

**TO COMPARE THE EFFICACY OF MIDAZOLAM IN DOSE OF 0.5 MG/KG AND 0.75 MG/KG FOR SEDATION.**

**Dr. Kunwar Singh Thakur<sup>1</sup>** (Senior Resident), **Dr. Utsav Sharma<sup>2</sup>** (Senior Resident), **Dr. Preeti Goyal<sup>3</sup>** (Professor) & **Dr. Bhanu Choudhary<sup>4</sup>** (Professor and Head)

Dept. of Anaesthesiology, Gajra Raja Medical College, Gwalior<sup>1,2,3&4</sup>

**Article Info:** Received 06 April 2020; Accepted 22 May 2020

**DOI:** <https://doi.org/10.32553/ijmbs.v4i5.1134>

**Corresponding author:** Dr. Utsav Sharma

**Conflict of interest:** No conflict of interest.

**Abstract**

Study was conducted on 60 patients of both sexes taken for various surgical procedures taking from 30 to 90 minutes at Gajra Raja Medical College, Gwalior.

We found that none of the children in the 0.75 mg/kg dose group cried compared with 4 children (20%) in the c group and one child (5%) in the 0.5 mg/kg dose group. The percentage of children who appeared uncomfortable (study recorded that they were crying or complaining) were the highest in the control dose group (45%). Only 25% of the children in the 0.5 mg/kg dose group and 10% of the children in the 0.75 mg/kg dose group appeared uncomfortable. Thus more children were comfortable (study recorded they were sleepy or quite but awake) in the 0.75 mg/kg dose group (90%) compared with the 0.5 mg/kg dose group (75%) and the control group (55%). This difference was statistically significant between the control group and the group that received the 0.75mg/kg dose.

The number of children who had desirable sedation was similar in the 0.75 mg/kg dose groups. Induction of general anaesthesia was poor for 25% the children in the group that received the 0.5 mg/kg dose.

**Keywords:** Efficacy, Midazolam, Sedation & Anaesthesia.

**Introduction**

Midazolam, with its rapid onset and relatively short duration of action, has proven to be a useful premedication to decrease preoperative anxiety and facilitate separation from parents with fewer unwanted side effects. The objectives of this study are to assess the efficacy and safety of oral midazolam in three different doses and to determine the optimal dose as a premedication in children undergoing surgical procedure.<sup>1</sup>

Midazolam maleate is a colourless crystal, which manifests a pH dependant ring phenomenon. In the prepared form it is buffered to a pH of 3.5 which keeps the benzodiazepine ring open while administration physiologic pH maintains the closed ring structure and the drug efficacy.<sup>3</sup> Because of the pH of solution midazolam maleate should not be administered concomitantly with alkaling solutions.<sup>3</sup>

Midazolam produces sleep quickly and smoothly. On injection it is a painless and have a short half life. The elimination half life of midazolam maleate was about 2 hours, with the urinary excretion data showing recovery of approximately 30-40% of administered dose as the conjugated form of first metabolite in first 12 hours.<sup>4</sup>

**Material Method**

**Selection of Patients**

Study was conducted on 60 patients of both sexes taken for various surgical procedures taking from 30 to 90

minutes at Gajra Raja Medical College, Gwalior from July 2018 to June 2019.

Age group considered was between 1-5 years.

All patients were of ASA grade - I or Grade II in every patients consent, physical examination entire investigation and special investigation (if required) were checked.

Patients were premedicated after being sure of nil oral by mouth, written consent and anesthetically fit.

Study group A: patients in this group were administered oral midazolam syrup 0.5mg/kg dose 30 min. prior to surgery

Study group B : patients in this group were administered oral midazolam syrup 0.75mg/kg dose 30 min. prior to surgery.

Control group C: patients in this group were administered apple juice 30 min. prior to surgery.

Premedication was done with inj.atropin 0.01mg/kg. and all procedure was The observation were discussed in terms of pulse rate, respiratory rate, Spo<sub>2</sub>, . patient's acceptance of the medication, reaction to separation from parents, sedation scores, and recovery conditions. performed under general anaesthesia.

Anaesthesia was indused with inj.Ketamin 2mg/kg and orotracheal intubation was facilitated with inj. succinylcoline 2mg/kg. Anaesthesia was maintained with

nitrous oxide +oxygen +Atracurium with intermittent positive pressure ventilation.

The observation were discussed in terms of pulse rate, respiratory rate, Sp<sub>o</sub><sub>2</sub>, patient's acceptance of the medication, reaction to separation from parents, sedation scores, and recovery conditions.

## Results

**Table 1:** Weight Distribution

Weight	A (0.5 mg/kg)	B (0.75 mg/kg)	C (placebo)
5-10	5	6	5
10-20	11	11	12
20-30	4	3	3
Mean ± SD	15.25±6.98	14.78±6.28	15.26±6.64

P> 0.05

No any significant differences seen in weight distribution.

**Table 2:** Sex distribution

Sex	A (0.5 mg/kg)	B (0.75 mg/kg)	C (placebo)
Male	13	12	14
Female	7	8	6

P> 0.05

No any significant differences seen in sex distribution.

