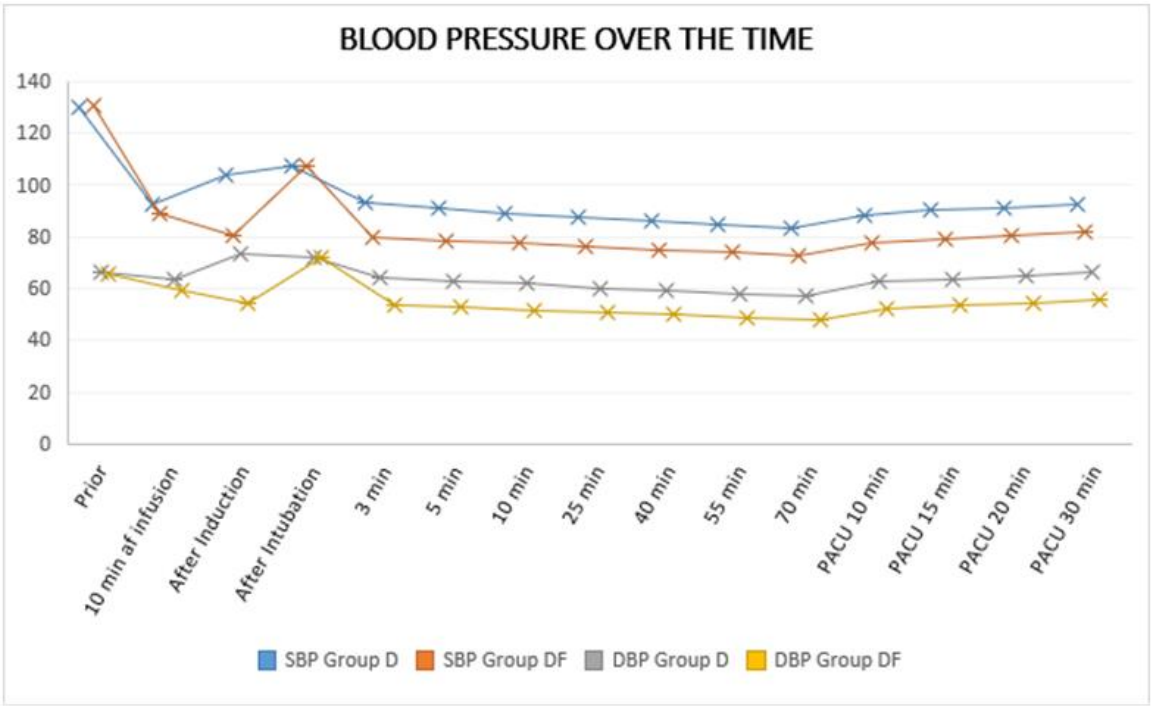


Graph.1 A line graph representation of heart rate over time

Systolic and diastolic blood pressure (SBP and DBP) values also showed significantly better suppression in Group DF. At 10 minutes post-infusion, the SBP was 89.1 ± 5.6 mmHg in Group DF versus 92.4 ± 6.5 mmHg in Group D ($p = 0.006$), while DBP was 59.1 ± 5.6 mmHg in Group DF compared to 63.5 ± 5.8 mmHg in Group D ($p < 0.001$). Post-induction and during the critical surgical phases, this trend remained highly significant, demonstrating that the combined use of dexmedetomidine and fentanyl ensured a smoother and more controlled hypotensive profile.



Graph.2 A line graph representation of blood pressure over the time

The mean arterial pressure (MAP) values mirrored this trend. After induction, MAP in Group DF dropped to 62.9 ± 3.1 mmHg, whereas in Group D it remained at 81.2 ± 3.1 mmHg ($p < 0.001$). Throughout the surgical duration and into the postoperative recovery period, Group DF maintained significantly lower MAP levels, consistently within the target range for controlled hypotension (50–65 mmHg), without inducing critical hypotensive episodes.

