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A comparison of chloral hydrate and diazepam sedation in young children

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Abstract

The purpose of this study was to compare a high and low dose of diazepam with chloral hydrate in the sedation of young children. Thirty healthy children between the ages of 20 and 48 months, with a mean age of 33.5 months, participated in the study. All children exhibited negative behavior during a screening visit and required at least two restorative appointments with the use of sedation. A dose of either 0.3 mg/kg or 0.6 mg/kg of diazepam at one visit and 50 mg/kg of chloral hydrate at another visit was administered in a double-blind manner. All children were restrained in a Papoose Board® with auxiliary head restraint and received 50% nitrous oxide/oxygen during treatment. The degree of sleep, body movement, crying, pulse rate, respiratory rate, and blood oxygen saturation were monitored before and during the operative procedures. Vital signs remained essentially unchanged during treatment, except for transitory elevations of the pulse during periods of stimulation. There were no statistically significant differences among the three drug regimens with regard to movement and crying. Significantly more patients who received chloral hydrate were asleep than when either dose of diazepam was given during the first 60 min of treatment. The only side effect found was vomiting in one patient with both chloral hydrate and diazepam. It is concluded that the sedative effects of chloral hydrate and diazepam are similar when young children are sedated for dental treatment. The use of diazepam might be more advantageous because chloral hydrate produces more sleep during the first hour of treatment.

Introduction

Sedation frequently is used when young children require extensive dental treatment and cannot be treated using ordinary behavior management techniques. Orally administered chloral hydrate often is used for this purpose because of its wide margin of safety and relatively few side effects (Robbins 1967; Barr et al. 1977; Smith 1979; Duncan et al. 1983; Moore et al. 1984; Houpt et al. 1985a; Houpt et al. 1985b; Houpt 1986; Houpt et al. 1986). Diazepam is a reliable agent for treating stress and anxiety in adults. The drug has a wide margin of safety with few side effects, and desirable anterograde amnesic properties have been reported (Healy and Hamilton 1971; Lundgen 1978; Flaitz et al. 1986). However, investigations into the use of diazepam as a sedative agent with pediatric dental patients are limited. Studies utilizing doses approximating 0.3 mg/kg diazepam have reported only fair sedative effects (Root and Loveland 1973; Auil 1983; Gallardo 1984), while a recent study (Koenigsberg 1988) demonstrated positive results with that dose supplemented with nitrous oxide. Higher doses were reported to give better sedative results with the very young dental patient (Lundgren et al. 1978; Flaitz and Nowak 1985).

The purpose of this study was to examine the sedative effects of 0.3 and 0.6 mg/kg diazepam and compare diazepam to oral chloral hydrate together with 50% nitrous oxide/oxygen when young children are sedated for dental treatment.

Methods

1. Subjects

Thirty subjects between the ages of 20 and 48 months, with a mean age of 33.5 months, participated in this study. They weighed between 24.5 and 41 pounds, with a mean weight of 31.5 pounds. All participants were in good health and required at least two restorative treatment sessions. The patients required sedation for treatment because of a "definitely negative" rating according to the Frankl rating scale (Frankl et al. 1962).

2. Procedure

The subjects were assigned randomly to receive either 50 mg/kg chloral hydrate (Noctec—E.R. Squibb and Company, Princeton, NJ) or diazepam (Diazepam Oral Solution—Roxanne Laboratories Inc., Columbus, Ohio) at either 0.3 mg/kg or 0.6 mg/kg for the first visit, with the alternative drug regimen administered at the second appointment. In addition, all patients received inhalation 50% nitrous oxide/oxygen and were restrained in a Papoose Board (Olympic Medical Group, Seattle, Washington) with head restraint during treatment.

Initial vital signs were taken by the operator, and behavior was evaluated. The medication was offered in a plastic cup to the patient by a member of the research team other than the operator or the independent evaluator in order to ensure that both were blind to the treatment regimen. If the child refused to drink, the medication was administered via a needleless syringe to the back of the patient's mouth. Of the 60 administrations, 39 were via cup and 21 were via syringe. The subjects were without liquids or solids for at least 4 hr prior to medication administration.

