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Effects of chloral hydrate on nitrous oxide sedation of children

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Abstract

This study was conducted to examine the effects of chloral hydrate on nitrous oxide sedation of young children for dental treatment. Nineteen children, ranging in age from 19 to 41 months (mean 30 months), participated in this double-blind study. The subjects were assigned randomly to receive either a placebo or chloral hydrate (50 mg/kg) for the first visit with the alternate regimen administered during the second appointment. In addition, all subjects received inhalation nitrous oxide/oxygen at a concentration of 50%, and were restrained in a Papoose® board (Olympic Medical Group; Seattle, WA) with head restraint. Seventy-four per cent of sedations were classified as very good or excellent when chloral hydrate was administered with nitrous oxide compared with only 26% when the placebo was administered.

Sedation is used frequently when comprehensive treatment is performed for very young children. Orally administered chloral hydrate is used because of its wide margin of safety and relatively few adverse effects (Robbins 1967; Barr and Wynn 1977; Judisch 1980; Duncan et al. 1983; Moody et al. 1986). Many practitioners supplement the use of chloral hydrate with inhalation nitrous oxide (Houpt 1986); however, there has been little research to substantiate the effects of the administration of both drugs compared with the use of nitrous oxide alone. In an earlier study, the effects of nitrous oxide on chloral hydrate sedation were examined (Houpt et al. 1986). This study was conducted to examine the converse, that is, the effects of chloral hydrate when nitrous oxide is used to sedate young children for dental treatment.

Method

Nineteen children ranging in age from 19 to 41 months (mean age 30 months) participated in this double-blind study. Requirements for participation were that the child be in good health and require 2 restorative dentistry appointments with the use of sedation. The subjects were randomly assigned to receive either a placebo or chloral hydrate (Noctec®—ER Squibb and Co; Princeton, NJ) administered orally at the standard dosage of 50 mg/kg (Physicians' Desk Reference 1985) for the first visit, with the alternate regimen administered during the second appointment. Consequently, a cross-over design was used with each subject serving as its own control and the 19 subjects participated in 38 treatment sessions. In addition, all subjects received inhalation nitrous oxide/oxygen at a concentration of 50%, and they were all restrained in a Papoose® board with head restraint.

Subjects were NPO for at least 6 hr and, following their arrival, the vital signs and behavior were evaluated. Chloral hydrate or the placebo was administered and in 27 cases the child was coaxed into drinking the solution. In the remaining 11, the solution was administered with a syringe to the back of the throat. Dosages of chloral hydrate ranged from 525 to 955 mg with a mean of 701 mg. The child then remained with the parent for 45 min during which time the onset of sleep was checked every 5 min.

The degree of sleep, body movement, crying, blood pressure, pulse, and respiration rate were evaluated before, during, and after operative procedures (Tables 1-4).

TABLE 1. Rating Scale for Sleep

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

In the operatory, pulse and blood oxygen saturation levels, were monitored with a pulse oximeter (Nellcor Inc; Hayward, CA) with a probe clamped to the child's toe. Respiration was monitored with a respiration monitor (TriMed 510 — Trimed Inc; Bellevue, WA) connected to a nasal respiration probe inserted in the nitrous oxide nasal hood.

TABLE 2. Rating Scale for Movement

No movement	−4
Movement that does not interfere with treatment	−3
Movement making treatment difficult	−2
Movement interrupting treatment	−1

TABLE 4. Rating Scale for Overall Behavior

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

The experiment was designed so that each subject served as its own control with time of day, operator, and type of procedure being relatively constant between the treatment visits. Both operators and the evaluator were blind to the drug regimens used and a fourth individual dispensed the drug to the patient. The independent variable in the study was the use of chloral hydrate and the dependent variable was the effectiveness of sedation.

Results

The results of the study are described with regard to evaluation of movement, crying, sleep, overall effectiveness of sedation, vital signs, and adverse effects.

Evaluation of Movement

The summary of ratings of movement for all subjects is illustrated in Figure 1. In most instances, subjects exhibited no movement or minimum controllable movement that did not interfere with the procedure. Illustrated in Figure 1 are the means of scores assigned to all patients when the mouth prop was placed, local anesthesia administered, rubber dam inserted, and at

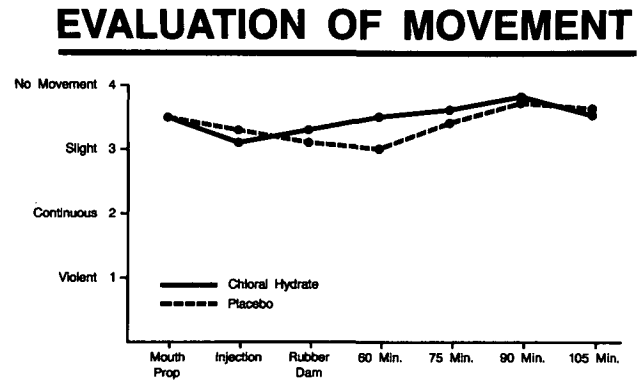

FIG 1. Evaluation of movement.

