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Preoperative midazolam influence on reducing anxiety and delirium in pediatrics receiving dental surgery

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Abstract:

Objective: This research looks at the potential consequences of giving children undergoing general anesthesia for dental surgery midazolam orally prior to the procedure. In particular, the research aims to look at how Midazolam affects separation from parents stress, the onset of delirium, and the length of stay in the unit for post-anesthesia care.

Methods: This research was conducted in Mayo Hospital, Lahore, Pakistan from October 2022 to October 2023. With 78 kids from the American Society of Anesthesiology (ASA), I group, double-blind research was carried out. The youngsters were split into 2 groups, each with 39 kids. Prior to the surgery, the first group was given 0.5 mg/kg of oral midazolam, while the control group was given a placebo. Emerging delirium following surgery, mask acceptance, parental separation, length of stay in the rehabilitation unit after anesthesia, and all of these variables were scored in the study and statistical comparisons were done.

Results: Parental separation ratings and the anesthetic mask acceptance rate were considerably lower in the test group. There were no significant variations observed between the two groups concerning the duration of time spent by patients in the post-anesthesia care unit or the occurrence of delirium.

Conclusions: Before a dental treatment, giving children oral Midazolam may help reduce anxiety, but it might not be able to eliminate emerging delirium following surgery. The dose seems to have little effect on how long patients stay in the unit for post-anesthesia care

Keywords: anesthesia, midazolam, anxiety

Introduction:

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Dental procedures are not an exemption to the rising trend of addressing kid fear during medical procedures.[1] Today's parents and other caretakers may find that non-pharmacological behavior management techniques like hand-over-mouth, intimidation, and voice control are insufficient.[2] Using physical restraint to treat a kid who has a low level of cooperation because of fear or anxiety may not be successful, particularly if the child needs extensive dental work that may need general anesthesia. In addition to hurting the child's self-respect at a very early stage of psychological development, physical restraint in the dental office has an impact on the pediatric dentist's reputation and has legal repercussions when it results in the exploitation of a helpless person.[3] However, if a pediatric dentist chooses to put a patient through the estimated risks of general anesthesia, the choice should not substitute a second psychic trauma in the operating room, such as parental anxiety about being separated, for the possibility of psychological trauma in the dental clinic. dentist general anesthesia (DGA) may shield the kid from any possible psychological harm that the dentist's office may cause while also enabling more precise dental treatment. According to a poll, up to 60% of anesthesiologists routinely employ physical restraints on recalcitrant and scared youngsters. [4] 60 children between the ages of 2 and 6 who were receiving DGA were the subjects of a prior study to examine the anxiolytic effects of various dosages of midazolam. According to their findings, greater dosages are required to have a desirable anxiolytic effect, increasing the chance of certain negative side effects. [5]

Figure 1: Oral Midazolam Sedation

In a different research in this field, 41 children aged 1 to 6 years old were divided into groups to examine the midazolam influence and dexmedetomidine on anxiety prior to surgery and the ED after surgery. It was discovered that the latter has the benefit of reducing the likelihood of post-operative ED. [6] More research on the subject is needed due to the peculiarity of the dental scenario, where children already

experience dental phobia and have a serious need for dental care in addition to their anxiety over the operating room environment.

Methods:

Study Design: Between May 2022 and April 2023, this study—which included children having comprehensive dental rehabilitation under general anesthesia at the Mayo Hospital in Lahore, Pakistan—was carried out using a double-blinded prospective, and randomized design. Figure 2 contains the research design flow chart. The American Society of Anesthesiology (ASA) I children who had DGA were chosen because they were healthy and their lack of cooperative behavior may have negatively impacted the quality of their dental care or because they required a significant number of dental treatments. Children with specific diseases that could have affected their behavior before to or during surgery were excluded from the research. These included kids who had a family history of Midazolam allergies, albeit no such instances were discovered during the trial. Children with special needs, those with an ASA (American Society of Anesthesiologists) score more than I (indicating a more serious medical condition), and those who had a history of post-anesthesia emergency room visits were also excluded from the research. The exclusion criteria were designed to rule out any confounding variables that may have impacted the study's findings and guarantee that Midazolam's effects weren't the consequence of unrelated elements.

