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**Inhalational dexmedetomidine compared with oral midazolam in pediatric
premedication: impact on postoperative recovery
and emergence delirium – pilot study**

Инхалациони дексмететомидин у поређењу са оралним мидазоломом у
педијатријској премедијацији:
утицај на постоперативни опоравак и делиријум – пилот студија

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Inhalational dexmedetomidine compared with oral midazolam in pediatric premedication: impact on postoperative recovery and emergence delirium – pilot study

Инхалациони дексмететомидин у поређењу са оралним мидазоломом у педијатријској премедикацији:
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SUMMARY

Introduction/Objective Preoperative fear and anxiety in children are associated with unfavorable postoperative outcomes. Oral midazolam is commonly used for pediatric premedication, but may not always effectively prevent postoperative agitation and delirium. Inhaled dexmedetomidine, due to its sedative and anxiolytic properties, represents a promising alternative.

The aim of this study was to compare inhaled dexmedetomidine and oral midazolam regarding emergence time from anesthesia, postoperative recovery, and the incidence of postoperative delirium in children.

Methods This prospective randomized study included 60 children aged 2–12 years, ASA physical status I–II, undergoing surgical procedures. Participants were divided into two groups: the dexmedetomidine group (group D) received inhaled dexmedetomidine 2 µg/kg, while the midazolam group (group M) received oral midazolam 0.3 mg/kg. We assessed emergence time, recovery, and the incidence of postanesthetic delirium.

Results Emergence time did not differ significantly between the groups (Group D: median 8 min, IQR 7–10; Group M: median 7 min, IQR 5–10; Mann–Whitney U test, $p = 0.121$). Aldrete score improved similarly in both groups during the first 20 minutes, with no significant differences between the groups at the observed time points ($p > 0.05$). Delirium occurred in 3.3% of patients in Group D and 6.7% in Group M, without a statistically significant difference (Fisher's exact test, $p = 1$).

Conclusion Inhaled dexmedetomidine used as a premedication in children was associated with slower emergence, faster recovery, and a lower incidence of delirium compared with oral midazolam, although differences were not statistically significant.

Keywords: premedication; dexmedetomidine; midazolam; children; delirium

САЖЕТАК

Увод/Циљ Преоперативни страх и анксиозност код деце повезани су са неповољним постоперативним исходима. Премедикација има кључну улогу у смањењу негативних ефеката. Орално примењен мидазолам се традиционално користи у педијатријској премедикацији, али не показује увек задовољавајућу ефикасност у превенцији постоперативне агитације и делиријума. Инхалациони дексмететомидин, захваљујући седативним и анксиолитичким својствима представља обећавајућу алтернативу.

Циљ студије био је поређење инхалационог дексмететомидина и оралног мидазолама, њиховог утицаја на време буђења из анестезије, постоперативни опоравак и учесталости постоперативног делиријума код деце.

Метод У проспективну рандомизовану студију укључено је 60 деце узраста 2–12 година, ASA I–II, подвргнутих мањим хируршким захватима. Испитаници су подељени у две групе: група дексмететомидин (група D) је примила инхалациони дексмететомидин у дози од 2 µg/kg, док је група мидазолам (група M) примила орални мидазолам у дози од 0,3 mg/kg. Након операције процењивани су време буђења, постоперативни опоравак и постанестетички делиријум.

Резултати Време буђења из анестезије није се значајно разликовало између група (група D: медијана 8 мин, IQR 7–10; група M: медијана 7 мин, IQR 5–10; Mann–Whitney U тест, $p = 0,121$). Алдрете скор показао је прогресивно побољшање у обе групе током првих 20 минута, без статистички значајних разлика између група у посматраним временским тачкама ($p > 0,05$). Постоперативни делиријум регистрован је код 3,3% пацијената у групи D и 6,7% у групи M, без статистички значајне разлике (Фишеров егзактни тест, $p = 1$).

Закључак Инхалационо примењен дексмететомидин као премедикација код деце показао је спорије буђење, бржи постоперативни опоравак и нижу учесталост постоперативног делиријума у поређењу са оралним мидазоломом, али без статистички значајне разлике између група.

