Comparison of the Efficacy of Oral Midazolam Alone Versus Midazolam and Meperidine in the Pediatric Dental Patient

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Abstract

Purpose: The purpose of this study was to compare midazolam alone (Group A: 1 mg/kg) vs midazolam plus meperidine (Group B: 0.5 and 1 mg/kg, respectively) in regard to physiology and behavior of young children sedated for dental restorative care.

Methods: Twenty healthy children who met selection criteria were randomly assigned to 1 of 2 groups and subsequently treated in a prospective, crossover design. All sedative agents were administered orally, and all sedations included 50% nitrous oxide administered via a nasal hood. Heart rate, systolic and diastolic blood pressure, and behavior were recorded at 8 procedural or time periods during the visits. Chi-square and ANOVA were used to analyze the data.

Results: No difference in physiology or behavior was found between groups. However, higher heart rates and disruptive behaviors occurred more frequently during or after local anesthesia administration.

Conclusions: Oral midazolam alone is just as effective as midazolam with meperidine. Disruptive behaviors accounted for increased heart rates. (*Pediatr Dent*. 2003; 25:468-474)

KEYWORDS: MIDAZOLAM, MEPERIDINE, SEDATION, PEDIATRIC DENTISTRY

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Historically, many different agents have been used to sedate children for dental care. Typically, more than one agent is used.[1] The most popular oral sedative agents have been chloral hydrate and meperidine,[1-3] either of which is often combined with an antiemetic such as hydroxyzine. In more recent years, other agents (eg, benzodiazepines and, in particular, midazolam) have become popular among pediatric dentists and physicians.[4-14] However, their effectiveness in producing cooperative behaviors in very young children during perceived painful or distressing procedures is questionable.[12]

Combinations of sedative agents with and without N_2O have been used for years.[2,5,12-35] Several popular combinations have been chloral hydrate and hydroxyzine; meperidine and promethazine or hydroxyzine; and chloral hydrate, meperidine, and hydroxyzine. Table 1 shows representative drugs, dosages, and characteristics of agents used in pediatric dentistry.

Several studies have indicated that when N_2O is added to a sedative agent, the amount of disruptive behaviors decreases, but such behaviors are not necessarily eliminated.[22,29-31] The quantity of quiet behaviors, compared to crying or struggling behaviors during sedation, ranges from near 0% to 100%, but typically is around 70%.[22,28,31,32]

Few pediatric dental studies have investigated the use of oral midazolam in combination with another sedative agent. Midazolam has several characteristics that make it desirable including its safety, rapid onset, and the potential of some degree of amnesia. One characteristic that is useful for very short emergency visits is its short duration of action, typically with a satisfactory clinical effect of 20 minutes working time. On the other hand, such a short working time can be limiting depending on the child's dental needs. Hence, it is desirable to find a second agent that, in combination with midazolam, can increase working time and simultaneously add its own desirable effect to the clinical situation (eg, analgesia). Although

several agents may complement midazolam, a narcotic would seem reasonable to investigate. Several dental studies have looked at these 2 classes of agents, but not in combination until only recently when a retrospective report was published.[36]

The objective of this prospective clinical trial was to evaluate the effect of midazolam alone and a combination of midazolam and meperidine, both administered orally, on physiological and behavioral measures in children undergoing dental treatment.

Table 1. Orally Administered Drugs and Drug Combinations Commonly Used in Pediatric Dentistry

Drugs	Dosages (mg/kg) oral only	Onset (ready for procedure)	Observable traits
Chloral hydrate+ hydroxyzine	Chloral hydrate (20-50) Hydroxyzine (1-2)	45 min	Hyperactive, cry, sleep
Chloral hydrate+ hydroxyzine+ meperidine	Chloral hydrate (20-35) Hydroxyzine (1-2) Meperidine (1-2)	30-45 min	Hyperactive, euphoria, dysphoria, sleep
Meperidine+ hydroxyzine	Meperidine (1-2) Hydroxyzine (1-2)	40-45 min	Hyperactive, euphoria, dysphoria, sleep
Midazolam	0.3-1	5-15 min	Floppy doll, slow to react, cry and/or struggle
Midazolam+ hydroxyzine	Midazolam (0.3-0.75) Hydroxyzine (1-2)	5-15 min	Floppy doll, slow to react, cry and/or struggle
Diazepam	2-5 y: 5 mg 6-10 y: 5-10 mg 11-20 y: 10-15 mg	30-45 min	Cry, slow to react, relaxed, mellow

Methods

Subjects

The children who participated in this study were recruited from the general population of Columbus Children's Hospital (CCH) dental program using an Institutional Review Board-approved informed consent procedure. Twenty children were recruited for this double-blind, crossover study. A convenience sample of children was drawn from the pool of patients associated with screening appointments in the CCH dental clinic. The children were deemed mildly or moderately anxious by a dentist at the time of screening, suggesting the need for a pharmacological adjunct in the management of the patient during restorative care.

