International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A Comparative Study between Intranasal Dexmedetomidine and Intranasal Ketamine to assess efficacy and safety as Premedication in Children: A Prospective Randomised Double-Blind Study

[1]Dr. Kanneboyina Vignesh*, [2]Dr. Ranjith Kumar R. T, [3]Dr. Arun N

[1]MBBS, Post graduate of anaesthesia final year, College -Basaveshwara medical college and hospital, Chitradurga, Karnataka, 577502. India.

[2]MD Anaesthesiology, Professor of department of Anaesthesiology, Basaweshvara Medical College and Hospital, Chitradurga, Karnataka-577501, India.

[3]Associate professor, Department of anaesthesiology and critical care, Basaveshwara medical college and hospital, chitradurga, karnataka -577501, India.

Corresponding Author:

Dr. Kanneboyina Vignesh
MBBS, Post graduate of anaesthesia final year, College - Basaveshwara medical college and hospital, Chitradurga, Karnataka, 577502. India

Received: 09-05-2026
Accepted: 20-06-2026
Available online: 08-07-2026

ABSTRACT

Context: Preoperative anxiety in children is a major concern in anaesthesia, leading to difficult parental separation, poor mask acceptance, and challenging induction with increased anaesthetic requirements and adverse outcomes such as emergence delirium and postoperative nausea and vomiting (PONV). Intranasal drug delivery offers a non-invasive, effective route for premedication. Dexmedetomidine and ketamine are widely used agents with differing sedative and hemodynamic effects.

Aims: To compare sedation and mask acceptance scores, hemodynamic stability, emergence delirium, and adverse events between Intranasal dexmedetomidine and ketamine.

Settings and Design: Prospective, randomized, double-blind study conducted in the Department of Anaesthesia at a tertiary care hospital.

Methods and Material: Sixty children aged 1–10 years, ASA I–II, undergoing elective surgery were randomized into two groups (n=30 each). Group I received intranasal dexmedetomidine 2 µg/kg and Group II received intranasal ketamine 5 mg/kg via atomizer 30 minutes before induction. Sedation was assessed using MOASS at 15 and 30 minutes. Mask acceptance score (MAS), hemodynamic changes, and adverse effects were recorded.

Statistical analysis used: Data were analysed using SPSS version 20. Continuous variables were compared using the independent t-test and categorical variables using Chi-square/Fisher's exact test. A p-value < 0.05 was considered significant.

Results: Intranasal dexmedetomidine produced significantly better sedation at both 15 and 30 minutes ($p < 0.001$), with greater hemodynamic stability, reduced sympathetic responses,reduced PONV, and smoother recovery. Mask acceptance and emergence behaviour were comparable.

Conclusions: Intranasal dexmedetomidine (2 µg/kg) is a more favourable paediatric premedicant than intranasal ketamine (5 mg/kg), providing superior sedation with enhanced cardiovascular stability and fewer recovery-related adverse effects.

Keywords*: Intranasal dexmedetomidine, Intranasal ketamine, Pediatric premedication, Preoperative anxiety.*

INTRODUCTION

For anaesthesiologists, relieving anxiety or stress in children before surgeries and procedures is a recurring concern, with up to 60–70% of children have experienced significant preoperative anxiety.[1] The alien hospital environment, separation from parents, and fear of surgery and pain can make children extremely anxious preoperatively. A frightened, uncooperative

child is stressful for both anaesthesiologists and parents. Preoperative anxiety complicates induction of anaesthesia and is associated with increased analgesic requirements, PONV, emergence delirium, and maladaptive behavioural changes. Measures to reduce anxiety include counselling, behavioural interventions, parental presence during induction, and premedication to facilitate smooth separation and induction. An ideal premedicant should have rapid onset, short duration, easy administration, good acceptability, minimal side effects, and provide analgesia with attenuation of sympathetic responses.[2]

Given the need to optimize sedation, various routes of drug delivery have been explored. The intranasal route is a practical option for procedural sedation, avoiding needle-related fear and pain, and providing a feasible, rapid, and predictable effect.[3]Intranasal drug administration is minimally invasive and offers advantages such as a large absorptive surface area, rich vascularity, and avoidance of first-pass hepatic metabolism, enhancing the bioavailability of many drugs. The introduction of intranasal atomizers improves drug delivery by ensuring uniform mucosal distribution and better absorption and minimal drug loss due to swallowing or anterior nasal runoff. Compared with conventional nasal drops or sprays, atomized delivery ensures more consistent absorption and dosing, leading to its increasing use in anaesthesia, emergency medicine, and paediatric practice, with improved patient comfort and safety.[4]

Ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, has been used as an effective premedicant due to its sedative and analgesic properties while preserving airway reflexes and respiratory function. However, it is not ideal because of undesirable effects such as paradoxical reactions, cognitive impairment, postoperative behavioural changes, and delayed recovery. Dexmedetomidine, a highly selective alpha-2 agonist with a relatively short half-life, provides anxiolysis, sedation, and analgesia without respiratory depression, making it a promising alternative in children. It also has high intranasal bioavailability (approximately 81.8%), making this route convenient and effective for paediatric premedication.[2]

