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Inhalational dexmedetomidine as a promising alternative to oral midazolam for pediatric premedication. A randomized pilot study

N. Marković[1,2], S. Kelić[1,2], V. Dolinaj[1,2], G. Rakić[1,3], D. Turanjanin[1,3], R. Zdravković[1,4]

[1]University of Novi Sad, Faculty of Medicine, Novi Sad, Serbia
[2]Clinical Center of Vojvodina, Department of Anesthesia and Perioperative Medicine, Novi Sad, Serbia
[3]Institute for Child and Youth Health Care of Vojvodina, Clinic for Pediatric Surgery, Novi Sad, Serbia
[4]Institute of Cardiovascular Diseases of Vojvodina, Department of Cardiovascular Surgery, Sremska Kamenica, Serbia

Corresponding author: N. Marković[1], University of Novi Sad, Faculty of Medicine, Novi Sad, Serbia.
Email: 911024d22@mf.uns.ac.rs

Keypoints

Inhalational dexmedetomidine provides effective and stable sedation for pediatric premedication.

Abstract

Introduction

Preoperative anxiety is a common and clinically significant problem in pediatric anesthesia. Oral midazolam has traditionally been used for premedication, however, it is associated with variable efficacy and potential adverse effects. Inhalational dexmedetomidine is increasingly being considered as a safer and promising alternative for pediatric premedication. The aim of this study was to compare the efficacy and safety of inhalational dexmedetomidine and oral midazolam in terms of sedation quality, hemodynamic and respiratory stability, as well as the child's cooperation during premedication.

Methods

This prospective randomized study included 60 children aged 2–12 years, ASA physical status I–II, undergoing abdominal or urological surgical procedures. The participants were divided into two groups: the dexmedetomidine group (group D) received inhalational dexmedetomidine at a dose of 2 μg/kg, while the midazolam group (group M) received oral midazolam at a dose of 0.3 mg/kg. Vital parameters and sedation levels were monitored 10, 20, and 30 minutes after drug administration. Cooperation was assessed during intravenous cannulation, separation from parents, and acceptance of the anesthesia mask during induction of general anesthesia.

Results

After 10 minutes, a statistically significant difference in sedation level was observed in favor of group M ($p = 0.003$). After 20 and 30 minutes, no statistically significant differences between the groups were observed ($p > 0.05$). During intravenous cannulation, no statistically significant difference was found ($p = 0.061$), although a clear trend favored group D. Successful separation from parents was comparable between groups ($p > 0.05$), whereas mask acceptance was more effective in group M (83.3%) compared with group D (53.3%; $p = 0.033$). Hemodynamic parameters remained stable, with transient bradycardia observed only in group D. No significant respiratory adverse effects were recorded.

Conclusion

Inhalational dexmedetomidine demonstrated comparable efficacy to oral midazolam with a favorable safety profile, making it a suitable alternative for premedication in pediatric anesthesia.

Keywords

dexmedetomidine; midazolam; premedication; children

Introduction

Preoperative anxiety is a common and clinically significant problem in pediatric anesthesia, as a large proportion of children experience fear and distress before surgical procedures [1]. Such anxiety may lead to poor cooperation, refusal of separation from parents, and difficulties during anesthesia induction, which may negatively affect the course of anesthesia and perioperative outcomes [2]. It is also associated with an increased risk of postoperative agitation, delirium, and long-term negative psychological consequences [3].

Therefore, adequate premedication represents a crucial part of preparing a child for anesthesia [4].

Midazolam, a benzodiazepine with pronounced anxiolytic and sedative effects, has long been considered the gold standard in pediatric premedication [5].

However, oral administration of midazolam is often associated with refusal due to its bitter taste and variable sedative effect [6]. In addition, midazolam has been shown to suppress explicit memory while preserving implicit memory, which may contribute to negative behavioral changes in the postoperative period [7].

Dexmedetomidine has emerged as a potential alternative to midazolam in pediatric premedication, with some studies demonstrating a more favorable effect regarding sedation quality and reduction of postoperative agitation [8,9].

When administered orally, it has a slow and variable onset of action, requiring higher doses because of its low bioavailability [10].

Intranasal administration enables good absorption through the respiratory mucosa and a rapid onset of action, with a favorable safety profile and minimal adverse effects [11].

