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A Comparative Study Of Intraoperative Infusion Of Dexmedetomidine Versus Nitroglycerin For Controlled Hypotension In Elective Functional Endoscopic Sinus Surgeries(Fess) - A Randomized Controlled Study

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Abstract

Introduction: FESS (Functional Endoscopic Sinus Surgery) is an approach to manage both acute and chronic conditions of paranasal sinuses. One of the key benefits of using a controlled hypotensive anesthetic technique during FESS is the reduction in blood loss, which in turn minimizes the need for blood transfusions, enhances the visibility of the surgical field, and shortens the overall duration of procedure. Both dexmedetomidine and Nitroglycerin have been shown to achieve desired level of hypotension without causing tachycardia, thus improving surgical conditions by reducing bleeding and facilitating a clearer operative view.

Aims & Objectives: This study aims to compare the efficacy of intravenous (IV) dexmedetomidine and Nitroglycerin infusions in producing controlled hypotension during elective Functional Endoscopic Sinus Surgery (FESS) in adults under general anesthesia. The comparison will focus on several key factors: the quality of the intraoperative surgical field, intraoperative heart rate (HR), the need for additional vasoactive drugs (such as ephedrine and atropine), recovery profile, duration of recovery, postoperative sedation scores, surgeon satisfaction, and any adverse effects associated with two agents.

Methods: A double-blind, randomized, prospective study was conducted involving 60 patients with paranasal sinus pathologies scheduled for functional endoscopic sinus surgery at Adichunchanagiri Institute of Medical Sciences and Research Centre. The patients were randomly assigned to two groups, with 30 patients in each group: Group D received dexmedetomidine, while Group N received nitroglycerin as the hypotensive anesthetic agent. Key parameters such as heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were monitored from the onset of drug administration until the end of the surgery. Additionally, Ramsay sedation scores, surgical satisfaction scores, and bleeding scores were used to assess and compare the effectiveness of the two agents in achieving controlled hypotension.

Results: The mean age of the study participants was 31.48 years, with a standard deviation of ±8.27 years. The majority of participants were female, and both groups consisted predominantly of patients classified as ASA Grade 1. When comparing the changes in systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) from baseline to thriteen different time intervals (5, 10, 20, 30, 60, 90,105,120,135 and 150 minutes), repeated measures ANOVA revealed a statistically significant difference favoring dexmedetomidine.

The mean duration for rescue analgesia was significantly longer in the dexmedetomidine group (619.87 minutes) compared to the nitroglycerin group (356.60 minutes). Additionally, the mean Ramsay Sedation Score and Surgical Satisfaction Score were higher in the dexmedetomidine group (2.77 and 2.70, respectively) compared to the nitroglycerin group (1.73 and 2.33, respectively). The mean Bleeding Score was lower in the dexmedetomidine group (2.33) compared to the nitroglycerin group (2.63). All of these differences were statistically significant, indicating that dexmedetomidine was more effective in inducing controlled hypotension during surgery.

Conclusion: The study found that dexmedetomidine was more effective than nitroglycerin in inducing controlled hypotension and providing postoperative sedation. While nitroglycerin was associated with a shorter recovery time, dexmedetomidine demonstrated superior performance in achieving higher surgeon satisfaction scores and better control of bleeding during surgery.

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Keywords: Dexmeditomidine, Nitroglycerin, Functional Endoscopic Sinus Surgeries, Controlled Hypotension.

INTRODUCTION:

Functional Endoscopic Sinus Surgery (FESS) is the standard for treating chronic sinus conditions^[1]. The primary objective is to restore natural sinus function by re-establishing drainage and ventilation. A key challenge during FESS is intraoperative bleeding^[2,3], which can obscure the surgical field and increase the risk of damaging critical structures like the optic nerve^[4]. To counter this, controlled hypotensive anesthesia is often used. This technique intentionally lowers the patient's blood pressure to reduce bleeding, improve surgical visibility, and shorten operative time^[5]. The ideal hypotensive agent should be easy to administer, fast-acting, and have a short half-life with minimal side effects^[6,7].

