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Comparison of triazolam to a chloral hydrate/hydroxyzine combination in the sedation of pediatric dental patients

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Abstract

The purpose of this study was to compare the effectiveness of triazolam to chloral hydrate with hydroxyzine when sedating young children for dental treatment. Twenty children, age 21 to 74 months, with a mean age of 44 months, were given triazolam. Twenty children, age 23 to 64 months, with a mean age of 42 months, were given chloral hydrate with hydroxyzine. The children were given an elixir of either .02 mg/kg triazolam or 40 mg/kg chloral hydrate with 25 mg hydroxyzine. All subjects received 50% nitrous oxide and were restrained with a Papoose Board®. The sedations were videotaped and evaluated by two pediatric dentists not involved in the study. They rated the success of the sedations by degree of sleep, crying, body movements, and overall behavior. Time until onset of action of the agents given, oxygen saturation of arterial blood, and heart rate were measured. The vital signs were consistent for the two groups. There was no statistical difference in the effectiveness of sedation between the two groups.

Introduction

The use of various sedation regimens to provide dental treatment for the fearful, immature, or otherwise unmanageable child is widespread in pediatric dentistry. A survey of the Diplomates of the American Academy of Pediatric Dentistry in 1983 revealed that 75% used sedatives. The agent used most widely was chloral hydrate (62%), either alone or in combination with other drugs. The comedicant used most often with chloral hydrate was hydroxyzine, an antihistamine with sedative and antiemetic properties (Duncan et al. 1983).

Chloral hydrate's disadvantages are poor taste, unpredictable sedation results, nausea and vomiting, and prolonged postoperative drowsiness (Malamed 1989). These disadvantages have led practitioners to consider other agents. This study was undertaken to investigate a possible alternative sedation regimen.

Triazolam, trade name Halcion® (The Upjohn Co., Kalamazoo, MI), is a potent, short-acting benzodiazepine sedative hypnotic, which has been used routinely by the medical community to treat insomnia and as a premedicant for general anesthesia (Smith et al. 1986). There is little evidence in the dental literature of its use in sedating uncooperative pediatric patients. In addition to its sedative properties, triazolam has anticonvulsant, muscle relaxant, and amnesic effects. It is well absorbed orally, with an absorption half-life of 13.3 min. Because of triazolam's high lipid solubility, it is readily absorbed by the central nervous system. Triazolam reaches a peak plasma concentration at 1.25 hr and an elimination half-life of 2.3 hr (Eberts et al. 1981). The most common side effects are drowsiness, dizziness, and headache. No adverse drug interactions have been reported. Triazolam has a low level of toxicity and is a safe sedative agent (Pakes et al. 1981). Because of its nature, this drug would seem to lend itself to use in pediatric dentistry for the behavior management of difficult patients. The purpose of this study was to compare the effectiveness of triazolam to chloral hydrate with hydroxyzine when sedating young children for dental treatment.

Materials and Methods

Twenty children, age 21 to 74 months with a mean age of 44 months, were given triazolam. Twenty children, age 23 to 64 months with a mean age of 42 months, were given chloral hydrate (Noctec® — E.R. Squibb and Sons, Inc., Princeton, NJ) and hydroxyzine (Vistaril® — Pfizer, New York, NY). These patients were selected because of their uncooperative behavior during their initial dental visit. Only patients with an ASA I classification were utilized. A comprehensive medical history and physical exam were completed before the child was selected as a participant in the study.

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.

On the day of the appointment, the patient presented to the clinic NPO for a minimum of 6 hr. There was a random administration of either an elixir of. 02 mg/kg triazolam or 40 mg/kg chloral hydrate combined with 25 mg hydroxyzine. This was administered orally by the operating dentist who was not blind to the drug. If the patient needed a second sedation, the alternate regimen was used.