It can be administered using a mucosal atomizer or drops, with the atomizer allowing reduced drug loss in the oropharynx, higher cerebrospinal fluid concentrations, better patient acceptability, and a more pronounced sedative effect [12].

Based on the assumption that children may more readily accept inhalational administration compared with intranasal administration, the aim of this study was to compare the efficacy, safety, sedation level, hemodynamic stability, and child cooperation during premedication by comparing two sedation regimens: inhalational dexmedetomidine and oral midazolam.

Methods

This prospective, single-center, randomized clinical study was conducted at the Clinic for Pediatric Surgery of the Institute for Health Care of Children and Youth of Vojvodina between December 1, 2024, and February 15, 2025. The study was approved by the institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki.

Written informed consent was obtained from the parents or legal guardians.

A total of 60 children aged 2–12 years with ASA physical status I–II scheduled for elective abdominal or urological surgery were included in the study.

Children younger than 2 years or older than 12 years, those undergoing other types of surgical procedures (orthopedic, ENT, ophthalmologic, or neurosurgical), and patients with ASA physical status III–IV were excluded (Figure 1).

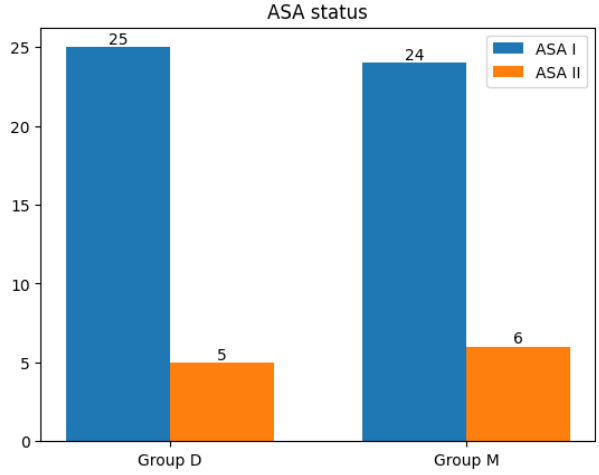

Figure 1. Distribution of ASA status of participants by groups

Participants were randomly assigned into two groups using the sealed-envelope method: the dexmedetomidine group (Group D), which received inhalational (nebulized) dexmedetomidine at a dose of 2 µg/kg, and the midazolam group (Group M), which received oral midazolam at a dose of 0.3 mg/kg. All children underwent standard preoperative preparation and remained with their parents until transfer to the operating room.

After recording baseline vital parameters (heart rate, blood pressure, and oxygen saturation), the medication was administered 30 minutes before induction of anesthesia.

Vital parameters and sedation levels were monitored 10, 20, and 30 minutes after drug administration.

The level of sedation was assessed using the Sedation Scale (SS-5), where scores of 1–3 were considered satisfactory (Table 1).

Twenty minutes after drug administration, an intravenous cannula was inserted, and the child's behavior was evaluated using the Emotional State Scale (ESS-4), where scores of 1–2 were considered satisfactory (Table 1).

After 30 minutes, separation from parents was assessed using the same scale. Acceptance of the oxygen mask during preoxygenation and induction of general anesthesia was evaluated using the Mask Acceptance Scale (MAS), where scores of 1–2 were considered satisfactory (Table 1).

SS-5	
1	Asleep, awakens to rough stimulation
2	Asleep, awakens easily
3	Drowsy
4	Awake
5	Agitated
ESS-4	
1	Calm
2	Frightened, withdrawn
3	Tearful
4	Restless, resists
MAS	
1	Excellent, cooperates without fear
2	Good, mild fear present, easily calmed
3	Moderate resistance, pronounced fear, difficult to calm
4	Cries loudly, resists

Table 1. Sedation Scale (SS-5), Emotional State Scale (ESS-4) and Mask Acceptance Scale (MAS)

Statistical Analysis

Continuous variables are presented as mean ± standard deviation or median (interquartile range), as appropriate, while categorical variables are presented as frequencies

and percentages. Normality of distribution was assessed using the Shapiro–Wilk test.

Comparisons between groups were performed using the Student's t-test or the Mann–Whitney U test, as appropriate. Repeated measurements within groups were analyzed using repeated-measures analysis of variance with Bonferroni correction or the Friedman test with Wilcoxon post hoc analysis for non-normally distributed data. Categorical variables were compared using the χ^2 test or Fisher's exact test.