Following drug administration, the child remained with the parent in a quiet, darkened room. After 45 min, the child was carried into the operatory and placed in the Papoose Board with head restraint. Fifty per cent nitrous oxide/oxygen then was administered, and treatment was rendered by one of the two operators. Vital signs were monitored continuously with a precordial stethoscope, a nasal respiration monitor (Trimed Incorporated, Bellevue, Washington), and a finger pulse oximeter (Nellcor Incorporated, Hayward, California), and were recorded every 15 min.

3. Evaluation

Each patient was evaluated by one of two independent observers for the degree of sleep, body movement, crying and overall behavior, as well as for vital signs before, during, and after the operative procedures. In the operatory, ratings were made during insertion of the mouth prop, injection of local anesthesia, rubber dam placement, and at 15-min intervals during treatment (Tables 1, 2, and 3). In addition, an overall evaluation was made of the child's behavior at the completion of the operative procedures (Table 4). One third of the time, behavior was recorded and videotaped in order to verify the reliability of the rating scales which had been established previously (Houpt et al. 1986).

4. Data Analysis

The study was designed so that each patient served as his/her own control, with time of day, operator, and type of procedure being relatively constant between the two treatment visits. Findings for movement, crying, sleep, and overall behavior were analyzed for statistically significant differences among the three treatment groups. Since the rating scales used the ordinal scale of measurement with related samples, the nonparametric Wilcoxon matched-pairs signed-rank test was used at the 95% level of significance. In addition, the Chi-Square

Table 1. Rating Scale for Sleep

	Score
Fully awake, alert	1
Drowsy, disoriented	2
Asleep	3

Table 2. Rating Scale for Movement

	Score
Violent movement that interrupts treatment	1
Continuous movement that makes treatment difficult	2
Controllable movement that does not interfere with treatment	3
No movement	4

Table 3. Rating Scale for Crying

	Score
Hysterical crying that interrupts treatment	1
Continuous, persistent crying that makes treatment difficult	2
Intermittent, mild crying that does not interfere with treatment	3
No crying	4

Table 4. Rating Scale for Overall Behavior

	Score
Aborted – no treatment rendered	1
Poor – treatment interrupted, only partial treatment completed	2
Fair – treatment interrupted but eventually all completed	3
Good – difficult, but all treatment performed	4
Very Good – some limited crying or movement, e.g. during anesthesia or mouth prop intersertion	5
Excellent – no crying or movement	6

analysis was used at the 95% level for comparison of the overall effectiveness of the drug regimens.

Results

1. Rater Reliability

When ratings made in the operatory were compared with consensus ratings made by the two evaluators from videotape recordings six months later, 212 ratings were identical, 48 differed by one scale point, and 10 differed by two scale points. The 79% agreement among the sets of ratings demonstrated reasonable reliability of the rating scales.

2. Onset of Sleep

Nineteen patients (63%) who received chloral hydrate were asleep at the end of the 45 min pretreatment period, whereas only two patients (13%) who received 0.3 mg/kg diazepam were asleep after this period of time. These patients remained quiet when they were carried into the operatory and placed in the Papoose Board. No patients who received 0.6 mg/kg diazepam were asleep at the end of the 45 min waiting period.

3. Evaluation of Movement

The mean ratings for movement for each drug group appear in Table 5, and Fig 1 (next page). The results indicate that while there was some limited movement with all drug groups, no statistically significant differences among drug groups were evident.

4. Evaluation of Crying

The mean ratings for crying for each drug group appear in Table 6, and Fig 2 (next page). The results indicate that there was some minimal or moderate crying with all three regimens but no statistically significant differences among drug groups. The greatest amount of crying was observed during local anesthesia injection and application of the rubber dam. The frequency of crying decreased with time, corresponding to an increased frequency of sleep.

5. Evaluation of Sleep

The mean ratings for sleep for each drug group appear in Table 7, and Fig 3 (next page). When the Wilcoxon test was used to compare chloral hydrate with each diazepam group, the results demonstrated statistically significant differences at mouth prop insertion (0.3 diazepam: T = 0 for 11 differences; 0.6 diazepam: T = 3.5 for 8 differences), administration of local anesthesia (0.3 diazepam: T = 0 for 12 differences; 0.6 diazepam: T = 3 for 8 differences), and rubber dam application (0.3 diazepam: T = 0 for 1 difference; 0.6 diazepam: T = 3 for 8 differences). Statistically significant differences were noted between chloral hydrate and 0.3 diazepam during the 60-min interval (T = 0 for 10 differences) and the 75-min interval (T = 0 for 7 differences).