In an effort to identify an ideal premedicant and a non-invasive route of administration, we compared intranasal (IN) dexmedetomidine with intranasal (IN) ketamine administered via a nasal atomizer (BVM Meditech Pvt. Ltd.) in paediatric patients. Our aims were to assess, document, and compare a) drug acceptance b) sedation score, c) mask acceptance score (MAS) during induction, d) hemodynamic parameter during induction, e) incidence of ED, and post operative nausea and vomiting(PONV) f) any perioperative and post operative adverse events.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, double-blind study was conducted at the Department of Anaesthesia, Basaveshwara Medical College and Hospital, Chitradurga, from February 2024 to August 2025, after approval from the Institutional Ethics Committee (Ref: BMC&H/IEC/198/23-24) and written informed consent from parents or guardians of all participants .

Study Population

Sixty children of either sex, aged 1–10 years, belonging to American Society of Anesthesiologists (ASA) physical status I and II and with Mallampati grade I or II, scheduled for elective surgery under general anaesthesia, were enrolled.
Children with anticipated difficult airway, emergency surgery or risk of aspiration, cardiovascular, neurological or renal disorders, obesity (body mass index >30), nasal pathology (mass or bleeding), or recent upper respiratory tract infection were excluded.

SAMPLE SIZE CALCULATION

Time to sedation and mask acceptance was considered as the primary outcome for the purpose of sample size calculation. To be able to detect a mean difference of at least 1.4[2] minutes difference between the two study groups, with an alpha error of 0.05 and 80% power of study, with population variance of 3, the required sample size was calculated using the following formula.

$$\text{Sample size } n = (Z\alpha/2+Z\beta)\ 2\ *2*\sigma^{2} / d2,$$

Where, $Z\alpha/2$ is the critical value of the Normal distribution at α of 0.05 = 1.96
$Z\beta$ is the critical value of the Normal distribution for 80% power (at β=0.2) = 0.84
σ^{2} is the population variance = 3 and
d is the different you would like to detect = 1.4

By using the above- mentioned parameters, the required sample size would be 25 subjects in each of the two study groups. Hence 30 subjects were included in each group in the final analysis.

RANDOMISATION AND BLINDING

Participants were randomly allocated into two groups (n = 30 each) using computer-generated random numbers and sealed opaque envelope technique.

- **Group I** received intranasal dexmedetomidine 2 µg/kg
- **Group II** received intranasal ketamine 5 mg/kg

The study drug was prepared by an anaesthesiologist not involved in patient management and administered by another anaesthesiologist blinded to group allocation. Data collection was performed by an independent observer who was also blinded.

PREANESTHETIC CHECKUP AND PREPARATION

Pre-anaesthetic evaluation was performed one day prior to surgery and included assessment of the general condition of the patient and history of recent upper respiratory tract infection. Airway assessment was carried out using Mallampati grading and the rule of 1–2–3. A general physical examination including height, weight, and body mass index was recorded, along with detailed systemic examination of the cardiovascular, respiratory, abdominal, and central nervous systems.

Relevant investigations, including complete haemogram, blood sugar levels, blood urea, serum creatinine, electrolytes, liver function tests, chest X-ray, and electrocardiogram, were performed as indicated.

The procedure of premedication was explained to the parents, and written informed consent was obtained. Patients were kept nil per oral as per ASA fasting guidelines. The anaesthesia machine, necessary equipment, and emergency drugs were checked and kept ready along with the crash cart. Appropriately sized endotracheal tubes, a functioning laryngoscope with suitable blades, and a working suction apparatus were ensured.

ANAESTHETIC TECHNIQUE

Patient shifted to the pre operative room, 30 min prior to induction of anaesthesia, patients of Group I received dexmedetomidine 2 mcg/kg in 1 mL of 0.9% saline intranasally through nasal atomizer and patients of Group II received ketamine 5 mg/ kg in 1 mL of 0.9% saline intranasally through nasal atomizer (0.5 mL in each nostril) in a recumbent position. The study drug was prepared by one anaesthesiologist as per the group allocation and administered by the other anaesthesiologist who was blinded to the group allocation. Incidences of sneezing or coughing after intranasal administration of study drugs were recorded to assess the patient acceptance of medication by a blinded observer. All children were nursed in either supine or recumbent position in the caregiver's lap and monitored for heart rate and oxygen saturation every 5 min for 30 min, in pre-operative holding area. Drug acceptance should be recorded, defines as crying or complaints like nasal stinging(cough and sneezing) after instillation of drug. The subsequent sedation scores were assessed using MOASS at 15 min, then at 30 min following premedication at the time of parental separation.