The criteria for inclusion in this study required children to:

1. be healthy (ASA I);
2. have tonsils not more than 50% of the airway;
3. have no allergies or contraindications to the drugs used in the study;
4. be naïve to operative dental treatment;
5. be in need of 2 restorative visits involving posterior teeth;
6. be 36 to 60 months of age.

Equipment

The equipment used in this study included routine restorative dental instruments and materials, pulse oximeter, blood pressure cuff, precordial stethoscope, and papoose board. A capnograph was available for use if level III of the American Academy of Pediatric Dentistry (AAPD) sedation guidelines was achieved.[37]

Procedure

Once selected, patients were randomly assigned into Group A or B using a table of random numbers. Group A received oral midazolam (1 mg/kg) on the first visit and an oral combination of midazolam and meperidine on the second visit (0.5 mg/kg and 1 mg/kg, respectively). Maximum dosages were 15 mg/kg for midazolam and 50 mg for meperidine. Midazolam was supplied and administered orally either as oral syrup or parenteral solution. Group B received the same drug dosages in reverse order. Nitrous oxide was used for all sedations at a fixed concentration of 50%. The interappointment period was kept reasonably constant between a window of 1 to 3 weeks.

On the morning of the sedation, the patient's medical history was reviewed with the parent and a physical examination of the child performed by the dentist. This included a tonsillar assessment of the airway, as per AAPD sedation guidelines.[37]

Nothing per oris (NPO) status of a minimum of 8 hours was confirmed, and informed consent was obtained. A dental assistant, using a blood pressure cuff (Dinamap) and an oxygen probe (Nellcor Pulse Oximeter) recorded preoperative vital signs. An assessment of the child's behavior at this time was also recorded.

Each patient received the appropriate dose of oral sedative(s) administered by cup or syringe based on their group. The drugs were flavored with Nuflavor (Lancer Orthodontics, San Marco, Calif), an alginate flavoring agent. When a patient was noncompliant, a knee-to-knee procedure involving the parent, child, and dentist was used, and the drug was administered slowly into the buccal vestibule with a 10-cc irrigating and needleless syringe. The coinvestigator administered the drug, and neither the parent nor the operator knew what agent(s) were administered. The assistant was informed of the drug(s) administered. In the event of an emergency, the dentist could then be informed should a reversal agent be needed (ie, Naloxone for meperidine, Flumazenil for midazolam). Following drug administration, the child remained in a quiet room with the parent for 20 minutes. Preliminary evidence from pilot stud-

ies has shown 20 minutes was appropriate (ie, children appeared overtly relaxed/limp, displayed little notable separation anxiety, and easily separated from parents).

At the end of the 20-minute latency period, the child was separated from the parent and carried or walked by the assistant to the treatment room where monitors were affixed. The blood pressure cuff was placed on the right arm, and the O_2 probe was placed on the left second toe. A flavored nasal hood was placed over the nose, and N_2O/O_2 was set at 50% concentration at 5 L/min flow. Behavior and vital signs were recorded again. The child was not initially wrapped in a papoose board (Olympic Medical Group, Seattle, Wash) because lack of the need for a papoose board during sedation has been considered one outcome measure of the success of sedation.[38] However, disruptive behaviors considered potentially harmful to the child or personnel, that could not be modified by routine talking, coaxing, or encouraging the child, resulted in the use of the papoose board for the remainder of the treatment. The papoose board, which did not include a head restraint, was used any time during the procedure at the discretion of the operator when this type of behavior occurred.

The dental procedure consisted of a mandibular block and long buccal injection of 2% lidocaine 1:100,000 epinephrine, or a maxillary infiltration along with palatal anesthesia, up to but not exceeding a maximal dose of 4 mg/kg with the aid of a mouth prop. A test for adequate anesthesia after 4 minutes was done by placing the explorer tine into the area of the anesthetized gingiva and monitoring for a reflexive response and crying. After adequate anesthesia was established, a rubber dam was placed on the primary second molar with mouth prop already in place. Restorative dentistry, requiring minimal to moderate technical complexity, was then completed (ie, pulpotomy and stainless steel crowns and/or extraction of primary molars).

