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# Effectiveness of Intranasal Dexmedetomidine for Sedation in Children

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## ABSTRACT

**Background:** Preoperative sedation in children is necessary as it is a common source of distress, potentially leading to difficult induction. Intranasal dexmedetomidine bypasses hepatic metabolism and has good availability. It is non invasive, easy with minimal respiratory depression. This study aimed to observe safety, efficacy, sedation level and parental separation score following a fixed dose of 1.5 mcg/kg

**Methods:** A cross sectional study design was conducted among 43 children posted for elective surgeries. After informed consent and assent were obtained, intranasal DEX 1.5mcg/kg was administered. Satisfactory sedation was defined as a Modified Observer's Assessment of Alertness/Sedation (MOAA/S) score of ≤ 3, and satisfactory parental separation as a score of ≤ 2 on a 4-point scale. Physiological parameters (HR, RR, SPO2 were monitored for 30 minutes. Statistical analysis involved the use of SAS version 9.4.

**Results:** Satisfactory sedation ≤ 3 was achieved in 93.0% of subjects by 30 minutes (95% CI: 80.9%–98.5%). Similarly, satisfactory parent-child separation ≤ 2 score was achieved in 93.0% of subjects. Mean heart rate progressively decreased from 107.12±14.20 at baseline to 85.47 ± 7.29 beats per minute at 30 minutes, which was well tolerated.

**Conclusions:** Intranasal DEX at a dose of 1.5 mcg/kg is safe and effective premedication for paediatric patients, which results in successful sedation with tolerated changes in vitals.

**Keywords:** Dexmedetomidine; intranasal; paediatric; premedication; sedation.

## INTRODUCTION

Preoperative sedation reduces patients' fear and anxiety regarding surgery. Therefore, streamlines the induction of general anaesthesia. Preoperative uncooperative behavior in children can have lasting psychological impact.[1] Various sedatives have been used in the past, but many are associated with undesirable side effects or difficult administration in a fearful child.

Dexmedetomidine (DEX) targets highly selective α2-adrenoceptor in locus coeruleus. Resulting sedation is natural sleep like state with minimal effect on tidal volume, respiratory rate with preserved hypercapnic drive and airway reflexes.[2] Intranasal DEX has high bioavailability and administration are easy even in uncooperative children as it is well tolerated with low adverse effects.[3, 4]

Although studies have claimed safety and efficacy of multiple dose regimen,[5] their applicability among Nepalese populations remains an important area of study. Therefore, the objective of the study was to observe safety, efficacy, sedation level and parental separation score of intranasal 1.5 mcg/kg as sedative agent in preoperative settings

## METHODS

A prospective, observational cross-sectional study was performed in 43 patients, in the preoperative room of Kathmandu Medical College teaching hospital,

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Kathmandu, Nepal from November 2024 to August 2025. The study was conducted after receiving ethical clearance from Institutional review committee (Ref: 16102024/07). Informed and written parental consent and verbal assent from children were obtained.

All children aged 2 to 9 years posted for elective surgery were assessed for eligibility, whereas children with nasal mass, epistaxis, seizure disorder, congenital heart disease, bradycardia, defined as heart rate <60 beats per minute, allergic history to DEX and upper respiratory tract infection were excluded.

A convenient sampling was used to recruit patients for the study. Based on a previous study,[6] the overall satisfactory sedation rate of Dexmedetomidine (1.5µg/kg) was of 85.7% (95% CI: 62.5% - 96.2%). Assumed a precision of 11.3% at 95% confidence level, the required sample size was estimated to be 37. To account for a potential 10% dropout, the final sample size increased to be 43 participants.

Children were brought to the preoperative holding room 30 minutes prior to the scheduled time of anaesthesia induction. Our preoperative area has monitors, wall mount oxygen supply and suction, oxygen facemask and resuscitation cart. For each subject, the dose of intranasal DEX was calculated based on his or her body weight. The precise calculated dose was drawn into a 1 ml tuberculin syringe. With the patient in a supine position, either on a preoperative bed or in their parent's arms, the drug was instilled: half of the total dose was administered into the right nostril, and the other half into the left. Following drug administration, a trained anaesthesiologist meticulously observed and recorded data physiological parameters including heart rate, respiratory rate, oxygen saturation, and sedation scores and noted any adverse events. Hypoxemia was defined as oxygen saturation < 92% . None of the children required supplemental oxygen, as saturation did not fall below 92%.

Level of sedation was assessed with Modified Observer's Assessment of Alertness/ Sedation scale (MOAA/S)[7] 5: Responds 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 painful trapezius squeeze. A score of 3 or less was considered satisfactory

Parental separation was also assessed using a 4-point scale,[8] where 1 indicated a calm and cooperative child, 2 meant the child was anxious but could be reassured, 3 was for a child who was anxious and not reassuring, and 4 represented a child who was crying or resisting. Parental separation scores of 2 or less will be considered satisfactory.