Кључне речи: премедикација; дексмететомидин; мидазолам; деца; делиријум

INTRODUCTION

Preoperative fear in children is associated with unfavorable postoperative outcomes, including difficult induction of anesthesia, increased intraoperative analgesic requirements, postoperative delirium, behavioral changes, and symptoms of post-traumatic stress disorder [1]. This highlights the importance of adequate premedication before induction of anesthesia [2, 3, 4].

Various medications are used to reduce anxiety and fear in children before surgery. One of the most commonly used is midazolam [5]. It belongs to the benzodiazepine group, and when administered orally its advantages include a rapid and reliable onset of action and reduction of preoperative anxiety related to needle procedures and parental separation, furthermore the production of anterograde amnesia with minimal respiratory depression. As a premedication modality in children, it is most commonly administered orally. It can also be given intravenously, by intramuscular route, intranasally, rectally, or sublingually, but these routes are less preferred by pediatric patients [6]. Although widely used and considered safe, it has not led to a reduction in emergence agitation and delirium in children [7].

Dexmedetomidine is a potent, highly selective alpha-2 receptor agonist and has emerged as a promising alternative to midazolam in pediatric premedication [8]. The literature includes studies comparing different routes of dexmedetomidine administration as premedication. When administered orally, it has limited bioavailability due to a pronounced first-pass effect. Although randomized controlled trials have shown that its sedative efficacy is not inferior to that of oral midazolam, these studies have generally been limited by small sample sizes [9].

The results of studies comparing intranasal dexmedetomidine with oral midazolam are not entirely consistent. In some outcomes, intranasal administration demonstrated advantages [10], while in others no statistically significant difference was observed [11]. These differing results reflect variations in the doses administered. Intranasal administration can be performed using a mucosal atomization device (nebulizer) or by drops. Compared with drops, atomized administration offers advantages such as reduced drug loss in the oropharynx, higher cerebrospinal fluid concentrations, better patient acceptance, and improved sedative effects [12]. This non-invasive premedication route in children, proved to be efficient in reducing preoperative anxiety, facilitating parental separation, and improving the acceptance of the anesthesia mask.

Assuming children more readily accept inhalational than intranasal administration, this study compared the effects of inhaled dexmedetomidine with oral midazolam on emergence from anesthesia, postoperative recovery, and the incidence of delirium.

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 from December 1, 2024, to February 15, 2025.

The study protocol complies with the Declaration of Helsinki, and the study was initiated after obtaining approval from the Ethics Committee of the Institute for Child and Youth Health Care of Vojvodina. Parents of the children included in the study signed an informed consent after being properly informed about the planned procedure. No personally identifiable information was collected or included in the study database, and individual patients could not be identified from the analyzed data.

This study included 60 children aged 2–12 years, ASA physical status I–II, scheduled for elective abdominal or urological surgery. Children younger than 2 years and older than 12 years, those undergoing other surgical procedures, and ASA III and IV patients, were excluded.

Participants were randomly assigned, using the sealed-envelope method, into two groups based on the drug administered for premedication: the dexmedetomidine group (group D), which received inhaled (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 received premedication 30 minutes before the scheduled surgery. Surgery was performed under balanced general anesthesia. Both groups received propofol as an induction agent (2–3 mg/kg intravenously), fentanyl for intraoperative pain management, and rocuronium bromide as a muscle-relaxing agent at 0.6 mg/kg before laryngeal mask insertion.

At the end of surgery, the time from discontinuation of anesthesia to emergence (return of spontaneous breathing and eye opening) was recorded.

Emergence from general anaesthesia is a critical transition phase in the perioperative period caused by the decrease of anaesthetic concentrations, and the return of normal activity of the central arousal networks [13]. After awakening and recovery of protective reflexes, the laryngeal mask airway was removed, and the children were transferred to the post-anesthesia care unit (PACU), where monitoring was continued.

In the PACU, postoperative recovery and postanesthetic delirium were assessed.

