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The American Academy of Pediatric Dentistry
Volume 7 Number 1

Comparison of chloral hydrate with and without promethazine in the sedation of young children

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Abstract

This study was performed to compare the effectiveness of chloral hydrate with and without promethazine when young children were sedated for dental treatment. Twenty-one children, participated in the study ranging in age from 15 to 45 months with a mean age of 32 months. Subjects were assigned randomly to receive either 75 mg/kg of chloral hydrate alone or 50 mg/kg together with 25 mg of promethazine; alternate regimens were administered at two appointments. (Eight children requiring three visits received 50 mg/kg chloral hydrate without promethazine at one visit. All children received 50% nitrous oxide and were restrained in a Papoose Board® with head holder. The degree of sleep, crying, body movements, blood pressure, pulse, respiration rate and pupil size were evaluated before, during, and after operative procedures. Successful sedation, as evidenced by lack of crying and/or movement which interrupted treatment, was found in 89% of the children administered chloral hydrate and promethazine compared with 72% adminstered chloral hydrate alone. Vital signs remained essentially unchanged throughout all treatments. The only adverse side effect noted was vomiting in 14% of the administrations with promethazine and 48% without.

Sedation is recommended frequently when extensive dental treatment is performed for young children. Chloral hydrate is used commonly because of its wide margin of safety and relatively few adverse side effects.[1] Numerous investigators have used different dosage regimens determined by behavior, age, or weight;[2-7] however, varying degrees of success were obtained. Some practitioners administer promethazine together with chloral hydrate to augment the sedation effect and lessen the vomiting which may occur with chloral hydrate alone.[1,8] Sim[9] reported that chloral hydrate effectiveness would be increased if supplemented with nitrous oxide.

This study compares chloral hydrate effectiveness with and without promethzine together with nitrous oxide when young children are sedated for dental treatment.

Method

Subjects

Twenty-one children participated in the study,ranging in age from 15 to 45 months with a mean age of 32 months. The children were all in good health, had no previous dental experience, and were selected because they required restorative dental treatment with the use of sedation in at least two appointments.

Medication

At the first appointment, subjects randomly were assigned to receive either 75 mg/kg of chloral hydrate alone (Noctec[a]) or 50 mg/kg of chloral hydrate together with 25 mg of promethazine (Phenergan Fortis[b]); at the second appointment the alternate regimen was administered. Eight children requiring three visits received 50 mg/kg chloral hydrate without promethazine during one of the three visits. In addition, all children received 50% nitrous oxide/oxygen analgesia and were restrained in a Papoose Board®[c] with head holder. The chloral hydrate was drawn into a disposable syringe covered with tape to prevent the

[a] Noctec-Squibb Co.: Princeton, NJ.
[b] Phenergan Fortis, Wyeth Laboratories: Philadelphia, PA.
[c] Papoose Board — Olympic Medical Group: Seattle, WA.

operator from knowing the amount of medication being given.

Vital signs were recorded and behavior was evaluated by the operator. The child then was restrained with his head tilted back over the lap of the seated operator and his arms held by a parent. The medication was deposited in the back of the mouth in amounts which allowed swallowing and prevented spitting. The solution was squirted slowly, to avoid aspiration, and administration took approximately .5 min. The dosages of chloral hydrate ranged from 570 mg to 1535 mg with a mean of 736 mg for those receiving 50 mg/kg; and a mean of 1104 mg for those receiving 75 mg/kg. The amount of promethazine was fixed at 25 mg.

Subjects were treated consistently either during the morning or early afternoon so that treatment time was constant for each subject. Similar types of treatment were planned for each of the treatment visits. Subjects were NPO 6 hr before the appointment.

Following drug administration, the child remained with the parent in a quiet area separated from the operatory for 45 min; behavior and onset of sleep (defined as closure of the eyes and lack of visible movement) were evaluated. The child then was carried to the operatory and placed in a Papoose Board® without auxiliary head restraint. A precordial stethoscope, abdominal pneumatic belt, sphygmomanometer cuff, and finger pulse transducer were attached and then the nitrous oxide was administered.