Physiological parameters were recorded continuously (eg, oxygen saturation) or continually (eg, blood pressure), and a dental assistant recorded the values of each parameter and behavior throughout the procedure at each of 8 procedural events as follows:

1. preoperative vital signs;
2. begin (child placed on the papoose board and monitors placed along with nitrous oxide hood);
3. local anesthesia administered;
4. rubber dam placed and child allowed to “settle”;
5. start operative treatment;
6. 5 minutes into treatment;
7. 10 minutes into treatment;
8. treatment end.

Behavioral analysis

The child’s behavior was assessed using a modified version of the Ohio State University Behavior Rating Scale. The original involved 4 behavioral categories based on head or bodily movements, crying, and physical resistance. The categories are:

1. Q for quiet behavior, no movement;
2. C for crying with no struggling;
3. M for movement only, no crying;
4. S for crying and struggling exhibited simultaneously.

This scale and its application have been previously reported.[38,39] The movement category (M) was eliminated so as to avoid possible skewing of the data should the interpretation of the child moving be attributed solely to being restrained in a papoose board, rather than movement due to inadequate sedation. A modified OS was used as follows: (1) Q for quiet behaviors; (2) C for crying only; and (3) S for crying/struggling.

A trained assistant recorded both behavior and physiology. Behavior was recorded only at the time of the procedural event rather than a continuous videotaped recording, as with the original OS.

Statistical analysis

Correlational and descriptive statistics were used to describe the sample. A Kruskal Wallis and repeated-measures ANOVA were used to analyze over time the behavioral and physiological data, respectively. A chi-square analysis was used to determine any significant differences in the frequency of occurrences for the 3 behavioral categories as a function of drug group.

Results

The behavioral and physiologic data of 20 children were collected and studied. The mean age and weight (± SD) of the children were 46±9 months and 15.2±2.2 kg, respectively. There was no significant difference in mean age, weight, and NPO status as a function of visit or drug.

As a result of the Roche drug recall on oral syrup during the study, 14 patients received the oral syrup and 6 received the parenteral formula by mouth. No difference was noted between the oral vs parenteral formulation. Some expectoration of the medication occurred in 4 instances by 3 different patients. The estimated amount lost was minimal.

Hiccups were noted 5 times using midazolam and only once with the drug combination of midazolam and meperidine. The incidence of hiccups began shortly after administration, which either subsided during the 20-minute latency time or continued for several minutes after operative treatment began. One child vomited after treatment was completed with apparent food contents in the vomitus. Fourteen patients were restrained with the papoose board, at least for 1 of 2 visits. Five patients had the drugs administered by the assistant using a syringe.

Physiology

The mean systolic blood pressure, diastolic blood pressure, and heart rate as a function of visit, drug, and drug order are shown in Table 2. A repeated measures ANOVA indicated that there was no difference in physiology as a function of drug; however, there were significant changes in heart rate across time ($P<.001$). The observed trends for

Table 2. Mean Physiological Values of Heart Rate and Systolic and Diastolic Blood Pressure as a Function of the 8 Time Periods Studied

Physiology	Drug*		Time periods							
			Preop	Begin	Local	RD	Start	5 min	10 min	End
Heart rate	Mid	Mean	98	94	114	114	114	125	126	129
		±SD	17	15	19	24	34	28	35	26
	M+M	Mean	102	97	121	120	123	119	128	123
		±SD	17	17	24	29	30	31	35	20
Systolic	Mid	Mean	99	98	99	96	97	103	102	110
blood pressure		±SD	18	8	11	9	9	17	12	23
	M+M	Mean	100	103	100	106	102	99	107	106
		±SD	11	11	7	16	14	20	22	18
Diastolic	Mid	Mean	62	57	59	58	59	63	62	72
blood pressure		±SD	13	8	9	7	9	16	13	24
	M+M	Mean	65	61	62	68	63	62	67	64
		±SD	10	11	10	18	15	13	18	13

*Mid=midazolam; M+M=midazolam and meperidine.

both groups were that, as the operative phase progressed, the heart rate significantly increased. No patients required the use of a reversal agent.

Behavior

Like the physiological measures, a Kruskal Wallis indicated that there were no significant effects of drugs on the percentage of quiet vs crying and struggling behaviors. However, there was a change in behavior across time. Again, initially more quiet behaviors dominated until the injection and rubber dam phases and beyond, when increased frequencies of crying and struggling were noted (Figures 1 and 2). Finally, there was no significant difference noted in physiology or behavior as a function of order of visit.

