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Intranasal dexmedetomidine Vs intranasal midazolam in pediatric tonsillectomy

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Abstract
Background: This randomized, double-blind study evaluated intranasal dexmedetomidine vs. midazolam as premedication in children undergoing tonsillectomy.
Methods: 100 children (ASA I/II, aged 6–12 years) were randomized to receive either intranasal midazolam (0.2 mg/kg) or dexmedetomidine (1 µg/kg). Sedation, mask acceptance, hemodynamics, recovery, and postoperative outcomes were assessed.
Results: Satisfactory sedation was achieved in 86% of the dexmedetomidine group and 68% of the midazolam group (p=0.03). Mask induction was satisfactory in 84% and 70%, respectively (p=0.09). Postoperative agitation scores showed no significant difference (p=0.30). No patients experienced hypotension, hypoxia, or life-threatening complications between premedication and anesthesia induction.
Conclusion: Intranasal dexmedetomidine (1 µg/kg) is a safe and effective alternative to midazolam (0.2 mg/kg), offering superior sedation.

Keywords: Dexmedetomidine, midazolam, tonsillectomy, intranasal, premedication

Introduction
Pediatric patients often experience significant anxiety and distress during tonsillectomy, particularly during parental separation, venipuncture, or mask application. Sedative premedication can help ease anxiety and ensure smoother anesthesia induction. Intranasal midazolam is a commonly used premedication due to its ease of administration, effectiveness, and quick onset. However, it may cause nasal irritation, behavioral changes, cognitive impairment, paradoxical reactions, and respiratory depression. Dexmedetomidine, a highly selective α2-adrenoreceptor agonist with sedative and analgesic properties, has gained popularity for pediatric use. Unlike midazolam, it acts on the locus ceruleus, inducing sedation akin to natural sleep with easy arousal. This study aimed to compare intranasal dexmedetomidine and midazolam in uncooperative children undergoing tonsillectomy. The primary endpoint was sedation during parental separation, while secondary endpoints included sedation onset, mask acceptance, recovery times, and postoperative outcomes

Methodology
This prospective, double-blind study was conducted with institutional ethical committee approval. It included children aged 6 to 12 years with ASA physical status I / II scheduled for tonsillectomy. Written informed consent was obtained from parents after explaining the study protocol. Exclusion criteria were a known allergy to study drugs, recent respiratory infections, congenital heart disease, mental retardation, or neurobehavioral issues. Children were randomly assigned to two groups using computer-generated random numbers. Group M (n=50) received intranasal midazolam (0.2 mg/kg) as nasal drops, while Group D (n=50) received intranasal dexmedetomidine (1 µg/kg) in the same manner, both administered using a 1 mL insulin syringe 60 minutes before anaesthesia induction, in the preoperative area. A separate investigator prepared the drug mixture to maintain blinding, and both the anaesthesiologists and observers were unaware of the group allocations. A blinded observer assessed sedation status every 10 minutes using a 6 point MOASS scale and evaluated anxiety levels at the same intervals using a four-point scale in the preoperative area. One

hour after nasal premedication, children were brought into the OR suite, were induced by mask induction with O_2/N_2O/Sevoflurane mixture. 3 point Mask induction scale was used to evaluate mask acceptance. Standard ASA monitors connected. Intravenous access was established after induction. Propofol (1–2 mg/kg) was administered for deepening anesthesia, if required. After induction, appropriate-sized endotracheal tubes were used for airway management. Anesthesia was maintained using sevoflurane (1.5%–2%) in a mixture of air and oxygen. Fentanyl (1 mcg/kg) was administered for intraoperative analgesia. Muscle relaxation was achieved using atracurium (0.5 mg/kg). Post-surgery, patients were extubated once they fulfilled the standard criteria for safe extubation. Postoperative agitation was measured immeadiatley & 10 minute after exubation using post-operative agitation score

Table 1: Modified Observer's Assessment of Alertness/Sedation Score

Score	Criteria
6	Appears alert and awake, responds readily to name spoken in normal tone
5	Appears asleep but responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly or repeatedly
2	Responds only after mild prodding or shaking
1	Does not respond to mild prodding or shaking
0	Does not respond to noxious stimulus

Table 2: Anxiety Score

Score	Criteria
1	Calm and cooperative
2	Anxious but could be reassured
3	Anxious and could not be reassured
4	Crying or resisting

Statistical Analysis

The sample size was calculated based on a study by Akin A *et al*., and 50 patients were recruited in each group to account for potential dropouts. Numerical data were analyzed using the unpaired Student's t-test and presented as mean ± standard deviation. Sedation and anxiety scores were assessed using the nonparametric Mann-Whitney U test. Categorical variables were compared using the Chi-square test and reported as median with interquartile range (IQR), as well as numbers and percentages. A p-value of 0.05 or less was considered statistically significant. Statistical analysis was performed using Epi Info 3.5.4.