Categorical variables are summarized as frequencies with percentages and corresponding 95% confidence level, while continuous variables are reported as mean with standard deviation or as median with interquartile range (IQR), depending on the distributional assumption. Heart rate, reparatory rate and oxygen saturation at baseline and at various time points after drug administration of drug were expressed as mean values with standard deviations. Similarly, proportion of patients with a sedation score of 3 at various time points was reported as percentage with corresponding 95% confidence limits. Statistical analyses were performed using SAS version 9.4 software.

## RESULTS

The primary outcome of satisfactory sedation, Modified Observer's Assessment of Alertness/ Sedation scale (MOAA/S) ≤ 3 was achieved in 93% of the subjects (Table 1). Sedation score data demonstrates the expected time-to-peak effect for intranasal DEX. Sedation score is considered adequate if it is less than or equal to 3. The drug dose is highly effective in achieving the target sedation in 93.0% of children by 30 minutes. The 95% CI at 30 minutes (80.9%–98.5%) is narrow and entirely above 80%, providing high confidence that the drug reliably produces successful sedation.

Similarly, the ≤2 score on the 4-point scale parent-child separation scores were achieved in 40 (93%).

**Table 1. Cumulative percentage of patients achieving sedation score ≤ over time with 95% confidence intervals. (n=43)**

| Time (minutes) | ≤3, n (%) | 95% CI for ≤3 | >3, n (%) | 95% CI for >3 |
|---|---|---|---|---|
| 0 | 0 (0.0) | 0.0 - 8.2 | 43 (100.0) | 91.8 - 100.0 |
| 5 | 0 (0.0) | 0.0 - 8.2 | 43 (100.0) | 91.8 - 100.0 |
| 10 | 2 (4.7) | 0.6 - 15.8 | 41 (95.3) | 84.2 - 99.4 |
| 15 | 15 (34.9) | 21.0 - 50.9 | 28 (65.1) | 49.1 - 79.0 |
| 20 | 24 (55.8) | 39.9 - 70.9 | 19 (44.2) | 29.1 - 60.1 |
| 25 | 31 (72.1) | 56.3 - 84.7 | 12 (27.9) | 15.3 - 43.7 |
| 30 | 40 (93.0) | 80.9 - 98.5 | 3 (7.0) | 1.5 - 19.1 |

The onset is relatively slow initially (only 4.7% sedated by 10 minutes), but the effect rapidly accelerates between 15 and 30 minutes (Figure 1)

