Comparison of a chloral hydrate/hydroxyzine combination with and without meperidine in the sedation of pediatric dental patients

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Abstract

The purpose of this study was to compare the effectiveness of a chloral hydrate/hydroxyzine combination with and without meperidine in the sedation of pediatric dental patients. Twenty children were given 40 mg/kg chloral hydrate and 25 mg hydroxyzine, and 20 children were given 40 mg/kg chloral hydrate and 25 mg hydroxyzine and 0.5 mg/kg meperidine. All children were between the ages of 24 and 60 months and all medications were given orally 1 hr before treatment. The children received 50% nitrous oxide for the entire procedure. All children were restrained in a Papoose Board®. The patients were videotaped and their behavior was rated by two independent pediatric dentists using the Houpt Scale. The independent evaluators did not know which sedation regimen had been used. They rated success of the sedations by degree of sleep, crying, body movements, and overall behavior. Oxygen saturation of arterial blood, and heart rate also were measured. The vital signs were consistent for the two groups. There was no significant difference in the effectiveness of the two drug regimens.

Introduction

Sedation regimens to provide dental treatment are being used as a viable practice alternative to general anesthesia. Sedatives can be administered orally, intramuscularly, intravenously, rectally, or subcutaneously. The oral route usually is preferred by most practitioners due to the ease of administration.

Chloral hydrate in combination with hydroxyzine was used most often, according to a 1983 survey of Diplomates of the American Academy of Pediatric Dentistry (Duncan et al. 1983). Chloral hydrate and hydroxyzine can have unpredictable sedation results. The manufacturer of chloral hydrate (ER Squibb and Sons, Inc.) has recommended a hypnotic dose of 50 mg/ kg up to a maximum of 1000 mg per single dose, while Mueller et al. (1985) have suggested using a higher dose of 100 mg/kg. Malamed (1989) has stated the dose of chloral hydrate may range from 500 to 2000 mg with the usual range between 750 and 1000 mg.

The safety of any sedative for premedication is the primary concern of practitioners who treat young patients. The most often reported side effects of chloral hydrate are nausea and vomiting. Chloral hydrate has CNS-depressant actions and its margin of error is too narrow with larger doses. In small doses (25 mg/kg), chloral hydrate results in very mild sedation. In intermediate doses, it acts as a soporific and produces calm, natural sleep. In higher doses its produces general anesthesia (Troutman 1988). Jastak and Pallasch (1988) stated that chloral hydrate in large doses is believed to be safe and to shorten the cardiac refractory period, depress myocardial contractility, and sensitize the myocardium to circulating catecholamines. The usual features of toxicity are deep stupor, marked vasodilation, low blood pressure, a decrease in body temperature, slow respiration, and cyanosis. Pinpoint pupils may be seen. Death results from respiratory depression and cardiac failure (Troutman 1988). There is no antagonist currently available that can reverse adverse side effects of chloral hydrate (Jastak and Pallasch 1988).

Hydroxyzine is an antihistamine with sedative and antiemetic properties. It has been used in conjunction with chloral hydrate to reduce the incidence of nausea and vomiting. There is no respiratory depression when used in the recommended doses (25–50 mg), and there are no known side effects (Jastak and Pallasch 1988).

Meperidine is a narcotic commonly used to elevate the pain threshold. The sedative action of meperidine is potentiated by other drugs and depending on the drug, the action is either synergistic or additive in its effect. Therefore, lower doses for multiple sedative drug regimens usually are recommended (Aubuchon 1982). In therapeutic doses (0.25–0.5 mg/kg), there is little effect on the cardiovascular system. However, respiration can be depressed before a toxic dose is reached. Meperidine can be reversed with Narcan® (Du Pont Pharmaceuti-

cals, Inc., Manati, Puerto Rico, .01 mg/kg up to a maximum of .4 mg IM or IV). The dose of Narcan should be repeated every 2–3 min until there is a response (Malamed 1989). The most frequently reported side effects are light headedness, dizziness, nausea, and vomiting. These side effects may be reduced if the patient is placed in the supine position (Physicians' Desk Reference 1989). Meperidine should not be used in patients taking monoamine oxidase inhibitors and in patients with acute asthmatic conditions. If liver disease is present, the response of meperidine may be exaggerated and the recovery prolonged. Meperidine should be used with caution in those patients with seizure disorders since it may precipitate convulsions (Jastak and Pallasch 1988). Nathan and West (1987) have suggested doses between 50–70 mg/kg for chloral hydrate and 20–30 mg/kg for meperidine if they are used together. The purpose of this study was to compare the effectiveness of a chloral hydrate/hydroxyzine combination with and without meperidine using nitrous oxide in the sedation of pediatric dental patients.