Postoperative recovery was evaluated using the Aldrete score at 5, 10, and 20 minutes after emergence [14]. The maximum score is 10 points. Discharge from the PACU is generally considered when the child achieves a score of ≥ 9 points.

Emergence agitation (EA) involves restlessness, disorientation, excitation, non-purposeful movement, and inconsolability during early recovery from general anesthesia. It is often referred to as emergence delirium [15]. It was assessed using the PAED (Pediatric Anesthesia Emergence Delirium) scale [16]. The maximum score is 20 points. A score of ≥ 10 points generally indicates clinically significant postanesthetic delirium.

In Table 1 Aldrete score and PAED scale are presented.

Statistical analysis

Continuous data were presented as median and interquartile range (IQR) or as mean and standard deviation, depending on data distribution. Categorical variables were expressed as frequencies and percentages.

Normality of distribution was tested using the Shapiro–Wilk test. The Mann–Whitney U test was used to compare continuous variables between two independent groups. Categorical variables were analyzed using the chi-square test, and in cases where expected values were < 5 , Fisher’s exact test was applied.

The level of statistical significance was set at $p < 0.05$. Statistical analysis was performed using IBM SPSS Statistics software, version 23.

RESULTS

The study included 60 children divided into two groups of 30 participants each.

Table 2 summarizes the participants’ demographic characteristics, body weight, and compares the study groups.

Group D had a lower mean age than Group M. The median age in Group D was four years (IQR 3–8). Children in Group D were statistically significantly younger compared to Group M ($Z = -0.980$; $p = 0.048$).

Age was further categorized into three groups: under 6 years, 6–9 years, and over 9 years.

In the distribution by groups, the largest number of children belonged to the youngest category. Notably, group D had no patients older than 9 years (Figure 1).

Emergence from anesthesia

The median emergence time in Group D was 8 minutes (IQR 7–10), and in Group M it was 7 minutes (IQR 5–10). Mann–Whitney U test results showed that the difference was not statistically significant ($Z = -1.549$; $p = 0.121$) (Table 3).

Postoperative recovery

Table 4 presents the median Aldrete scores at 10, 20, and 30 minutes in the observed groups.

Distribution of Aldrete scores at observed time points in groups D and M

After 5 minutes, satisfactory recovery (Aldrete score of 9 or 10) was achieved in 3.3% of children in Group D and 13.3% of children in Group M. After 10 minutes, this percentage increased to 36.7% in Group D and 20% in Group M. After 20 minutes, there was significant progress overall, 61.7% of children had satisfactory scores (70% in Group D and 53.3% in Group M). The difference between the groups was not statistically significant ($p > 0.05$).

Emergence delirium

Based on the results, in Group D, a PAED score ≥ 10 was recorded in 1 child (3.3%), while 29 children (96.7%) did not exhibit delirium. In Group M, delirium was recorded in 2 patients (6.7%), and 28 children (93.3%) showed no signs of delirium (Figure 2).

Due to the small number of patients with delirium in each group, Fisher's exact test was used instead of the χ^2 test, as it is more reliable for analyzing statistical significance in situations with a small sample size and rare events. The test results showed that the difference between the groups was not statistically significant ($p = 1$).

DISCUSSION

Preschool and school-aged children tolerate oral or intranasal premedication better when compared to intravenously or intramuscularly applied premedication medications [6]. Premedication should not prolong the duration of anesthesia; therefore short acting premedication agents are preferred among pediatric patients. In our study, time to emergence from anesthesia did not differ significantly between the observed groups. Similar results, without statistically significant differences, have been reported in previous studies [17, 18].

In our study, postoperative recovery assessed using the Aldrete scale was faster in the dexmedetomidine group compared with the midazolam group; however, the difference between the groups did not reach statistical significance. Although early recovery parameters were more favorable in Group D, a satisfactory level of recovery in both groups was most often achieved after 10 and even, more at 30 minutes, which is consistent with data from the literature [18].