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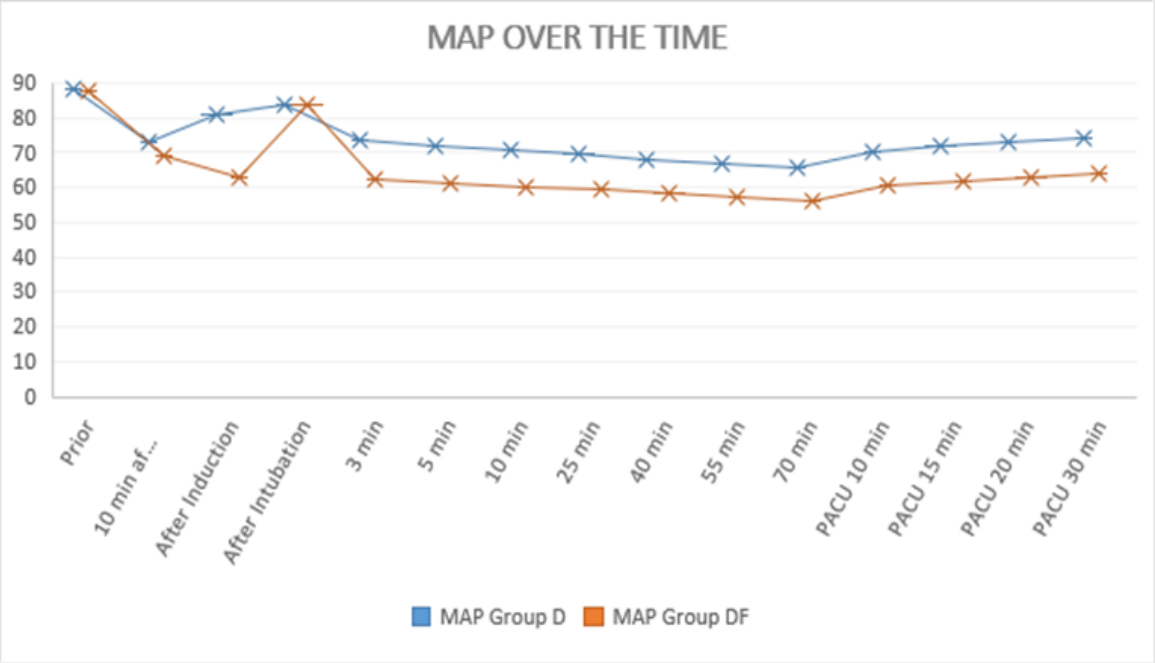

Graph.3 A line graph representation of MAP over the time

In terms of surgical field quality, assessed using the Boezaart grading scale, Group DF showed superior visibility with a mean score of 2.04 ± 0.6 compared to 2.42 ± 0.8 in Group D ($p = 0.006$). Surgeon satisfaction scores were also notably higher in the combination group, with 56.6% rating the field as "excellent" in Group DF compared to 45.3% in Group D.

Postoperative outcomes further supported the advantage of the combination therapy. Fewer patients in Group DF required rescue analgesia (5.6% vs 32% in Group D, $p < 0.05$), indicating a longer-lasting analgesic effect. Additionally, the incidence of intraoperative adverse events was significantly lower in Group DF. Bradycardia occurred in 30.1% of Group D patients versus only 7.5% in Group DF ($p = 0.002$). Similarly, hypotension was observed in 22.6% of Group D patients but only 5.7% in Group DF ($p = 0.012$). Incidence of postoperative nausea and vomiting (PONV) was also reduced (15 in Group D vs 3 in Group DF, $p = 0.019$).

These findings clearly suggest that the combination of dexmedetomidine and fentanyl provided a more stable hemodynamic profile, superior surgical conditions, better analgesia, and fewer side effects compared to dexmedetomidine alone, thus validating the rationale behind the study hypothesis.

Table: 2 Boezaart Grading Scale (0–5)

Group	Mean Boezaart Grade (± SD)
Group D (Dexmedetomidine)	2.42 ± 0.8
Group DF (Dexmedetomidine + Fentanyl)	2.04 ± 0.6
T-test t-2.76 at sig 0.006 (S)	

Table 3: Surgeon Satisfaction – Excellent (%)

