



# CONSCIOUS SEDATION WITH ORAL-TRANSMUCOSAL MIDAZOLAM : EFFECT ON ANXIETY LEVELS OF PRE-COOPERATIVE CHILDREN DURING A CLASS II RESTORATIVE PROCEDURE

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## INTRODUCTION

- Successful dentistry for children depends not only upon the dentists technical skills but also largely upon the ability to acquire and maintain a child's co-operation throughout treatment procedure.
- Behaviour management therefore is a major component of successful dental treatment in children of all age groups.
- The routine behaviour management techniques however may not succeed in a good number of pre-school children less than 2-4 years old who are potentially unco-operative and make a sizeable amount of children visiting the Out Patient Department for dental treatment.
- The children who can not be managed using routine behaviour management have the obvious option of being managed using conscious sedation, moderate to deep sedation or general anesthesia.
- The need for sedation in Pediatric Dentistry is on a rise due to decreased acceptance of more aversive behaviour management techniques among parents as well as the dentists, increase in general awareness among parents about recognition and early management of dental diseases and also increase in children with behavioral and emotional problems.
- Midazolam via the oral route is currently the most popular conscious sedation agent in young children inspite of having being shown not to be successful for all types of cases and age-groups by many investigators.
- There is no study in the literature, however, which has studied the effect of midazolam sedation on common anxiety provoking stimuli in a dental procedure.
- The following study, therefore, was carried out with an aim to evaluate the changes in the anxiety levels of a child during different steps of a class II restorative procedure after sedation with 0.5 mg/kg BW of midazolam via the oral-transmucosal route.

## METHODOLOGY

- A double blind randomized controlled trial was conducted.
- A total of 40 healthy children < than 4 years of age with ASA I status and having atleast one carious deciduous mandibular molar requiring a class II amalgam restoration were selected from those attending the Out Patient Department of Oral Health Sciences Centre, Post Graduate Institute of Medical Education and Research.
- Children with any history of allergy to benzodiazepines, mental retardation, emotional disturbance and those taking sedative drugs for any systemic causes or having impaired renal or hepatic functions were excluded from the study.
- The selected children were randomly divided into experimental (MDZ+ BMT) and control (BMT) groups of 20 children each. In the experimental group the treatment was carried out under the combined effect of midazolam and routine behaviour management techniques and in the control group the treatment was carried out using routine behaviour management techniques alone. To maintain the blind nature of the study, random allocation was not done by the principal investigator.
- A written informed consent was taken from the parents of children.
- Pre-operatively a thorough clinical examination of the child was performed for recording the cavitated tooth, patient's age and body weight and also the baseline anxiety level using Venham's anxiety scale. Appropriate fasting instructions were given.
- On the day of the operative procedure the children in experimental group were given a mixture of parenteral preparation of midazolam (Fulsed 1mg/ml, Ranbaxy Pharmaceuticals) in a dose of 0.5 mg/Kg Body weight via the oral-transmucosal route.
- The children in control group were given a test solution that comprised of a mixture of strawberry syrup diluted with normal saline to maintain a similar consistency. The prepared solutions were handed over to the principal investigator for administration, to maintain the blind nature of study.
- Following administration, the child of either group was taken into quiet room outside the operatory accompanied by one parent.
- Fifteen minutes after administration of the test solution, sedation score was recorded and the child was taken inside a fully equipped operatory by the principal investigator and the anesthetist for the restorative procedure.
- The anesthetist recorded the blood pressure, respiratory rate, oxygen saturation and pulse rate for children of both groups at baseline and at 15 minutes intervals thereafter for the entire restorative procedure.
- The entire treatment procedure was divided and recorded for anxiety levels and time duration in four stages; (i) Entry into dental operatory, (ii) Administration of local anaesthesia, (iii) Rubber dam application and, (iv) Restorative procedure, as each step was expected to arouse a different level of anxiety.
- Anxiety levels were recorded using Venham's Anxiety Scale twice during each step: Once at beginning of each step (baseline) and thereafter at completion of that particular step (final).
- The total treatment time to complete the procedure, success rates of completion of procedure, any adverse events and the frequency of use of different behaviour management techniques in the two groups were noted.