Multivariable logistic regression analysis was used to assess factors associated with children's reactions during premedication. A p value < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics version 23.

Results

The demographic characteristics and body weight of the 60 children randomized into two groups of 30 participants each are presented below: group D, which received inhalational dexmedetomidine, and group M, which received oral midazolam (Table 2).

The groups were generally comparable in terms of sex distribution and age range, although the median age was lower in group D compared with group M. Body weight was higher in group M, with the difference in median values reaching statistical significance (p = 0.033).

Sedation

The level of sedation of the participants after 10, 20, and 30 minutes is presented in Table 3. After 10 minutes, a statistically significant difference in sedation level was observed in favor of group M (p = 0.003). After 20 and 30 minutes, no statistically significant differences between the groups were observed (p > 0.05). Within-group analysis showed statistically significant changes in sedation levels over time in both groups (p < 0.001).

Emotional State

The emotional state of the children after premedication was assessed using the Emotional State Scale (ESS-4) 20 minutes after drug administration during intravenous cannulation and again after 30 minutes during separation of the child from the parents and transfer to the operating room.

Emotional state during intravenous cannulation

The distribution of ESS-4 scores showed that in group D most children had scores of 2 and 3 (12 and 13 cases, respectively), whereas in group M the most frequently recorded scores were 1 and 2 (8 and 11 cases, respectively). No statistically significant difference in emotional state was observed between the studied groups ($\chi^2 = 7.288$; df = 3; p = 0.060) (Table 4).

Emotional state during separation from parents

The emotional state of the children during separation from their parents did not differ significantly between the studied groups. The median ESS-4 score was the same in both groups, with a similar range of values and no statistically significant difference (p > 0.05) (Table 5).

Mask acceptance

Acceptance of the oxygen mask during anesthesia induction was assessed using the Mask Acceptance Scale (MAS). The distribution of frequencies and percentages across groups is presented in Table 6. In group M, lower scores (1 and 2) were recorded more frequently, whereas higher scores (3 and 4) were more common in group D. However, the difference in mask acceptance did not reach statistical significance (Monte Carlo exact test: $\chi^2 = 6.643$; df = 3; p = 0.090).

The effect of premedication on vital parameters was assessed by monitoring oxygen saturation (SpO_2), heart rate (HR), and systolic blood pressure (SBP) at defined time intervals after drug administration. During the monitoring of hemodynamic and respiratory parameters, no clinically significant differences between the groups were observed at most time points. Baseline systolic blood pressure values were significantly higher in group M compared with group D (101.00 ± 8.70 vs 96.70 ± 6.24 mmHg; p = 0.032), whereas during induction and the intraoperative period no statistically significant differences between the groups were observed (p > 0.05). Repeated-measures analysis showed statistically significant

changes in systolic blood pressure over time in both groups ($p < 0.001$). Heart rate changed significantly over time within both groups (group D: $p < 0.001$; group M: $p = 0.015$), but no statistically significant differences between the groups were found at any time point ($p > 0.05$). Bradycardia was recorded in three participants (10.0%) in group D, whereas it was not observed in group M, without a statistically significant difference between groups ($p > 0.05$). Oxygen saturation remained high and stable throughout the entire monitoring period in both groups, with median values between 98% and 99%. No statistically significant differences between the groups were observed at any time point ($p > 0.05$). Hypotension was recorded in four participants (13.33%), three in group D (10.0%) and one in group M (3.33%), without statistically significant differences between the groups ($p > 0.05$). The results are presented in Table 7.

Characteristic	**Group D (n = 30)**	**Group M (n = 30)**	**p value**
Age (years) — Mean ± SD	4.80 ± 1.96	6.50 ± 3.13	
Median (P25–P75)	4 (3–6)	6 (3–8)	
Min–Max	2–9	3–12	
Sex, n (%)			
Male	21 (70.0)	20 (66.7)	
Female	9 (30.0)	10 (33.3)	
Body weight (kg) — Mean ± SD	18.5 ± 6.3	24.5 ± 7.5	0.033*
Median (P25–P75)	18 (16–23.75)	24.5 (17.5–41)	
Min–Max	12–35	12–50	

