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Comparative Evaluation Of Intranasal Fentanyl And Dexmedetomidine As Premedication Agents In Elective Surgeries Under General Anaesthesia

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Abstract:
Background*: Premedication is essential in perioperative care to reduce anxiety, provide analgesia, suppress autonomic reflexes and facilitate smooth anaesthesia. Intranasal drug delivery offers a non-invassive route with rapid absorption through the nasal mucosa. Intranasal Fentanyl provides rapid analgesia and sedation within minutes, while Intranasal dexmedetomidine offers sedation, anxiolysis, and mild analgesia without significant respiratory depression, making both useful premedicant.*
Materials and Methods*: Following approval from the institutional ethics committee an informed consent was taken from 30 patients scheduled for elective surgery under General Anaesthesia at Akash Institute of Medical Sciences, Bengaluru. These patients were randomly divided into two groups (1:1) where Group F (Intranasal Fentanyl 1.5 mcg/kg) and Group D (Intranasal Dexmedetomidine 1.5mcg/hr). Drugs were administered via atomizer in equal doses to both the nostrils. Baseline OAA/S score and vitals were recorded, then monitored every 10 minutes for 45 minutes. Patients were then shifted to the OT for surgery. Postoperatively, they were observed for one hour before ward transfer. After 24 hours, patients rated their premedication experience on a 5-point scale.*
Results*: In this study, OAAS scores remained 4 in both groups, showing lethargic response at 20mins after administering the drug with no significant difference. Hemodynamic variables, including pulse rate, and MAP, were slightly lower in Fentanyl group but not statistically significant. SpO_2 was initially normal in Fentanyl group; however, five patients had low SpO_2 of 90% at 20 minutes. Patient experience was significant in Dexmedetomidine group, with 80% rating it as excellent compared to 33.3% in Fentanyl group ($p = 0.01$).*
Conclusion: *Intranasal Dexmedetomidine provided similar sedation and hemodynamic stability to Fentanyl, but better patient satisfaction and minimal respiratory effects. Thus making it a favourable drug for premedication in elective surgeries.*
Key Word: *Intranasal premedication; Fentanyl; Dexmedetomidine; general anaesthesia; OAAS score.*
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I. Introduction

Premedication plays a pivotal role in the perioperative management of surgical patients, aiming to enhance patient comfort, optimize physiological parameters, and reduce perioperative risks. The primary goals of premedication include anxiolysis, analgesia, suppression of undesirable autonomic reflexes, and facilitation of smooth induction and maintenance of anaesthesia.

Anxiety before surgery is common and has been associated with increased anaesthetic requirements, delayed recovery, and adverse cardiovascular responses such as tachycardia and hypertension. Agents such as midazolam are frequently used to provide anxiolysis and amnesia, while glycopyrrolate or atropine are administered to reduce airway secretions and prevent bradycardia. The choice of premedication must be individualized based on patient age, comorbidities, the nature of surgery, and anticipated anaesthetic technique [1].

The intranasal (IN) route of drug administration has gained significant attention in anaesthetic and emergency care settings due to its non-invasive nature, rapid onset, and ease of use, especially in paediatric, geriatric, and uncooperative patients. It offers a practical alternative when intravenous access is difficult or undesirable, leveraging the rich vascular supply of the nasal mucosa for efficient systemic absorption.

Intranasal fentanyl, a potent synthetic opioid, is widely used for acute pain management due to its rapid onset of action, typically within 5–10 minutes. It has proven effective in treating moderate to severe pain in

prehospital and perioperative settings. Its lipophilic nature facilitates rapid absorption, making it ideal for procedural sedation and breakthrough pain relief [2].

Intranasal dexmedetomidine, a selective α2-adrenergic receptor agonist, provides sedation, anxiolysis, and mild analgesia without causing respiratory depression. It is especially beneficial in preoperative settings and procedural sedation in children, with an onset of action within 25–45 minutes.[3]

II. Material And Methods

After getting permission from Institutional Ethics Committee, Department of Anesthesiology, Akash institute of medical sciences and research centre, Devanahalli, Bangalore, an informed consent obtained from the patients. The present study was conducted prospectively in 30 patients in the age group of 18–60 years of either sex of the American Society of Anesthesiologists (ASA), Physical status Class I and II scheduled to undergo elective surgery under general anesthesia.