TABLE 3. Rating Scale for Crying

No crying	−4
Intermittent mild crying	−3
Continuous persistent crying	−2
Hysterical crying	−1

15-min intervals beginning with 60 min after administration of the drug until the end of treatment. When scores for the 2 treatment regimens were compared, the Wilcoxon matched pairs signed-ranks test was used to test for statistically significant differences at the 95% level of probability. In regard to ratings of movement, there were no statistically significant differences between the scores with the exception of the 60-min time period when subjects receiving chloral hydrate moved slightly less than those receiving the placebo ($P < .05$, T = 7 for 10 differences).

Evaluation of Crying

Figure 2 shows the summary of ratings of crying for all subjects. Most subjects exhibited either no crying, intermittent mild crying, or continuous persistent crying. This figure demonstrates that subjects receiving chloral hydrate cried significantly less than subjects

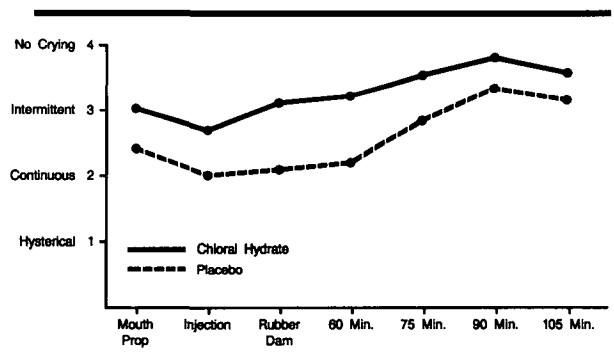

FIG 2. Evaluation of crying.

receiving the placebo, when the mouth prop was inserted ($P < .05$, T = 12 for 15 differences), the rubber dam applied ($P < .05$, T = 0 for 13 differences), and at the 60-min time period ($P < .05$, T = 4.5 for 14 differences). At later time periods, however, there were no statistically significant differences between the groups. These findings illustrate the beneficial effects of chloral hydrate with the relatively uncomfortable procedures at the start of treatment. Subjects who cried continuously tended to tire themselves by 75 min, and they cried less thereafter. This resulted in no differences between the 2 groups at later time periods.

Evaluation of Sleep

In regard to onset of sleep, 16 (84%) patients

receiving chloral hydrate were asleep or drowsy at the end of the 45-min waiting period compared with only 1 patient (5%) receiving the placebo. The remaining subjects were awake when brought into the operatory. Figure 3 shows the summary of ratings of sleep for all subjects. Most of the time subjects receiving chloral hydrate were asleep or drowsy, whereas with the placebo they were awake. Statistically significant differences between groups were evident at all time periods up to 90 min following drug administration demonstrating the effect of chloral hydrate in regard to sleep ($P < .05$, T = 0, 0, 0, 0, and 6 for 12, 18, 18, 14, and 10 differences, respectively).

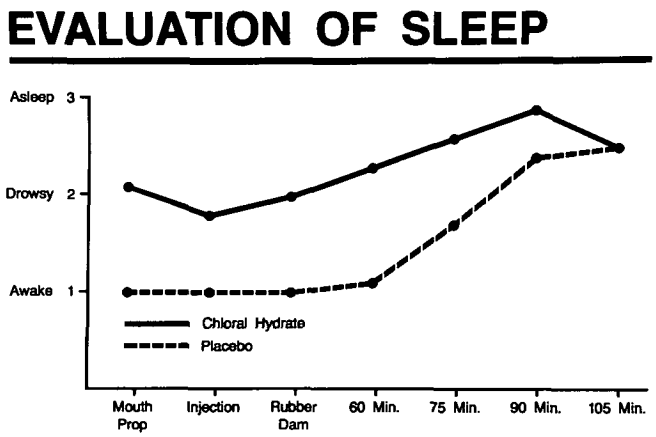

FIG 3. Evaluation of sleep.

Overall Evaluations

At the conclusion of each treatment session, an overall evaluation was made; these scores are illustrated in Figure 4. If success of sedation is operationally defined as providing a patient with little or no crying or movement during treatment, then the chloral hydrate was found to be more effective than the placebo ($P < .05$, T = 13 for 15 differences). Fourteen (74%) chloral hydrate administrations were rated as very good or excellent, whereas only 6 (32%) placebo administrations were rated equally good. If success of sedation is defined to include those instances in which crying and movement occurred but treatment was completed with no interruption, then success is increased to 84% with chloral hydrate and 63% with the placebo.