The patient was brought to the operatory when sombulant, or 1 hr after premedicant administration, whichever came first. The child was placed in a Papoose Board® (Olympic Medical Corp., Seattle, WA) without an auxiliary head restraint and monitored with a precordial stethoscope. Transcutaneous oxygen saturation of the arterial blood and heart rate were recorded using a Nellcor® pulse oximeter (Nellcor Co., Hayward, CA). A video recording of the procedure was made from the time the child was seated until the procedure was completed and the child was aroused and removed from the chair.

Fifty per cent nitrous oxide-oxygen was administered during the entire procedure. The local anesthetic was 2% Xylocaine® with 1:100,000 epinephrine. A quadrant of restorative dentistry was performed. This procedure ranged from 30 to 90 min. After the dental procedure the nitrous oxide apparatus was flushed and 100% oxygen was given for 5 min. The patient was aroused and returned to the parent or guardian. Patients were dismissed from the clinic when they were awake and responsive, which was usually within 30 min of the completion of the dental procedure for both drug regimens.

The videotapes were reviewed 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 sedations using the scale developed by Houpt et. al. (1985a), measuring degree of sleep, crying, body movements, and overall behavior. The evaluators arrived at a score for each category after reviewing the sedation in its entirety (Table 1).

TABLE 1. Rating Scales for Sleep, Movement, Crying, 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 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 Crying
4	No crying
3	Intermittent crying
2	Continuous persistent crying
1	Hysterical crying
	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

Results

The resulting data were analyzed using an analysis of variance with a significance 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. An analysis of variance was used so that multiple effects could be evaluated at the same time. Due to the averaging of responses from the two evaluators, and the central limit theorem, the responses approached a normal distribution so an analysis of variance could be used. The elapsed time from premedicant administration to start of the procedure was recorded as the time of onset of action of the sedative agent. The range was 20-75 min for both drug regimens with an average of 39 min for Halcion and 63 min for chloral hydrate. The drug effects on sleep, crying, body movements, and overall behavior were also analyzed using a Chi-square goodness of fit test; results similar to the analysis of variance were obtained.

A correlation of the scoring by the two evaluators was performed. The correlation coefficient between evaluators for the category of sleep was .4. For the other three categories — movement, crying, and overall behavior — the correlation was .8.

Ratings for Sleep

Sixty-five per cent of the ratings for sleep for both the chloral hydrate and Halcion groups were a 3 or higher, which corresponds to drowsy and disoriented or awake and responsive on the rating scale (Table 2).

The mean score for sleep for the chloral hydrate group was 3.2 and the mean for the Halcion group was 3.6 (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. Also, the difference in ages between the two groups and the

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

Sleep			*Movement*			*Crying*			*Behavior*		
Response	*C*	*T*	*Response*	*C*	*T*	*Response*	*C*	*T*	*Response*	*C*	*T*
1	00	00	1	00	05	1	00	00	1	00	05
1.5	00	15	1.5	05	10	1.5	10	15	1.5	10	00
2	20	15	2	20	05	2	10	10	2	05	05
2.5	15	05	2.5	10	05	2.5	25	00	2.5	00	05
3	10	65	3	35	55	3	25	45	3	10	05
3.5	20	00	3.5	10	10	3.5	05	15	3.5	05	15
4	30	00	4	20	10	4	25	15	4	05	05
									4.5	20	10
									5	15	25
									5.5	15	10
									6	15	15

C: Percentage of responses for chloral hydrate and hydroxyzine subjects.

T: Percentage of responses for triazolam subjects.

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

Drug			*Mean*		*STD Error*
Chloral hydrate			3.225		.2363
Triazolam			3.600		.2363
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	1.7784	.1907	N.S.
Age	1	1	.0314	.8605	N.S.
Time	1	1	.2806	.5996	N.S.

difference in the time of onset of action of the two drugs was tested to see if they had an impact on the effectiveness of either drug regimen used. The results were not statistically significant (Table 3).