Study Design: A Hospital based cross-sectional study

Study Location: This was a tertiary care teaching hospital based study done in Department of Anaesthesiology, at Akash Institute of Medical Sciences & Research Centre, Devanahalli, Bengaluru, Karnataka.

Study Duration: November 2024 to April 2025.

Sample size: 30 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 200. We assumed that the confidence interval of 10% and confidencelevel of 95%. The sample size actually obtained for this study was 15 patients for each group. We planned to include 30 patients (Group F – Intranasal Fentanyl, Group D – Intranasal Dexmedetomidine of 15 patients for each group)

Subjects & selection method: The study population was drawn from the patients who were posted for elective surgeries under General Anaesthesia in Akash Institute of Medical Sciences & Research Centre from November 2024 to April 2025.
Patients were divided into two groups (each group had 15 patients).
Group F (N=15 patients) – Intranasal Fentanyl 1.5mcg/kg to each patient;
Group D (N=15 patients) – Intranasal Dexmedetomidine 1.5mcg/kg to each patient;

Inclusion criteria:
1. Aged between 18 – 60 years
2. Either sex
3. Posted for Elective surgeries under General Anaesthesia,
4. Patients with American Society of Anesthesiologists (ASA) physical status I or II.
5. Patients giving written informed consent.

Exclusion criteria:
1. Pregnant women;
2. Patients with BMI >30kg/m^2
3. Patients with hepatic dysfunction.
4. Patients with cardiac conduction abnormalities.
5. Patients with Oral submucosal fibrosis.
6. Patients with history of allergy to the study Drug.
7. Patients taking antidepressant, antipsychotic, antiepileptic drugs.
8. Patients with a history of drug or alcohol abuse.

Procedure methodology

After obtaining clearance from the Institutional Ethics Committee, the patients were enrolled for the study as per inclusion criteria after obtaining written informed consent. Study was conducted in Akash Institute of Medical Sciences and Research Center, Devanahalli, Bangalore, Karnataka. Detailed pre-anesthetic evaluation was done. Patients were graded according to ASA classification.

American society of anaesthesiologists (ASA) grading[4]
Grade 1 – Normal healthy patient.
Grade 2 - Mild to moderate systemic disease that is well controlled.
Grade 3 – Severe systemic disease of at least one organ system.
Grade 4 – Severe systemic end stage disease of at least one organ system that is life threatening.
Grade 5 – Moribund patient who has little chance of survival.
Grade 6 – Declared brain dead patient.

Then the patients who were scheduled for elective surgeries under General anaesthesia were randomly allocated divided into two groups (1:1) as group F(Intranasal fentanyl) and group D (Intranasal Dexmedetomidine) of 15 patients each. Group F patients received Intranasal fentanyl 1.5mcg/kg and Group D patients received Intranasal Dexmedetomidine 1.5mcg/kg via atomizer, the volume so arrived was divided into two equal halves and atomized to both nostrils in equal proportion.

In preoperative room, baseline OAAS scale and hemodynamic variables were recorded in each patient before premedication. Group F and Group D were administered with the calculated dose of respective drug, given in equal proportions to both the nostrils via atomizer with the patient in semi- recumbent position. Patients were monitored with respect to OAA/S scale, Pulse rate (HR), oxygen saturation (SpO2) and Mean arterial blood pressures (MAP). The OAA/S scale was used to measure anxiety/alertness/sedation. The monitoring was done every 10mins, thereafter.

Observer's assessment of alertness sedation scale.[5]
Grade 5: Responds readily to name spoken in normal tone.
Grade 4: Lethargic response to name spoken in normal tone.
Grade 3: Responds only after name is called loudly and/or repeatedly.
Grade 2: Responds only after mild prodding or shaking.
Grade 1: Responds only after painful trapezius squeeze.
Grade 0: No response after painful trapezius squeeze.

45 min after premedication, patient was shifted to operation theatre for the planned surgical procedure. The surgery was carried out and after surgery the patients were reversed and extubated. They were observed for 1 h postoperatively for full recovery, and then, the patients were shifted to post-operative wards for further management. No complications were noted in either of the groups. 24 hrs after the conclusion of surgery the patient is requested to grade his/her experience with respect to premedication on a 5 point scale.