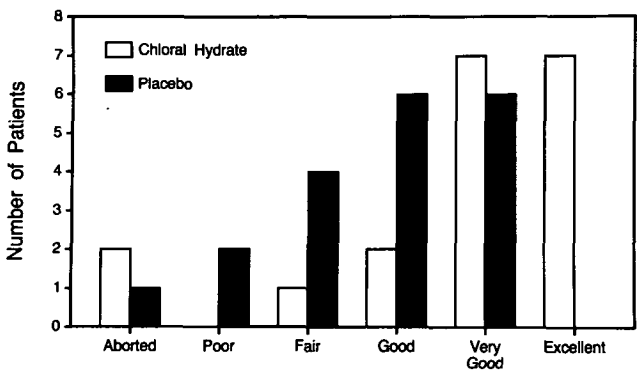

FIG 4. Overall evaluation of sedation.

Another method to examine the data for overall evaluation is presented in Table 5. For each subject, the overall ratings are shown together with the difference between the 2 regimens, i.e., whether subjects were better with chloral hydrate (+), better with the placebo (-), or the same with both regimens (0). The mean evaluation with chloral hydrate was 4.7 corresponding to a rating of between good and very good, compared with 3.7 for the placebo representing a rating between fair and good. It is interesting to note that although 12 subjects were better with the chloral hydrate, 5 subjects showed no difference, and 2 subjects were even better with the placebo.

Vital Signs

In regard to the vital signs, changes occurred with pulse and respiratory rates throughout the procedures. Pulse rate exhibited transitory, although dramatic, increases which were linked to specific events when the child was stimulated. For example, the pulse spiked on occasion when the mouth prop was inserted or when the rubber dam was being applied, however, the increase in pulse rate was transitory and quickly returned to normal when the stimulus ended. These changes appeared more frequently when the child was in a light level of sedation and similar changes occurred with the rate of respiration. In 8 instances, the blood oxygen saturation level dropped below (90%) for a few minutes. This was often associated with periods of crying and movement, and it was interpreted as artifact due to movement of the sampling probe. However, on one occasion, the drop occurred when the child slept after 20 min of strong crying. Since all other signs indicated adequate oxygenation, and the level returned to normal after 1 min, the cause of the drop was unexplained.

Adverse Effects

One patient receiving chloral hydrate experienced a transitory obstruction of the upper airway that was corrected effectively by elevating the mandible. In 3 instances (2 with chloral hydrate and 1 with the placebo), there was a small amount of vomiting which occurred during treatment.

TABLE 5. Overall Evaluation by Subject

Subject	*Chloral Hydrate*	*Placebo*	*Difference Between Chloral Hydrate/Placebo*
1	5	5	0
2	6	4	+
3	6	4	+
4	5	3	+
5	1	3	−
6	6	4	+
7	5	5	0
8	6	4	+
9	6	4	+
10	5	2	+
11	1	2	−
12	5	5	0
13	3	1	+
14	6	5	+
15	6	5	+
16	4	4	0
17	4	3	+
18	5	3	+
19	5	5	0
	$\bar{X} = 4.7$	$\bar{X} = 3.7$	

+ = 12 subjects better with chloral hydrate.

− = 2 subjects better with placebo.

0 = 5 subjects no difference between drug regimens.

Discussion

The results of this study indicate that chloral hydrate significantly augments the effects of nitrous oxide when young children are sedated for dental treatment. These findings are not surprising in that it would be expected that subjects would cry less and more likely sleep if they would be sedated with the chloral hydrate. The lack of difference in ratings of movement was due to the degree of restraint provided by the Papoose board with head holder, that is, the degree of restraint seemed to be great enough to prevent most movement even if the child attempted to move. Although the chloral hydrate improved the effect of the nitrous oxide sedation, it did not do so uniformly with all subjects. This finding similarly occurred in a study of nitrous oxide sedation by Houpt et al. (1986). It appears that nitrous oxide and chloral hydrate will sedate most children most of the time. Nevertheless, practitioners should note that this combination is not effective for all children all of the time. Furthermore, these agents are used to produce conscious sedation, not general anesthesia, and some limited amount of crying should be expected when young children are sedated for dental treatment.

Conclusion

It may be concluded from this study that in regard to the control of behavior, chloral hydrate augments the effects of nitrous oxide sedation frequently but not uniformly in young patients.

This clinical research project was conducted in accordance with the American Academy of Pediatric Dentistry *Guidelines for Conscious Sedation.*

Dr. Houpt is a professor and chairman, and at the time of the study Drs. Manetas and Joshi were postgraduate students, pediatric dentistry, and Dr. Desjardins is an associate professor, biodental sciences, University of Medicine and Dentistry of New Jersey. Currently, Dr. Manetas is in the private practice of pediatric dentistry in Athens, Greece, and Dr. Joshi is in the private practice of pediatric dentistry in Moncton, New Brunswick, Canada. Reprint requests should be sent to: Dr. Milton I. Houpt, Dept. of Pediatric Dentistry, New Jersey Dental School, 110 Bergen St., Newark, NJ 07103-2425.

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