Discussion

The results of this double-blind, randomized, crossover study indicated that there were no significant difference in physiology or behaviors as a function of drug groups. These findings are somewhat at odds with a very recent publication using the same drugs as those in this study. Nathan and Vargas,[36] in a retrospective study involving various dosage combinations of meperidine and midazolam, noted that the best behaviors were observed when the combination of meperidine and midazolam in 1 mg/kg dose for each were used.

Differences in the protocols and designs (ie, retrospective vs prospective) between the studies could account for the variance in outcome. For example, in their study, the dose of meperidine and midazolam producing the best outcome was higher than used in this study. This suggests that higher doses of these two agents used in combination may produce a sedation outcome more acceptable to the practitioner in terms of ease of delivery of operative treatment. It is not clear, however, what depth of sedation is achieved using the higher doses, and this study clearly showed that no child ever exceeded level II. Likewise, dif-

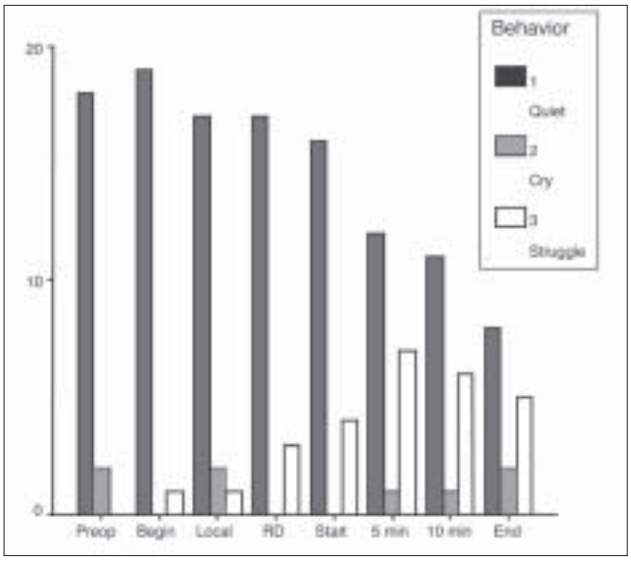

Figure 1. Behavior as a function of the 8 time periods for midazolam sedations.

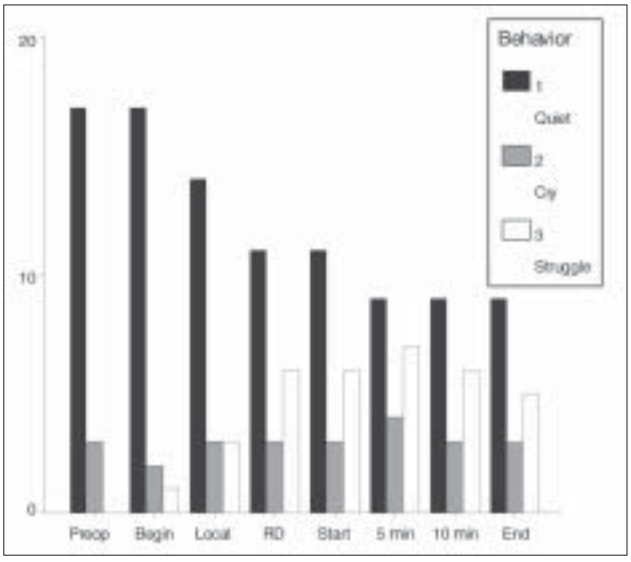

Figure 2. Behavior as a function of the 8 time periods for midazolam and meperidine sedations.

ferences in behavioral rating scales may have influenced the outcomes of the studies.

Physiology

As in many studies involving sedation, the physiological variables of heart rate and blood pressure in this study increased over time, beginning on average around the time of local anesthesia injection. There was no difference between drug groups on these variables, suggesting that the increases in heart rate and blood pressure were more a function of behavior associated with certain procedures.[4] The increase in struggling and crying behaviors noted in the later phases of treatment would normally be associated with increased heart rate in children. Furthermore, since the increases were noted in both drug groups and the difference was more notable in the midazolam+meperidine combination, it may be hypothesized that the doses used in this combination were insufficient to offset the patient's responses to dental procedures. Nathan and Vargas[36] reported less disruptive behaviors with higher doses of this combination supporting such a hypothesis.