Results

Table 3: Parameters Comparison between Group D and Group M

Parameters (min)	Group D (Mean ± SD)	Group M (Mean ± SD)	p value
Duration of Surgery (min)	34.24±3.52	34.58±3.32	0.620
Duration of Anaesthesia (min)	47.44±3.69	47.04±4.50	0.628
Extubation Time (min)	8.10±1.52	8.00±1.41	0.733

A total of 100 patients were enrolled, with both groups comparable in demographics, including age (Dexmedetomidine: 9.00±2.11 years, midazolam: 8.98±2.18 years, p=0.962), gender distribution, and mean durations of surgery, anesthesia, and extubation (Dexmedetomidine: 34.24, 47.44, 8.1 minutes; midazolam: 34.58, 47.04, 8 minutes). Satisfactory sedation for parent separation was achieved in 86% of the dexmedetomidine group and 68% of the midazolam group (p=0.03). Mask induction was satisfactory in 84% and 70% of patients, respectively (p=0.09). Postoperative agitation scores showed no significant difference (p=0.30).Sedation scores were significantly better in the dexmedetomidine group at 50 and 60 minutes, while anxiety scores were similar between groups without statistical significance In the dexmedetomidine group, heart rate decreased by 13.41% compared to a 7.56% reduction in the midazolam group by the 60th minute, with a significant reduction starting from the 20th minute intraoperatively. Peripheral oxygen saturation remained above 95% in all patients throughout the preoperative, intraoperative, and postoperative periods. Blood pressure decreased modestly in both groups (Dexmedetomidine: 13.19%, midazolam: 10.46%) with no statistically significant difference between them during the preoperative and intraoperative periods. No patient experienced hypotension, hypoxia, or laryngospasm from premedication administration to anesthesia induction.

Table 4: Separation from parents, quality of mask induction and agitation score

Score	Group D (n, %)	Group M (n, %)	p Value
Separation from Parents (Anxiolysis Score)			
Calm, cooperative	43 (86)	34 (68)	0.03
Anxious but could be reassured	5 (10)	10 (20)	0.16
Anxious and could not be reassured	1 (2)	4 (8)	0.16
Crying, or resisting	1 (2)	2 (4)	0.56
Quality of Mask Induction			
Calm, cooperative or asleep	42 (84)	35 (70)	0.09
Moderate fear of mask but cooperative with reassurance	4 (8)	10 (20)	0.08
Combative, crying	4 (8)	5 (10)	0.72
Postoperative Agitation Score			
Calm, easily arousable, follows commands	35 (70)	30 (60)	0.30
Restless or crying but calms to verbal commands	14 (28)	18 (36)	0.39
Disoriented, Combative, thrashing	1 (2)	2 (4)	0.56

Table 5: Preoperative sedation and anxiety score (median IQR)

Time	Sedation Score (Group D)	Sedation Score (Group M)	P-value	Anxiety Score (Group D)	Anxiety Score (Group M)	P-value
Baseline	6 (6-6)	6 (6-6)	-	2 (1-4)	2 (1-4)	0.680
10 min	5 (5-6)	5 (5-6)	0.322	1 (1-4)	2 (1-4)	0.065
20 min	5 (4-5)	5 (4-5)	0.117	1 (1-4)	1 (1-4)	0.349
30 min	4 (3-5)	4 (3-5)	0.058	1 (1-4)	1 (1-4)	0.192
40 min	3 (3-5)	3 (3-5)	0.194	1 (1-4)	1 (1-4)	0.244
50 min	3 (3-5)	3 (3-5)	0.046	1 (1-4)	1 (1-4)	0.244
60 min	3 (2-5)	3 (2-5)	0.022	1 (1-4)	1 (1-4)	0.244

Discussion

This study aimed to compare the effects of intranasal dexmedetomidine (1 µg/kg) and midazolam (0.2 mg/kg) on mask induction and sedation in children undergoing tonsillectomy. We found that dexmedetomidine was more effective than midazolam in reducing anxiety during separation from parents, but both drugs were equally effective for sedation during mask induction. Midazolam is a commonly used premedication, but its intranasal administration can cause nasal irritation, making it less preferred in routine practice. However, studies suggest that children tolerate intranasal midazolam better than oral administration. Walbergh *et al*. and Malinovsky *et al*. have shown that intranasal midazolam quickly achieves sedative plasma concentrations and provides adequate sedation within 10 minutes. Dexmedetomidine, with its anxiolytic, sedative, and sympatholytic properties, is a useful premedication, especially for children at risk of preoperative stress. Studies have shown that intranasal dexmedetomidine is effective and well-tolerated, and Yuen *et al*. concluded it was more convenient for administration. Our study used a 1 µg/kg dose of dexmedetomidine, based on evidence showing similar effects for doses between 0.5 and 1 µg/kg. The study also showed that 86% of children in the dexmedetomidine group achieved satisfactory sedation, compared to 68% in the midazolam group. Additionally, 84% of those sedated with dexmedetomidine tolerated mask induction without distress. Although the lower dose of midazolam might have affected its efficacy, intranasal dexmedetomidine reduced heart rate and systolic blood pressure significantly compared to midazolam. There were no major differences between the two groups regarding postoperative agitation or adverse effects. However, the timing of drug administration may have influenced the results, and the unvalidated scales used to assess outcomes pose another limitation.

