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ORIGINAL RESEARCH

Intranasal Dexmedetomidine vs. Oral Midazolam in Pediatric Emergence Agitation Management Following Anesthesia; A Double Blind Randomized Clinical Trial

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Abstract: **Introduction:** Emergence agitation (EA) occurs shortly after emergence from anesthesia in pediatric patients causing disorientation, restlessness, and non-purposeful movement. This study aimed to compare intranasal dexmedetomidine (DEX) and oral midazolam in managing EA in pediatric patients scheduled for neurosurgical procedures. **Methods:** This double-blinded randomized clinical trial was conducted on 50 pediatric patients who underwent neurosurgical procedure in an educational hospital between March and June 2024. One group received intranasal DEX (2 mcg/kg) and other group received oral midazolam (1 mg/kg of midazolam) before induction of anesthesia. The rate of EA as well as vital signs changes were compared between the two groups using statistical analysis. **Results:** 50 participants were enrolled in the study and randomly divided to DEX and midazolam groups (25 participants in each group). The two groups were similar regarding age (p = 0.538); sex (p = 0.417); pre-operation heart rate (p = 0.675); systolic (p = 0.226) and diastolic (p = 0.753) blood pressure; and pre-operative mean arterial blood pressure (p = 0.634). Among all participants, 13 (26.00%) patients showed signs of EA after extubation (2 patients (8.00%) in DEX group and 11 (44.00%) patients in midazolam group; p = 0.004). Regrading vital signs, only the decrease in heart rate after extubation in the DEX group was significantly greater than that observed in the midazolam group (-9.28±12.88 vs. -2.48±8.23, respectively; p = 0.0310). The number needed to treat (NNT), relative risk reduction (RRR), and absolute risk reduction (ARR) of using intranasal DEX in management of EA were 2.77 (95%confidence interval (CI): 1.72-7.19), 81.8% (95%CI: 26.0%-95.5%), and 36.0% (95%CI: 13.9%-58.1%) respectively. **Conclusion:** Intranasal DEX compare to oral midazolam demonstrated superior efficacy in managing postoperative EA in pediatric patients.

Keywords: Dexmedetomidine; Emergence agitation; Midazolam; Pediatrics; Neurosurgery

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1. Introduction

Emergence from general anesthesia can be complicated by alterations in mental status level, causing disruptive behaviors particularly in pediatrics (1). First described in 1961, emergence agitation (EA) is a condition characterized by behavioral dysregulation following emergence from general anesthesia (2). EA after pediatric surgery typically occurs within the first 30 minutes (Mean=14±11 minutes) and is self-limiting (3). However, in some cases, it may persist for up to 48 hours post-surgery (4). Literature shows a highly variable incidence of ED, ranging from 10–80% (5, 6).

The exact mechanism of EA remains unclear (7, 8). However, several risk factors have been identified, including rapid awakening in an unfamiliar and noisy environment, pain (such as wounds, sore throat, and urinary retention) (9), airway obstruction (10), anesthesia techniques (more common with volatile agents (11)), and premedications (12). Also male sex, preschool age, higher preoperative anxiety level, and baseline sleep-disordered breathing are more associated with EA (13, 14). EA can be detrimental and distressing for pediatric patients, leading to multiple burdens on the healthcare system (15). Therefore, predicting and managing EA is crucial in pediatric anesthesia.

Premedication agents are among the most common tools for managing postoperative EA. Midazolam is commonly used as premedication to alleviate preoperative anxiety and post-anesthesia EA (16-18). However, various side effects, such as respiratory depression, postoperative delirium, and paradoxical reactions, have restricted its use (19). Preoperative dexmedetomidine (DEX) is another agent with efficacy in the

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prevention of EA (20). Nowadays, DEX is used as premedication, a sedative agent in intensive care units, an anesthetic for invasive procedures, and for managing postoperative nausea, vomiting, and EA (21). This drug is an alpha-2 agonist with sedative and analgesic properties, hemodynamic stability and without respiratory depression effects (22, 23). Based on the above-mentioned points, this clinical trial aimed to compare the effectiveness of intranasal DEX and oral midazolam in managing EA in pediatric patients scheduled for neurosurgical procedures.

2. Methods

2.1. Study design and setting

This study was designed as a prospective, randomized controlled trial conducted on patients aged <18 years, who were scheduled for neurosurgical operations at Mofid Hospital ,Tehran, Iran, between March and June 2024. The efficacy of nasal DEX and oral midazolam in management of postoperative EA was studied.

The researchers adhered to the ethical considerations of Helsinki protocols for clinical studies. Ethical approval was obtained from the Institutional Review Board (IRCT20200518047491N2), and written informed consent was secured from the parents of all participants.

