

A comparative study of a commercial syrup and oral administration of injectable midazolam in pediatric dental sedation

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Abstract

Objective: The purpose of this study was to compare the efficacy and safety of "midazolam syrup" versus "orally administered IV midazolam (PO midazolam)" among uncooperative dental patients. Second outcome was to assess the prevalence as well as the impact of General anxiety and Dental fear on sedation success.

Method: Eighty eight uncooperative dental patients (Frankl Scales 1,2) aged 3 to 6 years, and ASA I were participated in this double blind, parallel randomized controlled clinical trial. Physiologic parameters including heart rate, respiratory rate, oxygen saturation and blood pressure were recorded. Behavior assessment was conducted throughout the course of treatment by Houpt Scale and at critical moments of treatment (injection and cavity preparation) by North Carolina Scale. General anxiety, dental fear and personality characteristics were evaluated by the means of Child Dental Fear (CFSS), Strength and Difficulties Questionnaire (SDQ) and Conners' questionnaires. Independent T-test and Chi-Square, and Pearson correlation were used for statistical analysis.

Findings: Acceptable behavior was observed in 90.9% of syrup groups and 86.4% of PO group revealed acceptable behavior by Houpt scale ($P=0.51$). The ratings of sleep, crying and movement domains were not significantly different between groups. Physiological parameters remained in normal range without any significant difference between groups and no adverse effect was observed. No significant relationship was found between behavior after receiving midazolam sedation and personality aspects including: dental fear, general anxiety, and gender ($P>0.05$).

Conclusion: PO midazolam formulation can be used as an acceptable alternative for midazolam syrup.

Key words: Sedation, Pediatric dentistry, Oral midazolam, Behavior and personality