

## Oral Midazolam Premedication for Children Undergoing Surgery below Umbilicus under General Anaesthesia

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### Abstract:

**Background:** To ensure a smooth induction and to reduce the preoperative anxiety, oral premedication is widely being used in paediatric anaesthesia. Midazolam is most commonly used premedication in children currently.

**Aim:** The aim of this study was to find out the efficacy of oral Midazolam as an anxiolytic and sedative in children undergoing surgery below umbilicus and also the quality of induction as measured by the acceptance of the mask.

**Settings & Design:** Single blind study on 60 children aged between 1-10 yrs over a period of 6 months.

**Methods & Material:** The childrens randomly allotted into two groups. Group I: received atropine 0.03mg/kg in 5ml of orange flavoured syrup orally and Group II: received atropine 0.03mg/kg + 0.5mg/kg midazolam in 5ml of orange flavoured syrup. The drug acceptance, vitals, sedation and anxiolysis, parental separation, quality of induction were evaluated.

**Statistical Analysis:** Unpaired t test, chi square test were used. P value <0.05 was considered as statistically significant.

**Results & Conclusion:** In conclusion, oral midazolam 0.5mg/kg along with atropine 0.03mg/kg is a safe and effective pre medication in children from 1-10 years. It increased sedation, decreased separation anxiety and improved the quality of induction. It does not significantly prolong either the periop or postoperative period and reduced the psychological effect of hospitalization in children

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### I. Introduction

Paediatric induction appears to be most difficult for the anaesthesiologist and for the anxious children – cant tolerate the separation anxiety and cant accept the strange surroundings. Anaesthesia for paediatric ambulatory surgery aims to rapidly return the child to a home readiness. For reducing the incidence of preoperative anxiety in children number of approaches have been proven to be useful. Pharmacological attenuation of normal response to pain presents the child who is cooperative and calm when separated from parents & also during induction of anaesthesia and then calmness help allay parental anxiety immediately prior to the surgery.

The ideal premedicant should be available in preparation that is readily acceptable by the children/ should be relatively rapid onset/ provide anxiolysis, sedative effects /free of side effects /provide rapid recovery and return to alertness postoperatively thereby permitting early discharge. Midazolam which provides anxiolytic, amnestic, hypnotic and skeletal muscle relaxants is very popularly used pharmacological agent for alleviating pre operative anxiety in day care surgery because of its short half time and rapid onset. Usual dose is 0.5mg /kg for children as a premedicant. This study therefore sought to find out the efficacy of oral midazolam as an anxiolytic and sedative and the quality of induction and the effects on haemodynamics and side effects if any were recorded.

### II. Material And Method

After institutional ethical approval 60 ASA I & II children aged between 1-10 years posted for surgery below umbilicus not >100 min were included in the study. Exclusion criteria: children already on anti convulsant or sedative medication, known sensitivity to benzodiazepine and presence of GI pathology and weight <10 kg. Children were randomly assigned two groups to receive either only atropine (0.03 mg/kg) or atropine (0.03mg/kg) & oral midazolam 0.5mg/kg. Both drugs dissolved in 5ml of orange flavoured syrup & premedication was given 30 min before surgery.

Following administration, acceptability of premedication in the children was recorded noting whether the solution was accepted readily, with grimace or complaint.

Heart rate, respiratory rate, saturation, sedation score and anxiolysis score were noted every 15 min till entry into OT. The level of sedation was assessed by using scale 1=alert/active, 2=awake/calm, 3=drowsy, 4=asleep

Anxiety was evaluated by using the scale 1=tearful 2=anxious but easily reassured 3=calm not cooperative 4=asleep.

A sedation score of 2 or 3 was considered for adequate sedation for anxiety the quality of sedation was assessed with a 4-point scale 1=poor (crying, combative) 2=fair (moderate fear for mask) 3=good (slight fear for mask, reassured) 4=excellent (readily accept the mask). score 2-3 was regarded as a successful response to premedication. IV line secured and IV infusion started with RL. Anaesthesia was induced with Inj. Thiopentone 5 mg/kg IV, 70% N<sub>2</sub>O :30% O<sub>2</sub>, Halothane 2-3%, succinyl choline 2mg/kg, after incubation anaesthesia was maintained with N<sub>2</sub>O/O<sub>2</sub>, Halothane 0.5%, Inj. Atracurium 0.5mg/kg. caudal anaesthesia given with 0.25% Bupivacaine.

Heart rate, respiratory rate, saturation were recorded. At the end, after reversal with Inj. Atropine 0.01mg/kg + Inj. Neostigmine 0.05mg/kg IV children extubated and sent to recovery room. HR/RR/SpO<sub>2</sub> were recorded 0, 10, 20, 30 min after arrival in recovery room and behaviour was assessed using a 5-point scale 1=asleep 2=calm 3=mild distress 4=moderate distress 5=severe distress. The following day parents were asked about the occurrence of following behaviour- nocturnal enuresis/nightmare/fear of dark/nausea/vomiting/shivering/temper tantrum/crying/fear of strangers.