78 kids met the requirements for inclusion, and their parents gave their consent to take part in the research. 39 kids were randomly selected and placed in Group A, commonly known as the intervention group. They received oral Midazolam at a rate of 0.5 mg per kilogram of body weight before to the surgery, with a maximum total dose of 20 mg. The drug was supplied 30 minutes before to the surgery in a solution comprising 20 ml of 10% sodium citrate. Twenty milliliters of a simple 10% sodium citrate solution were given to the 39 kids in group B, the control group, as a premedication. Premedication was administered

by a blinded anesthesia helper 15-20 minutes before the child was separated from their parents and 20–25 minutes before intubation.

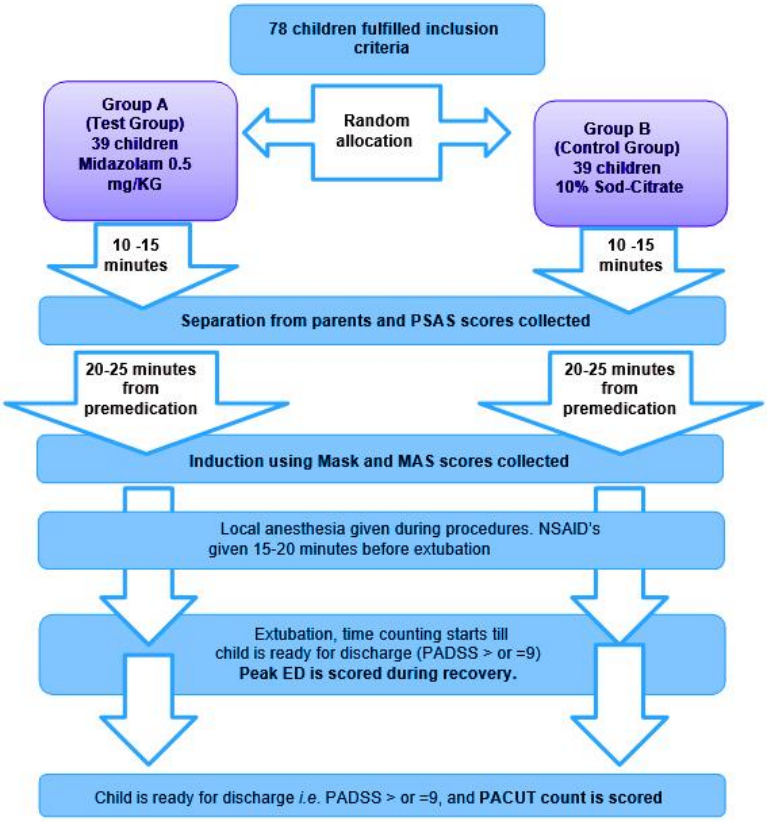

Figure 2: Study Flow Chart

It was done using the Parental Separation Anxiety Scale (PSAS) [Table 1]. A PSAS score of 1-2 was regarded as an "acceptable separation," while a score of 3–4 was seen as a "unacceptable separation" on the 4-point scale. A 3-point Mask Acceptance Scale (MAS) was used to rate the ease of induction [Table 2]. ED was evaluated using the Paediatric Anesthesia Emergence Delirium Scale (PAEDS) [Table 3]. A score of more than 10 out of 20 was considered to be ED. The height of the ED incident was when PAEDS' scoring was completed. Members of the research team received training on data collecting and tool grading. Two unbiased and impartial team members handled the scoring. There were no noticeable changes between the two.

The definition of PACUT in this study was the interval between the time of extubation and the blinded anesthesia assistant's determination that the child was ready for discharge. When a patient's Post Anesthesia Discharge Scoring System (PADSS) score reached 9 or above, it was deemed that they were ready for release [Table 4].