Statistical analysis

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software and Epi-info version 7.2.1 (CDC Atlanta) software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Normality of the continuous data, was tested by Kolmogorov–Smirnov test and the Shapiro–Wilk test. Independent t test was used as test of significance to identify the mean difference between two quantitative variables. Mann Whitney U test was used for Non parametric data between two groups. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as Line diagram, bar diagram. p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests. [6-8]

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

III. Result

The study was conducted in the Department of Anesthesiology, Akash Institute of Medical Sciences and Research Center, Devanahalli, Bangalore, Karnataka from March, 2024, to November, 2024. The study population included 30 patients aged between 18 and 60 years belonging to ASA class I and II undergoing elective surgeries under general anesthesia. The participants were the patients who satisfied the inclusion criteria. The baseline OAAS score and hemodynamic variables was assessed initially and reassessed periodically at the time of administration, 10 min, 20 min, 30 min, and 45 min after administration of drugs in both groups and was compared.

In this study, both groups Fentanyl and Dexmedetomidine had identical OAAS scores before the intervention and at the time of administration, with a mean score of 5.00 ± 0.00 and a median of 5, indicating no sedation and a p-value of 1.000, suggesting no significant difference. However, at 10 minutes, the OAAS score in the Fentanyl group dropped to 4.20 ± 0.41 (median 4) compared to 5.00 ± 0.00 (median 5) in the

Dexmedetomidine group, with a statistically significant difference ($p < 0.001$). This trend continued at 20 minutes (Fentanyl: 3.47 ± 0.52, Dexmedetomidine: 4.20 ± 0.41, $p = 0.003$), 30 minutes (Fentanyl: 3.13 ± 0.35, Dexmedetomidine: 4.00 ± 0.53, $p < 0.001$), and 45 minutes (Fentanyl: 2.87 ± 0.52, Dexmedetomidine: 3.80 ± 0.41, $p < 0.001$), indicating significantly better sedation scores in the Fentanyl group over time. (Table 1)

Table 1: OAAS score comparison between two groups at different periods of follow-up

OAAS score	Group						P value
	Fentanyl			Dexmedetomidine			
	Mean	SD	Median	Mean	SD	Median	
Before	5.00	.00	5	5.00	.00	5	1.000
At the Time	5.00	.00	5	5.00	.00	5	1.000
10 Mins	4.20	.41	4	5.00	.00	5	<0.001*
20 Mins	3.47	.52	3	4.20	.41	4	0.003*
30 Mins	3.13	.35	3	4.00	.53	4	<0.001*
45 Mins	2.87	.52	3	3.80	.41	4	<0.001*

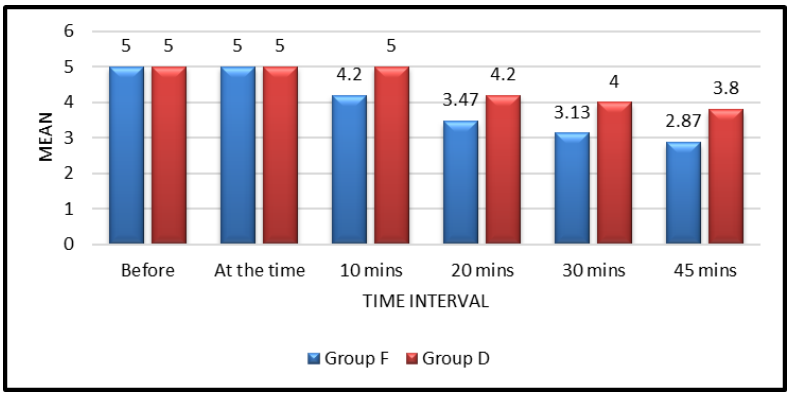


Table 2: Records the oxygen saturation Before administration and at the time of intervention, SpO_2 levels were significantly higher in the Fentanyl group (98.07 ± 1.44 and 97.73 ± 1.44) compared to the Dexmedetomidine group (96.87 ± 1.36 and 96.40 ± 1.35), with p-values of 0.026 and 0.014 respectively. However, at subsequent time points, no statistically significant differences were noted between the groups ($p > 0.05$).