2.2. Participants

Patients aged 2 to 12 years, scheduled for elective neurosurgical procedures. who were classified as American Society of Anesthesiologists (ASA) physical status I or II, with no prior history of EA or behavioral disturbances, and with provided informed consent by guardians, were included in the study. We excluded patients who had known hypersensitivity to DEX or midazolam, as well as those with contraindications to intranasal or oral administration of these medications. Patients with significant cardiorespiratory, neurological, or hepatic impairments were also excluded. Patients with a history of psychiatric or neurodevelopmental disorders impacting behavior, along with those undergoing emergency surgeries or procedures requiring urgent intervention, were also excluded from the study.

2.3. Intervention

Patients were randomly assigned to either the DEX (received DEX as premedication) group or the midazolam group (received midazolam as premedication) using blocks-of-four randomization and computer-generated allocation, which were performed by a third party before the study began and medications were prepared in opaque envelopes (numbered consecutively). The allocation was a secret to all participants and healthcare experts.

In the DEX group, patients received 2 mcg/kg of intranasal DEX diluted with sterile water to a total volume of 2 cc in an unlabeled syringe, along with 5 cc of oral dextrose 5% 30 minutes before induction of anesthesia. In the midazolam group, patients received 2 cc intranasal sterile water and 1 mg/kg of midazolam diluted with dextrose 5% to a total volume of 5 cc at the same time. All medicines were prepared by an anesthesiologist and administrated by a blind anesthetic nurse in similar unlabeled syringes with equal volumes.

2.4. Data gathering

After preoperative routine monitoring, heart rate and blood pressure were registered by a blind anesthetic nurse. At the end of the operation and after extubation, heart rate and blood pressure were registered again. Patient's EA signs including disorientation, restlessness, inconsolability, non-purposeful movement, and thrashing were evaluated by an anesthetic nurse and presence of EA was registered as a qualitative variable. All data were gathered before, during, and after the surgery by the anesthesiologist in charge of the patient using a predefined checklist.

EA in this study was defined as any sign of disorientation, restlessness, inconsolability, non-purposeful movement and thrashing in the first 30 minutes after extubation.

2.5. Outcome measures

Primary outcome: Incidence of EA after extubation with identification of the proportion of patients exhibiting signs of EA (disorientation, restlessness, non-purposeful movement) within the first 30 minutes of postoperative period.

Secondary Outcomes: Comparison of vital sign changes (such as heart rate, systolic and diastolic blood pressure, mean arterial pressure) before and after extubation between the two groups.

2.6. Statistical analysis

The sample size was calculated via Cochran's formula ($n=(z^2 \times p(1-q))/d^2$). Where n is required sample size, z is desired confidence level, p is estimated proportion of the attribute present in the population and d is desired level of precision (0.05). 25 patients were enrolled in each group using simple randomization method. Frequency, mean, and standard deviation (SD) were used to characterize the variables. In the case of a non-normal distribution, the median and interquartile range (IQR) were utilized. The normality of the outcome variables was examined with the Shapiro–Wilk test. Kruskal–Wallis and Spearman's correlation tests were used for further nonparametric testing. A P-value of less than 0.05 was considered statistically significant. The SPSS version 24.0 was used for all analyses. The study adhered to intention to treat analysis. The number needed to treat (NNT), relative risk reduction (RRR), and absolute risk reduction (ARR) of using intranasal DEX in management of EA were calculated and reported with 95% confidence interval (CI).

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3. Results

3.1. Baseline characteristics of studied cases

50 participants were enrolled in the study and randomly divided into DEX and midazolam groups (25 participants in each group; figure 1). Table 1 compares the baseline characteristics between DEX and midazolam groups. The two groups were similar regarding age (p = 0.538); sex (p = 0.417); pre-operation heart rate (p = 0.675); pre-operation systolic (p = 0.226) and diastolic (p = 0.753) blood pressure; and pre-operative mean arterial blood pressure (p = 0.634).

3.2. Outcomes

Table 2 compares the studied outcomes between DEX and midazolam groups. Among all participants, 13 (26.00%) patients showed signs of EA after extubation. 2 patients (8.00%) in DEX group and 11 patients (44.00%) in midazolam group had agitation after emergence from general anesthesia (p = 0.004).

There was no statistically significant difference between groups regarding post-operative heart rate (p = 0.889), systolic blood pressure (p = 0.10), diastolic blood pressure (p = 0.978), mean arterial blood pressure (p = 0.822); and mean arterial pressure difference (p = 0.534). The decrease in heart rate (HR) after extubation in the DEX group was significantly greater than that observed in the midazolam group (-9.28±12.88 vs. -2.48±8.23, respectively; p = 0.0310). The NNT, RRR, and ARR of using intranasal DEX in management of EA after anesthesia in pediatrics were 2.77 (95%CI: 1.72-7.19), 81.8% (95%CI: 26.0%-95.5%), and 36.0% (95%CI: 13.9%-58.1%), respectively.

