

The Use of Midazolam to Modify Children's Behavior in the Dental Setting

by Fred S. Margolis, D.D.S.

I. **Introduction:** One of the most common challenges that the dentist who treats children faces is the behavior management of the difficult child. Most children react favorably to the traditional behavior management technique of "tell-show-do." (1) Some children are not accepting of treatment due to fear, pain, anxiety, maturity or a combination of these. Pharmacologic methods of modifying children's behavior are sometimes necessary in order to accomplish the necessary treatment for the child. Nitrous oxide is a commonly used pharmacologic agent but has the main disadvantage in children of being a nasal inhalation agent. One of the newer medications available to the dentist for use in children is midazolam (Versed). Midazolam is a benzodiazepine and has been approved by the Food and Drug Administration in November 1998. (1)

More than 2000 benzodiazepenes have been synthesized since 1933; the most common are diazepam and midazolam. The factors that should be taken into account when using a sedative include: safety, amnesic effect, half-life, and working time. Midazolam is a short-acting benzodiazepine with a half-life, in children, of two hours compared to 18 hours for diazepam. Midazolam has a short working time of 25 minutes with peak plasma levels at 25 minutes after oral administration. (1) Other

studies have shown that the orally administered Midazolam had a duration of action of 30-40 minutes. (2)

Midazolam can be administered rectally, intranasally, intramuscularly, intravenously, and orally. The recommended dose for oral administration in pediatric patients is 0.25-1.0 mg/kg with a maximum of 20 mg. The range, clinically, has been shown to be 0.5-1.0 mg/kg with a maximum dose of 20 mg. Most studies show the intranasal route dosage to be between 0.2 and 0.3 mg/kg. One of the most beneficial side effects of utilizing midazolam is the amnesic effect that is often reported.(1) The reversal agent for all benzodiazepines is flumazenil.(1) Flumazenil can be administered intravenously, intramuscularly, or intramucosally. If given intravenously the dosage is 1 mg. with the onset of clinical antagonism within one to five minutes. For young children, the clinician should check with the Physician's Desk Reference, or other valid resource. (3)

Using sedation in children to provide oral health care is recognized by the American Academy of Pediatric Dentistry (AAPD) as a "unique clinical challenge." (4) Factors to consider include the patient's age and levels of cognitive and coping skills. The intended goals when using sedation and indications for the use of sedation are as follows:

- 1) facilitate and augment the provision of dental patient care
- 2) minimize the extremes of disruptive behavior
- 3) promote a positive psychological response to treatment
- 4) promote patient welfare and safety

- 5) return the patient to a physiological state in which safe discharge is possible
(4)

Indications for minimal to moderate sedation, according to the AAPD are:

- 1) preschool children requiring dental treatment who cannot understand or cooperate for definitive treatment
- 2) patients requiring dental care who cannot cooperate due to lack of psychological or emotional maturity
- 3) patients requiring dental treatment who cannot cooperate due to a cognitive, physical, or medical disability
- 4) patients who require dental care but are fearful and anxious
- 5) patients who require extensive dental care and would require or benefit from prolonged visits (4)

The advantages of midazolam as a sedative in children are the following effects: anxiolysis, hypnotic, anticonvulsant, muscle relaxant and anterograde amnesia. (5)

II. Monitoring the Sedated Patient:

Monitoring the sedated patient who is minimally and moderately sedated:

According to the AAPD guidelines, the practitioner responsible for the patient's treatment and/or the administration of drugs for minimal and moderate sedations shall:

1) be appropriately trained in the use of such drugs and techniques

Author's Note: Each state has its own laws pertaining to the licensing of practitioners in the use of conscious sedation. In Illinois, where the author practices pediatric dentistry and dentistry for the disabled person, a conscious sedation permit is required through the Department of Professional Regulations for conscious sedation (other than nitrous oxide sedation and for anxiolysis).

2) provide appropriate monitoring

3) be capable of managing and rescuing the patient from any reasonable foreseeable complications, including loss of airway, hypoxia, apnea, or unintended progression to a deeper level of sedation.

The monitoring should include a pre-cordial stethoscope, a pulse oximeter and an automatic blood-pressure device as well as routine observation. Values should be recorded every 15 minutes for the duration of the sedation, and during recovery until vital signs are stable. (5)

III. Personnel.

Training and certification in basic life support is required. Training and certification in advanced pediatric airway management and

advanced life support is recommended. In addition to the operating dentist, an individual trained to monitor appropriate physiologic parameters and assist in any supportive or resuscitative measures shall be present. This individual must have training and certification in basic life support, have specific assignments, and be familiar with the emergency kit inventory. The practitioner and all treatment personnel should participate in periodic reviews of the emergency protocols, the emergency drug kit, and simulated exercises to assure proper emergency management response. (4)