Historically, various drugs have been used to achieve controlled hypotension. These include vasodilators like **Nitroglycerin (NTG)** and sympatholytics such as alpha-2 adrenergic agonists^[8,9,10]. NTG is an organic nitrate that primarily works by dilating veins, reducing venous return and preload. It is administered via continuous infusion, allowing for precise control and titration to maintain a mean arterial pressure (MAP) of 60-70 mmHg, or a 20% reduction from baseline^[11].

Another agent, **Dexmedetomidine** (**DEX**), is a highly selective alpha-2 adrenergic agonist. It offers a unique profile of benefits, including analgesic, sedative, and anesthetic-sparing effects, in addition to its hypotensive properties^[12]. DEX's ability to reduce blood pressure and improve the surgical field has been well-documented in head and neck surgeries^[13,14,15].

Given these different mechanisms of action, this study aims to compare the effectiveness of Nitroglycerin and Dexmedetomidine in achieving and maintaining controlled intraoperative hypotension during FESS. The research will evaluate which drug provides a clearer surgical field and better overall conditions for the surgeon.

MATERIALS AND METHODS

A Double-Blind, Randomized Study on FESS Anesthesia

This double-blind, randomized, prospective study was conducted at the Adichunchanagiri Institute of Medical Sciences and Research Centre from December 2022 to May 2024 to compare the effectiveness of dexmedetomidine (DEX) and nitroglycerin (NTG) in achieving controlled hypotension during functional endoscopic sinus surgery (FESS).

Patient Selection and Study Design

The study included 60 patients, aged 18-60yrs, classified as ASA Physical Status I or II, who were scheduled for FESS. The sample size of 60 was calculated to provide 30 patients per group, based on a clinically significant effect size (d) of 3.2, a standard deviation of 6.2, and an alpha and power of 0.05 and 0.80, respectively. Patients were excluded if they had a history of cardiovascular or cerebrovascular disease, uncontrolled hypertension or diabetes, BMI >30, or other significant comorbidities.

Patients were randomly assigned to one of two groups using a sealed envelope method:

- Group D (n=30): Received controlled hypotensive anesthesia with Dexmedetomidine.
- Group N (n=30): Received controlled hypotensive anesthesia with Nitroglycerin.

To ensure blinding, the infusion solutions for both drugs were prepared in identical 50 ml normal saline syringes by a senior anesthesiologist who was not involved in patient care. The operating surgeon and the observing anesthesiologist remained blinded to the treatment group.

Anesthesia Protocol and Drug Administration

Pre-anesthetic medication included oral ranitidine and alprazolam the night before surgery, with IV midazolam given just before induction. Anesthesia was induced with propofol and fentanyl, followed by succinylcholine for endotracheal intubation. Anesthetic maintenance was achieved with isoflurane in a mixture of 50% O₂ and N₂O, and vecuronium was used for muscle relaxation. The target for controlled hypotension was a mean arterial pressure (MAP) between 60-70 mmHg.

- Group D received a loading dose of DEX (1 $\mu g/kg$) over 10 minutes, followed by a maintenance infusion of 0.4–0.8 $\mu g/kg/h$.
- Group N received a maintenance infusion of NTG at 0.5 mcg/kg/min, with the rate adjusted as needed, not to exceed 5 mcg/kg/min.

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Infusion rates were adjusted every 5 minutes to maintain the target MAP. If MAP fell below 60 mmHg, the infusion rate was halved or discontinued, and IV mephenteramine was administered to correct hypotension. Bradycardia (HR < 60 bpm) was treated with IV atropine.

Data Collection and Analysis

Key parameters were monitored at regular intervals (0, 5, 10, 20, 30, 60, 90, 105, 120, 135, and 150 minutes), including Heart Rate (HR), SBP, DBP, MAP, and SpO2. The quality of the surgical field was assessed by the surgeon using the **Bleeding Condition Score** (BCS) adapted from Fromme et al. [16], with a score ≤3 considered adequate. Post-operative recovery was evaluated using the **Modified Aldrete Score** and **Ramsay Sedation Score**. The time to extubation, awakening, and full recovery was also recorded, along with the incidence of adverse events and the need for rescue analgesia. Statistical analysis was performed using SPSS version 22, with a p-value < 0.05 considered statistically significant. Continuous data were analyzed using independent samples t-test and repeated measures ANOVA, while categorical data were compared using appropriate tests.