Table 2 : SpO_2 comparison between two groups at different periods of follow-up

SpO2	Group						P value
	Fentanyl			Dexmedetomidine			
	Mean	SD	Median	Mean	SD	Median	
Before	98.07	1.44	99	96.87	1.36	97	0.026*
At the Time	97.73	1.44	98	96.40	1.35	97	0.014*
10 Mins	95.93	1.79	96	95.87	2.20	96	0.928
20 Mins	94.53	2.13	95	95.67	2.64	97	0.206
30 Mins	96.20	2.18	96	95.13	2.00	96	0.173
45 Mins	96.33	1.99	96	95.53	2.00	96	0.281

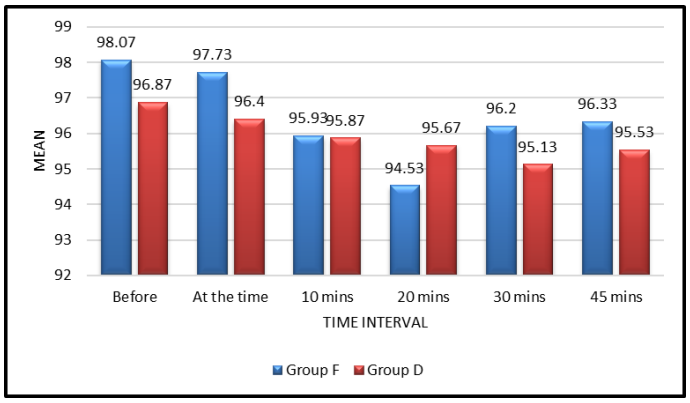


Table 3: Shows that there was no statistically significant difference in pulse rates between the Fentanyl and Dexmedetomidine groups before the intervention (85.27 ± 10.67 vs. 89.13 ± 11.14, p = 0.340) and at the time of administration (84.33 ± 9.99 vs. 89.07 ± 12.31, p = 0.257). However, at 10 minutes, the Dexmedetomidine group exhibited a significantly higher pulse rate (85.80 ± 9.44) compared to the Fentanyl group (77.67 ± 9.90) with a p-value of 0.029. This significant difference persisted at 20 minutes (Fentanyl: 75.73 ± 9.45, Dexmedetomidine: 84.00 ± 9.02, p = 0.021), 30 minutes (Fentanyl: 73.27 ± 8.84, Dexmedetomidine: 80.53 ± 9.01, p = 0.034), and 45 minutes (Fentanyl: 73.07 ± 9.47, Dexmedetomidine: 81.60 ± 10.36, p = 0.026), showing a significantly higher pulse rate in the Dexmedetomidine group during follow-up.

Table 3 : Pulse rate comparison between two groups at different period of follow-up

Pulse rate	Group						P value
	Fentanyl			Dexmedetomidine			
	Mean	SD	Median	Mean	SD	Median	
Before	85.27	10.67	88	89.13	11.14	86	0.340
At the Time	84.33	9.99	86	89.07	12.31	86	0.257
10 Mins	77.67	9.90	80	85.80	9.44	82	0.029*
20 Mins	75.73	9.45	79	84.00	9.02	82	0.021*
30 Mins	73.27	8.84	78	80.53	9.01	80	0.034*
45 Mins	73.07	9.47	74	81.60	10.36	81	0.026*