6. Overall Evaluation

At the conclusion of treatment each administration was evaluated for overall effectiveness. Analysis using the Wilcoxon matched-pairs sign-ranks test showed no statistically significant differences when the sedation effectiveness of all first visits was compared to all second visits (T = 75 for 15 differences). Similarly, no statistically significant differences were found between any of the three drug regimens (0.3 diazepam: T = 20 for 8 differences; 0.6 diazepam: T = 8 for 12 differences).

If the data for overall evaluation is dichotomized to represent success or failure of the sedative technique, success could be defined to include the ratings "excellent" and "very good". Fourteen of the 30 administrations of chloral hydrate (46.6%) were rated as "excel-

TABLE 5. Overall Means for Movement

Drug Regimen (mg/kg)	*Mouth Prop*	*Local Anesthesia*	*Rubber Dam*	*60 Min.*	*75 Min.*	*90 Min.*	*105 Min.*
50 CH	3.6	3.1	2.8	3.0	3.5	3.6	3.3
0.3 DZ	3.7	3.3	3.3	3.4	3.8	3.7	3.4
0.6 DZ	3.3	3.0	3.1	3.3	3.7	3.6	3.6

TABLE 6. Overall Means for Crying

Drug Regimen (mg/kg)	*Mouth Prop*	*Local Anesthesia*	*Rubber Dam*	*60 Min.*	*75 Min.*	*90 Min.*	*105 Min.*
50 CH	3.4	2.5	2.4	2.9	3.4	3.4	3.3
0.3 DZ	3.0	2.3	2.3	2.6	3.3	3.2	2.8
0.6 DZ	3.2	2.6	2.3	2.9	3.6	3.4	3.4

TABLE 7. Overall Means for Sleep

Drug Regimen (mg/kg)	*Mouth Prop*	*Local Anesthesia*	*Rubber Dam*	*60 Min.*	*75 Min.*	*90 Min.*	*105 Min.*
50 CH	1.6	1.9	1.9	2.1	2.6	2.7	2.4
0.3 DZ	1.2*	1.2*	1.2*	1.5*	2.2*	2.3	2.1
0.6 DZ	1.3*	1.3*	1.3*	1.8	2.5	2.7	2.5

CH = Chloral Hydrate.
DZ = Diazepam.
* = Significant difference @ $P < .05$ using Wilcoxon matched-pairs signed-rank test.

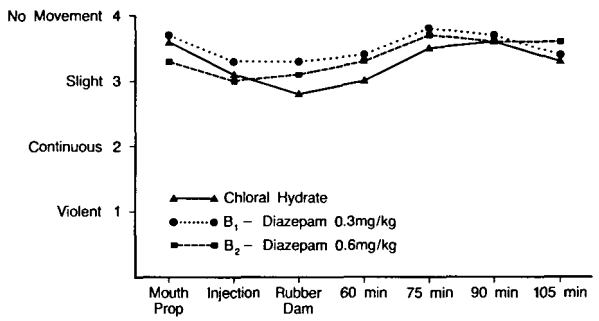

Fig 1. Evaluation of movement.

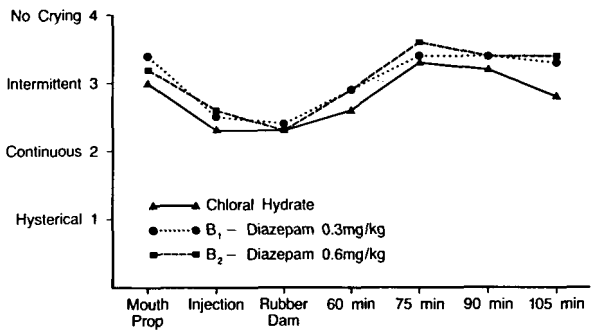

Fig 2. Evaluation of crying.

