

## Original Article

### Intricate Assessment and Evaluation of Sedation Efficacy of Two Different Dosage of Oral Midazolam in Uncooperative Paediatric Patients Undergoing Dental Treatment: An Observational Study

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#### ABSTRACT

**Background & Aim:** One of the common problems while treating paediatric patients is dental fear and anxiety. The most common drug used is midazolam, which is having a short duration of action. Hence; we planned the present study to compare the efficacy of 0.3 and 0.5 mg/kg Oral Midazolam in Three to Six year-old uncooperative children scheduled to undergo dental treatment.

**Materials & Methods:** Authors have outlined this study to explore the relative effectiveness of 0.3 and 0.5 mg/kg Oral Midazolam in three to six years-old obstinate kids those listed dental treatment. A total of 60 fearful paediatric dental patients between the age group of 3 to 6 years were included in the present study. All the patients were broadly divided into two study groups- group 1 included patients who were given 0.3 mg/Kg oral midazolam, while group 2 included patients who were given 0.5 mg/Kg. We recorded all the physiological parameters in all the subjects, which included- SpO<sub>2</sub>, heart rate and respiratory rate; at different time intervals. 'Houpt' scale was used for evaluating the level of sedation. **Results:** Total of 60 subjects was studied wherein they were divided largely into two study groups. Group 1 included the patients who were given 0.3 mg/Kg oral midazolam, while group 2 included patients who were given 0.5 mg/Kg. 'Houpt' scale was used for comparing the results. Data were obtained and compiled in various tables in logical manner. All the results were finally entered on Microsoft excel sheet and were analyzed by SPSS software. **Conclusion:** Approximately similar level of conscious sedation is produced by oral midazolam, in terms of efficacy, at both the dosages.

**Key words:** Conscious Sedation, Dental, Midazolam

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#### INTRODUCTION

Dental scariness and anxiety are usually considered as one of the greatest dilemma in dealing paediatric patients. However various researchers and clinicians have shown different techniques to manage them. The relative incidences of unintentional loss of consciousness must be monitored very carefully specially while using conscious techniques. Literature has shown that medication those used for sedation purpose can be routed via various channels like oral, nasal, intramuscular, intravenous (IV), subcutaneous, and inhalational routes.<sup>1-3</sup> In terms of onset of action, midazolam is one of the most commonly used drug. In most of the pediatric dental clinics, midazolam is the drug of choice for conscious sedation.<sup>4</sup> Consequently,

the clinical usages of midazolam requires experienced physicians with comprehensive knowledge those are skilled in pediatric airway management and resuscitation. In some other studies, pediatric emergency physicians has also shown 2.3% adverse event rate for procedural sedation and analgesia (PSA) with no serious complications noted.<sup>5-7</sup> Hence; we planned the present study to compare the efficacy of 0.3 and 0.5 mg/kg Oral Midazolam in uncooperative children wherein dental treatment has been scheduled to be done.

#### MATERIALS & METHODS

The present study was planned and completed in the department of Anaesthesiology. It included evaluation

and comparison of efficacy of 0.3 and 0.5 mg/kg Oral Midazolam in three to six years-old uncooperative children wherein dental treatment has been scheduled to be done. Ethical clearance for the present study was taken from the institutional ethical committee after explaining in detail the entire research methodology. A total of 60 fearful paediatric dental patients between the age group of 3 to 6 years were included in the present study. All the patients were broadly divided into two study groups- group 1 included patients who were given 0.3 mg/Kg oral midazolam, while group 2 included patients who were given 0.5 mg/Kg. Both the study group consisted of 30 patients in each group. Only those fearful children were included in the present study, which ranked as Frankl scale 1.<sup>8</sup> Comprehensive demographic and clinical details of all the subjects was obtained. We recorded all the physiological parameters in all the subjects, which included- SpO<sub>2</sub>, heart rate and respiratory rate; at different time intervals. Houpt scale was used for evaluating the level of sedation. All obtained observations were tabulated and sent for statistical analysis. Statistical analysis was executed using SPSS ‘Statistical Package for the Social Sciences’ software version 21 (IBM Incorporation, New York, U.S.A.). Chi- square test was