Score	Response
5	Respond readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Response only after name is called loudly and /or repeatedly
2	Response only after mild prodding or shaking
1	Response only after painful trapezius squeeze
0	No response after thr painful trapezius squeeze

TABLE 1: Modified observer assessment of alertness/sedation scale

After shifting patients to operation theater (OT), connected to ASA standard monitoring comprising heart rate, non-invasive measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO2), end tidal carbon dioxide (EtCo2), temperature probe and continuous ECG monitoring. Baseline readings will be recorded by anaesthesiologist who will be blinded for the study. Anaesthesia was induced with oxygen (O2) and air (50:50%) with a high concentration of sevoflurane [3-4 minimum alveolar concentration (MAC) percentages] on spontaneous respiration (tidal volume breathing) using Jackson-Rees modification of Ayre's T-piece (Mapleson F) circuit via face mask. MAS was recorded at this point

Score	Response
1(good)	Patient allows mask over his face without any resistance
2(average)	Patient allows mask over his face with some resistance which can be overcome by the person holding the mask
3(poor)	Patient allows mask over his face with significant resistance, that cannot be overcome by the person holding the mask alone and requires additional help.

TABLE 2: Mask acceptance score.

Intravenous line will be secured using either 22G or 24G IV cannula. Injection propofol 2 mg /kg and fentanyl 2 mcg /kg along with atracurium 0.6 mg /kg as a muscle relaxant, was used. An endotracheal tube (ETT) or a laryngeal mask airway (LMA) of appropriate size was used to secure the airway. Maximum and minimum HR at induction was recorded. Induction

time was defined as the time from the application of the mask till securing the airway. At the end of the surgery, after the reversal of general anaesthesia, emergence agitation (EA) was assessed using the Watcha scale.

Score	Response
0	Asleep
1	Calm
2	Crying but can be consoled
3	Crying but cannot be consoled
4	Agitated and thrashing around

TABLE 3: Watcha scale for emergence delirium.

A score of more than 2 indicates the presence of EA. Patients with agitation scores of more than 2 received IV midazolam (0.01-0.02 mg/ kg). In the post-anesthesia care unit (PACU), the patients were monitored according to PACU protocol. The incidence of peri-operative adverse events such as hypotension, bradycardia, tachycardia, and PONV was also recorded.

OUTCOME MEASURES

The primary outcomes were sedation score and mask acceptance score.

Secondary outcomes included drug acceptance, induction time, haemodynamic parameters (heart rate and oxygen saturation), emergence agitation, and perioperative adverse events.

ADVERSE EFFECTS:

Tachycardia, defined as heart rate ≥25% above baseline, was treated with intravenous esmolol (0.5 mg/kg). Bradycardia, defined as heart rate <60 beats/min, was treated with intravenous atropine (0.6 mg bolus).

Postoperative nausea and vomiting (PONV), defined as the occurrence of nausea and/or vomiting in the immediate postoperative period, was treated with intravenous ondansetron (4 mg). Persistent or refractory symptoms were managed with metoclopramide (10 mg IV) and dexamethasone (4–8 mg IV). Supplemental oxygen and adequate hydration were ensured, and antiemetics were repeated as required.

STATISTICAL ANALYSIS

Data were compiled in Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) version 20 (IBM Corp., Armonk, NY, USA).

Categorical variables were expressed as frequency and percentage and analysed using the Chi-square test. Continuous variables were expressed as mean ± standard deviation (SD). Pearson correlation coefficient was used to assess correlation between variables. A p-value <0.05 was considered statistically significant.

RESULTS

Sixty patients were enrolled and completed the study, with 30 patients in each group. Demographic characteristics, including age, weight, gender distribution, and ASA physical status, were comparable between the two groups.