Evaluation

The degree of sleep, body movement, crying, blood pressure, pulse, respiration rate, and pupil size were evaluated before, during, and after the operative procedures. In the operatory, ratings were made during mouth prop insertion, administration of the local anesthesia, and every 15 min thereafter. Vital signs were recorded with the Beckman[d] R511A polygraph unit. Rating scales were used to evaluate degree of sleep, body movements, and crying (Tables 1, 2, 3).

In addition, at the conclusion of each session, an overall evaluation of the child's behavior was made according to a separate rating scale. (Table 4). These ratings were performed by the principal investigator (MH) who was blind to the medication given during the procedure. One month later, a consensus rating was made by two investigators (MH and SK) from video-tapes of the procedures to establish the reliability of the rating scales.

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 interrupting treatment	—	1
Continuous movement making 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 demands attention	—	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

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 insertion	—	5
Excellent — no crying or movement	—	6

Data Analysis

The experiment was designed so that each subject could serve as his own control with time of day, operator, and type of procedure being relatively constant. The independent variable was the drug regimen, that is, dose of chloral hydrate with and without pro-

[d] Beckman Instruments: Somerset, NJ.

methazine. The dependent variable was the effectiveness of sedation as measured by the degree of crying and movement which interfered with treatment. Since the rating scales used the ordinal scale of measurement with related samples, the nonparametric Friedman two-way analysis of variance by ranks was used to compare the groups for statistically significant differences.

Results

Rater Reliability

When the ratings of crying and movement made in the operatory were compared with the consensus ratings of the two raters made one month later from videotapes of the procedures, there was 90% agreement between sets of ratings.

Onset of Sleep

There was no significant difference in the onset of sleep between the groups receiving different drug regimens. Seventeen of the 21 patients who received the 75 mg chloral hydrate without promethazine and 16 of the 21 patients who received the medication with promethazine fell asleep in the reception area, that is, within 45 min of receiving the chloral hydrate. Four of the 8 patients who received the 50 mg/kg chloral hydrate alone fell asleep in the reception area. Consequently, 13 patients, or 26% of the total, were fully awake when brought into the operatory.

Evaluation of Movement

The summary of ratings of movement for all subjects in the operatory is illustrated in Table 5. In most instances, subjects exhibited no movement or minimum controllable movement which interfered with the procedure. In some instances movement was continuous making treatment difficult. Violent movement which interrupted treatment occurred less than 1% of the time. The averages of the mean ratings indicated that patients in the three drug groups moved little, if at all (mean ratings for drug groups 1, 2, and 3 = 3.59, 3.50, and 3.55, respectively). There were no statistically significant differences between the groups when tested with the Friedman two-way analysis of variance by rank at the .05 level of significance ($df = 2$, $F = 0.95$).

Evaluation of Crying

Table 6 illustrates the summary of ratings of crying for all subjects in the operatory. Most subjects did not cry or cried mildly and intermittently and did not interfere with the procedure. Continuous, persistent crying making treatment difficult was infrequent (10% of the time) and rarely was there hysterical crying that demanded the operator's attention (less than 1% of the time). The averages of the mean ratings over all the time periods for the three drug groups were 3.53, 3.58, and 3.29. These were not statistically significantly different at the .05 level of significance ($df = 2$, $F = 0.25$).

Evaluation of Sleep

In most instances, all subjects were asleep during the seven periods of evaluation. However, subjects were drowsy and disoriented 15% of the time, and subjects were fully awake 10% of the time. Subjects who were awake most frequently were awake in the first 15 min in the operatory. There were no statistically significant differences between the various drug groups at any single time period and no differences in the averages of the mean ratings over all time periods ($df = 2$, $F = 1.65$).