Ratings for Movement

Thirty-five per cent of the chloral hydrate subjects and 55% of the Halcion group scored a 3 for movement. This was the most frequent response for both groups (Table 2).

Table 4. Mean Scores for Movement for the Two Subject Groups and Analysis of Variance Test

Drug			*Mean*		*STD Error*
Chloral hydrate			2.925		.2345
Triazolam			2.825		.2345
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	1.3412	.2545	N.S.
Age	1	1	2.1248	.1536	N.S.
Time	1	1	1.0540	.3114	N.S.

The mean score for movement for the chloral hydrate group was 2.9, and was 2.8 for the Halcion subjects (Table 4).

An analysis of variance was not statistically significant for movement between the groups dependent on drug type, age, or time of onset of action of the drug (Table 4).

Ratings for Crying

Twenty-five per cent of the chloral hydrate subjects scored a 3 or a 4 for crying and 45% of the Halcion group scored a 3 (Table 2).

The mean score for crying for both groups was 2.9 (Table 5). An analysis of variance was not statistically significant for crying between the groups dependent on drug type, age, or time of onset of action of the drug (Table 5).

Table 5. Mean Scores for Crying for the Two Subject Groups and Analysis of Variance Test

Drug			*Mean*		*STD Error*
Chloral hydrate			2.900		.2477
Triazolam			2.900		.2477
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	.0400	.8427	N.S.
Age	1	1	2.2916	.1388	N.S.
Time	1	1	.1432	.7074	N.S.

Ratings for Overall Behavior

Seventy per cent of the chloral hydrate subjects scored a 4 or higher for overall behavior and 65% of the Halcion subjects also scored 4 or higher (Table 2).

The mean rating for overall behavior for both groups was 4.3 (Table 6).

An analysis of variance was not statistically significant for overall behavior between the groups dependent on drug type, age, or time of onset of action of the drug (Table 6).

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

Drug			*Mean*		*STD Error*
Chloral hydrate			4.300		.4354
Triazolam			4.300		.4354
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	.0000	.9961	N.S.
Age	1	1	2.1648	.1499	N.S.
Time	1	1	.0135	.9081	N.S.

Ratings for Heart Rate and Oxygen Saturation

Using the pulse oximeter, heart rate and oxygen saturation were recorded for all of the subjects. The mean heart rate for the chloral hydrate group was 116.8 and for the Halcion group was 112.1 (Table 7).

An analysis of variance was not statistically significant for heart rate between the groups dependent on drug type, age, or time of onset of action of the drug (Table 7).

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

Drug			*Mean*		*STD Error*
Chloral hydrate			116.85		7.1924
Triazolam			112.10		7.1924
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	1.0863	.3042	N.S.
Age	1	1	1.1052	.3001	N.S.
Time	1	1	.8406	.3653	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			98.75		.3228
Triazolam			99.20		.3228
ANOVA					
Source	*N*	*DF*	*F Ratio*	*Prob >F*	*Sig.*
Drug	1	1	1.1077	.2996	N.S.
Age	1	1	4.2605	.0463	S.
Time	1	1	.2246	.6385	N.S.

The mean transcutaneous oxygen saturation of the arterial blood for the chloral hydrate subjects was 98.7 and was 99.2 for the Halcion subjects (Table 8).

An analysis of variance shows no statistical significance for oxygen saturation between the groups dependent on drug type or time of onset of action of the drug. However, the age of the patient was statistically significant (Table 8).

Discussion

The subjective ratings used to assess sedation success for patients given triazolam and those given chloral hydrate and hydroxyzine 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 only pair of variables that proved statistically significant was oxygen saturation with the age of the patient. This probably can be attributed to the fact that the younger patients have more difficulty than the older ones in keeping the finger/toe oxygen probe on their smaller digits. Also, younger patients who cry do so in a sob-like manner that biases the oxygen saturation readings.