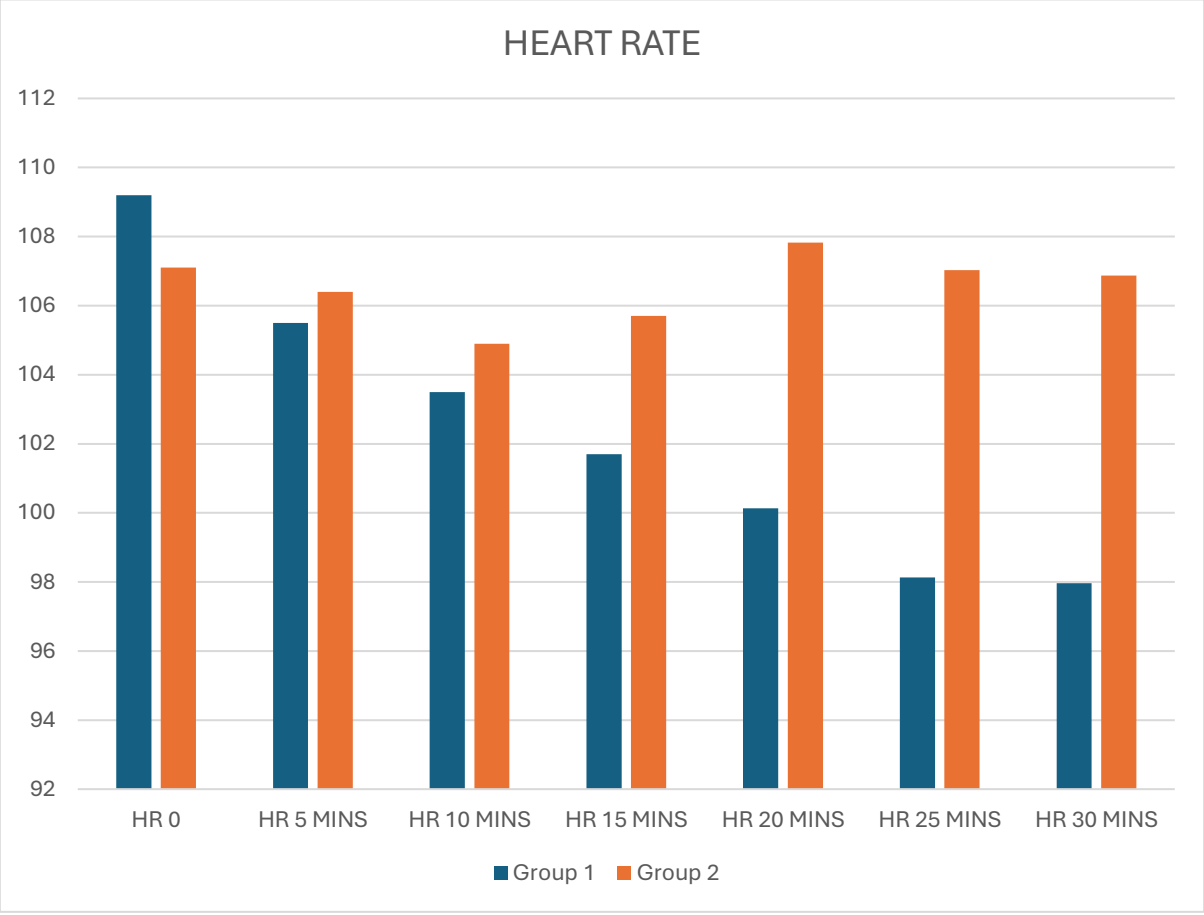
Haemodynamic parameters and adverse events were recorded. Baseline haemodynamic variables were comparable between the two groups. Heart rate (HR) was comparable at baseline and at 5, 10, and 15 minutes (P > 0.05). However, at 20 minutes, HR was significantly lower in Group I compared to Group II (100.13 ± 10.45 vs 107.83 ± 10.2 bpm; P = 0.0054). This difference became more pronounced at 25 minutes (98.13 ± 9.20 vs 107.03 ± 10.23 bpm; P = 0.0008) and 30 minutes (97.96 ± 10.30 vs 106.87 ± 8.9 bpm; P = 0.0007), indicating better haemodynamic stability in Group I. Oxygen saturation (SpO_2) was comparable between the two groups at all time intervals except at baseline (98.46 ± 0.57% vs 98.13 ± 0.68%; P = 0.0462), which was clinically insignificant. At subsequent time intervals, SpO_2 remained comparable (P > 0.05) and within normal physiological limits in both groups, with no episodes of desaturation. These findings indicate that while early haemodynamic responses were similar, Group I demonstrated better attenuation of heart rate response, with both groups maintaining adequate oxygenation throughout the study period [Table 4, Figure 1; Table 5, Figure 2].

SPO2	***GROUP I*** ***Mean*** ± SD	***GR0UP II*** ***Mean*** ± SD	***P VALUE***
SPO2 0 MINS	98.46±0.57	98.13±0.68	0.0462
SPO2 5 MINS	98.33±0.71	98.43±0.568	0.5493
SPO2 10 MINS	98.23±0.89	98.467±0.82	0.2879

SPO2 15 MINS	98.3±0.794	98.467±0.63	0.3706
SPO2 20 MINS	98.53±0.681	98.4±0.813	0.5046
SPO2 25 MINS	98.26±0.83	98.53±0.63	0.1612
SPO2 30 MINS	98.33±0.80	98.43±0.63	0.5927