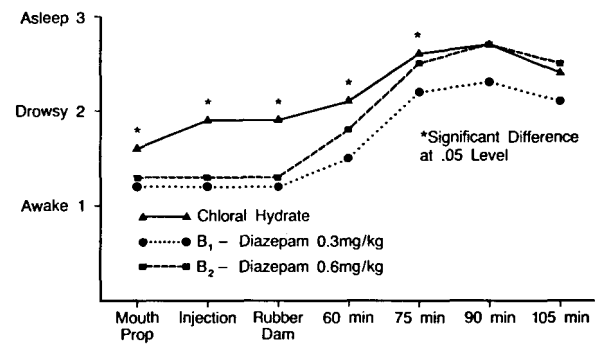

Fig 3. Evaluation of sleep.

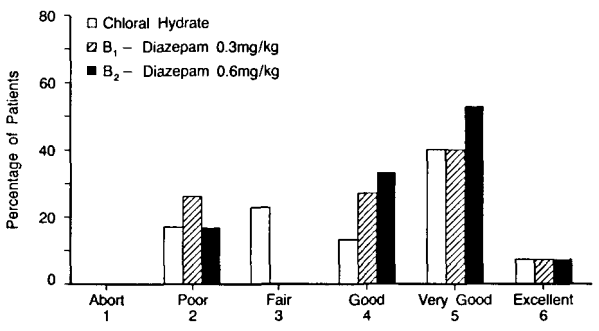

Fig 4. Overall evaluation of sedation.

lent" or "very good." With diazepam, seven of the 15 administrations of 0.3 mg/kg (46.6%) and nine of the 15 administrations of 0.6 mg/kg (60%) were rated as "excellent" or "very good" (Fig 4). These results demonstrate no statistically significant difference in overall effectiveness if success of sedation is defined to include only these two ratings (Chi-Square = 2.21; df = 2).

If sedation is considered successful, even if there is some movement or crying but treatment is completed without interruption, then the rating of "good" also is included. The 0.6 mg/kg dose of diazepam then would be found to be significantly more effective than chloral hydrate (Chi-Square = 7.37; df = 2). Ninety-three per cent of the 0.6 mg/kg diazepam sedations and 73% of the 0.3 mg/kg diazepam sedations were rated as "good," "very good", or "excellent" compared with only 60% of the chloral hydrate sedations which were rated similarly.

7. Vital Signs

In general, vital signs remained stable throughout the treatment procedures. Pulse rate became elevated during periods of stimulation from a baseline mean of 103 to a mean of 134 with insertion of the mouth prop, a mean of 154 with injection of local anesthesia, and a mean of 155 with placement of the rubber dam. In all cases the pulse returned to normal when the adverse stimulus ended.

There were 16 instances of decreases in the oxygen saturation levels as indicated on the pulse oximeter. Twelve decreases occurred during periods of movement and were interpreted as artifact due to sampling probe movement. Four decreases were found in one patient with both chloral hydrate and diazepam sedation. These decreases did not occur during periods of movement, and when the mandible was raised the oxygen saturation quickly returned to normal.

8. Adverse Effects

Vomiting occurred with one administration of chloral hydrate on four separate occasions (interval 75, 105, 120, and 135 min). There also was one occurrence of vomiting in the same patient after administration of 0.6 mg/kg of diazepam at the 75-min interval. The emesis was suctioned from the mouth and no complications resulted.

Discussion

The results of this study demonstrate that diazepam is a safe and effective agent when used to sedate young children for dental treatment. Diazepam appears to be a

more useful agent than chloral hydrate because similar sedation effect is produced without as much sleep. If the patient is awake during treatment, it is much easier to monitor the depth of sedation and differentiate conscious sedation from deep sedation.

In this study there was little movement in the presence of crying, and this might be attributed to the use of the Papoose Board with head restraint, which restricts movement. The Papoose Board also facilitates the delivery of nitrous oxide by keeping the nasal hood in place over the nose, thereby augmenting the supplemental nitrous oxide effect.