used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

**STATISTICAL ANALYSIS AND RESULTS**

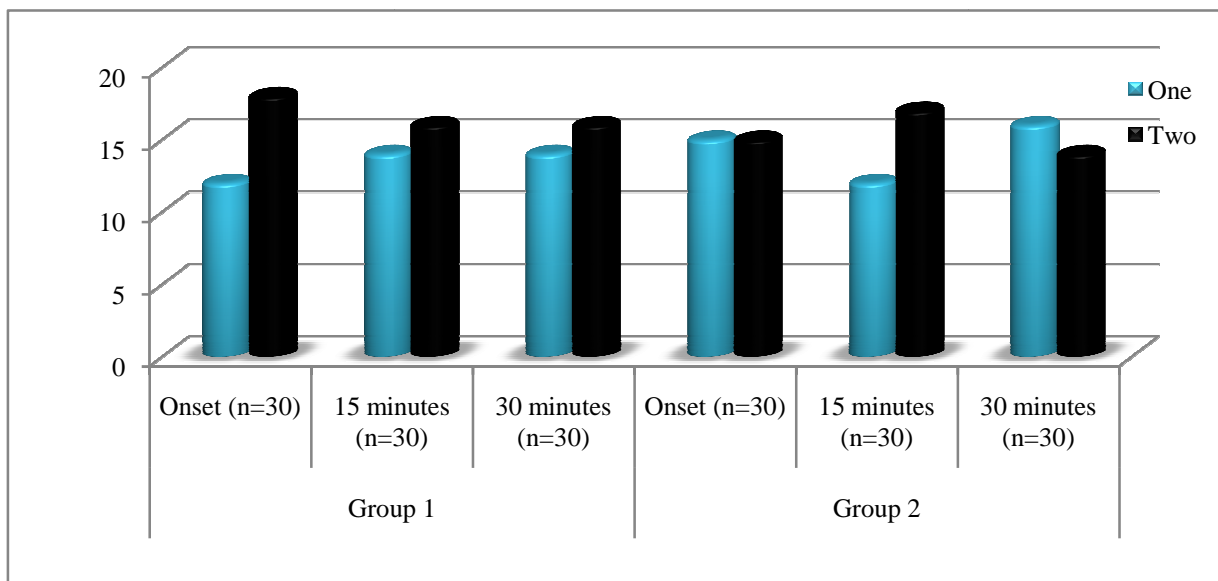
A total of 60 subjects were included in the present study. All the subjects were divided broadly into two study groups; Group 1- subjects who were given 0.3 mg/Kg oral midazolam, while group 2 included patients who were given 0.5 mg/Kg. Houpt scale was used for comparing the results. In group 1, at the time of onset, 18 subjects had sleep score of ‘Two’, while 12 subjects had score of ‘One’ as shown in **Table 1**. After thirty minutes, 16 and 14 subjects of group 1 had score of ‘Two’ and ‘One’ respectively, whereas in Group 2, after thirty minutes, 14 and 16 subjects of group 1 had score of ‘Two’ and ‘One’ respectively (**Graph 1**). After thirty minutes, 16 and 14 subjects of group 1 had score of ‘Two’ and ‘One’ respectively, whereas in Group 2, after thirty minutes, 14 and 16 subjects of group 1 had score of ‘Two’ and ‘One’ respectively (**Graph 1**). We didn’t observed any significant difference while comparing the overall behaviour score on the basis of Houpt scale in between the two study groups (**Table 2, Graph 2**).