Group	Surgeon Satisfaction – Excellent (%)
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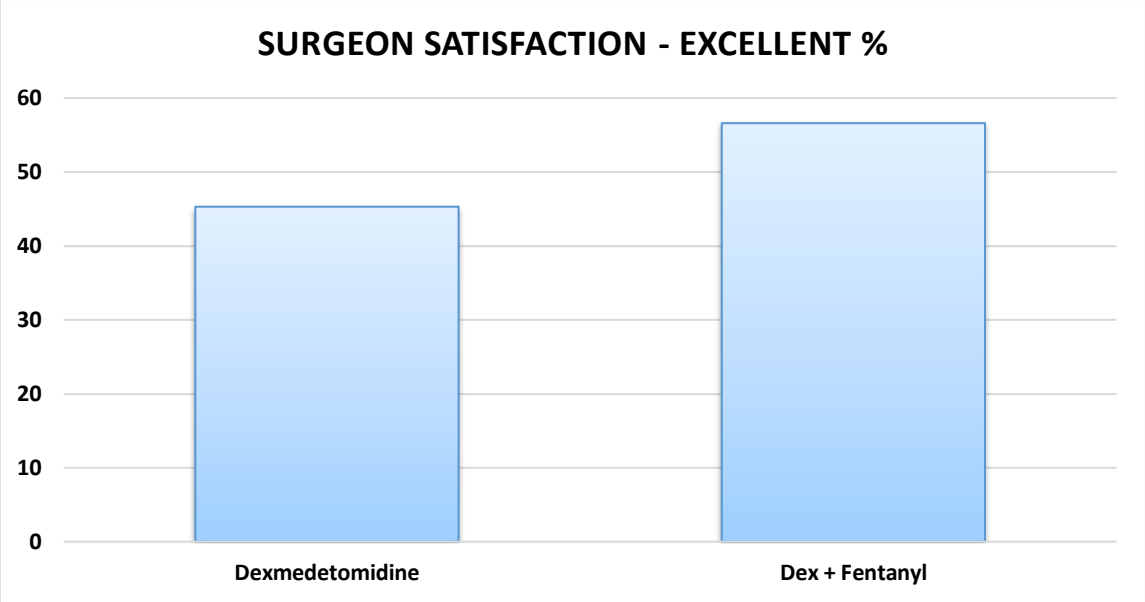
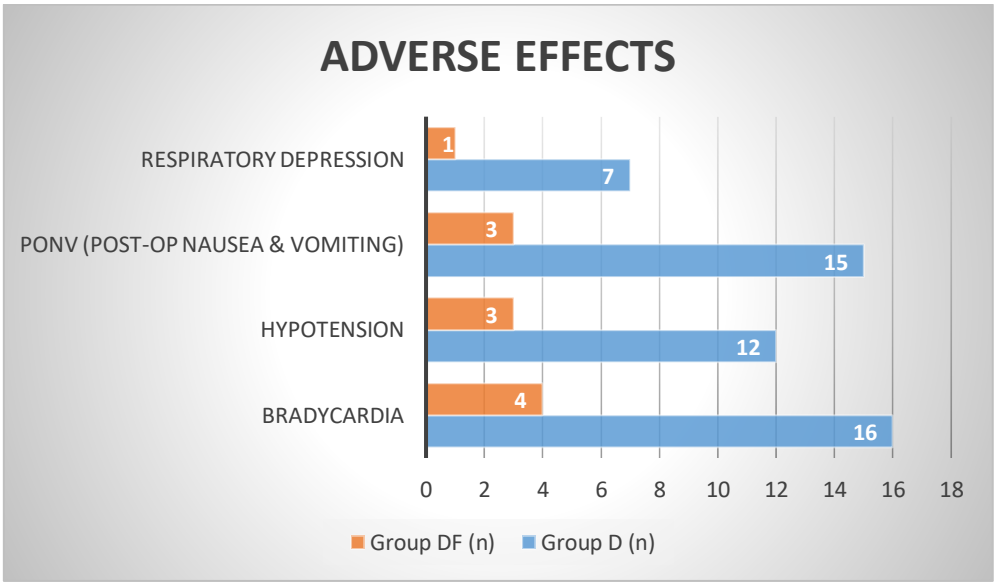


Graph.4 A bar graph representation of Surgeon Satisfaction – Excellent

Table 4: Intraoperative Adverse Events

Adverse Event	Group D (n)	Group DF (n)	P Value
Bradycardia	16	04	0.002
Hypotension	12	03	0.012
PONV (Post-op Nausea & Vomiting)	15	03	0.019
Respiratory Depression	07	01	0.273

Adverse events were **lower in Group DF**, suggesting improved hemodynamic tolerance when fentanyl is combined with dexmedetomidine.