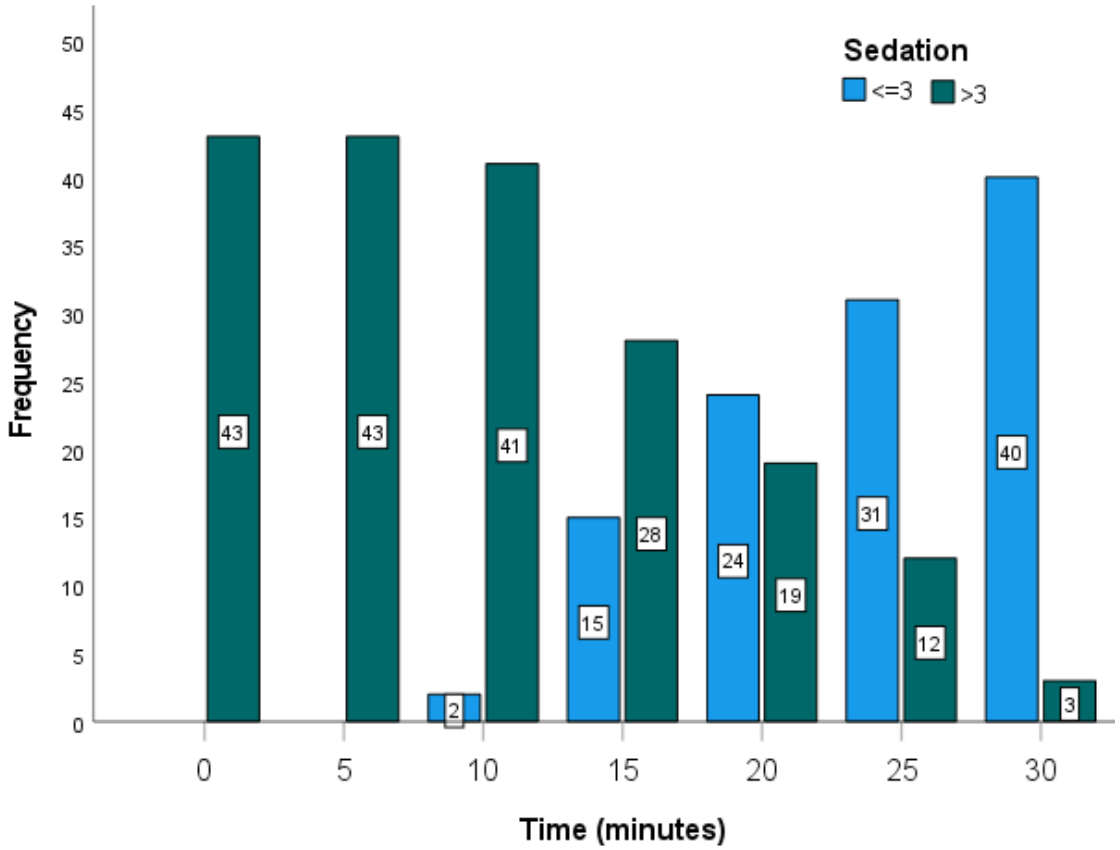


**Figure 1. Sedation score in the preoperative holding area with time.**

Demographic characteristics for all children have been summarized in (Table 2). The study sample is predominantly male (79.1). The age distribution is relatively balanced, with slightly more participants in the 6–9 years group (53.5%). The mean age of the participants was 5.64 years, with a mean weight of 19.65 ± 6.75 kg.

| Table 2. Demographic data. | |
|---|---|
| Variable | Frequency (%) |
| Gender | |
| Male | 34 (79.1) |
| Female | 9 (20.9) |
| Age (years) | |
| 2 - 5 | 20 (46.5) |
| 6 - 9 | 23 (53.5) |
| Surgery type | |
| Laparotomy | 7 (16.3) |
| Herniotomy | 14 (32.6) |
| Adenotonsillectomy | 4 (9.3) |
| Orthopedic/plastic/limb surgeries | 12 (27.9) |
| Penile surgery / Circumcision | 6 (14.0) |
| Weight (kg) | |
| Mean ± SD | 19.65 ± 6.75 |
| Median (IQR) | 17 (15, 25) |

The mean heart rate (HR), respiratory rate (RR), and peripheral oxygen saturation ($SpO_2$) were recorded at baseline and at 5-minute intervals for 30 minutes following the administration of intranasal DEX (Table 3).

| Table 3. Physiological parameters during the preoperative sedation. | | | |
|---|---|---|---|
| Time (Minutes) | Heart rate | Respiratory rate | Oxygen Saturation |
| | Mean ± SD | | |
| 0 | 107.12 ± 14.20 | 19.26 ± 2.50 | 97.79 ± 0.91 |
| 5 | 102.86 ± 14.29 | 18.95 ± 2.54 | 93.33 ± 0.99 |
| 10 | 95.58 ± 9.17 | 19.65 ± 2.09 | 97.44 ± 1.39 |
| 15 | 93.84 ± 8.03 | 18.09 ± 1.96 | 97.02 ± 1.08 |
| 20 | 90.79 ± 8.95 | 18.42 ± 2.26 | 96.16 ± 4.28 |
| 25 | 86.30 ± 7.93 | 17.58 ± 2.44 | 97.19 ± 1.30 |
| 30 | 85.47 ± 7.29 | 17.19 ± 2.95 | 96.93 ± 1.44 |

## DISCUSSION

This observational study in a paediatric population provides valuable insight into the effectiveness of intranasal DEX as a preoperative sedative. Our findings indicate that a fixed-dose regimen of 1.5 mcg/kg provided satisfactory sedation and improved parent-child separation scores in 93% of the subjects. The 95% CI at 30 minutes (80.9%-98.5%) is narrow and entirely above 80%, providing high confidence that the drug reliably produces successful sedation

This is consistent with previous studies that have established DEX's anxiolytic and sedative properties. Previous studies have shown that successful sedation rates for intranasal DEX typically fall between 81% and 92%, with reported doses ranging from 1 to 4 mcg/kg.[5] The demographic split between the challenging pre-school (2-5 years) and the school-age (6-9 years) groups suggests that the findings are applicable across the developmental spectrum most affected by pre-operative anxiety. Our results align with and, in some cases, build upon the existing body of research.[9] This meta-analyses establishes efficacy of intranasal DEX, our study reinforces this evidence by demonstrating 93% success rate for satisfactory sedation. Our finding further contribute the evidence supporting 1.5 mcg/kg dose as a reliable regimen and identifying 30 minutes

as optimal onset window for preoperative sedation. Additionally, our data characterizes the safety profile of this dose.

While many studies have focused on comparative trials,[5] our observational approach specifically highlights the real-world application of this sedative in a specific clinical setting. The satisfactory sedation rates observed in our study are comparable to those reported in trials where intranasal DEX was found to be as effective as, or even superior to, other agents like midazolam. This high success rate is a significant finding that validates the selection of the 1.5-mcg/kg intranasal DEX dose as an optimal balance.