TABLE 4: COMPARISON OF HEART RATE IN BOTH GROUPS

GRAPH 1: COMPARISON OF HEART RATE IN BOTH GROUPS

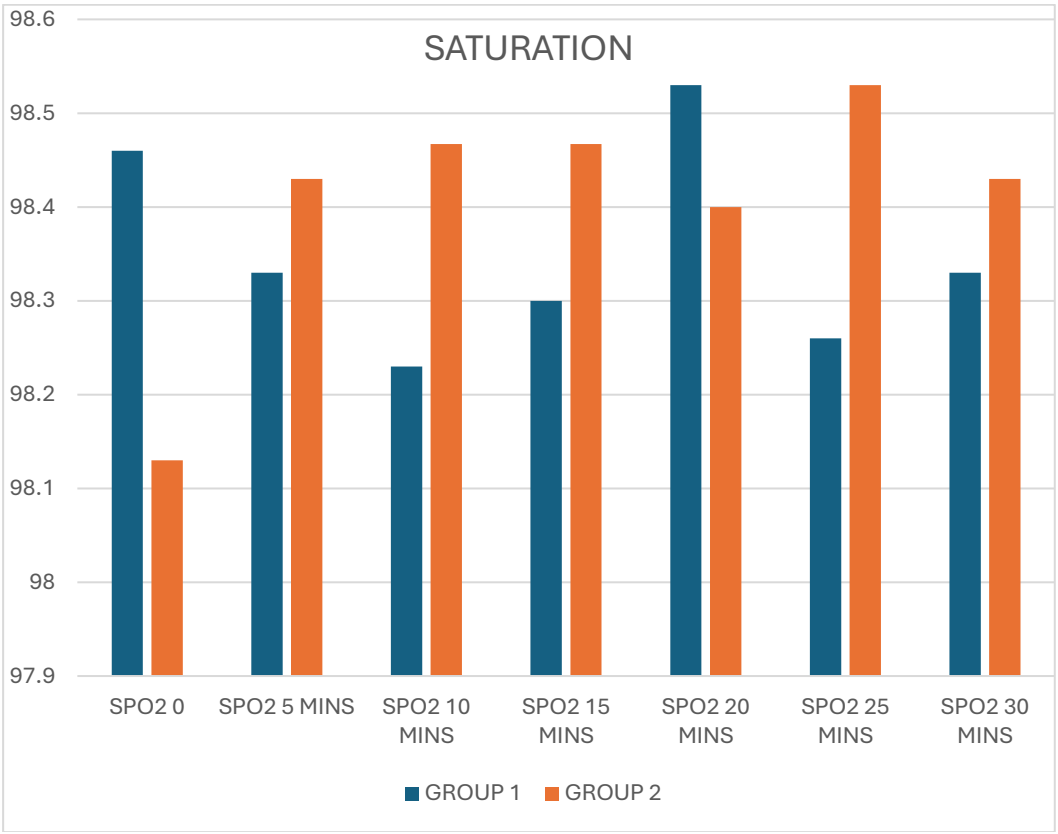


HR	GROUP I [mean±SD]	GROUP II [mean±SD]	P VALUE
HR 0	109.2±13.53	107.1±11.34	0.5173
HR 5 MINS	105.5±12.71	106.4±10.5	0.7660
HR 10 MINS	103.5±11.15	104.9±10.4	0.6169
HR 15 MINS	101.7±11.22	105.7±10.31	0.1559
HR 20 MINS	100.13±10.45	107.83±10.2	0.0054
HR 25 MINS	98.13±9.20	107.03±10.23	0.0008*
HR 30 MINS	97.96±10.30	106.867±8.9	0.0007*

TABLE 5: COMPARISON OF SATURATION IN BOTH GROUPS

Data expressed as Mean ± SD.
Group I -Intra nasal Dexmedetomidine Group II – Intranasal Ketamine
SD standard deviation
HR – Heart Rate.
Independent Student's t-test used for comparison between groups. $p < 0.05$, $p < 0.01$ considered statistically significant, *$p<0.001$ is highly significant, $p > 0.05$ is not significant

GRAPH 2: COMPARISON OF SATURATION IN BOTH GROUPS



Sedation scores assessed using the Modified Observer's Assessment of Alertness/Sedation (MOASS) scale were comparable at baseline. At 15 minutes, sedation scores were significantly lower in Group I compared to Group II (3.0 ± 0.98 vs 4.3 ± 0.66; P < 0.001). At 30 minutes, Group I remained more sedated than Group II (2.1 ± 0.80 vs 3.67 ± 0.55; P < 0.001) [Table 6, Figure 3].Minimum heart rate at induction was significantly lower in Group I compared to Group II (91.43 ± 12.02 vs 97.2 ± 8.1; P = 0.0333), whereas maximum heart rate was comparable between the groups (P = 0.7115).Mask acceptance scores were comparable between the two groups (1.56 ± 0.68 vs 1.46 ± 0.57; P = 0.5388). Emergence agitation assessed using the Watcha scale was also comparable (2.0 ± 0.64 vs 1.83 ± 0.79; P = 0.3648).These findings indicate that although sedation was significantly better in Group I, mask acceptance and emergence behavior were similar between the groups.

The incidence of adverse events is summarized in [Table 7]. Sneezing and coughing were the most common events in both groups (Group I: 10 [33.33%] vs Group II: 11 [36.67%]).Hypotension was observed in 3 (10%) patients in Group I and 1 (3.33%) in Group II, whereas hypertension was more frequent in Group II (5 [16.67%] vs 1 [3.33%]). Bradycardia occurred more commonly in Group I (6 [20%] vs 2 [6.66%]), while tachycardia was more frequent in Group II (4 [13.33%] vs 1 [3.33%]).The incidence of postoperative nausea and vomiting (PONV) was low in both groups (1 [3.33%] vs 3 [10%]).Overall, all adverse events were mild, transient, and manageable, with no serious complications observed.