### Venham's Clinical Anxiety Rating Scale (1977)

- RELAXED**, smiling, willing, able to converse, best possible working conditions. Displays the behaviour desired by dentist spontaneously, or immediately upon being asked.
- UNEASY** concerned. During stressful procedures may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression and breathing is sometimes held in (high chest). Capable of cooperating well with treatment.
- TENSE** tone of voice, questions and answers reflect anxiety. During stressful procedures, verbal protest, hand tense and raised but not interfering much. Child interprets situation with reasonable accuracy and continues to cope with his/her anxiety. Protest more distracting and troublesome. Child still complies with request to cooperate. Continuity is undisturbed.
- RELUCTANT** to accept the treatment situation. Difficulty in assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop the procedures. Protest out of proportion to threat or is expressed vehemently before the threat. Copes with situation with great reluctance. Treatment proceeds with difficulty.
- INTERFERENCE** of anxiety and ability to assess situation. General crying not related to treatment. Prominent bodily movements, sometimes needing physical restraint. Child can be reached through verbal communication, and begins eventually to cope. Though with reluctance and great effort. Protest disrupts procedure.
- OUT OF CONTACT** with the reality of threat. Hard, loud crying, screaming, swearing. Unable to listen to verbal communication. Regardless of age, reverts to primitive flight responses. Physically involved in escape behaviour. Physical restraint required.

### Sedation Score

- 1 = Asleep / not readily arousable
- 2 = Asleep / responds slowly to gentle stimulation
- 3 = Drowsy / readily responds
- 4 = Awake / calm & quiet
- 5 = Awake / active

## RESULTS

### Level of Sedation (Table 1)

The children in the MDZ+ BMT group were found to be significantly more sedated than children in the BMT group, 15 minutes after administration of the test solution and also during the operative procedure. The sedation produced by midazolam was however of a mild degree with children being calm or slightly drowsy rather than being in a state of sleep.

Table 1 : Comparison of mean sedation scores in the two groups

	MDZ + BMT (X ± SD)	BMT (X ± SD)	p-value
15 minutes after administration of test solution	3.75 ± 0.85	4.60 ± 0.50	< 0.01
At time of procedure	3.25 ± 0.85	4.60 ± 0.50	< 0.01
p - value	< 0.01	< 0.01	< 0.01

### Anxiety Levels (Table 2, 3, 4)

The children in the two groups were well matched in terms of the baseline anxiety levels with most children displaying a negative behaviour according to the Venham's scale. The anxiety levels however, significantly reduced (p< 0.001) when the child was brought inside the operatory, 15 minutes after administration of the drug in MDZ+BMT group. The anxiety levels in the BMT group instead showed a slight increase at this clinical step, which was however, not statistically significant (p>0.1). Following this, successive introduction of anxiety provoking stimuli like local anaesthesia and rubber dam produced a somewhat similar increase in the child's anxiety in the two groups. The start of operative procedure however, did not produce such an increase in the anxiety levels in either group. It was however appreciable that in spite of the heightened anxiety, in the MDZ+ BMT group the anxiety levels were always lower than that of the BMT group. (Graph 1). This was significant (p> 0.01) for steps 'on entry' & 'local anaesthesia' and non-significant (p> 0.05) for steps 'rubber dam application' & 'operative procedure'.

Table 2 : Comparison of baseline anxiety levels

MDZ + BMT (X ± SD)	BMT (X ± SD)	p-value
2.05 ± 1.43	1.85 ± 0.98	> 0.1

Table 3 : Comparison between baseline anxiety and anxiety level on entry into operatory 15 minutes after administration of the test solution

	Baseline (X ± SD)	On Entry (X ± SD)	p-value
Midazolam + BMT	2.05 ± 1.43	0.35 ± 0.49	< 0.001
BMT	1.85 ± 0.98	1.97 ± 1.67	> 0.1

Table 4 : Mean anxiety scores during treatment

	MDZ + BMT		p-value	BMT		p-value
	Baseline (X ± SD)	Final (X ± SD)		Baseline (X ± SD)	Final (X ± SD)	
On entry till patient sits on chair (OE)	0.35±0.49	0.25±0.44	> 0.1	1.95±1.67	2.15±1.93	> 0.1
Local Anaesthesia (LA)	1.35±0.87	1.0 ± 0.86	> 0.5	2.78±1.39	2.31±1.70	> 0.1
Rubber dam application (RDA)	1.55±1.32	1.40±1.57	> 0.1	2.62±1.90	2.18±2.23	> 0.1
Operative procedure (OP)	1.15 ± 1.31	0.89 ± 0.1	> 0.1	1.38 ± 1.92	1.38 ± 1.85	> 0.1

### Treatment Time (Table 5)

It was seen that the overall time taken to complete the treatment was significantly lower in midazolam and behaviour management group (25.88±/ 7.50) than in the BMT group (35.71±/15.11) (p<0.05). The time taken for accomplishment of each clinical step was lower in MDZ + BMT group compared to BMT group. The difference was significant (p< 0.05) for all steps, except 'rubber dam application' (p> 0.1).

