

STUDY OF ORAL MIDAZOLAM AS A PREANAESTHTIC MEDICATION FOR ELECTIVE SURGERY IN PAEDIATRIC PATIENTSJaya Dighe¹**HOW TO CITE THIS ARTICLE:**

Jaya Dighe. "Study of Oral Midazolam as a Preanaesthetic Medication for Elective Surgery in Paediatric Patients". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 72, December 22; Page: 15266-15270, DOI: 10.14260/jemds/2014/4053

ABSTRACT: BACKGROUND: Pre anaesthetic medication is a real challenge specially in cases of paediatric age group. A good quality oral preanaesthetic must fulfill criteria like easily application, rapid absorption, short duration of action and have minimal side effect. Present study carried out with objective of evaluation of oral Midazolam as a pre-anaesthetic in elective surgical cases in paediatric age group. **METHODS:** Paediatric cases for elective surgery were included for receiving oral midazolam (0.5/kg) pre anaesthetic medication in prospective observational study. Total 50 cases from age group (01-10 yrs), weight (13-23kg), ASA grading I & II, normo-tensive patients were selected. Evaluation of drug was assessed with a scale from 1-4 which includes sedation, separation from parent, and child behaviour at induction. Data analyzed with percentage and mean standard deviation of the scale score. **RESULTS:** Sedation score mean after pre medication was 2.76+ 0.58. Child behaviour at the time of separation from parents score mean was 2.96+ 0.44. Mean score of behaviour of child during induction was 2.80+0.49. 70% of the cases achieved sedation, 86 % of the cases achieved separation from parents while 76% of the cases had more than 2 score of child behaviour at the time of induction. **CONCLUSION:** Oral midazolam as a preanaesthetic medication in children allay the anxiety & facilitate separation of children from their parents when they enter surgical unit. These can be overcome by lower degree of sedation in our study.

KEYWORDS: Oral Midazolam, Premedication, Paediatric cases.

INTRODUCTION: Pre anaesthetic medication is a real challenge specially in cases of paediatric age group. An Atraumatic premedication can minimize these problems when a calm separation from parents and a smooth induction is achieved.¹ There is a need exists for a safe and effective oral preanaesthetic medication for use in children undergoing elective surgical procedure.²

A good quality oral preanaesthetic must fulfill criteria like easily application, rapid absorption, short duration of action and have minimal side effect. Ketamine and midazolam is widely used as oral pre-anaesthetic medication. Midazolam is water soluble benzodiazepine with an imidazole ring in structure which accounts for its stability in aqueous solution and rapid metabolism. Initial studies on adults have indicated that midazolam produces a profound anterograde amnesia.³ It is available in IV, IM, Oral preparations with minimal to no discomfort even during parental.

It rapidly absorbs from GI tract and prompt passage across the blood barrier. Only 50% of orally administers reaches the systemic circulation reflecting substantial first pass effect. The short duration of action of a single dose of midazolam is due to its lipid solubility leading to rapid redistribution from brain to inactive tissue sites and rapid hepatic clearance. Therefore it has become more widely used premedication in developed countries like U.S.⁴

Hence the present study carried out with objective of evaluation of oral Midazolam as a pre-anaesthetic in elective surgical cases in paediatric age group.

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METHODS: The present prospective observational study carried out at anaesthesia department of tertiary care hospital located at a rural area of Maharashtra during 2010.

The study included the cases with age group (01-10 yrs), weight (13-23kg), ASA grading I & II, normo-tensive patients undergoing elective surgical procedure. Those who having age more than 10 yrs, weight >23 kg, medical disorder like heart disease, Juvenile Diabetes, , anemia, allergy, bronchial asthma, patient on medication for CNS disorder, psychiatric patients, suffering from liver disease, oral pathology were excluded from the study.

A total of 50 cases were selected undergoing elective surgical procedure and enrolled for the study purpose during the period of six months. Informed and valid consent was obtained from patient's guardian. Institutional ethical committee approval was taken prior to study. All selected patients were gone under all routine investigation which includes Haemoglobin, Complete Blood Count, Blood Sugar Level (Random), Bleeding time, Clotting Time, urine examination, Chest X ray. The age, sex, weight, pulse rate, respiratory rate, blood pressure & oxygen saturation were recorded preoperatively.

Patients undergoing elective surgical procedure were given midazolam 0.5mg/kg orally 30 min before surgery as a preanaesthetic medication. The calculated dose is given and children advice to swallow in presence of health care worker. In recovery room, patient is put on the IV cannulation. Anesthetic drugs with emergency drugs, endotracheal tubes, laryngoscope & other resuscitative measures kept ready.