4. Discussion

In our study, we found that intranasal DEX was significantly more effective than oral midazolam in reducing the incidence of EA without any significant change in perioperative vital signs in neurosurgical patients.

EA occurs shortly after emergence from anesthesia in pediatric patients, causing disorientation, restlessness, inconsolability, non-purposeful movement and thrashing (15, 24). One of the pharmacological methods to prevent EA is using alpha-2 agonists (25). DEX is an alpha-2 agonist that possesses sedative and analgesic properties, featuring a slower onset of action and a longer duration of effects compared to midazolam (26, 27). Intranasal DEX is a colorless and fragrance-free agent, which is a proper choice for purposes like managing EA (28, 29).

Recent studies have examined the use of DEX in pediatric patients (30, 31). A 2018 systematic review concluded that DEX emerges as an attractive alternative to standard sedative and analgesic modalities applied in spine surgery, by attaining a notable sedative and opioid-sparing effect (32). In 2021, Zhang et al. examined different methods of DEX administration for preventing EA in children and showed the efficacy of this agent (33). Premedication with DEX showed promising results. In 2022, Xiong and coworkers showed increased sedation and reduced intubation-induced stress in adults using DEX as premedication (34). A 2023 systematic review showed the efficacy of intranasal DEX in reduction of the incidence of EA or emergence delirium in pediatric patients after general anesthesia (35). Another 2024 randomized clinical trial showed greater sedative advantage of intranasal DEX compared to intranasal ketamine with no adverse effects (36).

The effect of preoperative oral DEX on EA was compared with oral benzodiazepine in 2018 and similar to our study, the results showed significantly lower EA (37). However, they used similar routes of administration for DEX and midazolam in that study. In 2018, in a case control study, Li et al. evaluated the preoperative administration of intranasal DEX (1–2 mcg/kg) 20 minutes prior to the induction of general anesthesia. Just like our study, they showed that DEX premedication was associated with less postoperative agitation. They also recorded the postoperative recovery time and the results didn't show prolonged recovery due to administration of DEX (20).

Unlike our findings, Cho et al. in 2019 showed similar efficacy of minimum dosages of DEX and midazolam in preventing EQ. However, in their study, children received agents at the end of surgery. The other difference was examining the efficacy of analgesia in both groups, which DEX showed significantly higher analgesic effect (38). In 2024, a randomized double blinded clinical trial showed the superior efficacy of preoperative DEX in management of EA in comparison to propofol (39). Results showed significant reduction of 4.1 times in the risk of EA when DEX was administered. Additionally, that trial examined the postoperative pain in both groups, and DEX group exhibited a lower incidence of postoperative pain.

5. Limitations

Qualitative assessment of EA: Our study is limited by qualitative assessment of EA. Evaluation of a quantitative variable will be more valuable. Type of surgery: Neurosurgical procedures consist of a wide variety of operations that should be identified in studies. Evaluating a specific type of procedure may prove valuable.

Patient satisfaction and postoperative hospital admission duration were not measured in this study.

Intraoperative drug consumption may be different in groups and measuring opioid and anesthetic consumption may be valuable.

Future Directions:

Comparison and evaluation of different drugs as premedication.

Comparison and evaluation of method's efficacy in different types of procedures.

Comparing different routes of administration.

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6. Conclusions

In comparison to oral midazolam, intranasal DEX demonstrated superior efficacy in managing postoperative EA in pediatric patients. We recommend conducting further studies to investigate the advantages and disadvantages of DEX and to compare its efficacy with other sedative agents.

7. Declarations

7.1. Acknowledgments

We express our sincere gratitude to all the participants, their guardians, and the healthcare staff who contributed to the successful completion of this study.

7.2. Authors' Contributions

Dr. Nastaran Sadat Mahdavi conceptualized the study design and supervised data collection. Data was collected by Dr. Fatemeh Jafari and Dr. Farnaz Shahabi Shojaei. Dr. Sajjad Razavi assisted in reviewing and revising the manuscript, while Dr. Ali Reza Mahdavi and Dr. Morteza Mortazavi contributed to manuscript drafting. All authors read and approved the final version of manuscript.

7.3. Conflict of Interest

The authors declare no conflicts of interest related to this study.

7.4. Funding and Support

This study did not receive any financial support or funding.

7.5. Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request, ensuring compliance with ethical and confidentiality considerations.

7.6. Use of Artificial Intelligence Chatbots

No AI-generated content was used to influence study results or conclusions.