Overall Evaluation

The summary of the overall evaluations for all subjects is illustrated in Table 7. Most subjects experienced either excellent or very good effects of the sedation. The overall evaluation was only good 20% of the time (i.e., the behavior was difficult, but all treatment was performed), and the effect of the sedation was only fair 16% of the time (i.e., treatment had to be interrupted although it eventually was completed). The mean ratings for drug regimens 1, 2, and 3 were 4.71, 4.76, and 4.63, respectively, and there were no statistically significant differences between groups as indicated by the Friedman analysis ($df = 2$, $F = 0.71$). Of those receiving the promethazine, 90% had an overall evaluation of good or better as compared with 80% and 75% of those receiving either the higher or lower dose of chloral hydrate alone.

Vital Signs

There were few changes in the vital signs throughout the procedure. Blood pressure remained unchanged and pulse rate exhibited a transitory increase linked to specific occurrences when the child was either awake or in a very light plane of sleep. For example, it occasionally increased when the mouth prop was inserted, when the rubber dam was being applied, or during periods of vomiting. This increase was only transitory and quickly returned to normal when the stimulus ended. These changes did not occur more frequently with any particular drug regimen.

Respiratory rate changes occurred in approximately 10% of the subjects at some time during their procedures. These changes were similar to the changes in pulse rate occurring at a time of a particular stimulus. Constriction of the pupils was found to be related to the patient's degree of sleep, in that when the patient was asleep, the pupils were constricted

Table 5. Summary of Ratings of Movement for All Subjects

Time	Regimen	1 Violent Movement	2 Continuous Movement	3 Controllable Movement	4 No Movement	Mean** Rating
During mouth prop insertion	I		1 (5)*	6 (29)	14 (67)	3.62
	II	1 (5)	3 (14)	8 (38)	9 (43)	3.19
	III		1 (13)		7 (88)	3.75
During injection	I			8 (38)	13 (62)	3.62
	II	1 (5)	3 (14)	3 (14)	14 (67)	3.43
	III		1 (13)		7 (88)	3.75
60 minutes post-administration	I	1 (5)	1 (5)	4 (19)	15 (71)	3.57
	II		3 (14)	5 (24)	13 (62)	3.48
	III	1 (13)		3 (38)	7 (88)	3.25
75 minutes post-administration	I	1 (5)	2 (10)	3 (14)	15 (71)	3.52
	II		2 (10)	3 (14)	16 (76)	3.67
	III	1 (13)		1 (13)	6 (75)	3.50
90 minutes post-administration	I		1 (5)	5 (24)	15 (71)	3.67
	II		1 (5)	4 (19)	16 (76)	3.71
	III	1 (13)		2 (25)	5 (63)	3.38
105 minutes post-administration	I	1 (5)	1 (5)	4 (19)	15 (71)	3.57
	II		1 (5)	10 (48)	10 (48)	3.38
	III		2 (25)		6 (75)	3.50
120 minutes post-administration	I	1 (5)	1 (5)	4 (19)	15 (71)	3.57
	II			8 (38)	13 (62)	3.62
	III		1 (13)		7 (88)	3.75
		Pooled Rating *** I 3.59; II 3.50; III 3.55				

* Number of subjects receiving this rating, bracketed number = percentage of total (may not equal 100 per cent due to rounding). **Mean rating over all subjects. ***Pooled rating of all subjects over all times.

Regimen I: 75 mg/kg chloral hydrate; Regimen II: 50 mg/kg chloral hydrate with 25 mg promethazine; Regimen III: 50 mg/kg chloral hydrate.

with little reaction to light. However, if the patient was awake, the pupils were normal and reactive to light. Rarely, a patient became excited and the pupils were dilated and reactive to light. These changes in pupil size were similar to those observed in an unsedated child during sleep.[10]

Adverse Effects

The most frequently occurring adverse effect was vomiting. It occurred in 48% and 38% of the patients receiving the high and low doses of chloral hydrate alone compared with only 14% of those receiving chloral hydrate with promethazine. This difference was statistically significant at the .05 level of significance when tested with the chi-square analysis. Spitting up the medication immediately after administration occurred approximately 20% of the time with drug regimens 1 and 2, but did not occur with drug regimen 3. Three patients became febrile some hours after returning home; in two the fever was only transitory and the third developed a bad cold and was ill for a few days. One other patient (who withdrew from the study after the first treatment session) developed petechiae on her forehead and the upper part of her face during drug administration due to screaming and the degree of restraint necessary. No other symptoms became evident and the petechiae disappeared the following day.

