Scientific Article

Conscious sedation of pediatric dental patients using chloral hydrate, hydroxyzine, and nitrous oxide — a retrospective study of 382 sedations

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Abstract

This retrospective study assessed the effectiveness and safety of chloral hydrate (55 mg/kg), hydroxyzine (1 mg/kg), and nitrous oxide in the sedation of 336 uncooperative pediatric dental patients over 382 sedation sessions, and identified variables associated with effectiveness including: sex, weight, age, and preoperative behavior of the patient; route and combinations of the sedative drugs; and sex of the operating and monitoring dentists. The operating and monitoring dentists rated the sedation session as either effective or ineffective and also as either heavy, moderate, light or poor. The mean age of the children was 2.6 years and mean weight was 14.1 kg. Seventy-four percent of the sedation sessions were deemed effective. Boys had more effective sessions (80.6%) than girls (65.1%) (P = 0.001). Also, the percentage of sedations rated as effective increased as the preoperative behavior was more positively rated (P = 0.001). Oral regimen of chloral hydrate alone or in combination with oral hydroxyzine was more effective (75.5%) than rectal administration of chloral hydrate alone (65.7%) (P = 0.09). There was no significant difference in effectiveness when chloral hydrate was administered orally alone or in combination with oral hydroxyzine. Sedation sessions rated effective had longer operative times, included more sextants of treatment, were more likely to include restorative treatment, and were less likely to include extractions than the ineffective sedations. Vomiting was the only complication reported, occurring in 8.1% of the sedations. Vomiting did not vary significantly with either route of administration or inclusion of hydroxyzine in the oral regimen. Pulse rates were significantly higher for children in the ineffective sedation sessions. This sedative drug regimen was deemed safe and effective for treating young and uncooperative pediatric dental patients. (Pediatr Dent 17:424–31, 1995)

The combination of chloral hydrate and hydroxyzine is one of the safest and most commonly used drug regimens for sedating young, uncooperative pediatric dental patients.[1–5] Previous studies using this regimen report success rates ranging from 20 to 70%.[6–14] These studies investigated the effectiveness of the choral hydrate and hydroxyzine regimen as a function of drug dosage and route, and also compared its effectiveness to other sedative drugs or combinations of drugs. In addition, these studies evaluated various drug regimens and their effect on vital signs, patient airway maintenance, complications, and recovery time. Because most of these studies involved both small sample sizes and limited numbers of operators, they were unable to evaluate factors, other than dosage or route of administration, that might influence the success or failure of the oral chloral hydrate and hydroxyzine regimen.

The purpose of this study was to assess the effectiveness and safety of chloral hydrate, hydroxyzine, and nitrous oxide in the sedation of a large number of uncooperative pediatric dental patients and to identify variables associated with their effectiveness.

Methods and materials

Subject selection

Four hundred and twenty-six conscious sedations were performed in the Department of Dentistry, Children's Hospital, between October 1985 and April 1992. Patients selected for sedation: 1) were 12–62 months of age, 2) required no more than three sextants of operative or simple surgical dental treatment, and 3) exhibited fearful or refractory behavior at previous dental appointments as documented by Frankl behavioral rating scores of 1 or 2.[15] Only children with an ASA physical status I or certain II classifications were considered candidates for conscious sedation.

Procedure

The standard protocol included oral administration of both chloral hydrate (55 mg/kg, Noctec®, Squibb and Sons Inc, Princeton, NJ) and hydroxyzine hydrochloride (1 mg/kg, Vistaril®, Pfizer, New York, NY). If the child's cooperation precluded oral administration,

Table 1. Levels of Sedation

Heavy	Patient well sedated as evidenced by the lack of crying or movement.
Moderate	Patient mostly cooperative, but occasionally asleep. Occasional crying or movement at times interrupting treatment.
Light	Patient often uncooperative and awake with periods of continuous crying or movement. Occasionally only partial treatment completed with physical restraint or no treatment rendered.
Poor	Patient uncooperative and fully awake with uncontrollable crying or movement. Treated with restraint or no treatment rendered.

chloral hydrate alone was administered rectally (55 mg/kg). In addition to the oral/rectal premedicants, nitrous oxide/oxygen was administered via nasal inhaler. Nitrous oxide concentrations ranged from 40 to 60% intraoperatively at the discretion of the operator, based on patient cooperation.

Preoperative written instructions included preoperative dietary restrictions and health contraindications for sedation. A preoperative health evaluation included weight, chest sounds, and visual evaluation of airway patency. The child's preoperative behavior on the day of the sedation also was determined utilizing the Frankl scale. Each child was medicated and remained with the parent in a "quiet room" until drowsy or asleep. The child then was brought into a darkened operatory and restrained using a Pediwrap® (Clark Association, Charlton City, MA) to prevent significant movement during treatment.