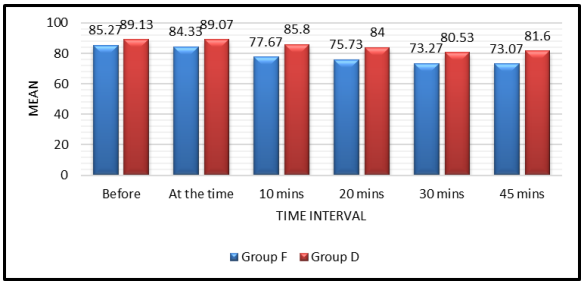


Table 4: Shows comparison of mean arterial pressure (MAP), where the baseline MAP was higher in the Dexmedetomidine group (99.20 ± 9.99) compared to the Fentanyl group (94.47 ± 5.28), but the difference was not statistically significant (p = 0.116). At the time of administration and at 10 minutes, MAP remained higher in the Dexmedetomidine group (98.47 ± 9.60 vs. 93.53 ± 7.06, p = 0.120; and 95.73 ± 7.20 vs. 90.87 ± 4.79, p = 0.038*, respectively). The MAP continued to be significantly higher in the Dexmedetomidine group at 20 minutes (95.13 ± 5.94 vs. 89.27 ± 5.23, p = 0.008), 30 minutes (93.07 ± 5.09 vs. 88.67 ± 6.42, p = 0.047), and 45 minutes (91.93 ± 7.32 vs. 86.53 ± 6.17, p = 0.038), indicating that Fentanyl maintained more stable blood pressure profiles over time.

Table 4: MAP comparison between two groups at different periods of follow-up

MAP	Group						P value
	Fentanyl			Dexmedetomidine			
	Mean	SD	Median	Mean	SD	Median	
Before	94.47	5.28	93	99.20	9.99	98	0.116
At the Time	93.53	7.06	93	98.47	9.60	99	0.120
10 Mins	90.87	4.79	92	95.73	7.20	98	0.038*
20 Mins	89.27	5.23	89	95.13	5.94	94	0.008*
30 Mins	88.67	6.42	89	93.07	5.09	93	0.047*
45 Mins	86.53	6.17	87	91.93	7.32	91	0.038*

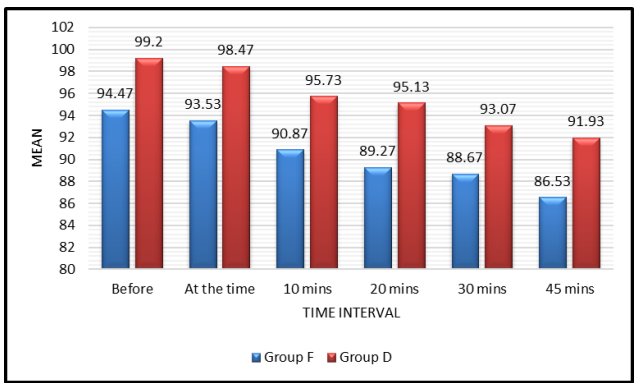
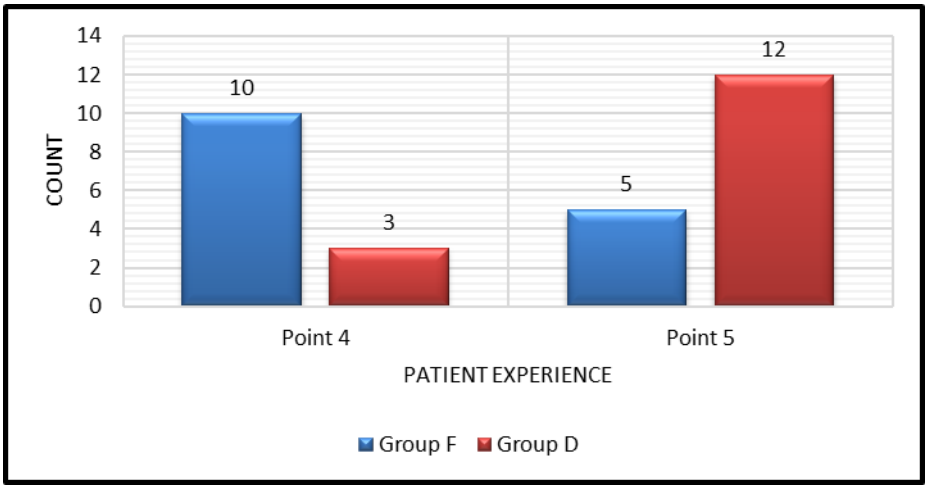


Table 5 Shows the comparison of patient experience between the two groups, who rated significantly higher in the Dexmedetomidine group. In the Fentanyl group, only 33.3% of patients rated their experience as "5" (excellent) and 66.7% as "4" (good). In contrast, 80.0% of patients in the Dexmedetomidine group rated their experience as "5" and 20.0% as "4", with a statistically significant difference (p = 0.01), suggesting that Dexmedetomidine was associated with a more favorable patient experience.

Table 5: Patient Experience.