The finding of little difference between the two doses of diazepam was surprising, although it was similar to the finding of Koenigsberg (1988). The lack of difference might be due to the use of the supplemental nitrous oxide which was used in both studies. Additional research should be performed with diazepam to examine its effect without supplemental nitrous oxide. In addition, the potential anterograde amnesic effects of the drug should be studied.

Conclusion

We conclude that the sedative effects of diazepam are similar to chloral hydrate when young children are sedated for dental treatment. The use of diazepam might be more advantageous, because chloral hydrate produces more sleep during the first hour of treatment.

At the time of writing, Dr. Badalaty was a clinical assistant professor. Dr. Badalaty is now in the private practice of pediatric dentistry in Ocean Township, New Jersey; Dr. Houpt is a professor and chairman; Dr. Koenigsberg is an associate professor, department of pediatric dentistry and community health; Dr. DesJardins is an associate professor, department of oral pathology, biology and diagnostic services; all are at the University of Medicine and Dentistry of New Jersey, New Jersey Dental School. Dr. Maxwell is a commander in the U.S.N.D.C., Tokosuka, Japan. Reprint requests should be sent to: Dr. Milton Houpt, dept. of pediatric dentistry, University of Medicine and Dentistry of New Jersey, 110 Bergen St., Newark, NJ 07103-2425.

Auil B, Cornejo G, Gallardo F: Flunitrazepam and diazepam compared as sedatives in children. ASDC J Dent Child 50:442-44, 1983.

Barr ES, Wynn RL, Spedding RH: Oral premedication for the problem child: placebo and chloral hydrate. J Pedod 1:272-80, 1977.

Duncan WK, Ashrafi MH, Pruhs RJ, Post AC: Chloral hydrate and other drugs used in sedating young children: a survey of American Academy of Pedodontic Diplomates. Pediatr Dent 5:252-56, 1983.

Flaitz C, Nowak A: Evaluation of the sedative effect of rectally administered diazepam for the young dental patient. Pediatr Dent 7:292-96, 1985.

Flaitz C, Nowak A, Hicks MJ: Evaluation of the anterograde amnesic effect of rectally administered diazepam in the sedated dental patient. ASDC J Dent Child 53:17-20, 1986.

Frankl S, Shiere F, Fogels H: Should the parent remain with the child in the dental operatory? ASDC J Dent Child 29:150-63, 1962.

Gallardo F, Cornejo G, Auil B: Premedication with flunitrazepam, diazepam and placebo in the apprehensive child. ASDC J Dent Child 51:208-10, 1984.

Healy T, Hamilton M: Intravenous diazepam in the apprehensive child Br Dent J 130:25-27, 1971.

Houpt MI, Koenigsberg SR, Weiss NJ, DesJardins PJ: Comparison of chloral hydrate with and without promethazine in the sedation of the young child. Pediatr Dent 7:41-46, 1985a.

Houpt MI, Sheskin RB, Koenigsberg SR, DesJardins PJ, Shey Z: Assessing chloral hydrate dosage for young children. ASDC J Dent Child 52:364-69, 1985b.

Houpt MI: Pharmacological methods and research issues in the management of child patients. Anesth Prog 33:25-29, 1986.

Houpt MI, Rosivack G, Rozenfarb N, Koenigsberg SR: Effects of nitrous oxide on chloral hydrate sedation of young children. Anesth Prog 33:209-302, 1986.

Koenigsberg SR, Guelmann M, Shapira J, Kagan A, Holon G: Assessing diazepam sedation in children. J Dent Res 67:128, 1988.

Lundgren S, Ekman A, Blomback U: Rectal administration of diazepam in solution. Swed Dent J 2:161-66, 1978.

Moore PA, Mickey EA, Hargreaves JA, Needleman HL: Sedation in pediatric dentistry: a practical assessment procedure. J Am Dent Assoc 109:564-69, 1984.

Robbins MD: Chloral hydrate and promethazine as premedicants for the apprehensive child. ASDC J Dent Child 34:327-31, 1967.

Root B, Loveland JL: Pediatric premedication with diazepam or hydroxyzine: oral versus intramuscular route. Anesth Analg 52:717-23, 1973.

Smith RC: Chloral hydrate sedation for handicapped children: a double blind study. Anesth Prog 24:159-68, 1979.