TABLE 6: COMPARISON OF SCORING SYSTEMS IN BOTH GROUPS

SCORES	**GROUP I[n=30] Mean ± SD**	**GROUP II[n=30] Mean ± SD**	**P VALUE**
MOASS @ 15 MINS	3±0.982	4.3±0.66	<0.001*
MOASS @ 30 MINS	2.1±0.803	3.67±0.546	<0.001*
MIN HR	91.43±12.02	97.2±8.1	0.0333
MAX HR	115.8±14.41	114.5±12.63	0.7115
MAS	1.56±0.678	1.46±0.57	0.5388
WATCHA SCALE	2±0.643	1.83±0.791	0.3648

Data expressed as Mean ± SD.
n = total number of patients in each group
Group I -Intra nasal Dexmedetomidine Group II – Intranasal Ketamine
SD standard deviation
MOASS – Modified Observer's Assessment of Alertness/Sedation Scale; MAS – Modified Aldrete Score; HR – Heart Rate; Watcha scale – scale used to assess emergence agitation.

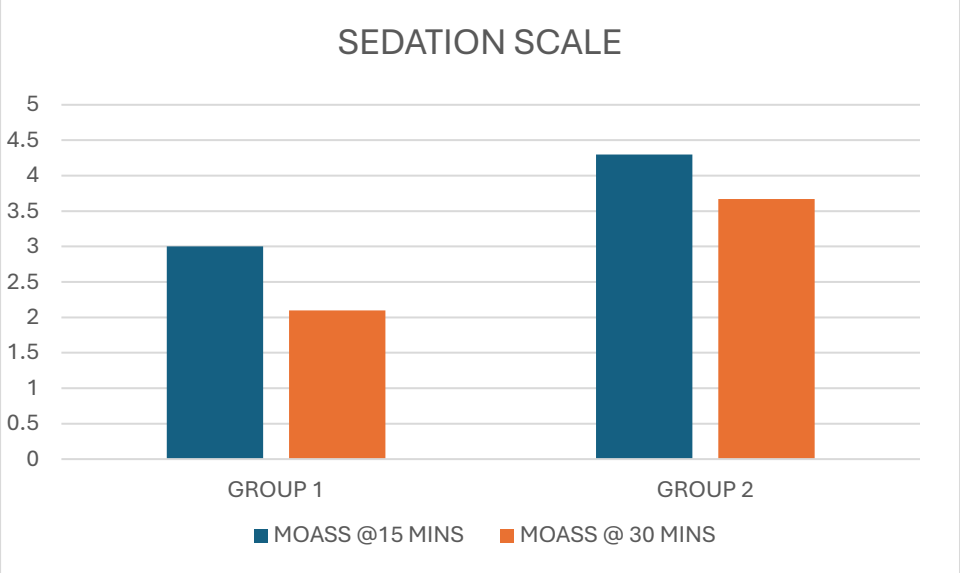
Independent Student's t-test used for comparison between groups. $p < 0.05$, $p < 0.01$ considered statistically significant, *$p < 0.001$ is highly significant, $p > 0.05$ is not significant

TABLE 7: COMPARISON OF ADVERSE EVENTS IN BOTH THE GROUPS

SL.NO	ADVERSE EVENTS	GROUP 1 n=30	GROUP 2 n=30
1	SNEEZING AND COUGHING	10(33.33%)	11(36.67%)
2	HYPOTENSION	3(10%)	1(3.33%)
3	HYPERTENSION	1(3.33%)	5(16.67%)
4	BRADYCARDIA	6(20%)	2(6.66%)
5	TACHYCARDIA	1(3.33%)	4(13.33%)
6	PONV	1(3.33%)	3(10%)

Values expressed as n (%).
Group I -Intra nasal Dexmedetomidine Group II – Intranasal Ketamine
n = total number of patients in each group
PONV – Postoperative Nausea and Vomiting.
Chi-square test/Fisher's exact test used for comparison between groups. $p < 0.05$, $p < 0.01$ considered statistically significant, $p < 0.001$ is highly significant, $p > 0.05$ is not significan

GRAPH 3: COMPARISON OF SEDATION SCALEN BOTH GROUPS



DISCUSSION:

Separation anxiety is common in children, particularly between 1 and 5 years of age, and can be effectively minimised with pharmacological premedication. Various routes such as oral, intravenous (IV), intramuscular (IM), rectal, and transmucosal have been used; however, each has limitations. The oral route is associated with variable absorption and reduced bioavailability, while IV and IM routes are invasive and distressing. The rectal route is generally less acceptable due to issues of convenience and social acceptability. Transmucosal routes, especially intranasal and sublingual, have gained popularity due to better patient acceptance, rapid absorption through highly vascular mucosa, and avoidance of first-pass metabolism. However, intranasal administration may cause nasal irritation, sneezing, or coughing, particularly with larger volumes. To minimise these effects, a small volume (0.5 mL per nostril) was used in the present study, which may explain the lower incidence of coughing and sneezing (Group I: 33.33%, Group II: 36.67%). Previous studies have also shown that the intranasal route is an effective and well-tolerated method for paediatric premedication.[2] Among available agents, ketamine and dexmedetomidine remain the most commonly used drugs. The present study compared the efficacy, sedation profile, hemodynamic effects, and adverse events of IN dexmedetomidine (2 µg/kg) and IN ketamine (5 mg/kg) administered 30 minutes before surgery in children aged 1–10 years.