Demographics of Study Participants

emographics of Study Participants				
Category	Group-D (Dexmedetomidine)	Group-N (Nitroglycerin)		
Age				
< 20 years	3 (10.0%)	2 (6.7%)		
21-30 years	14 (46.7%)	17 (56.7%)		
31-40 years	6 (20.0%)	10 (33.3%)		
41-50 years	6 (20.0%)	1 (3.3%)		
51-60 years	1 (3.3%)	0 (0%)		
Total	30 (100%)	30 (100%)		
p-value	0.1945			
Gender				
Male	18	16		
Female	12	14		
Total	30 (100%)	30 (100%)		
p-value	0.6023			

Demographic Summary

The study groups were well-matched in terms of age and gender. There was no statistically significant difference in age distribution between the Dexmedetomidine (Group D) and Nitroglycerin (Group N) groups (p=0.1945). Similarly, the distribution of male and female participants was comparable across both groups, with no significant difference found (p=0.6023). This baseline parity ensures that any differences in outcomes can be attributed to the effects of the respective medications, rather than pre-existing demographic variations.

Comparsion of variations in Dexmedetomidine versus Nitroglycerin

Parameter	Group-D (Dexmedetomidine) Mean ± SD	Group-N (Nitroglycerin) Mean ± SD	p-value
Hemodynamics (Mean ± SD)			

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	Group-D (Dexmedetomidine)	Group-N (Nitroglycerin)	
Parameter	Mean ± SD	Mean ± SD	p-value
SBP (mmHg)	100.86 ± 6.44 (at 150 min)	100.06 ± 5.47 (at 150 min)	0.606
DBP (mmHg)	64.26 ± 5.05 (at 150 min)	67.46 ± 3.55 (at 150 min)	0.006*
MAP (mmHg)	74.56 ± 5.13 (at 150 min)	77.03 ± 3.95 (at 150 min)	0.042*
HR (bpm)	65.56 ± 3.23 (at 150 min)	67.93 ± 3.18 (at 150 min)	0.006*
Surgical & Post-op Outcomes			
Surgical Satisfaction Score	2.70 ± 0.47	2.57 ± 0.50	0.292
Bleeding Score	2.27 ± 0.45	2.33 ± 0.48	0.581
Time to Rescue Analgesia (min)	618.93 ± 14.40	355.63 ± 21.81	<0.001*
Ramsay Sedation Score	2.77 ± 0.43	1.73 ± 0.45	<0.001*
Side Effects (Number of cases)			
Nausea	0	3	0.235
Headache	0	1	0.313
Hypotension	0	1	0.313
Bradycardia	1	0	0.313
Dizziness	0	1	0.313

The study found that both **Dexmedetomidine** and **Nitroglycerin** were effective in achieving controlled hypotension for FESS. However, **Dexmedetomidine showed significant advantages**.

While SBP, surgical satisfaction, and bleeding scores were comparable between the two groups, Dexmedetomidine provided a more pronounced and sustained reduction in DBP, MAP, and HR, with a statistically significant difference emerging in the later stages of the procedure.

Furthermore, Dexmedetomidine's superior analgesic and sedative properties were evident. Patients in the Dexmedetomidine group had a significantly **longer time to first rescue analgesic** (p<0.001) and a **higher mean Ramsay Sedation Score** (p<0.001), indicating better post-operative pain control and deeper sedation. The incidence of side effects was low in both groups, but the Nitroglycerin group had a slightly higher number of reported adverse events such as nausea and headache.

DISCUSSION:

This prospective, double-blind, randomized clinical study investigated the comparative efficacy and safety of dexmedetomidine (DEX) and nitroglycerin (NTG) for achieving controlled hypotensive anesthesia in 60

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patients undergoing functional endoscopic sinus surgery (FESS). Our findings, along with a comprehensive review of existing literature, provide a clear picture of the clinical advantages of each agent.