Table 2. Demographic characteristics and body weight of the study population. *Mann–Whitney U test; SD — standard deviation; P25/P75 — 25th/75th percentile

Time	**Parameter**	**Group D&*****	**Group M&*****	**P#**
10 minutes[a]	Median (P25–P75)	4 (4–4)	4 (3–4)	**>0.003**
	Range	(4–5)	(3–5)	
20 minutes[b]	Median (P25–P75)	3 (3–4)	3 (3–4)	0.792
	Range	(2–4)	(2–5)	
30 minutes[c]	Median (P25–P75)	3 (3–3)	3 (2–3)	1.000
	Range	(2–4)	(2–5)	

Table 3. Median sedation level after 10, 20 and 30 minutes in the study groups. # Mann–Whitney U test & Friedman test; § Wilcoxon test; *** $p < 0.001$; ** $p < 0.01$; P25: 25th percentile; P75: 75th percentile; Bold values indicate statistically significant results.

ESS-4	Group D	Group M	p value
Median (P25–P75)	3 (2–3)	2 (1–3)	0.061
Range	1–4	1–4	
Score 1, n (%)	1 (3.33)	8 (26.67)	
Score 2, n (%)	12 (40.00)	11 (36.67)	
Score 3, n (%)	13 (43.33)	7 (23.33)	
Score 4, n (%)	4 (13.33)	4 (13.33)	

Table 4. Emotional state during IV cannulation (ESS-4). Monte Carlo exact test ($\chi 2=7,288$; df=3; p=0,060); ESS-4: Emotional State Scale, Mann–Whitney U test; p25: 25ti percentile:P75:75 percentile

ESS-4 score	Group D n (%)	Group M n (%)	Total n (%)
1	7 (23.33)	9 (30.00)	16 (26.67)
2	9 (30.00)	13 (43.33)	22 (36.67)
3	11 (36.67)	6 (20.00)	17 (28.33)
4	3 (10.00)	2 (6.67)	5 (8.33)
Median (P25–P75)	2 (2–3)	2 (1–3)	-
Range	1–4	1–4	-
p value	0.198 (Mann–Whitney U)		0.476 (Monte Carlo)

Table 5. Emotional state at parental separation ESS-4 : n (%). Monte Carlo exact test ($\chi 2$=2,648; df=3; p=0,0476); ESS-4 : Emotional State Scale, Mann–Whitney U test; p25: 25ti percentile:P75:75 percentile

Parameter	Group D	Group M	p value
ESS-4 = 1	7 (23.33%)	12 (40.00%)	0.090*
ESS-4 = 2	9 (30.00%)	13 (43.33%)	
ESS-4 = 3	8 (26.67%)	2 (6.67%)	
ESS-4 = 4	6 (20.00%)	3 (10.00%)	
Emotional state – median (IQR)	2 (2–3)	2 (1–2)	0.033**
Range	1–4	1–4	

Table 6. Mask acceptance (ESS-4) and emotional state. * Monte Carlo exact test; ** Mann–Whitney U test. Values are presented as mean ± SD or median (IQR).

Parameter	Group D	Group M	p value
Systolic BP – baseline (mmHg)	96.7 ± 6.24	101.0 ± 8.70	**0.032**
Systolic BP – induction	87.8 ± 5.35	90.9 ± 9.37	0.117
Systolic BP – intraoperative	89.0 ± 5.85	88.9 ± 11.60	0.967
Heart rate – baseline (bpm)	100.5 (95.5–108.5)	93.5 (79.5–112.5)	0.131
Heart rate – 10 min	100.0 (91.5–105.8)	93.0 (79.5–111.0)	0.149
Heart rate – 20 min	98.5 (89.8–110.3)	95.0 (75.8–108.5)	0.115
Heart rate – 30 min	99.5 (89.8–110.3)	93.5 (79.5–108.5)	0.147
Hypotension, n (%)	3 (10.0)	1 (3.3)	—
Bradycardia, n (%)	3 (10.0)	0 (0.0)	—
SpO2 (%) - baseline	99 (99–100)	99 (98–99)	0,056
SpO2 (%)- induction	99 (98–99)	99 (99–100)	0,449
SpO2 (%)- intraoperative	98,5 (98–99)	99 (98–99)	0,589

Table 7. Hemodynamic parameters and adverse events. # Man-Vitnijev U test; & Wilcoxon test; P25: 25percentile: P75: 75percentile
#t-test ; & repeated-measures ANOVA; ***p<0,001; SD: Standard deviation; Bold values indicate statistical significance.