Both groups were comparable with respect to age, weight, gender distribution, and ASA physical status. This baseline homogeneity ensured that observed differences in outcomes could be attributed to the pharmacological effects of the study drugs rather than demographic confounders.

In our study, baseline mean sedation scores were comparable between the two groups, confirming similar pre-intervention sedation status. Following intranasal administration of the study drugs, sedation was assessed at 15 and 30 minutes using the Modified Observer's Assessment of Alertness and Sedation Scale (MOASS).

At 15 minutes, the mean sedation score (SS15) was significantly lower in Group I (dexmedetomidine) compared to Group II (ketamine), indicating better early sedation with dexmedetomidine despite ketamine's rapid onset of action. At 30 minutes, children in Group I continued to demonstrate significantly lower MOASS scores compared to Group II, indicating more profound and sustained sedation with dexmedetomidine, likely due to its central α_2-agonist action, which produces cooperative sedation through reduced sympathetic outflow and locus coeruleus inhibition.

These findings indicate that intranasal dexmedetomidine provides superior sedation compared to intranasal ketamine at both 15 and 30 minutes, demonstrating better early onset and sustained sedation. This makes dexmedetomidine a reliable premedicant for pediatric patients requiring calm separation and smooth induction.

Mask acceptance during induction is an important indicator of the effectiveness of pediatric premedication, as it reflects the child's cooperation and anxiety level at the time of anesthetic induction. In the present study, the mask acceptance scores were comparable between the two groups (P = 0.5388). This indicates that both intranasal dexmedetomidine (2 µg/kg) and intranasal ketamine (5 mg/kg) were equally effective in facilitating smooth mask acceptance.This suggests that despite differences in sedation depth at different time points, both intranasal dexmedetomidine and ketamine were equally effective in facilitating smooth induction.

Surendar et al. [5] conducted a triple-blind randomized comparative study in 84 uncooperative pediatric dental patients (4–14 years, ASA I) evaluating intranasal dexmedetomidine (1 and 1.5 µg/kg), midazolam (0.2 mg/kg), and ketamine (5 mg/kg). They reported that all three agents were safe and effective for moderate sedation, with dexmedetomidine showing the highest overall success and a better analgesic profile. The improved sedation observed with dexmedetomidine in our study is consistent with their findings.

Nidhi Arun et al [2] Conducted a Comparative Study of Intranasal Dexmedetomidine and Intranasal Ketamine and concluded that Intranasal dexmedetomidine (1 mcg kg-1) is clinically less effective as a premedicant in terms of sedation and mask acceptance in older children as compared to ketamine (5 mg kg-1) but associated with lower incidence of ED and PONV. The authors suggested that higher doses of dexmedetomidine (1.5–2 µg kg^{-1}) administered via nebulization or atomization may provide better sedation. In contrast, the present study demonstrated that intranasal dexmedetomidine 2 µg kg^{-1} produced better sedation than intranasal ketamine 5 mg kg^{-1}, possibly due to the higher dose used.

Hemodynamic stability is an important consideration in selecting a pediatric premedicant. In the present study, heart rate trends were comparable between groups during the initial 15 minutes. However, from 20 minutes onward, Group I showed a significantly lower and more stable heart rate compared to Group II, reflecting the sympatholytic action of dexmedetomidine via central α2-agonism. In contrast, ketamine, due to its sympathomimetic effects, was associated with higher heart rates and more frequent tachycardia and hypertension, consistent with its known pharmacological profile.

SpO_2 remained within normal physiological limits in both groups throughout the study period. The baseline statistical difference was clinically insignificant. Importantly, no episodes of respiratory depression were observed in either group, confirming the safety of both drugs when administered intranasally at the studied doses.

Narendra et al. [6] compared intranasal ketamine and intranasal midazolam and found both effective for sedation and mask acceptance, with ketamine showing better mask acceptance but causing mild increases in heart rate and blood pressure due to its sympathomimetic effect, while overall hemodynamic stability was maintained. Similarly, in the present study, ketamine group showed relatively higher heart rate and blood pressure compared to dexmedetomidine, with overall hemodynamically stability preserved.

Diwan et al. [7] compared intranasal dexmedetomidine and intranasal midazolam as pediatric premedication and reported that dexmedetomidine provided better sedation, smoother parental separation, and improved mask acceptance, although it had a slower onset of sedation. Hemodynamic parameters remained stable, with a mild reduction in heart rate observed with dexmedetomidine due to its sympatholytic effect. Similarly, in the present study, intranasal dexmedetomidine produced effective sedation with good mask acceptance while maintaining stable hemodynamic parameters.