Graph.5 A column bar graph representation of adverse effects distribution

Table 8: Postoperative Analgesia Requirement (Inj. Paracetamol 1g)

Group	Patients Requiring Analgesia (n, %)
Group D (Dexmedetomidine)	17
Group DF (Dexmedetomidine+ Fentanyl)	03
Chi-square test <0.05 (S)	

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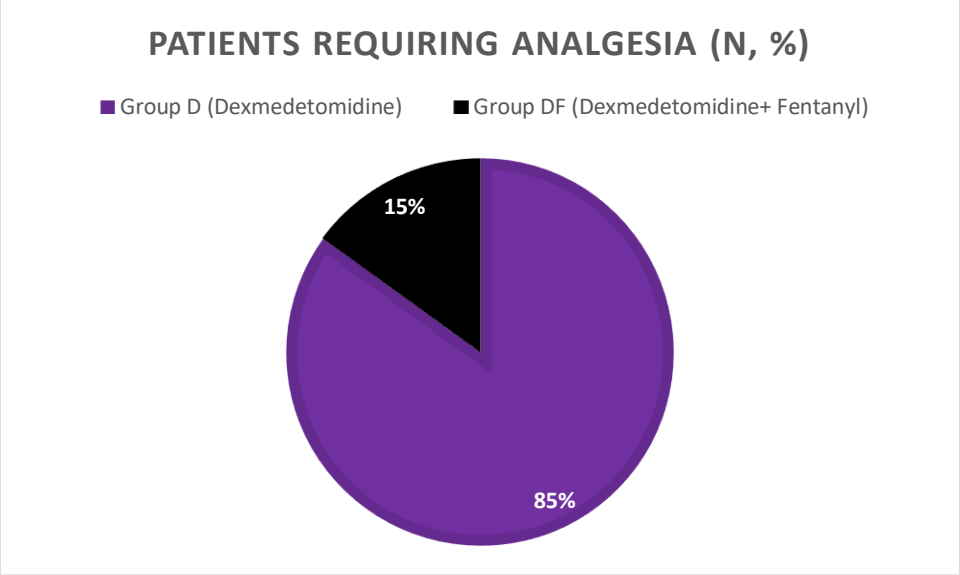
Group DF had a **lower need for rescue analgesia**, confirming the **better sustained analgesic effect** of the combination.



Graph.6 A pie chart representation of patients requiring analgesia

DISCUSSION

Achieving a bloodless operative field remains a cornerstone of anaesthetic management during Functional Endoscopic Sinus Surgery (FESS). Controlled hypotension is a well-established technique that enables better visualization, reduces intraoperative bleeding, and improves surgical precision, especially within the narrow confines of the nasal cavity. In this randomized controlled trial, we compared the efficacy and safety of dexmedetomidine alone (Group D) versus dexmedetomidine combined with fentanyl (Group DF) for providing hypotensive anaesthesia in adult patients undergoing elective FESS. Our findings demonstrated superior hemodynamic control, surgical field quality, and analgesic outcomes in the combination group, validating our hypothesis and aligning with prior literature in this domain.

Our study revealed that the mean heart rate (HR) and mean arterial pressure (MAP) were significantly lower in Group DF throughout the intraoperative period. For instance, at 10 minutes post-infusion, HR was 68.7 ± 5.1 bpm in Group DF vs 72.1 ± 5.9 bpm in Group D ($p = 0.001$), and MAP was 62.9 ± 3.1 mmHg vs 81.2 ± 3.1 mmHg ($p < 0.001$). This consistent trend of enhanced hemodynamic suppression in Group DF was corroborated by El Shama et al., who observed that dexmedetomidine-fentanyl infusion led to more stable intraoperative hemodynamics and improved stress attenuation during nasal surgeries compared to dexmedetomidine alone [1].