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Table 1: Comparing the baseline characteristics between intranasal dexmedetomidine (DEX) and oral midazolam groups (n = 25 cases in each group)

Variables	DEX	Midazolam	P-Value
Age (Years)			
Mean ± SD	6.74 ± 4.06	7.52 ± 4.78	0.538
Sex			
Female	12 (48.0)	14 (56.0)	
Male	13 (52.0)	11 (44.0)	0.417
Vital signs			
Heart rate (/minute)	104.32±20.172	100.16±18.00	0.675
Systolic BP (mmHg)	96.92±10.303	90.76±11.155	0.226
Diastolic BP (mmHg)	61.96±13.551	58.04±15.205	0.753
Mean arterial pressure (mmHg)	73.61±11.56	68.94±12.63	0.634

Data are presented as mean ± standard deviation (SD) or frequency (%). BP: blood pressure.

Table 2: Comparing the outcomes between intranasal dexmedetomidine (DEX) and oral midazolam groups (n = 25 cases in each group)

Outcomes	DEX	Midazolam	P-Value
Emergence agitation	2 (8.00)	11 (44.0)	0.004
Post-operative vital signs			
HR (/minute)	95.04±18.075	97.68±17.820	0.889
SBP (mmHg)	90.40±8.597	88.84±12.324	0.10
DBP (mmHg)	59.92±13.735	56.24±13.992	0.978
MAP (mmHg)	70.08±11.09	67.10±12.53	0.822
Pre/post-operative difference			
HR difference (/minute)	-9.28±12.88	-2.48±8.23	0.031
MAP difference (mmHg)	-3.53±8.70	-1.84±10.34	0.534

Data are presented as mean ± standard deviation or frequency (%). HR: heart rate; SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure.

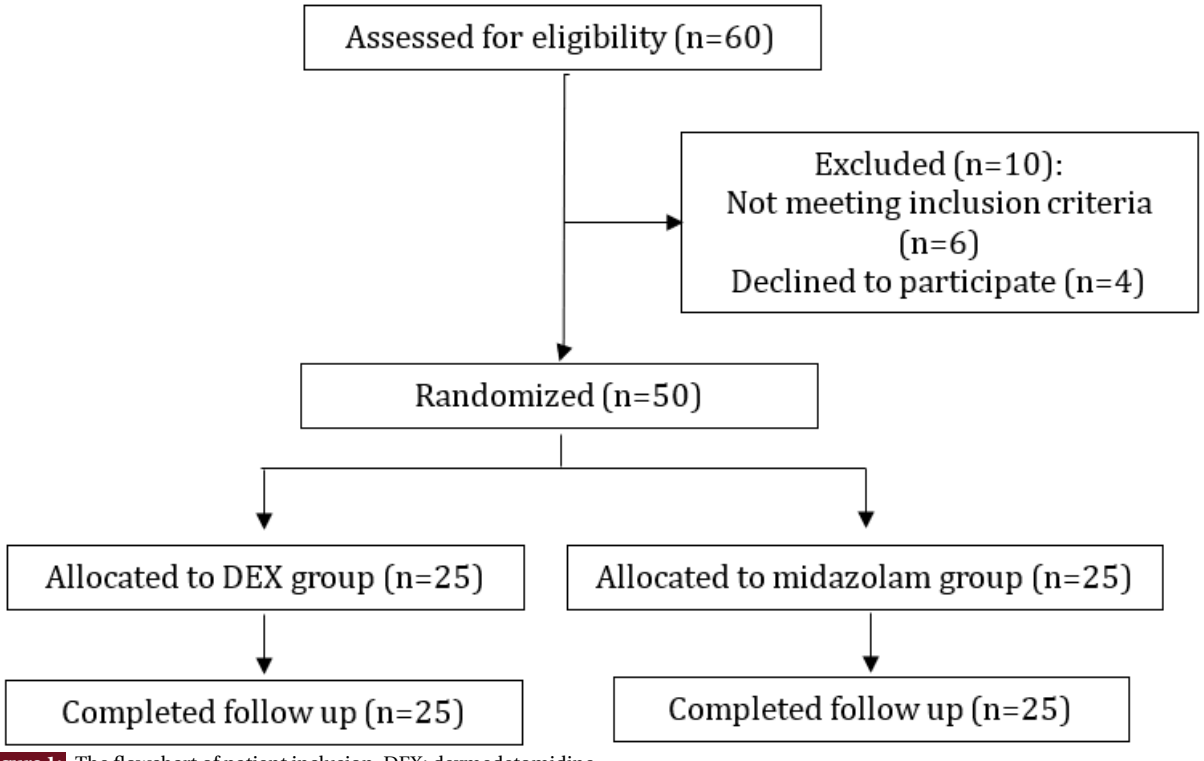

Figure 1: The flowchart of patient inclusion. DEX: dexmedetomidine.

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