Previously published studies show contradictory results. In some studies, dexmedetomidine has been associated with slightly earlier recovery [19, 20], in others, no difference was observed [20]. Some studies report the opposite, showing that dexmedetomidine prolongs recovery compared with midazolam [21–23]. This prolonged recovery could also be related to the route of administration, as intravenous dexmedetomidine has been associated with longer recovery times [21].

Premedication plays an important role in reducing anxiety before induction of anesthesia, which can directly influence the incidence and severity of emergence delirium [24, 25]. Emergence delirium in children is a common, especially in the age group of children in our research, and is a clinically significant complication following general anesthesia, particularly in the early post-anesthesia period [10]. As in the studies of other authors, sex of children did not have a serious impact on the occurrence of emergence delirium. This was probably due to the age of patients (mean age in years 4.8 vs. 6.5).

In our study, the incidence of emergence delirium assessed using the PAED scale was lower in the dexmedetomidine group than in the midazolam group (3.3% vs. 6.7%); however, this difference did not reach statistical significance. Recent systematic reviews and meta-analyses have demonstrated a significantly lower incidence of emergence delirium with dexmedetomidine compared with midazolam,

which is similar to our results. Dexmedetomidine proves to be an efficient medication in preventing this complication [6].

In contrast to our findings, several previous studies have demonstrated a significantly lower incidence of emergence delirium in patients receiving dexmedetomidine compared with those receiving midazolam [26–28].

In this context, a large meta-analysis by Zhang highlighted that the route of dexmedetomidine administration is also important: intravenous, perineural, and intranasal administration reduces emergence agitation, whereas orally administered dexmedetomidine did not show differences compared to orally administered midazolam [29, 30].

The small size of the studied sample of children is a limitation of the study. To gain better results, it is necessary to better select the patients to reduce even this slight difference in the age of the patients.

CONCLUSION

Inhaled dexmedetomidine showed a trend toward faster postoperative recovery and a lower incidence of postoperative delirium compared to oral midazolam, which is considered the gold standard for premedication in pediatric anesthesia, although the differences between the groups were not statistically significant. Nevertheless, further research is needed to more precisely define the optimal doses and long-term outcomes of dexmedetomidine use in pediatric anesthesia.

Ethics: The study protocol received approval from the Ethics Committee of the Institute for Child and Youth Health Care of Vojvodina (November 29, 2024; No. 17-44).

Conflict of interest: None declared.

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Table 1. Aldrete score and PAED scale

Parameter	0	1	2		
Activity	Unable to move extremities	Moves 2 extremities	Able to move all extremities		
Breathing	Apneic	Dyspneic, shallow or limited breathing	Breathes deeply and coughs freely		
Circulation/blood pressure	> 50% from preanesthetic level	20–50% from preanesthetic level	± 20% from preanesthetic level		
Consciousness	Not responding	Arousable on calling	Fully awake, oriented		
Skin colour/oxygen saturation	Significant cyanosis / < 92% with O ₂ supplementation	Pale, cyanotic / > 90% with O ₂ supplementation	Normal skin color / > 92% on room air		
PAED scale					
Parameter	Not at all	Just a little	Quite a bit	Very much	Extreme
The child makes eye contact with the caregiver	4	3	2	1	0
The child's actions are purposeful	4	3	2	1	0
The child is aware of his or her surroundings	4	3	2	1	0
The child is restless	0	1	2	3	4
The child is inconsolable	0	1	2	3	4

Table 2. Demographic characteristics and body weight of the study population

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)	20 (66.7)	
	Female	9 (30)	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	

*Mann–Whitney U test;