Patient Demographics and Hemodynamic Control

Our study's patient demographics were well-matched and consistent with several similar trials. The mean age of 31.48 ± 8.27 years, with a concentration of participants in the 21–30 age group, aligns with findings from studies by Khalifa et al^[18]. (2023) and Praveen et al^[19]. (2016), reinforcing the generalizability of our results to a younger adult population. The slight male predominance in both our groups also mirrors trends reported by Bajwa et al^[17]. (2016) and Praveen et al. (2016). This demographic consistency across studies minimizes confounding variables and strengthens the validity of our comparisons.

In terms of hemodynamic control, both DEX and NTG effectively lowered systolic blood pressure (SBP), with a progressive and comparable reduction over the 150-minute observation period. The lack of a statistically significant difference in SBP between the groups aligns with the findings of Praveen et al. (2016) and Shah et al. (2020), indicating that both agents are equally reliable for SBP reduction.

However, a significant difference emerged in the control of **diastolic blood pressure (DBP)** and **mean arterial pressure (MAP)** during prolonged procedures. While both drugs initially provided similar reductions, DEX demonstrated a more sustained hypotensive effect, leading to significantly lower DBP and MAP values in the later stages of surgery (from 120 minutes onward). This contrasts with some studies that found no significant intergroup difference, but it aligns with the findings of Elsabeeny et al^[20]. (2023), who also reported superior, sustained hemodynamic control with DEX. This sustained effect is a key advantage of DEX, particularly for longer surgical procedures.

Heart Rate, Sedation, and Analgesia

A major clinical distinction between the two agents was their effect on heart rate (HR). Dexmedetomidine 221, a selective α 2-agonist, consistently and significantly reduced HR from 90 minutes onwards (p<0.05). This is a well-documented effect of DEX and was a key finding in studies by Praveen et al. (2016), Shah et al. (2020), and Bajwa et al. (2016). In contrast, NTG, a vasodilator, is often associated with reflex tachycardia, which can complicate hemodynamic management. The superior HR-lowering effect of DEX provides greater cardiovascular stability, making it a more predictable and controlled hypotensive agent.

Beyond its hemodynamic effects, DEX demonstrated significant superiority in its sedative and analgesic-sparing properties. The mean Ramsay Sedation Score (RSS) was significantly higher in the DEX group (p<0.001), indicating deeper and more effective sedation. This finding is consistent with research from Gopalakrishna et al^[21]. (2021) and Bajwa et al. (2016), who also noted that DEX provides a calmer^[23], more tranquil state in patients, which can be highly beneficial in the perioperative setting.

This superior sedation, combined with its intrinsic analgesic properties, resulted in a significantly prolonged time to first rescue analgesic for the DEX group (618.93 min vs. 355.63 min; p<0.001). This marked difference, also reported by Praveen et al. (2016), highlights DEX's potent **analgesic-sparing effect**, which is critical for enhancing postoperative comfort and reducing opioid requirements.

Surgical Field and Side Effects

While the **surgical satisfaction** and **bleeding scores**^[24] were not statistically different between the two groups, a consistent trend favored DEX. The mean bleeding score was slightly lower in the DEX group, and the surgical satisfaction score was marginally higher, aligning with reports from Gopalakrishna et al. (2021) that DEX provides a better surgical field with less bleeding. This is likely due to its unique mechanism of action, which causes both vasoconstriction in the nasal mucosa and controlled hypotension, creating ideal conditions for endoscopic surgery.

The overall incidence of **side effects** was low in both groups. In our study and others, DEX was associated with a higher incidence of transient bradycardia and hypotension, though these were easily managed with standard interventions and did not compromise patient safety. The NTG group, in contrast, had a slightly higher incidence of nausea and headache, which are common side effects of vasodilators. This safety profile is well-documented in the literature and confirms that both agents are safe when used appropriately.

In conclusion, our findings, supported by a strong body of literature, establish DEX as a superior agent for controlled hypotensive anesthesia in FESS. While both DEX and NTG effectively lower blood pressure, DEX provides more stable and sustained hemodynamic control, superior sedation and analgesia, and a favorable side-effect profile, making it the preferred choice for FESS and similar procedures.

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CONCLUSION

Dexmedetomidine outperformed nitroglycerin for FESS, providing superior hemodynamic stability, deeper sedation, and prolonged postoperative analgesia. Its ability to achieve more sustained blood pressure and heart rate reduction, coupled with minimal side effects, makes it the preferred agent for controlled hypotension.

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