The drugs used for the purpose of sedation shall be administered in the treatment facility and shall be prescribed, dispensed, or administered only by appropriately licensed individuals, or under the direct supervision, according to state law. (4)

IV. Common Problems During Sedation:

Midazolam “appears to decrease the body’s response to CO₂ and produce some respiratory depression.” “By far the most common problems during sedation procedures in children are airway related.” Vomiting and re-gurgitation of stomach contents is one of the leading causes of morbidity and mortality in children undergoing anesthesia. Aspiration does not usually occur unless inadvertent deep sedation or general anesthesia from an overdose. In high doses, an increase in

local anesthesia toxicity can occur. (5) Other side effects include vomiting one to two hours after the operative dentistry appointment in about 10% of patients. Drowsiness for 2-4 hours after the appointment is typical. Hallucination and beligerant behavior have also been observed by the author. This idiosyncratic reaction has been reported in the literature. (2)

V. Case History:

Jamie is an eight year old female who was referred to me by a family friend. Jamie has severe learning disabilities and has been to three dentists who were unsuccessful in treating Jamie and restoring the four carious teeth. Jamie would not cooperate with the previous pediatric dentist and would not even sit in the dental chair. When Jamie's mother called our office and explained the behavior problem of her daughter, my receptionist suggested a tour of the office prior to her dental examination. Jamie toured the office with her mother and was shown the treatment area and was introduced to her new dentist. Jamie came in the following week for her examination and at that time her medical and dental history was reviewed. I suggested to Jamie's mother that a sedative might help Jamie overcome her dental anxiety. The informed consent form (see attached) was reviewed with Jamie's mother. At the subsequent visit, Jamie was given 0.5 mg/kg of midazolam plus 5

cc (160 mg.) of acetaminophen orally, one-half hour prior to her scheduled visit. The acetaminophen is used to mask the flavor of the midazolam in addition to the analgesic effect).

Jamie's behavior was excellent during this first operative visit and one restoration was completed. At the second operative visit, Jamie and her mother felt she did not need the sedative. I completed her remaining three restorations with excellent patient cooperation.

Discussion of case history: This patient's behavior was modified with the use of an oral sedative, midazolam. Her previous pediatric dentist had sent the mother home with a note to an oral surgeon suggesting that he extract the moderately carious teeth, due to the patient's poor cooperation. The patient was able to overcome her anxiety with the aid of a sedative agent, midazolam.

(Figures 1 and 2)



First operative visit

After successful first separate visit

INFORMED CONSENT FOR VERSED (MIDAZOLAM) *

Information for parents and guardians about your child's sedation:

- a) Versed can be give orally or nasally depending on the cooperation of your child.
- b) Please arrive 30 minutes prior to the appointment time.
- a) If given orally it is mixed with a flavoring agent, such as Tylenol.
- c) Meals: The patient can have a light meal up to four hours prior to appointment. (Example: toast and clear juice)(NOT Grapefruit juice)
- d) Please let the dentist know if any other medication has been given.
- e) Versed has the following effects on children:
 - i. Drowsiness—this will last from 2-4 hours after the appointment. Please watch your child because his/her stability will not be normal for this period of time.
 - ii. Amnesic effect – most children will forget about the dental procedures due to the medication.
 - iii. Vomiting—this may occur; it usually occurs 1-2 hours after the dental appointment.
 - iv. Some parents report that their children have daydreams during the appointment.
 - v. A very small number of children get overexcited during the procedure, usually after a period of drowsiness.

I have read and understand the background information above and instructions given verbally by the dentist. I have had the opportunity to ask the dentist questions regarding any aspect of this treatment and procedure which I do not understand. I accept and understand these pre-operative instructions.

Patient's Name _____

Parent/Guardian signature _____ Date _____

Witness signature _____ Date _____

* Please check with your attorney/dental society for completeness of this document.

References:

1. Varas, K.G. Pharmacological Management of the Healthy but Uncooperative Preschool Child. J.Pediatric Dental Care 2003; 9:14
2. Marshall W.R., Weaver B.D., McCutcheon P. A study of the effectiveness of oral midazolam as a dental pre-operative sedative and hypnotic. Spec. Care Dentist. 1999 Nov.-Dec; 19(6): 259-266
3. Brogden, R.N, Goa, K.L. Flumazenil. A Preliminary review of its benzodiazepine antagonist properties, intrinsic activity and therapeutic use. ADIS Drug Information Services, Auckland
4. Reference Manual. Pediatric Dentistry, Volume 26, No. 7; 95-101
5. Duperon,D.F. Conscious Sedation for Very Young Pediatric Dental Patients. J.Pediatric Dental Care 2003; 9:12-13
6. Wilson, S. Monitoring and the Pediatric Dental Patient. J.Pediatric Dental Care 2003; 9: 20-21