Behavior

All proposed treatment was accomplished using either drug regimen. Although studies frequently report varying definitions of a sedation success, the authors did not specifically define one. Obviously the more crying and struggling a sedated child demonstrates, even while immobilized, the more difficult it becomes to perform dentistry in a comfortable setting, and the quality of the sedation may be judged as less desirable or successful.

The increase in disruptive behaviors during or after the injection of local anesthesia may be expected. It is not clear if significant interventions by the operator or a different operator would have altered the pattern of behaviors observed. For instance, strong voice control or suggestive statements at strategic stages of the procedures may have interacted differentially with the drug(s) used. The operator in this study tends to respond with less intense emotional overtones in behavior management techniques. Hence, the children may have reacted more from an internal focus rather than being guided more emphatically and externally by the operator. This possibility is conjecture and needs further study.

Other findings

Hiccups were observed infrequently and primarily when midazolam was used alone. Hiccups–the occurrence of which is reportedly more frequently than noted in this study–resulting from rectally administered midazolam has been reported and successfully treated with ethyl chloride sprayed intranasally.[42] However, inhalation of ethyl chloride should be avoided because of its potential to produce narcotic and general anesthetic effects, deep anesthesia, or fatal coma with respiratory or cardiac arrest.

Only 1 child vomited and apparently ate prior to being sedated as food contents were noted in vomitus. The child did not suffer any adverse events as a result of vomiting. Sedation guidelines and protocol were followed throughout the study, but this incidence serves as a reminder that parents are not always truthful in relating patient information.

Although desirable in a clinical research protocol, a negative control group (ie, placebo) was not included in the research design. The institutional review board deemed the use of a control or placebo group as inappropriate considering the entry criterion of determining that the children needed some form of sedation. Furthermore, in this study subjects served as thier own control in regard to the effect of meperidine.

Conclusions

The following conclusions can be derived from this study.

1. In the doses used and with 50% nitrous oxide/oxygen, midazolam alone was similar to the combination of midazolam and meperidine for sedation of preschool age children for dental care.
2. The behavioral patterns likely to occur with either regimen begin primarily with quiet behaviors followed by increases in disruptive behaviors, especially after the injection of local anesthesia.
3. Key physiological parameters in preschool children (ie, heart rate and blood pressure) are not clinically affected by the drug regimens per se, but increase and parallel the onset and duration of disruptive behaviors.

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Abstract of the Scientific Literature

Bracket Base Design and Bond Strength

Displacement of a bracket is a common problem during active orthodontic treatment. The bracket base-cement interface has been reported to be the weakest point in orthodontic bonding. The purposes of the present study were to compare shear bond strength (SBS) of 6 different types of stainless steel brackets and to compare the bond strength of reused sandblasted brackets with a new bracket under conditions simulating clinical use of those brackets. Two groups of 12 specimens of 6 types of metal brackets were bonded to bovine incisors with Transbond XT (3M Unitek) light-cured composite resin. The brackets used in this study were American Master Series (80-gauge, foil-mesh base), nickel-free brackets (injection molded, 100-gauge, microetched, foil-mesh base), Orthos Optimesh XRT/ORMCO (100-gauge, microetched, foil-mesh base), Ovation Roth/GAC (80-gauge layered into 150-gauge, microetched, foil-mesh base), Speed (60-gauge, microetched, foil-mesh base), and Time (machined, integral, microetched base with mechanical undercuts). Brackets were debonded in 1 hour or 24 hours, and the shear bond strength values were determined. Debonded brackets were sandblasted and assessed under the scanning electron microscope. After the teeth were cleaned, half were rebonded with the previously used sandblasted brackets, and the other half were bonded with new brackets. Bond strength was measured again after 1 hour or 24 hours. The results showed that the bond strength of brackets varied with base designs. Speed and Time brackets demonstrated the highest mean SBS values in the 1-hour period, which is followed by American Master Series, Ovation Roth/GAC, Orthos Optimesh XRT/ORMCO, and, lastly, the nickel-free brackets. The wider mesh of the Speed bracket and the open undercut configuration of the Time bracket allowed for more efficient and complete penetration of the cement. The results were similar in the 24-hour group, and, in general, bond strength for all 6 bracket types increased over time. As for rebonding, sandblasted reused brackets had significantly higher mean SBS values than those bonded brackets without sandblasting. Overall, the result of this study showed clinically acceptable bond strengths were achieved with Transbond XT cement, with the exception of nickel-free brackets.

Comments: Information about bond strength of various base designs tested allows an informed choice of brackets in clinical practice. Sandblasted brackets can be reliably reused. The study is well designed and provides scientific data that are important in treatment decisions. BL

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