The dose of triazolam (.02 mg/kg) was derived by converting the recommended dose of .25 to .50 mg for adults to a per kilogram dose applicable for children. The dose of chloral hydrate, hydroxyzine, and nitrous oxide was obtained by reviewing the literature, particularly an article by Moody et al. (1986) studying chloral hydrate alone and with hydroxyzine and a paper by Houpt et al. (1985b) evaluating chloral hydrate alone and with nitrous oxide.

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

The only significant side effect noted in the study was that one of the subjects given the chloral hydrate regimen vomited after the restorative procedure. None of the subjects given triazolam experienced nausea, nor did they vomit.

For future studies the evaluators may want to consider rating 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 could rate the sedation and a correlation could be done between this and the scores by the independent evaluators. Also, since the total doses of triazolam given were near the minimal recommended levels, an increase may be warranted. The length of time the drug was effective should also be investigated.

Conclusions

Based on the subjective evaluation of effectiveness of sedation and the physiologic data provided by the pulse oximeter, it can be concluded that triazolam .02 mg/kg and 50% nitrous oxide are as effective a sedative agent as chloral hydrate 40 mg/kg with hydroxyzine 25 mg and 50% nitrous oxide.

The procedures, possible discomforts or risks, as well as possible benefits were explained fully to the human subjects involved, and their informed consent was obtained prior to the investigation.

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Black teenaged crack users at high risk for sexually transmitted diseases: study

Although they are afraid of contracting AIDS, many black teenagers often trade sex for crack and are at high risk for sexually transmitted diseases (STDs), a study in the February 9, 1990 issue of the *Journal of the American Medical Association* concluded.

Because of their fear of AIDS, these teenagers may take advantage of community-based prevention programs if they were established, said Robert E. Fullilove, EdD, of the Center for AIDS Prevention Studies, University of California at San Francisco, and colleagues. Seventy-six per cent of teens surveyed said they were either "very worried" or "somewhat worried" they would get AIDS.

The "impetuous nature" of crack-related sexual activity puts teens and their partners at risk for contracting gonorrhea, syphilis, human immunodeficiency virus (HIV) and other STDs.

"That such activity is being reported by adolescents only underscores the gravity of crack's impact on a community and its destructive potential," the authors wrote. "A campaign of widespread distribution of condoms might change the opportunity structure in such a way as to make it possible for even the worried, impulsive crack user to have safer sexual encounters."

The researchers interviewed 222 black teenaged crack users recruited from neighborhoods in San Francisco and Oakland where drug deals and use are commonplace. The teens' use of the drug was verified via observation, or by referral from a trusted person in the community or from juvenile authorities.

Black teenaged male crack users reported an unusually high level of sexual activity. Crack-using boys were five times more likely to report more than 10 sexual partners a year than the most sexually active group of male respondents in a 1988 general survey. In that study, 5% of males aged 18 to 29 said they had more than 10 sexual partners in the past year. In the Fullilove study, 27% of young males had as many partners.

Seventy-three per cent of the teens surveyed in this *JAMA* study reported engaging in at least one of the following five risk behaviors for STDs:

- having more than five sexual partners per year
- failure to use a condom in the last sexual encounter
- having a history of an STD
- exchanging sex for drugs or money
- engaging in sexual relations while under the influence of drugs, including alcohol.

Nearly two-thirds of the teens had sold crack and 41% reported having had an STD in the past. The teens who had sex on crack were more likely to have had an STD (51%) than those who didn't smoke crack and have sex concurrently (32%).

This report bodes ill for crack users and their friends.

"If crack users are, indeed, engaged in sexual practices that increase their likelihood of being infected with an STD (including HIV), then their non-crack using sexual partners will also be at considerable risk," the authors wrote.

One in four teens said they exchanged sexual favors for drugs and/or money, either as a recipient or as a provider. The immediate exchange of sex for crack appears to be a "new form of prostitution," the authors suggested. "Our findings suggest that such activity is common and that it is linked both to daily use of crack and to a history of engaging in sexual activity while under the influence of crack."