Similarly, Bajwa et al. also emphasized the advantage of combining fentanyl with dexmedetomidine for reducing sympathetic tone and enhancing bradycardic effects without compromising perfusion [2]. In the context of FESS, where even minor fluctuations in HR or MAP can lead to obscured visibility, these results underscore the clinical superiority of combination therapy.

The quality of the surgical field, measured via Boezaart's grading, was significantly better in Group DF (mean score 2.04 ± 0.6) compared to Group D (2.42 ± 0.8; $p = 0.006$). Surgeon satisfaction was higher as well, with 56.6% rating the field as excellent in Group DF versus 45.3% in Group D. These outcomes are consistent with the findings of Aysan et al., who showed improved Boezaart scores and reduced bleeding when dexmedetomidine was combined with opioids during endoscopic sinus surgery [3].

The enhanced surgical field in Group DF can be attributed to fentanyl's central analgesic and sympatholytic effects, which complement dexmedetomidine's vasodilatory and sedative actions, thus maintaining a targeted hypotensive range (MAP 50–65 mmHg) more reliably.

One of the primary concerns with dexmedetomidine is dose-dependent bradycardia and hypotension. In our study, Group DF had a significantly lower incidence of bradycardia (7.5% vs 30.1%, $p = 0.002$) and hypotension (5.7% vs 22.6%, $p = 0.012$) compared to Group D. This finding suggests that fentanyl allows for effective dose sparing of dexmedetomidine, thereby reducing its adverse cardiovascular profile.

Comparable safety benefits were documented by Tufanogullari et al., where patients receiving dexmedetomidine in lower doses, supported by opioid adjuncts, exhibited fewer hemodynamic perturbations during surgery [4]. Furthermore, the combination regimen led to a lower incidence of postoperative nausea and vomiting (PONV) (3 in Group DF vs 15 in Group D, $p = 0.019$), echoing the opioid-sparing

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benefit of dexmedetomidine and the emetogenic modulation by fentanyl at lower infusion rates.

Another noteworthy finding in our study was the reduced requirement for rescue analgesia in Group DF. Only 5.6% of patients in the combination group required paracetamol postoperatively, compared to 32% in Group D ($p < 0.05$). This result aligns with the work by Goyal et al., who demonstrated prolonged pain relief and reduced analgesic consumption in patients receiving dexmedetomidine-fentanyl infusions during maxillofacial and sinus procedures [5].

The synergistic analgesic effect of fentanyl and dexmedetomidine likely accounts for this outcome, reducing nociceptive transmission both intra- and postoperatively. Given the opioid crisis and the need for balanced analgesia, this finding holds considerable clinical value in minimizing postoperative opioid use without compromising pain control.

These findings collectively highlight the multimodal advantages of combining dexmedetomidine with fentanyl in FESS. The approach allows for better hemodynamic modulation, enhanced surgeon working conditions, and improved patient safety. Additionally, it facilitates early emergence from anaesthesia without increasing opioid-related side effects or the duration of postoperative monitoring.

Considering the limitations of individual hypotensive agents—such as cyanide toxicity with sodium nitroprusside or delayed emergence with inhalational agents—the dexmedetomidine-fentanyl combination emerges as a balanced, rational, and clinically safe alternative for hypotensive anaesthesia in FESS.

Study Limitations

Our study includes the use of fixed dosing without titration may not accurately reflect the individualized needs of patients, potentially impacting treatment effectiveness. our study did not assess sedation depth or recovery time, which are important for understanding the procedural impact. Furthermore, subjective grading of the surgical field introduces the possibility of observer bias, and the absence of biochemical markers for stress or inflammation limits the ability to measure objective physiological responses. Finally, surgical outcomes may be influenced by the operator's skill and technique, leading to potential variability in the results.

CONCLUSION

FESS demands a blood less operative field and stable hemodynamics,controlled hypotension is a optimal technique to achieve these parameters hence our study demonstrated that infusion of injdexmedetomidine with fentanyl (Group DF) provided significantly better hemodynamic stability, surgical field quality, and postoperative outcomes compared to dexmedetomidine alone (Group D) in patients undergoing FESS. Boezaart grading and surgeon satisfaction rated excellent in Group DF and Postoperative analgesia need was significantly lower in Group DF. Thus, the combination therapy is both efficacious and safer, making it a preferred choice for controlled hypotension during FESS.

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