Table 5 : Time taken (in minutes) for various clinical steps 15 minutes after drug/ placebo administration

	MDZ + BMT (X ± SD)	BMT (X ± SD)	p-value
From entry till patient sits on chair	1.90 ± 0.64	4.60 ± 5.08	< 0.05
Sitting till LA is injected	4.70 ± 2.50	7.23 ± 3.81	< 0.05
Rubber dam application	6.55 ± 3.17	8.30 ± 5.01	< 0.01
Operative procedure	13.06 ± 3.34	18.71 ± 5.9	< 0.01
Total time taken	25.88 ± 7.50	35.71 ± 15.11	< 0.05

### Unaccomplished Procedures (Table 6)

The difference in number of successfully completed procedures between the two groups was highly appreciable with 90 % of the procedures being completed in MDZ + BMT group compared to 35% in BMT group. In MDZ+BMT group; bringing the child into operatory and administration of local anaesthesia, could be accomplished in all the cases compared to BMT group where it was not possible to bring 2 children inside the operatory and another 5 children refused local anaesthesia administration, making a total of 7 children in whom this step could not be accomplished. One child in MDZ+ BMT group refused rubber dam application (never reached the next clinical step) and one more did not allow the operative procedure to be completed, thus having unaccomplished procedures in 2 cases. In BMT group, the total number of children in whom rubber dam application could not be accomplished were 12 and there was one child who refused the operative procedure making a total of 13 children in whom cavity cutting and filling remained unaccomplished.

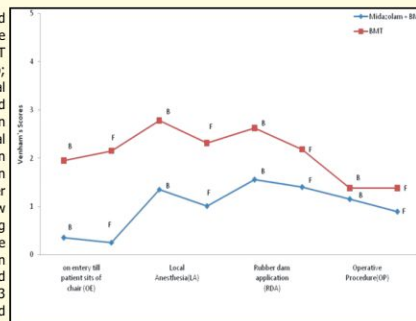


Table 6 : Number of unaccomplished procedural steps in children with incomplete treatment

Groups	OE (n)	LA (n)	RDA (n)	OP (n)
MDZ + BMT	0	0	01	02
BMT	02	07	12	13

### Use of Behaviour Management Techniques (Table 7)

It was observed that almost all children in the MDZ+BMT group could be managed using TSD only, except for two children who required use of voice control and physical restraint during rubber dam application. On the contrary, in the BMT group, 2 children required restraint even during entry into operatory, 3 during administration of local anaesthesia and 2 during rubber dam application. None of the children in this group, however, required restraint for the operative procedure. The differences in the use of type of behavior management technique between the two groups were, however, not found to be statistically significant (p>0.1).

Table 7 : Behavior management techniques used for successfully completed procedural steps

Groups	MDZ + BMT				BMT				p - value
	TSD		Restrain		TSD		Restrain		
	n	%	n	%	n	%	n	%	
OE	20	100	00	00	16	89	02	11	> 0.1
LA	20	100	00	00	10	77	03	23	> 0.1
RDA	17	90	02	10	06	75	02	25	> 0.5
OP	18	100	00	00	07	100	00	00	> 1

## ADVERSE EVENTS

No undesirable effects were seen except for two cases of mild hiccups in MDZ+BMT group. The vital parameters of the sedated children, remained stable and within normal limits. (graph 2)

## CONCLUSIONS

- A waiting period of 15 minutes is sufficient after oral-transmucosal administration of 0.5 mg/kg body weight of midazolam, as sufficient sedation was produced after this waiting period.
- The sedation produced by midazolam (0.5 mg/Kg body weight) via the oral-transmucosal route is significant compared to control and is of sufficient duration to outlast a moderate time duration dental procedure such as a class II amalgam restoration.
- Midazolam (0.5 mg/kg body weight) via the oral-transmucosal route significantly reduces a child's anxiety thus keeping him in a more manageable state throughout treatment even during invasive procedures like local anaesthesia and fear evoking ones like rubber dam application.
- There are greater chances of a successful treatment when routine behaviour management techniques are supplemented with midazolam sedation than when they are used alone.
- The children under the effect of midazolam sedation require aversive means of behaviour management such as physical restraint much less frequently for successful accomplishment of the dental procedure compared to non-seated children.
- The treatment done under midazolam sedation is a time saving endeavor as much less time is consumed in accomplishing different steps. Moreover, the superiority of treatment in terms of ease and treatment time is not doubtful even if the 15 minutes waiting period after drug administration is included in the overall treatment time.
- Midazolam, therefore is a useful agent in a pediatric dentist's armamentarium to reduce patient anxiety and a useful adjunct to routine behaviour management techniques as it increases the chances of successful completion of a planned procedure without having to resort to deep sedation or general anesthesia.