Table 1: PSAS Score

	PSAS score
Wailing and grabbing at their parents	4
Crying and difficulty getting comfort	3
The child whimpers but is not dependent on the parents	2
Child readily separates	1

Table 2: MAS Score

	MAS score
Cries, is aggressive, and requires restraint	3
Moderate dread of the mask, which may be overcome with assurance	2
Child is peaceful, helpful, or sleeping	1

Table 3: PAEDS Score

	PAEDS Score	
	Extremely	0
Child makes eye contact with care givers	A lot	1
Child's actions are purposeful	A little Bit	2
Child is aware of surroundings	Just a little	3
	Not at all	4
	Extremely	4
Child is restless	A lot	3
Child is inconsolable	A little Bit	2
	Just a little	1
	Not at all	0

Table 4: Scores for post-anesthesia discharge

Vital signs	40% of the value before surgery	0
	20% to 40% of the value before surgery	1
	Within 20% of the value before surgery	2
Mental status and ambulation	Neither	0
	oriented X 3 or moves steadily	1
	oriented X 3 and moves steadily	2

Ache or nauseous or vomiting	Severe	0
	Moderate	1
	Minimum	2
Bleeding	Severe	0
	Moderate	1
	Minimum	2
Intake and output	Neither	0
	Postoperative fluids or urinated	1
	Postoperative fluids and urinated	2

Statistical Analysis: The gathered information was put into a Microsoft Excel file. Using Excel's data analysis toolkit, a statistical comparison between the two groups was made. We had to determine if the sample variances were equal before applying the Student's t-test for comparing the means of the two groups. An F test was used to get this result. We selected the appropriate t-test variant based on the outcomes of the F test. Along with examining the groups' acceptance of masks and a measure of their behavior, we also looked at the groups' demographic data. Significant data was defined as a significance level of 0.05 or below. The Pearson Chi-squared test was the statistical method utilized to compare PAEDS and PSAS. P = 0.05 was chosen as the criterion of significance for that test.

Results:

The ages of the 78 study participants varied from 34 months to 102 months, and there were no significant variations in gender, weight, age, or duration of anesthesia between the research and control groups. [Table 5] In comparison to the control group, the children in the intervention group (group A) demonstrated considerably reduced levels of distress during parental separation and a greater acceptance of the anesthesia mask. In addition, while the difference was not statistically significant, group A had a lower postoperative distress score. There was no discernible difference between the two groups' 83-minute average anesthesia and surgical times. These results imply that the intervention could help young children experience less discomfort during anesthesia induction. [Table 6]

Table 5: Participants' demographics

	Groups	
Demographics	**A**	B
	Mean (SD)	**Mean (SD)**
Gender		
Male	18	22

Female	21	7
Age	5.4 (1.4)	5.6 (1.2)
Weight	19.5 (2.1)	19 (3.1)
DGA Duration	95.4 (11.2)	98 (8.9)

Table 6: Comparison of study variables

	Control Group				**Midazolam Group**				**p-value**
	n	**%**	**Mean**	**SD**	**n**	**%**	**Mean**	**SD**	
PSAS									
Difficult separation	36	92.31			13	33.33			
Acceptable separation	3	7.9			26	66.67			<0.01
PACUT			83.7	4.8			83	3.4	>0.5
PAEDS									
No emergence delirium	23	58.9			27	69.23			
Emergence delirium	16	41.1			12	30.77			>0.05
MAS									
Scale of 1 (easy) to 3 (very difficult)			2.2	0.72			1.7	0.76	<0.05

Discussions:

The results of the current study demonstrate that midazolam, when given at a dose of 0.5 mg/kg, is an effective adjunct in minimizing preoperative dental anxiety and accelerating the induction of general anesthesia, but it was ineffective in reducing the occurrence of ED. The findings are consistent with several earlier investigations. [6,7,8,9]

Children's psychological well-being is often negatively impacted by the waiting area before surgery [10], particularly if they already have dental phobia. Extreme anxiety during the induction of anesthesia may result from this. Extreme preoperative anxiety has been linked in studies to the development of unfavorable postoperative behavioral alterations. [11] Although the results of this research seem to be in conflict with one another about the lack of an impact on postoperative ED, it was shown that lowering preoperative anxiety did in fact decrease the frequency of postoperative behavioral disorders but not following surgery ED. This finding is supported by our research, which may also put an end to the debate over how Midazolam affects postoperative ED.