The child's condition was evaluated after preanaesthetic medication i.e. after 30 min by anaesthetics as per scale assigned as shown in Table 1. The score adopted from published studies investigating premedication.^{5,6} the child was constantly observed to see change in mood, behavior as per the scale after premedication. Side effects like nausea, vomiting increase salivation, hiccough & Nystagmus also noted by the observing anaesthetics. All the patients were monitored intra operatively for pulse rate, respiratory rate, oxygen saturation & other abnormal behavior. Post operatively patients were observed for level of consciousness, respiratory complications such as laryngospasm / bronchospasm.

All the data entered, cleaned and analyzed using MS Excel 2010. Mean \pm standard deviation was used for comparing both the groups. For statistical analysis score is dichotomized into two groups like less than 2 and more than 2 for each variable of scale of evaluation.

RESULTS: Total 50 cases were included during the study period. The participants characteristics including age & weight were 5.36 yrs + 0.67 & 15kg + 1.23 respectively as shown in table 1. The ratio of male: female was 1.17:1.

Table 2 shows the evaluation criteria score after medication. Pre-operative sedation after 30 minutes of premedication was observed as per scale. It shows mean score + S.D. was 2.76+ 0.58. Child behaviour at the time of separation from parents score was 2.96+ 0.44. Mean score of behaviour of child during induction was 2.80+0.49. Graph 1 shows the score wise distribution of each variable (less than 2 and more than 2) of each variable in scale. 70% of the cases achieved sedation with score more than 2. Child behaviour at the time of separation score more than 2 found in 86 % of the cases. 76% of the cases have scored more than 2 for child behaviour at the time of induction.

Preoperatively no other side effect observed except 4 (8%) cases had had hiccough. Post operatively 6(12%) & 3(6%) had vomiting and nausea respectively.

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DISCUSSION: Preanaesthetic medication specially for paediatric cases is much concern to both anaesthetics and parents. Forceful separation of children from parent prior to anaesthesia with induction by painful injection can be overcome by orally acceptable premedication in addition to psychological separation of children. In view of this we have conducted study in which midazolam was given orally to the elective surgical cases of paediatric age group (1-10 yrs).

In the present study, operative procedures were eventually distributed as they come during the study period. The mean age was 5.63 yrs with minimum age was 1.8 yrs while maximum was 10 yrs. Average weight observed among the cases was 15 kg. Sex wise ratio was 1.17:1. These findings were comparable with other studies.^{1,2,4}

All the study cases have administered the 0.5 mg/kg midazolam orally as per calculated dose as a preanaesthetic medication 30 min before induction. The mean score sedation scale (1-4) after 30 minutes of premedication was 2.76 with 0.55 S.D. 70% patients achieved sedation within 30 minutes. The mean score of child separation from parent scale (1-4) was 2.96 with 0.44 S.D. & 86% patient had score more than 2. The mean score of child behaviour at the time of induction scale (1-4) was 2.80 with 0.49 S.D. & 76% had scored more than 2. This shows that 70% achieved sedation, 86% didn't cry at the time of separation and 76% had no fear at the time of induction. Mc Graw T & Kendrick A found the children receiving midazolam cried significantly less during induction ($p < 0.02$).⁷ W. Funk et al⁵ used sedation, anxiolysis, separation from parent and behaviour at induction as a separate for scoring.

He observed success rate (more than 2 score) for anxiolysis and behaviour at separation were approximately 70 % & 90% respectively with midazolam. Beebes's et al found separation was satisfactory with midazolam in 92% cases and only 60 % with ketamine.⁶ These findings are almost similar with the present study. While Lin YC et al reported no difference in behaviour or induction after administration of midazolam, ketamine or same combination.⁸ Preoperatively and postoperatively no major side effect observed except hiccough (8%) and nausea (6%) vomiting (12%) respectively. This findings are similar with other studies.^{1,7,8}

Only 15-30% of an orally administered dose reaches the systemic circulation in its non-metabolized form due to an extensive first pass hepatic effect. Thus, the oral dose should be approximately double or triple the IV dose to achieve similar clinical effects. Oral doses ranging between 0.3-0.75 mg/kg commonly are recommended to be given 20-30 min prior to treatment. Oral midazolam, with this dose produces amnesia in children undergoing surgical procedures.² The degree of amnesia is not dependent on the route of administration, as there was no significant difference when the amnesic effect of oral (0.45 mg / kg) was compared with midazolam (0.2 mg/kg) in children.¹⁰ Midazolam also facilitate induction of general anaesthesia by easy mask acceptance by the child without prolonging the recovery period. Midazolam is used as benzodiazepine for preoperative medication in paediatric patients.