Emergence delirium is a common postoperative behavioral disturbance in pediatric patients and is characterized by agitation, inconsolability, and disorientation during recovery from anesthesia. In the present study, emergence delirium was assessed using the Watcha scale and was found to be comparable between the two groups (P = 0.3648). Although ketamine has traditionally been associated with a higher incidence of emergence reactions, the comparable Watcha scores observed in our study may be due to the intranasal route of administration, appropriate dosing, and a standardized anesthetic

technique. Furthermore, dexmedetomidine is known to reduce the incidence of emergence delirium due to its sedative and analgesic properties, which contribute to a smoother recovery profile.

Postoperative nausea and vomiting are common adverse effects that may delay recovery and discharge in paediatric patients. In the present study, the incidence of PONV was higher in the ketamine group compared to the dexmedetomidine group, consistent with ketamine's known emetogenic profile. Dexmedetomidine, however, showed lower incidence of PONV, possibly due to its opioid-sparing effect and better hemodynamic stability. The reduced PONV in the dexmedetomidine group supports its favourable recovery profile as a paediatric premedicant.

Adverse effects were mild and transient in both groups. Sneezing and coughing were the most common events, likely related to intranasal administration rather than the drug itself. Bradycardia and hypotension were more frequent in the dexmedetomidine group, consistent with its pharmacodynamic profile, whereas hypertension, tachycardia, and PONV were more common with ketamine. Dexmedetomidine was associated with lower incidence of PONV and emergence delirium, reinforcing its favorable recovery profile.

Bingchen Lang et al. [1] conducted a meta-analysis of 16 randomized controlled trials involving 1066 pediatric patients comparing intranasal midazolam and intranasal ketamine for premedication. The study found that intranasal midazolam provided better sedation with faster onset and recovery and more stable hemodynamic parameters compared to ketamine. In addition, ketamine was associated with a higher incidence of adverse effects such as increased salivation, nausea, vomiting, and emergence reactions. Similarly, in the present study, ketamine was associated with more adverse effects and greater hemodynamic variations compared to dexmedetomidine**.**

Although the initial hypothesis proposed that intranasal dexmedetomidine would be more effective with fewer adverse effects compared to ketamine, the present study confirmed this hypothesis. Intranasal dexmedetomidine demonstrated superior sedation at both 15 and 30 minutes, along with better hemodynamic stability and fewer recovery-related adverse effects when compared to intranasal ketamine. While ketamine remains an effective premedicant, its use was associated with relatively higher heart rate variability and a greater incidence of sympathetic responses. Therefore, intranasal dexmedetomidine appears to offer a more balanced and favorable profile as a pediatric premedicant, providing effective sedation with enhanced cardiovascular stability and smoother recovery.

However, the present study has the following limitations. Small sample size may limit the generalizability of the results. Being a single-centre study, the findings may not represent all clinical settings or populations. There may be variability in intranasal drug absorption due to differences in nasal mucosa and administration technique. The assessment was limited to perioperative outcomes without evaluation of long-term behavioural effects in children. Lastly, the comparison was restricted to only two drugs, dexmedetomidine and ketamine, without inclusion of other commonly used paediatric premedicants.

Conflicts of Interest

The authors have declared that no competing interests exist.

REFERENCES:

1. Lang B, Wang H, Fu Y,et al. Efficacy and safety of intranasal midazolam versus intranasal ketamine as sedative premedication in pediatric patients: a meta-analysis of randomized controlled trials. BMC Anesthesiol. 2022 Dec 22;22(1):399.
2. Nidhi Arun , Annu Choudhary , Mukesh Kumar Comparative study of intranasal dexmedetomidine versus intranasal ketamine as premedicant in children. Cureus. 2022 Jul 5;14(7):e26572.
3. Jafarnejad S, Mehrabi I, Rezai M et al. Comparison of intranasal ketamine and midazolam in peripheral IV access in children presenting to the emergency department: a randomized clinical trial. Pakistan J Med Sci Online. 2020 Sep 8;14:1412-1417.
4. Djupesland PG. Nasal drug delivery devices: characteristics and performance in a clinical perspective. *Drug Deliv Transl Res*. 2013;3(1):42–62.
5. Surendar MN, Pandey RK, Saksena AK, Kumar R, Chandra G. A comparative evaluation of intranasal dexmedetomidine, midazolam and ketamine for their sedative and analgesic properties: a triple blind randomized study. J Clin Pediatr Dent. 2014;38(3):255–262.
6. Narendra PL, Naphade RW, Nallamilli S, Mohd S. A comparison of intranasal ketamine and intranasal midazolam for pediatric premedication. Anesth Essays Res. 2015;9(2):213–218.
7. Diwan G, Bharti AK, Rastogi K, Gupta PK. Comparison of intranasal dexmedetomidine and midazolam as premedication in pediatric surgical patients: A prospective, randomized double-blind study. Anesth Essays Res. 2020;14(3):384-389.