**Table 1:** Comparison of subjects in terms of sleepiness on the basis of ‘Houpt’ Scale

Sleep score (Houpt scale)	Group 1			Group 2		
	Onset (n=30)	15 minutes (n=30)	30 minutes (n=30)	Onset (n=30)	15 minutes (n=30)	30 minutes (n=30)
One	12	14	14	15	13	16
Two	18	16	16	15	17	14
Three	0	0	0	0	0	0
Total subjects	30	30	30	30	30	30

Scores; One: Fully awake, Two: Dizzy and sleepy, Three: sleepy

**Graph 1:** Distribution of subjects in terms of sleepiness on the basis of Houpt Scale

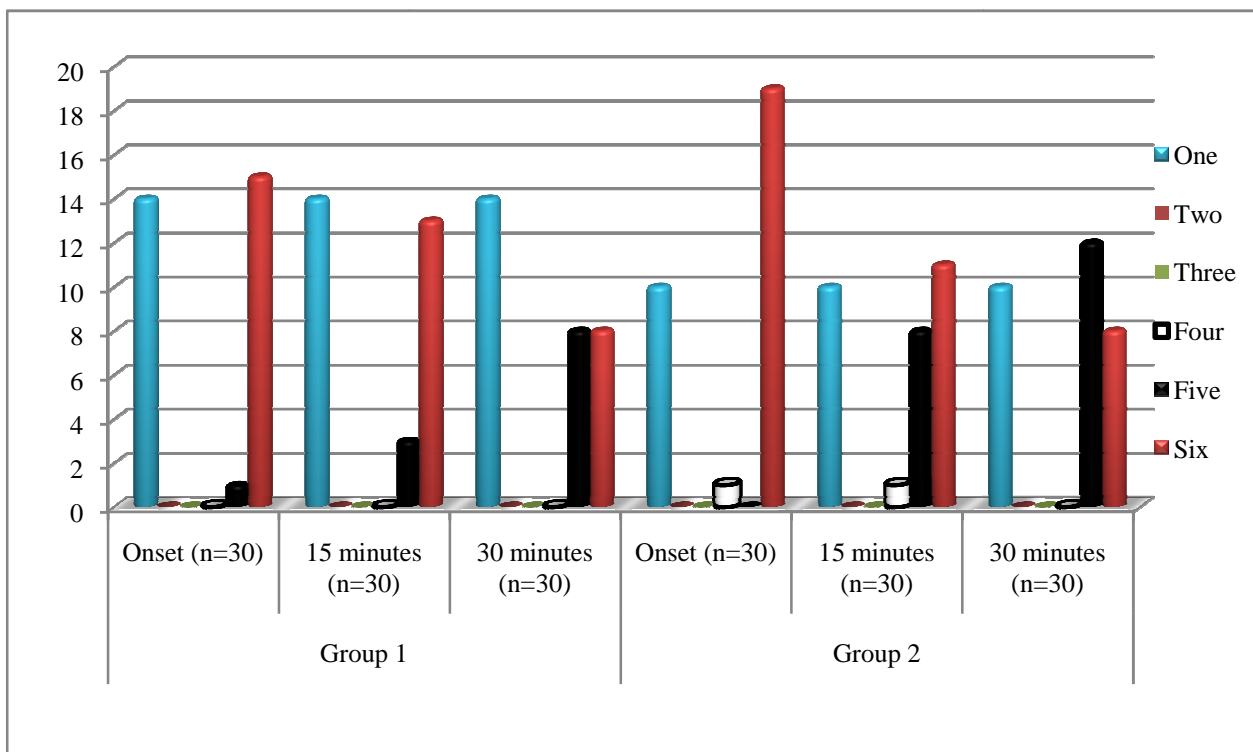


**Table 2:** Comparison of subjects in terms of overall behaviour score on the basis of Houpt Scale

Sleep score (Houpt scale)	Group 1			Group 2		
	Onset (n=30)	15 minutes (n=30)	30 minutes (n=30)	Onset (n=30)	15 minutes (n=30)	30 minutes (n=30)
One	14	14	14	10	10	10
Two	0	0	0	0	0	0
Three	0	0	0	0	0	0
Four	0	0	0	1	1	0
Five	1	3	8	0	8	12
Six	15	13	8	19	11	8
<b>Total subjects</b>	30	30	30	30	30	30