Materials and Methods

Twenty patients, age 24 to 60 months, with a mean age of 42 months, were administered 40 mg/kg chloral hydrate (Noctec® — ER Squibb and Sons, Inc., Princeton, NJ) and 25 mg hydroxyzine (Vistaril® — Pfizer, New York, NY). Twenty patients, ages 24 to 60 months, with a mean age of 38.2 months, were administered 40 mg/kg chloral hydrate, 25 mg hydroxyzine and 0.5 mg/kg meperidine (Demerol® — Winthrop/Breon, New York, NY). Only patients with an ASA I classification and uncooperative behavior during their initial visit were selected. The uncooperative behavior included crying, hitting, spitting, and inability to hold still.

Parents or guardians of all subjects completed a consent form and were given preoperative instructions before the sedation appointment. An explanation of the study was given and any questions were answered.

The medications were given orally by the operating dentist 1 hr before the dental treatment. All children had taken nothing by mouth (NPO) at least 6 hr before their morning appointment.

The child was placed in a Papoose Board® (Olympic Medical Corp., Seattle, WA) without an auxiliary head restraint and monitored with a precordial stethoscope. The Papoose Board was used to restrain all patients, even well-sedated patients, for their safety as well as the operator's safety. Oxygen saturation of the arterial blood and heart rate were recorded using a Nellcor® pulse oximeter (Nellcor Co., Hayward, CA). Patients were administered 50% nitrous oxide-oxygen during the entire procedure.

The procedure was videotaped from the time the child was seated until the procedure was completed and the child was aroused and removed from the chair. The success of the sedation was assessed independently by two pediatric dentists who were not operators in the study and who were blind to the drug given. They rated the success of the procedure using a scale developed by Houpt et al. (1985). The scale rates the degrees of sleep, crying, movement, and overall behavior (Table 1). A score for each category was determined after reviewing the sedation in its entirety. The responses from the two evaluators were averaged.

Results

The data were analyzed by using a parametric analysis of variance with a significant level set at .05. The tabulated F ratio of 2.9 or greater is the value for which the analysis of the data proves statistically significant. This method was selected because of the ordinal nature of the data.

A correlation of the two evaluators' scoring was performed. The correlation coefficient between evaluators for the category of sleep was .4. For the other three categories — movement, crying, and overall behavior

TABLE 1. Rating Scales for Sleep, Crying, Movement, and Behavior

	Rating Scale for Sleep
4	Awake and responsive
3	Drowsy, disoriented
2	Asleep but easily aroused
1	Asleep and difficult to arouse
	Rating Scale for Crying
4	No crying
3	Intermittent crying
2	Continuous persistent crying
1	Hysterical crying
	Rating Scale for Movement
4	No movement
3	Intermittent movement that did not interfere with treatment
2	Continuous movement making treatment difficult
1	Violent movement interrupting or preventing treatment
	Rating Scale for Overall Behavior
6	Excellent — no disruption
5	Very good — limited disruption, but treatment completed without difficulty
4	Good — some difficulty, but all treatment performed
3	Fair — treatment interrupted but eventually completed with difficulty
2	Poor — treatment interrupted and only partially completed
1	Aborted — no treatment completed

TABLE 2. Frequency of Mean Responses by Evaluators for Sleep, Crying, Movement, and Behavior

Sleep Response	C	M	Crying Response	C	M	Movement Response	C	M	Behavior Response	C	M
1	00	00	1	00	00	1	00	00	1	00	00
1.5	00	00	1.5	10	05	1.5	05	05	1.5	10	00
2	20	15	2	10	05	2	20	10	2	05	10
2.5	15	20	2.5	25	05	2.5	10	05	2.5	00	00
3	10	20	3	25	30	3	35	25	3	10	00
3.5	20	20	3.5	05	25	3.5	10	10	3.5	05	05
4	35	25	4	25	30	4	20	45	4.0	05	05
									4.5	20	10
									5	15	25
									5.5	15	15
									6	15	30

C: Percentage of responses for chloral hydrate/hydroxyzine subjects.
M: Percentage of responses for chloral hydrate/hydroxyzine/meperidine subjects.

— the correlation was .8.

Ratings for Sleep

Forty-five per cent of the ratings for sleep for the chloral hydrate/ hydroxyzine group and 55% of the CH/H/M group scored either a two or three, which corresponds to asleep but easily aroused or drowsy and disoriented on the rating scale. An additional 35% in the CH/H group and 25% in the CH/H/M group scored a four, which corresponds to awake and responsive (Table 2).

The mean score for sleep for the CH/H group was 3.2 and the mean for the CH/H/M was 3.1 (Table 3).

An analysis of variance was performed between the two subject groups testing for a significant difference in effectiveness between the drug regimens used. The results were not statistically significant (Table 3).

Ratings for Crying

Fifty-five per cent of the CH/H subjects and 85% of the CH/H/M subjects scored a three or four, which corresponds to intermittent or no crying on the rating scale (Table 2).

The mean score for crying for the CH/H group was 2.9 and for the CH/H/M group was 3.3 (Table 4).

An analysis of variance was not statistically significant between the two drug regimens (Table 4).