The current study has many notable strengths, including the use of updated research instruments (scales) that were uniformly appraised by several authors and standardized for ease of replication in future studies, double blinding, and the randomization process.

In pediatric dentistry, an ideal Midazolam dose that strikes a compromise between safety and effectiveness has not yet been determined. The present study supports a prior study's [12] finding that a dosage of 0.5 mg/kg greatly lowers preoperative anxiety and aids in children's acceptance of anesthetic masks. As preoperative anxiolytic drugs, they compared Dexmedetomidine to Midazolam and found that the latter had the benefit of lowering postoperative ED. The present trial, however, was restricted to Midazolam since Dexmedetomidine has not yet been licensed for use in children by the US Food and Drug Administration. Other studies [13,14] showed that Midazolam dosages up to 1.0 mg/kg produced superior anxiolytic results. However, it was decided to stick with the 0.5 mg/kg dosage of Midazolam suggested by the manufacturer for the present trial, which is being conducted at a private hospital. It is important to note that while taking this dosage, children in the research group did not experience any side effects that may be related to the medication. In contrast to 0.5 mg/kg, different research [15] found no benefit from larger dosages of 0.75 mg/kg and 1.0 mg/kg. With larger dosages, they also reported additional adverse effects, such as delayed surgical recovery time and excessive oversedation. Routine preoperative treatment raises serious concerns about the possibility of negative side effects. Therefore, further large-scale studies are advised to identify people who may not benefit from Midazolam preoperative treatment before recommending its normal usage. In this regard, different research [16,17] has shown that children with impulsive temperaments do not experience any anxiolytic effects from midazolam.

The PAEDS scale was employed in the research to evaluate postoperative emergent delirium in kids who had received oral midazolam. Ten to fifteen minutes after administering midazolam, the researchers made the decision to separate the youngster from their parents. The scale's creation on the basis of dental procedures and the absence of a sufficient cut-off value for diagnosing ED were two drawbacks of the research. [18,19,20] at order to comply with regulations, the research was carried out at a private hospital using midazolam at the dosage suggested by the manufacturer. Furthermore, since parents may not be the main carers in Pakistan, the research did not look at the potential effects of midazolam on postoperative behavior. Instead, the main carer might be a paid domestic helper or stepmother.

To further, the outcomes of the research may have been impacted by the administration of midazolam at the indicated amount, since some kids may have needed a larger or lower dose based on their age and weight. The PAEDS scale's development centered on dental procedures may have also reduced its accuracy in detecting ED in other kinds of surgery. It is significant to highlight that the absence of a suitable cut-off point for the diagnosis of ED may have led to some instances being misdiagnosed, which might have impacted the study's results.

Furthermore, the study's limitations in analyzing midazolam's effects on postoperative behavior in Pakistan may have repercussions for future investigations. Future research, for instance, may look at how midazolam influences kids' behavior while their main carer isn't there. These studies could also take into account cultural variations in how postoperative behavior is seen and treated in various parts of the globe. This makes it difficult to get accurate information, particularly in settings where intergender interaction is prohibited. Additional research is required to examine the potential impact of the medication on long-term postoperative child behavior as well as to test additional drugs that may have an impact on postoperative

ED and PACUT. These studies may result in the adoption of standard procedures that make dental anesthesia more economical for both parents and insurance providers.

Oral Midazolam has been flavored with a variety of substances, including pomegranate juice, orange juice, and cola beverages. The present study supports a previous study's [20] finding that children generally accept the addition of 10% sodium citrate solution to Midazolam since just one kid in the test group (A) was reported to have refused to take the medication because of its taste.

Conclusions:

Successful pediatric dental surgery under general anesthesia depends on effective control of anticipatory dental anxiety. Parental separation anxiety may be reduced, acceptance of the anesthesia mask encouraged, and the induction of anesthesia may proceed more quickly with the use of oral Midazolam at a dose of 0.5 mg/kg. Preoperative Midazolam administration, it is crucial to note, does not seem to shorten postoperative delirium in children receiving dental surgery under general anesthesia, nor does it appear to impact the length of stay in the unit for post-anesthesia care.

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