Scores; One: No treatment, Two: Treated partially, Three: Completion of treatment despite of interruption, Four; Difficult but done, Five: Little crying, Six: No crying

**Graph 2:** Comparison of subjects in terms of overall behaviour score on the basis of Houpt Scale



**DISCUSSION**

Early efforts to provide sedation in the dental office were largely unregulated, In the past most of the methods of providing sedation were highly uncontrolled and unregulated. Therefore for the assessment of depth of sedation, the clinicians had to rely only of the observational parameters like quality of respiration and patient colour to assess the sedated patient. With the advancements in medical sciences and establishments of professional associations and regulatory bodies, all such dilemmas has been reduces by many folds. They have also set up an environment of judicial practice with safety rights. With regards to sedations procedures, they have also been improved in terms of safely particularly in rural outreach regions.<sup>10-12</sup> The present study compared the efficacy of two doses of Oral Midazolam in uncooperative children where dental treatment scheduled. Statistical analysis and results revealed that there was no

significant difference during analyzing the overall behaviour score on the basis of Houpt scale in between the two study groups (**Table 2, Graph 2**). Our study results were quite comparable to the study results of Shabbir A and co-workers.<sup>9</sup> They estimated and evaluated the safety and efficiency of two oral conscious sedation dugs, Triclofos 70mg/kg and Midazolam 0.5mg/kg in pediatric dental patients. Paediatric patients those showing negative outlook according to ‘Frankl’ behaviour rating scale (Rating No.2) were selected. Shabbir A and co-workers has randomly assigned patients to receive oral midazolam 0.5mg/kg or triclofos 70mg/kg. Logical scoring was completed for both midazolam and triclofos observations and also for those which were tried without medication. Comparable and in contrast to our study there were high levels of significances when compared for different doses with different clinical conditions. However the scoring for midazolam was

significantly higher than triclofos. They had concluded that midazolam in (0.5mg/kg) is more efficient in managing patient behaviour when compared to triclofos. Golpayegani MV and co-workers also studied in detail about the behavioural changes in kids undergoing dental treatment. They explored the effects of administration of combination of Midazolam/Ketamine or Midazolam/Promethazine.<sup>10</sup> Their results were in accordance with the study results of ours especially in regards to the efficiencies. In all cases, they recorded anxiety scores well before other scorings such as Frankel's anxiety scoring system. To diminish the effects of other affecting factors, it was ensured that each case must serve as control for him/herself. They reported patients mean age as 3.5 years with 43% being male. The significant amount of behavioural changes was noticed only in 10% of Ketamine/Midazolam group. The statistical significant difference what exactly revealed was illustrated (P=0.029). Stamp AJ and colleagues estimated effectiveness of midazolam in facilitating surgical procedures in dentistry in young orthodontic patients. A retrograde assessment was carried out exploring clinical records of kids from departmental archives. All patients undergoing surgical extraction of teeth under IVCS midazolam were included in their study. They found that Midazolam dose range of 2-7mg/kg illustrated good or excellent cooperation in 79.1% patients.<sup>11</sup> These are somewhat in accordance and comparable to the study results of our study. Wood M and co-workers also studied the similar clinical methods with the aim to determine whether a combination of intranasal midazolam and inhalation sedation with nitrous oxide and oxygen is a safe and perfect substitute to general anaesthesia in dentistry.<sup>12</sup> They showed that more than 95% patients (those seeking dental treatments) have been treated successfully using said technique. This was also in accordance with our study result's recommendations. Consequently, most of these findings have also been shown by other pioneer researchers in the literature.<sup>13-16</sup>

### CONCLUSION

Under the light of above results, the authors concluded that approximately similar level of conscious sedation is produced by oral midazolam at both the studied dosages. Our study results can be treated as suggestive for formulating accurate treatment planning. Nevertheless, we anticipate some other larger scale researches to be performed that could further establish certain reliable guidelines in this prospect.

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