Conclusion

Our study demonstrated that intranasal dexmedetomidine is a more effective sedative than intranasal midazolam, making it a preferred premedication option for young children. However, both dexmedetomidine and midazolam are equally effective in achieving satisfactory conditions during mask induction.

References

1. Kain ZN. Preoperative psychological trauma in children. 1st ed. Philadelphia: W.B. Saunders Company; c1999.
2. Kain ZN, Caldwell-Andrews AA, Krivutza DM, Weinberg SM, Wang D, Gaal D. Trends in the practice of parental presence during induction of anesthesia and the use of preoperative sedative premedication in the United States, 1995-2002: results of a follow-up national survey. Anesth Analg. 2004;98(5):1252-1259.
3. Watson AT, Visram A. Children's preoperative anxiety and postoperative behavior. Paediatr Anaesth. 2003;13(3):188-204.
4. Dave NM. Premedication and Induction of Anaesthesia in paediatric patients. Indian J Anaesth. 2019;63(9):1320-1324.
5. Impellizzeri P, Vinci E, Gugliandolo MC, Cuzzocrea R, Larcan T, Russo T. Premedication with melatonin vs midazolam: efficacy on anxiety and compliance in paediatric surgical patients. Eur J Pediatr. 2017;176(7):475-453.
6. Kain ZN, Mayes LC, O'Connor TZ, Cicchetti DV. Preoperative anxiety in children: predictors and outcomes. Arch Pediatr Adolesc Med. 1996;150(12):1238-1245.
7. Wang J, Bu G. Influence of intranasal medication on the structure of the nasal mucosa. 2002;11:546-579.
8. Almenrader N, Passariello M, Coccetti B, Haiberger R. Premedication in children: a comparison of oral

midazolam and oral clonidine. Pediatr Anesth. 2007;17(1):121-124.
9. Fazi L, Jantzen EC, Rose JB, Kurth MF, Watcha MF. A comparison of oral clonidine and oral midazolam as preanesthetic medications in the pediatric tonsillectomy patients. Anesth Analg. 2001;92(1):156-161.
10. Wang J, Bu G. Influence of intranasal medication on the structure of the nasal mucosa. Chin Med J. 2002;11:546-579.
11. Deshmukh PV, Kulkarni SS, Parchandekar MK, Sikchi SP. Comparison of preanesthetic sedation in pediatric patients with oral and intranasal midazolam. J Anaesthesiol Clin Pharmacol. 2016;32(3):358-363.
12. Giovannitti JA, Thoms SM, Crawford JJ. Alpha-2 adrenergic receptor agonists: review of current clinical applications. Anesth Prog. 2015;62(1):31-38.
13. Yuen VM. Dexmedetomidine: perioperative applications in children. Paediatr Anaesth. 2010;20(3):256-264.
14. Sajid B, Mohamed T, Jumaila M. A comparison of oral dexmedetomidine and oral midazolam as premedicants in children. J Anaesthesiol Clin Pharmacol. 2019;35(1):36-40.
15. Akin A, Bayram A, Esmaoglu Z, Tosun R, Aksu R, Altuntas R. Dexmedetomidine vs midazolam for premedication of pediatric patients undergoing anesthesia. Paediatr Anaesth. 2012;22(9):871-876.
16. Mehdi I, Parveen S, Choubey S, Rasheed A, Singh M, Ghayas M. Comparative Study of Oral Midazolam Syrup and Intranasal Midazolam Spray for Sedative Premedication in Pediatric Surgeries. Anesth Essays Res. 2019;13(2):370-375.
17. Kumar L, Kumar A, Panikkaveetil BK, Vasu S, Rajan SG, Nair E. Efficacy of intranasal dexmedetomidine versus oral midazolam for paediatric premedication. Indian J Anaesth. 2017;61(2):253-230.
18. Cao J, Shi X, Miao X. Effects of premedication of midazolam or clonidine on perioperative anxiety and pain in children. Biosci Trends. 2009;3(3):115-118.
19. Diwan G, Bharti AK, Rastogi PK, 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.
20. Kumari S, Agrawal N, Usha V, Talwar P, Gupta P. Comparison of Oral Clonidine, Oral Dexmedetomidine, and Oral Midazolam for Premedication in Pediatric Patients Undergoing Elective Surgery. Anesth Essays Res. 2017;11(1):185-191.

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