Hence, study concludes, oral midazolam as a preanaesthetic medication in children allay the anxiety & facilitate separation of children from their parents when they enter surgical unit. These can be overcome by lower degree of sedation in our study. Midazolam 0.5 /kg orally pre-operative is an effective alternative to intramuscular injection for paediatric patients requiring pre-anaesthetic medication. Oral midazolam is safe non-invasive , cost effective & without complication.

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Scale	Preoperative sedation 30 min. after Pre-medication	Childs behavior at the time of separation from parent	Childs behavior at the time of induction.
1	Tearful/Combative	Poor (Anxious/Panic)	Poor (Afraid/Crying)
2	Alert /Aware	Fair (anxious/ Combative)	Fair (Easily calmed)
3	Drowsy	Good (Easily leisured)	Good (Slight fear of mask)
4	Sleeping	Excellent (Calm/drowsy).	Excellent (Co-operative/ Unafraid)

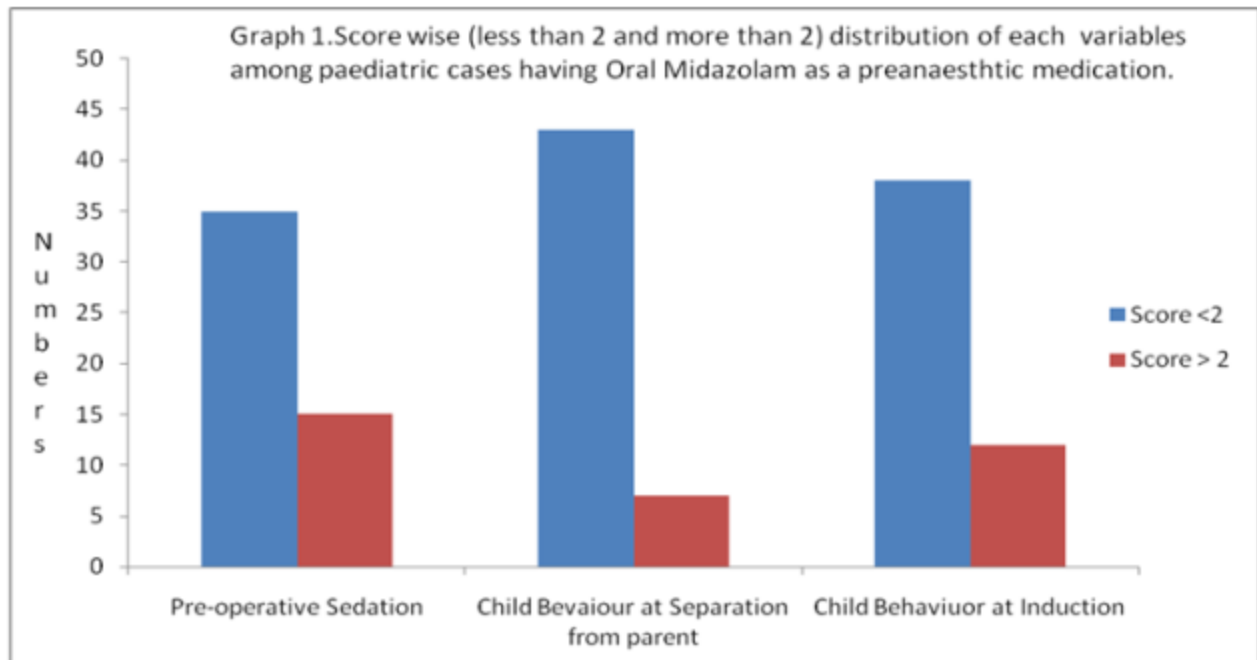
Table 1: Scale for evaluation of child's condition after pre-anaesthetic medication

Variables	Mean + S.D.
Age (yrs.)	5.36 + 0.67
Weight (kg.)	15+ 1.23
Height (wt.)	116+ 9.83

Table 2: Characteristics of the cases for elective surgery from both the group during the study period

Evaluation criteria	Score (1-4) Mean + S.D.
Preoperative sedation 30 min after premedication	2.76+ 0.58
Child behaviour at the time of separation from parent	2.96+ 0.44
Behaviour during induction of anaesthesia.	2.80+0.49

Table 3. Evaluation criteria wise score distribution (mean + S.D.) among the paediatric cases given oral midazolam as a pre anaesthetic medication for elective surgery

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