Most practitioners who sedate children for dental procedures monitor the depth of sedation by observing chest movement in accordance with the child's respiration. In this study, respiration was monitored with one sensor attached to the chest to monitor chest movements and a second sensor attached to the inhalation unit to monitor gas exchange. The monitor on the inhalation unit was used to detect possible obstructions which would restrict respiration. Because both monitoring methods were used, an incidental finding was observed — gas exchange was reduced although chest movements continued unchanged (Fig 1). This occurred when the mandible inadvertently was depressed and a transitory partial blockage of the airway was produced (for example, when a stainless steel crown was being fitted or when the mouth prop was inserted). Figure 1 illustrates

Table 6. Summary of Ratings of Crying for all Subjects

Time	Regimen	1 Hysterical Crying	2 Continuous Crying	3 Intermittent Crying	4 No Crying	Mean** Rating
During mouth prop insertion	I		1 (5)*	6 (29)	14 (67)	3.62
	II	1 (5)	4 (19)	5 (24)	11 (52)	3.24
	III	1 (13)		2 (25)	5 (63)	3.38
During injection	I		1 (5)	9 (43)	11 (52)	3.48
	II		5 (24)	4 (19)	12 (57)	3.33
	III	1 (13)		1 (13)	6 (75)	3.50
60 minutes post-administration	I	1 (5)		5 (24)	15 (71)	3.62
	II		5 (24)	2 (10)	14 (67)	3.43
	III	2 (25)	1 (13)	1 (13)	4 (50)	2.88
75 minutes post-administration	I		3 (14)	3 (14)	15 (71)	3.57
	II	1 (5)	1 (5)	4 (19)	15 (71)	3.57
	III	2 (25)			6 (75)	3.25
90 minutes post-administration	I		2 (10)	8 (38)	11 (52)	3.43
	II		3 (14)	2 (10)	16 (76)	3.62
	III	1 (13)		3 (38)	4 (50)	3.25
105 minutes post-administration	I		2 (10)	5 (24)	14 (67)	3.57
	II		1 (5)	8 (38)	12 (57)	3.52
	III	1 (13)		3 (38)	4 (50)	3.25
120 minutes post-administration	I	1 (5)	2 (10)	5 (24)	13 (62)	3.43
	II		2 (10)	4 (19)	15 (71)	3.62
	III	1 (13)		1 (13)	6 (75)	3.50
Pooled Rating *** I 3.53; II 3.48; III 3.29						

* Number of subjects receiving this rating, bracketed number = percentage of total (may not equal 100 per cent due to rounding). **Mean rating over all subjects. ***Pooled rating of all subjects over all times.

Regimen I: 75 mg/kg chloral hydrate; Regimen II: 50 mg/kg chloral hydrate with 25 mg promethazine; Regimen III: 50 mg/kg chloral hydrate.

Table 7. Summary of Ratings of Overall Behavior for All Subjects

Regimen	1 Aborted	2 Poor	3 Fair	4 Good	5 Very Good	6 Excellent	Mean** Rating
I			4 (19)*	2 (10)	11 (52)	4 (19)	4.71
II			2 (10)	6 (29)	8 (38)	5 (24)	4.76
III			2 (25)	2 (25)	1 (13)	3 (38)	4.63

* Number of subjects receiving this rating. **Mean rating over all subjects.