### III. Statistical Analysis

The data collected @ analysis was performed using unpaired student t test and chi square test

### IV. Result

Table 1: Patient data

	G r o u p A					G r o u p B					
	3					0					
A g e ( i n y e a r s )	4	.	8	±	1 . 5	6	5	.	0	2 ± 1 . 8	6
G e n d e r ( M / F )	1	9	/	1	1	2	2	/	0	8	8
W e i g h t ( k g )	1	5	.	3	± 3 . 4	1	6	.	4	± 3 . 5	5
D u r a t i o n o f s u r g e r y	4	3	.	8	± 6 . 6	7	4	4	.	9 ± 6 . 0	7

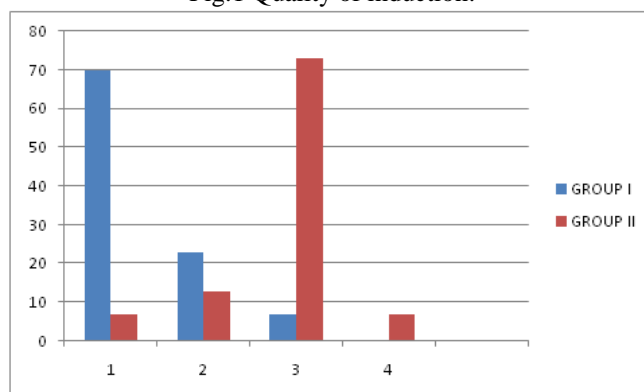
Table no: 2 Sedation score:

Time	G r o u p 1					G r o u p 2					df	Chi-Square	p value and Significance									
	1	2	3	4	n	1	2	3	4	n												
0	30	0	0	0	30	30	0	0	0	30	1	0	1									
1 0	24	6	0	0	30	25	4	1	0	30	2	1 . 4	2	0 . 4	9	1	6	4	4	2		
2 0	14	10	4	0	28	6	18	6	0	30	1	5 . 8	2	4	0 . 0	1	5	8	0	8	9	5
3 0	2	6	8	0	14	1	6	0	0	7	1	5 . 5	8	7	0 . 0	1	8	0	9	4	2	6

Table no. 3 Anxiolysis score :

Time	G r o u p 1					G r o u p 2					df	Chi-Square	p value and Significance						
	1	2	3	4	n	1	2	3	4	N									
0	24	6	0	0	30	26	6	0	0	32	1	0 . 0	1	6	0.8993				
1 0	0	2	15	15	32	0	0	24	2	26	2	1	3 . 5	4	2	0 . 0	0	1	1
2 0	0	0	6	8	14	0	0	6	0	6	1	5 . 7	1	4	0 . 0	1	6	8	
3 0	0	0	2	3	5	0	0	0	1	1	1	0 . 6			0.4386				

Fig:1 Quality of induction:



Age, weight, duration of surgery did not differ among the groups. (table 1.) the onset of the sedation was 30.5±12.38 in group A and it was 20.8±10.76. the difference was statistically significant (p<0.05) however the level of sedation was significantly better in group B.

The quality of the preoperative anxiolysis was significantly better with oral midazolam ( $p < 0.05$ ). The mask acceptance and quality of induction were significantly better in the midazolam group as compared to group A.

There were no episodes of bradycardia, hypotension, apnea, airway obstruction at any time. None of the children were sedated to the extent that they failed to respond to stimulation or were unarousable.

95% of the children grimaced after taking oral preparation and younger children cried after taking the drug. The time interval from end of the surgery to transfer to PACU and the time to spontaneous eye opening to discharge from PACU to ward were almost similar for both the groups with little prolongation in midazolam group. However it did not delay the discharge of the patient from the ward the next day.

Untoward events noted were dysphoria and loss of balance in 2 patients (7%). These resolved at the time of discharge from PACU. Post operative behavioural disturbances were asked with parents and it was noted in 3 children compared with 9 of the control. Most frequently reported disturbances were night cries and increase in temper tantrums.

## V. Discussion

Adequate preoperative preparation of a child is most important in order to reduce the emotional trauma which can be experienced preoperatively by the child and his/her family. However the prescription of a premedicant drug as a part of this preparation must be considered carefully bearing in mind the relative advantages and side effects. This is particularly so in the setting of day care surgery, where prolonged sedation or nausea and vomiting may delay discharge. Midazolam possesses many desirable properties of a premedicant for the children undergoing day care surgery.

Its elimination half life is 1.5 to 2 hours shorter than those of diazepam or trimeprazine. It has dose dependent anxiolytic effect and sedation and produces minimal cardiorespiratory effects. Furthermore the amnesia produced by midazolam reduces the psychological trauma of anaesthesia and surgery.

Midazolam can be administered by any route each having its own particular advantages and disadvantages. It is well absorbed intramuscularly, but injections are painful and constitute one of the fears of children. Ectal administration is reliable and painless, but children and parents may find the procedure distressing. Sublingual and intranasal midazolam are effective within 10 min but acceptability of oral preparation is more with children than any other routes. Midazolam has a bitter taste not easily masked. Most of the children who accepted the formulation complained it was bitter or made facial expressions which suggested that the taste was unpleasant. The limited bioavailability of oral midazolam may explain the high dose requirements for sedation anxiolysis after oral route.

## VI. Conclusion

In conclusion, oral midazolam 0.5 mg/kg along with atropine 0.03 mg/kg is a safe and effective premedication in children from 1-10 years. It increased sedation, decreased separation anxiety and improved the quality of induction. It does not significantly prolong either the preop or postoperative period and reduced the psychological effect of hospitalization in children.

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