		Group				P value
		Fentanyl		Dexmedetomidine		
		Count	%	Count	%	
Patient Experience	4	10	66.7%	3	20.0%	0.01*
	5	5	33.3%	12	80.0%	



IV. Discussion

Pre-operative anxiety is common in all patients. Relieving anxiety preoperatively can make induction of anesthesia smooth. Our study was aimed at comparing the efficacy of intranasal fentanyl and intranasal dexmedetomidine when used as a premedicant.

We conducted the study in 30 patients with age group of 18–60 years scheduled to undergo elective surgery under general anesthesia, who received either fentanyl or dexmedetomidine intranasally and the difference in efficacy of the two drugs was compared.

Xiong et al. conducted a study in 2021, 100 patients of age group 18-70 years were studied and were found that Oral dexmedetomidine premedication was an effcient intervention to increase preoperative sedation and reduce stress reaction induced by general anesthesia tracheal intubation, but also it was with the stable hemodynamic during the process of general anesthesia tracheal intubation, and improved the satisfaction of patient[(9)].

Study done by Rajan et al. observed that fentanyl and dexmedetomidine have comparable hemodynamic stability[(10)]. In our study, also we found that both fentanyl and dexmedetomidine were not associated with any significant hemodynamic fluctuations and both the drugs were comparable in terms of hemodynamic stability. We observed in our study that, that there was no significant deviation from the base line vitals such as HR, MAP, and SpO2 in the two groups.

Yadav et al. compared fentanyl-midazolam and dexmedetomidine midazolam combinations and concluded that both are effective for awake fiberoptic intubation under topical anesthesia[(11)]. They found that dexmedetomidine was associated with more stable hemodynamics. In our study, we found that both the drugs were comparable in terms of hemodynamics.

In our study, we found that there was no significant difference between the two groups in terms of sedation scoring using OAAS scale. Li C et al. also obtained results[(12)] similar to our study.

Another study conducted in a group of 40 pediatric patients in 2022 by Rishikesh et al. compared intranasal fentanyl and intranasal dexmedetomidine as a premedication, showed that children who received intranasal fentanyl as premedication had better quality and onset of anxiolysis as compared to dexmedetomidine group [(13)]

The baseline characteristics of the population in terms of age, gender, weight, and ASA grades were compared in our study and no significant differences were seen. Among the total 30 participants, the majority of subjects in both the Fentanyl and Dexmedetomidine groups were aged >50 years and 31–40 years, respectively,

with 33.3% in each category. The mean age in the Fentanyl group was 44.20 ± 13.82 years, and in the Dexmedetomidine group, it was 40.07 ± 12.04 years. There was no significant difference in age distribution between the two groups (p = 0.390). Females constituted the majority in both groups—93.3% in the Fentanyl group and 73.3% in the Dexmedetomidine group—with no statistically significant gender difference (p = 0.142). Regarding ASA status, 53.3% in the Fentanyl group and 73.3% in the Dexmedetomidine group were ASA grade 1; the difference was not statistically significant (p = 0.256).

The base line OAAS score was found to be comparable in both the groups. The onset of anxiolysis was found to be early in the fentanyl group compared to dexmedetomidine group. Fentanyl had early onset with mean onset of anxiolysis of 10 min, whereas dexmedetomidine had mean onset of anxiolysis at 20 min, but with no statistical significance.

Here patient experience was rated significantly higher in the Dexmedetomidine group. In the Fentanyl group, only 33.3% of patients rated their experience as "5" (excellent) and 66.7% as "4" (good). In contrast, 80.0% of patients in the Dexmedetomidine group rated their experience as "5" and 20.0% as "4", with a statistically significant difference (p = 0.01), suggesting that Dexmedetomidine was associated with a more favourable patient experience.

No adverse effects were noted in any of the patients who received drugs intranasally, except some patients under fentanyl group experienced burning sensations in nose after intranasal administration.

V. Conclusion

Intranasal Dexmedetomidine provided similar sedation and hemodynamic stability as that of Fentanyl, but with better patient satisfaction and minimal respiratory effects.
Thus making Intranasl Dexmedetomidine, a favourable drug for premedication in elective surgeries.

Limitations of the study

- Small sample size.
- Short duration of study.

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