**Table 3:** Reaction to parent's separation.

Groups	A	B	C
Midazolam Dose	0.5 mg/kg (%)	0.75mg/kg (%)	Placebo (%)
Inconsolable cry	5	0	20
Complaining	20	10	25
Total number of uncomfortable children	25	10	45
Quiet-but-awake	65	65	50
Sleepy	10	25	5
Total number of comfortable children	75	90	55

P≤.05 versus group A

The children's reaction to being separated from their parent(s) 30 minutes after receiving premedication.

We found that none of the children in the 0.75 mg/kg dose group cried compared with 4 children (20%) in the c group and one child (5%) in the 0.5 mg/kg dose group. The percentage of children who appeared uncomfortable (study recorded that they were crying or complaining) were the highest in the control dose group (45%). Only 25% of the children in the 0.5 mg/kg dose group and 10% of the children in the 0.75 mg/kg dose group appeared uncomfortable. Thus more children were comfortable (study recorded they were sleepy or quite but awake) in the 0.75 mg/kg dose group (90%) compared with the 0.5 mg/kg dose group (75%) and the control group (55%). This difference was statistically significant between the

control group and the group that received the 0.75mg/kg dose.

## Discussion

Oral midazolam has proved effective in treating preoperative anxiety. Orally administered midazolam can be given in a dose of 0.25 to 1.0 mg/kg up to a total dose of 20 mg depending on the duration of surgery and the anxiety level of the child<sup>4</sup>. In this study, oral midazolam given as a premedication was effective in 0.75 mg/kg dose, while the 0.50 mg/kg dose was less effective. A dose of 1.0 mg/kg may produce more sedation over a 0.75 mg/kg dose but does delay recovery and may compromise safety<sup>5</sup>.

In our study We found that a dose of 0.75 mg/kg of oral midazolam given as premedication for children undergoing surgical procedures more effective and a dose of 0.50 mg/kg is less effective<sup>6</sup>.

Feld et al<sup>7</sup>.(1990) also reported a superior anxiolysis 30 minutes after a 0.75 mg/kg dose of oral midazolam as compared to 0.25 mg/kg and 0.5 mg/kg doses or placebo. Similarly, it was reported that the use of a 0.75 mg/kg dose of oral midazolam did not result in clinically respiratory depression or upper airway obstruction, but in some children caused an increased level of sedation beyond simple conscious sedation. Our study match with this study.

McMillan et al<sup>8</sup>.(1992) reported no added advantage but more side effects for both 0.75 mg/kg and 1.0 mg/kg doses compared to the 0.5 mg/kg dose. We found that the 0.75 mg/kg dose gave superior effects and lesser side effects.

## Conclusion

Observation were made in terms of pulse rate, respiratory rate,Sp<sub>o</sub><sub>2</sub>, patient's acceptance of the medication, reaction to separation from parents, sedation scores, and recovery conditions. 90% children were comfortable with parent separation in the group that received the 0.75 mg/kg dose compared to the group that received the 0.5 mg/kg dose (75%) and the group that received the apple juice (55%). The number of children who had desirable sedation was similar in the 0.75 mg/kg dose groups. Induction of general anaesthesia was poor for 25% the children in the group that received the 0.5 mg/kg dose.

There were smooth induction and recovery with 0.75mg/kg dose as compared to 0.5mg/kg.

## References

1. C. A. Pywell, Y.-J. Hung, and J. Nagelhout, "Oral midazolam versus meperidine, atropine, and diazepam: a comparison of premedicants in pediatric outpatients," Journal of the American Association of Nurse Anesthetists, vol. 63, no. 2, pp. 124–130, 1995.

2. P. J. Alderson and J. Lerman, "Oral premedication for paediatric ambulatory anaesthesia: a comparison of midazolam and ketamine," *Canadian Journal of Anaesthesia*, vol. 41, no. 3, pp. 221–226, 1994.
3. D. Patel and G. Meakin, "Oral midazolam compared with diazepam-droperidol and trimeprazine as premedicants in children," *Paediatric Anaesthesia*, vol. 7, no. 4, pp. 287–293, 1997.
4. K. K. Brosius and C. F. Bannister, "Midazolam premedication in children: a comparison of two oral dosage formulations on sedation score and plasma midazolam levels," *Anesthesia and Analgesia*, vol. 96, no. 2, pp. 392–395, 2003.
5. C. J. Coté, I. T. Cohen, S. Suresh, et al., "A comparison of three doses of a commercially prepared oral midazolam syrup in children," *Anesthesia and Analgesia*, vol. 94, no. 1, pp. 37–43, 2002.
6. L. D. Mishra, G. K. Sinha, P. Bhaskar Rao, V. Sharma, K. Satya, and R. Gairola, "Injectable midazolam as oral premedicant in pediatric neurosurgery," *Journal of Neurosurgical Anesthesiology*, vol. 17, no. 4, pp. 193–198, 2005.
7. L. H. Feld, J. B. Negus, and P. F. White, "Oral midazolam preanesthetic medication in pediatric outpatients," *Anesthesiology*, vol. 73, no. 5, pp. 831–834, 1990.
8. C. O. McMillan, I. A. Spahr-Schopfer, N. Sikich, E. Hartley, and J. Lerman, "Premedication of children with oral midazolam," *Canadian Journal of Anaesthesia*, vol. 39, no. 6, pp. 545–550, 1992.