In a significant subset of patients, studies using the lower 1 mcg/kg dose frequently indicate satisfactory sedation rates at 30-45 minutes, occasionally concluding that the amount of sedation is insufficient for a non-traumatic separation.[2,10] On the other hand, increasing dose from 1 mcg/kg to 2 mcg/kg halved the time to peak concentration and lead to better sedation. The most common adverse effect of DEX is unambiguously bradycardia and hypotension; noteworthy is that high dose has been linked to cardiac arrest. Even further, there are reports that DEX can reduce ventilatory response to hypoxia and hypercapnia due to interaction with peripheral and central control of respiration, leading respiratory inhibition.[11]

This cohort's 93.0% success rate indicates that the 1.5 mcg/kg dose may be able to lessen the more severe side effects while still capturing the high efficacy of the higher dose. For constant and dependable sedation scores below 4, doses more than 1.0 mcg/kg have frequently been recommended by prior meta-analyses and systematic reviews and also 1.5mcg/kg seems to be both effective and safe.[11]

With a notable rise in sedated patients from 34.9% at 15 minutes to 93.0% at 30 minutes, the rapid onset profile is in line with the drug's absorption profile and published pharmacodynamic data, which typically indicates that the maximal sedative effect (Emax) and peak plasma concentration (Cmax) happen 30 to 45 minutes after intranasal administration.[12]

This strongly implies that 30 minutes after drug administration is the best time to move the patient to the operating room, allowing for the peak medication action and excellent induction settings, thus fulfilling a major study goal.

Evaluating the effect of intranasal DEX on parental separation anxiety was a crucial secondary goal. According to the study, most patients had a favourable parental separation score (≤ 2 on the 4-point scale), and 93.0% of them behaved calmly or in a way that was nervous but manageable. Preventing preoperative anxiety, a proven predictor of adverse post-operative behavioral changes, is the aim of pre-procedural sedation.[13] The study's 93.0% good separation score shows that this important stressor has been effectively attenuated. This degree of effectiveness in treating separation anxiety is frequently higher than that of oral benzodiazepines. Research comparing intranasal DEX to oral midazolam frequently reveals that intranasal DEX offers better anxiolysis and higher-quality sedation.[10]

Effective safety profile for the 1.5 mcg/kg dose is provided by the specific objectives addressing hemodynamic changes: Heart Rate and Oxygen Saturation at specified time points. This enables additional comparison across the dose spectrum.

An expected, dose-dependent pharmacological impact of the inhibition of sympathetic outflow is the progressive decrease in mean heart rate (from 107.12 bpm to 85.47 bpm). This bradycardia is a hallmark of DEX (an α2-agonist) and, in this context, does not appear to be clinically alarming, as the final mean HR remains well above critical levels for this age group.

Although often less noticeable, there is a significant drop in heart rate in patients receiving 2 mcg/kg than those receiving 1 mcg/kg.[14] The bradycardia in this trial was always well tolerated. Importantly, and consistent with accepted pharmacology, the respiratory rate remained constant during the 30-minute monitoring period, indicating no clinically severe respiratory depression. This maintenance of spontaneous breathing demonstrates intranasal DEX notable safety benefit over GABAergic sedatives (such as Propofol or Midazolam) in the pre-anaesthetic holding area.

A crucial safety finding was the fall in mean SpO2 to 93.33% at 5 minutes point after the drug administration. This could be due to the drug's rapid systemic absorption from the nasal mucosa, leading to peak plasma concentrations between 5 and 10 minutes post-intranasal administration.[12] This transient drop in oxygen saturation at 1.5 mcg/kg dose, points to clear fact that this early physiological effect might be common in the higher dose range. In order to decrease the risk of hypoxemia, it is critical that ongoing pulse oximetry is mandated for all patients in the preoperative area while

under intranasal DEX sedation.

A key strength of this study is its focus on a specific patient population, providing unique data from a tertiary hospital in Kathmandu. This observational design, while useful for providing a snapshot of clinical practice, is a limitation as it lacks a control group for direct comparison. This design makes it difficult to definitively isolate the effect of the drug from other factors. Furthermore, we did not assess key secondary outcomes such as mask acceptance, ease of intravenous (IV) placement, intra and postoperative hemodynamic stability, postoperative nausea and vomiting, or analgesic requirements. Future research could address these limitations to broaden the horizon.

## CONCLUSIONS

The findings of this study support the use of 1.5 mcg/kg intranasal DEX as a safe and effective premedication for paediatric patients in a clinical setting. The non-invasive administration route and its favourable side-effect profile make it a valuable tool for improving the preoperative experience for children and their families. Further research is warranted to validate these findings with a larger cohort and to compare different dosing strategies.

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## CONFLICT OF INTEREST

Authors declare there are no any conflicts of Interest.

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