SD – standard deviation; P25/P75 – 25th/75th percentile

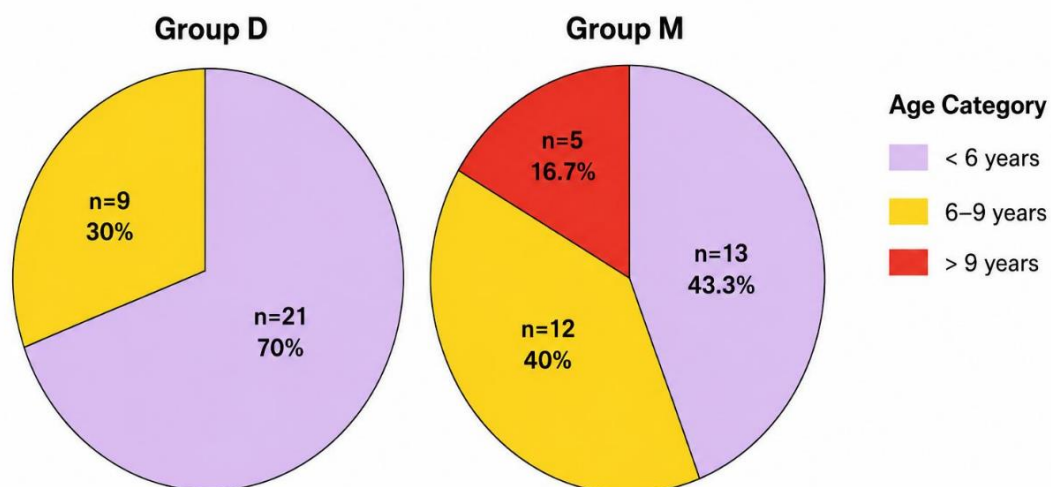


Figure 1. Age categories by groups.

Figure 1. Age categories by group

Table 3. Wake-up time (minutes) from anesthesia by groups

	Group D	Group M	Significance[#]
Average	8.5	7.87	
SD	3.64	3	
Minimum	5	4	
Maximum	13	15	
Median	8	7	0.121
(P25–P75)	(7–10)	(5–10)	

SD – standard deviation; P25 – 25th percentile; P75 – 75th percentile;

[#]Mann–Whitney U test;

Table 4. Median values of the Aldrete scale after 10, 20, and 30 minutes in the observed groups

		Group D	Group M	Significance [#]
5 minutes	Median	7	6	0.378
	(P25–P75)	(6–7.25)	(6–7)	
10 minutes	Median	8	8	0.132
	(P25–P75)	(7–9)	(7–8)	
20 minutes	Median	9	9	0.175
	(P25–P75)	(8–9)	(9–9)	

Mann–Whitney U test; P25: 25th percentile; P75: 75th percentile.

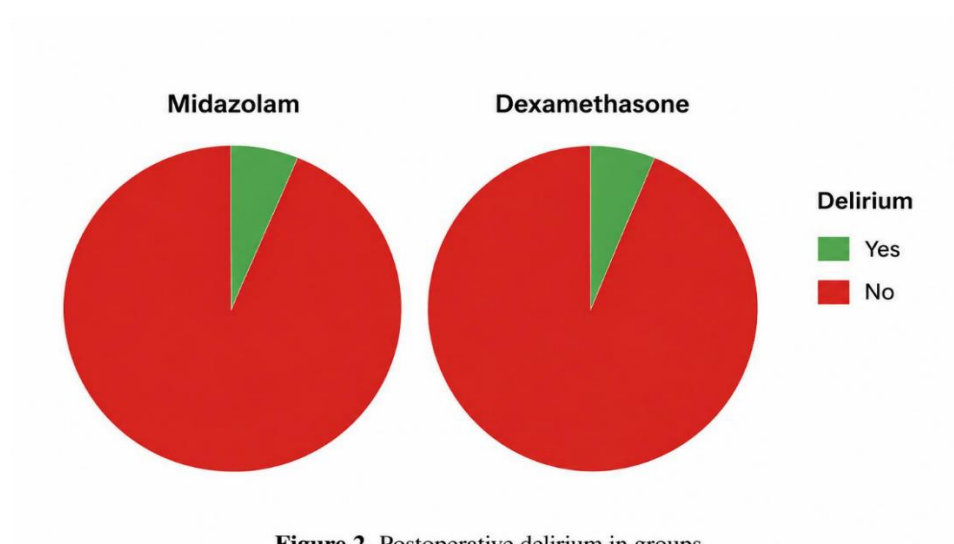


Figure 2. Postoperative delirium in groups.

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