Discussion

The inhalational route of dexmedetomidine administration for premedication represents a relatively novel approach that enables rapid drug absorption through the nasal, respiratory, and buccal mucosa [13].

In this study, a time-dependent effect of premedication on sedation level in children was observed. A statistically significant difference between the study groups was recorded after 10 minutes, with group M achieving a higher level of sedation compared with group D. This finding suggests a faster onset of action of premedication in group M, which may have clinical relevance in situations where rapid achievement of adequate sedation prior to anesthesia induction is required. However, after 20 and 30 minutes, no statistically significant differences in sedation levels between the groups were observed, suggesting that the effects of the administered premedications become comparable over time. This phenomenon may be explained by a combination of factors, including the relatively low administered dose, variable absorption through the respiratory epithelium, and the pharmacokinetic profile of dexmedetomidine, which requires time to reach the target concentration in the central nervous system [14]. Similar results were reported in a study comparing intranasal dexmedetomidine administered as drops with oral midazolam [15].

The difference in the emotional state of children during intravenous cannulation was not statistically significant; however, a clear trend favoring group D was observed. A higher median ESS-4 score and a more favorable distribution of results in this group indicate better emotional tolerance of the procedure compared with group M. Our findings are consistent with previous studies in which intranasal dexmedetomidine was used [16,17].

Regarding mask acceptance, children in group M demonstrated a significantly better emotional response, which was confirmed by a statistically significant difference between the groups (Mann–Whitney U test; $p = 0.033$), although the median values were identical. Our results are not consistent with most previously published studies, which suggest similar or even better efficacy of dexmedetomidine. These differences may be explained by several factors, including individual variability among children, sample size, or the subjective assessment of cooperation [18,19].

Hemodynamic and respiratory parameters were also monitored during the perioperative period. Although baseline systolic blood pressure values were significantly higher in group M, this difference did not persist during induction or the intraoperative period, suggesting that the administered premedication does not lead to clinically relevant differences during later phases of anesthesia.

Significant changes in systolic blood pressure and heart rate over time within both groups were expected and are consistent with the physiological response to anesthesia induction and maintenance [22]. The absence of intergroup differences at all measured time points confirms the hemodynamic stability of both therapeutic options.

Bradycardia occurred in three children (10%) in group D and did not require intervention. These findings indicate that dexmedetomidine may cause a more pronounced reduction in heart rate [20,21].

Adverse events associated with the doses used for premedication in most pediatric studies have generally been mild and rarely required intervention [23].

Our study did not demonstrate a significant effect of midazolam or dexmedetomidine on respiratory function, measured by oxygen saturation. Therefore, the use of these drugs for premedication provides respiratory stability without significant respiratory depression during the perioperative period. This finding is partly consistent with previous studies. Dexmedetomidine demonstrates good respiratory tolerability and does not cause significant respiratory depression even with increasing doses [24]. On the other hand, midazolam has been associated in some studies with a higher incidence of respiratory adverse events, depending on the administered dose [25].

Conclusion

Inhalational dexmedetomidine provides effective and stable sedation for pediatric premedication, with

comparable emotional separation from parents and good cooperation of children. Although mask acceptance was better in the midazolam group, dexmedetomidine demonstrated a favorable safety profile, with stable hemodynamic parameters and no significant respiratory adverse effects, making it a safe and promising alternative to standard sedatives.

The absence of statistically significant differences may be explained by the relatively small sample size. In addition, the scales used to assess emotional state and mask acceptance, although validated, may have limited sensitivity for detecting subtle clinical differences within the short time interval during anesthesia induction.

Further studies with larger sample sizes and potentially different dosing regimens or administration protocols could provide additional insight into possible differences in behavioral and hemodynamic responses in children.

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Author contributions

N. Marković, S. Kelić, G. Rakić contributed to study conception and design. N. Marković, S. Kelić, G. Rakić, V. Dolinaj, R. Zdravković contributed to data acquisition and analysis. All authors contributed to manuscript drafting and revision and approved the final version. N. Marković is the corresponding author

Conflict of interest

None declared.

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