Number in brackets = percent of total (may not equal 100 per cent due to rounding).

Regimen I: 75 mg/kg chloral hydrate; Regimen II: 50 mg/kg chloral hydrate with 25 mg promethazine; Regimen III: 50 mg/kg chloral hydrate.

that chest movements continued although there was reduced air exchange.

Discussion

The results of this study indicate that there was no significant difference between 75 mg/kg of chloral hydrate and 50 mg/kg of chloral hydrate with 25 mg of promethazine when supplemented with 50% nitrous oxide in the degree of sedation. Of the sedations with the first regimen, 80% were judged as good or better, as compared with 90% of the sedations with the second regimen. A dosage of 50 mg/kg of chloral hydrate alone produced similar effectiveness, i.e., 75% of the sedations were judged as good or better, although the small number of subjects with this regimen makes

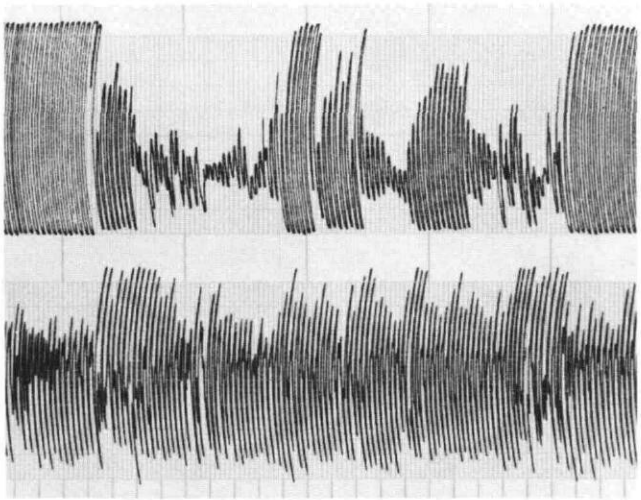

Fig 1. Sample recording to monitor respiration of patient. The lower sample recorded chest movements, whereas the upper sample monitored gas flow through the airway. Note that when there was partial airway blockage with decrease in gas flow, the record of chest movements continued with similar amplitude and frequency.

a comparison to the other regimens somewhat inappropriate. The use of promethazine significantly decreased vomiting and, consequently, it is recommended whenever chloral hydrate is used to sedate young children for dental treatment.

These results were somewhat better than those obtained by Sheskin in a similar study of chloral hydrate without promethazine. However, in that study, the auxiliary head restraint connected to the Papoose Board® was not used, and this might have accounted for the lack of effectiveness of the sedation due to movement of the child. It would appear that there is a distinct advantage in using the head restraint rather than the Papoose Board® alone. The head restraint not only prevents some undesirable movement, but it also facilitates the delivery of nitrous oxide by keeping the nasal hood directly over the nose.

Nitrous oxide was used in this study because of its current use in pediatric dentistry. A uniform concentration of 50% nitrous oxide was used with all patients in order to keep the nitrous oxide concentration constant; it is possible that a lower concentration would have reduced the frequency of vomiting. It is also possible that with a lower concentration — or with no nitrous oxide — greater differences in effectiveness of the various drug regimens would have become evident. Additional study of the drug regimens without nitrous oxide should be performed.

The incidental finding of partial blockage of the airway during treatment was important. Although the clinical significance of transitory reduction in the respiration is not known, it should be assumed that children who are sedated for dental treatment must be monitored carefully in order to detect airway blockage. Further study should investigate the implications of such transitory obstruction of the airway.

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Quotable quote: the boss is to blame

The cause for a breakdown in communication between two subordinates because of a feud can generally be laid at the boss's door, reports Theodore Caplow in his book *Managing an Organization*. Often, the people who refuse to communicate have substantial differences of interest imposed on them by their positions. Neither one can give in without jeopardizing his or her own interests. This situation often happens because the boss failed to specify which path to follow.

Leadership update. Elected Leader, Fall, 1984.