Ratings for Movement

Sixty-five per cent of the CH/H group and 80% of the CH/H/M group scored either a three or four for movement which corresponds to intermittent or no movement (Table 2).

The mean score for movement for the CH/H group was 2.9, and for the CH/H/M group was 3.2 (Table 5).

An analysis of variance was not statistically significant between the two drug regimens (Table 5).

TABLE 3. Mean Scores for Sleep for the Two Subject Groups and Analysis of Variance Test

Drug	Mean	STD Error
Chloral hydrate/hydroxyzine	3.175	.1699
With meperidine	3.100	.1699

ANOVA

Source	N	DF	F Ratio	Prob >F	Sig.
Drug	1	1	0.0974	0.7566	N.S.

TABLE 4. Mean Scores for Crying for the Two Subject Groups and Analysis of Variance Test

Drug	Mean	STD Error
Chloral hydrate/hydroxyzine	2.900	.1876
With meperidine	3.325	.1876

ANOVA

Source	N	DF	F Ratio	Prob >F	Sig.
Drug	1	1	1.7932	0.1184	N.S.

TABLE 5. Mean Scores for Movement for the Two Subject Groups and Analysis of Variance Test

Drug	Mean	STD Error
Chloral hydrate/hydroxyzine	2.925	.1683
With meperidine	3.250	.1683

ANOVA

Source	N	DF	F Ratio	Prob >F	Sig.
Drug	1	1	1.8750	0.1794	N.S.

TABLE 6. Mean Scores for Behavior for the Two Subject Groups and Analysis of Variance Test

Drug	Mean	STD Error
Chloral hydrate/hydroxyzine	4.300	.3032
With meperidine	5.000	.3032

ANOVA

Source	N	DF	F Ratio	Prob >F	Sig.
Drug	1	1	2.5707	0.1176	N.S.

Ratings for Overall Behavior

Seventy per cent of the CH/H subjects and 85% of the CH/H/M subjects scored a four or higher for overall behavior (Table 2).

The mean rating for overall behavior for the CH/H group was 4.3 and for the CH/H/M group was 5.0 (Table 6).

An analysis of variance was not statistically significant between the two drug regimens (Table 6).

Ratings for Heart Rate and Oxygen Saturation

Using the pulse oximeter, heart rate and oxygen saturation was recorded for all of the subjects. The mean heart rate for the CH/H group was 116.8 and for the CH/H/M group was 107.9 (Table 7).

An analysis of variance was not statistically significant for heart rate between the two drug regimens (Table 7).

The mean transcutaneous oxygen saturation of the arterial blood for the CH/H group was 98.7 and 98.6 for the CH/H/M group (Table 8).

An analysis of variance was not statistically significant for oxygen saturation between the two groups (Table 8).

Discussion

The subjective ratings used to assess sedation success for patients given CH/H and those given CH/H/M indicate that these regimens are similarly effective. The fact that there was no statistical difference in heart rate or oxygen saturation between the two groups gives credence to the subjective scoring system.

The interevaluator reliability was low for sleep due to a misunderstanding by one of the evaluators on how to make that assessment. He used only two of the four rating scales of sleep, thus dichotomizing his data. This accounted for the low correlation.

For future studies, the researchers may want to consider having evaluators rate the sedation during specific points in the procedure (i.e., injection, rubber dam placement, during restorative procedures). This would better reflect the efficacy of the premedicant during maximum stimulation of the patient. Perhaps the operating dentist also could rate the sedation and a correlation could be done between that score and those of the independent evaluators.

The independent evaluators rated 70% of the CH/H and 85% of the CH/H/M subjects as having good or better overall behavior. The subjective ratings used to evaluate the sedations indicate that both drug regimens were effective. In this study, chloral hydrate/hydroxyzine was shown to be a safe and effective method of premedication when used in low doses, as well as in conjunction with meperidine.

Conclusion

Based on the subjective evaluation of the effectiveness of sedation and the physiologic data provided by the pulse oximeter, it can be concluded that chloral hydrate 40 mg/kg with hydroxyzine 25 mg and 50% nitrous oxide-oxygen are as effective a sedative agent as

TABLE 7. Mean Scores for Heart Rate for the Two Subject Groups and Analysis of Variance Test

Drug			Mean	STD Error
Chloral hydrate/hydroxyzine			116.85	4.6767
With meperidine			107.95	4.6767
ANOVA				

Source	N	DF	F Ratio	Prob > F	Sig.
Drug	1	1	1.5159	0.2262	N.S.

TABLE 8. Mean Scores for Oxygen Saturation for the Two Subject Groups and Analysis of Variance Test

Drug			Mean	STD Error
Chloral hydrate/hydroxyzine			98.75	.2493
With meperidine			98.60	.2493
ANOVA				

Source	N	DF	F Ratio	Prob > F	Sig.
Drug	1	1	0.1859	0.6689	N.S.

chloral hydrate 40 mg/kg, hydroxyzine 25 mg and meperidine 0.5 mg/kg and 50% nitrous oxide-oxygen.

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