An operating dentist (either a second-year pediatric dental resident or an attending pediatric dentist) performed the dental procedures; a monitoring dentist (either a second-year pediatric dental resident or an attending pediatric dentist) monitored and recorded the patient's vital signs, behavior, and complications; and a dental assistant assisted the operating dentist. Respiratory sounds and rates were monitored with a precordial stethoscope. Heart rate and transcutaneous oxygen saturation of the arterial blood (SaO_2) were monitored using a Nellcor® pulse oximeter (Nellcor Co, Hayward, CA) placed on the patient's toe. Oxygen desaturation (O_2 desat) less than 95% was recorded as a significant hypoxemic event. Physiologic values were recorded by the monitoring dentist at 5-min intervals.

The child's cooperation level during the procedure was recorded by the monitoring dentist using the Frankl scale at 5-min intervals. The overall level of sedation for each session was evaluated by the monitoring dentist as heavy, moderate, light, or poor as defined in Table 1. The overall success of the sedation was evaluated by both operating and monitoring dentists as either effective or ineffective. An effective sedation was defined as any session in which both the operating and monitoring dentist agreed that the combination of drugs improved the child's behavior enough to allow satisfactory completion of the planned treatment without significant behavioral disturbances such as thrashing about in the restraint and/or excessive uncontrollable crying.

Following the sedation session, expected postoperative behaviors were explained to the parent. The child was discharged when preoperative levels of responsiveness and consciousness were obtained.

Data analysis

The following variables were collected and entered on computer: sex, age, and weight of the child; effectiveness and level of sedation; preoperative and intraoperative Frankl ratings; route of administration; drug combinations; physiological parameters (pulse and respiration rate, SaO_2, O_2 desat); sex of both the operating and anesthetic dentist; intraoperative complications; induction time (interval between administration of the sedative agents and entrance into the dental operatory); operative time (interval from entrance into the operatory and completion of the treatment); and treatment rendered.

Chi-square tests were used to assess statistically significant differences for categorical data, and *t*-tests and ANOVA were used for continuous data. Bivariate correlational analyses and multivariate logistic regression analyses were done to assess the effect on sedation effectiveness of biological variables (patient's age, sex, and weight), drug combinations and routes of administration, preoperative Frankl, and gender of the operating and monitoring dentist. Forty-four of the records were incomplete, therefore, the analyses were based on a maximum of 382 sedative sessions of 336 patients. The majority of patients (88.4%, 297/336) had only one sedation session. The remaining children had either two (84.6%, 33/39), three (12.8%, 5/39), or four (2.6%, 1/39) sedation sessions.

Results

Sample demographics and overall effectiveness

The mean age of the children in the study was 2.6 years (SD = 0.67), with a mean weight of 14.1 kg (SD = 2.23). Fifty-six percent (216/382) of the sessions were performed on boys. The gender distribution of patients with one sedation session or more than one sedation session was identical. The average dosages of drugs administered were; chloral hydrate 776 mg (55 mg/kg), hydroxyzine 14 mg (1 mg/kg), and nitrous oxide 55%. Approximately three-quarters (73.8%, 282/382) of the sedations were rated as effective, and 26.2% (100/382) ineffective. Fifty-one percent (144/282) of the children having effective sedation sessions were rated moderately sedated, 38.3% (108/282) as heavy, and 10.6% (30/282) as light. Sixty-four percent (64/100) of the children having ineffective sedation sessions were rated lightly sedated, while the remainder (36.0%, 36/100)

were rated poor. None of the poor sedation sessions was rated as effective.

The sedation effectiveness was similar for the children with one sedation session (71%) and those having more than one sedation session (84%); 64.1% (25/39) of the patients who had more than one session had the same sedation effectiveness outcome in all sessions (all effective). Therefore, the following analyses were carried out with data available from all 382 sedation sessions contributed by 336 patients.

Effectiveness and associated correlates

Tables 2 and 3 contain the results of the initial bivariate analyses performed to investigate the association between the effectiveness of the sedation and potential correlates. The average age of the effectively sedated children was 0.21 years greater than those whose sedations were rated as ineffective ($P = 0.01$), although this difference disappeared in the multiple logistic regression analysis. When the effective and ineffective sedations were analyzed as a function of weight, no significant differences were found. ANOVA failed to reveal any differences in the weights or ages of children at the four different levels of sedation.

A highly significant difference ($P = 0.001$) was found in the sex distribution between the effective and ineffective groups. Eighty-one percent (174/216) of the sedations of male patients were rated as being effective compared with only 65.1% (108/166) of those of female patients. Of the effective sedations performed, 61.7% (174/282) were on males, while only 38.3% (108/282) were on females. Table 4 compares the distribution of patients by sex for the various sedation levels. This analysis also reveals a significant association ($P = 0.002$) between the patient's sex and the sedation level, i.e., boys were more likely to be moderately to heavily sedated, while girls were more likely to be lightly or poorly sedated.

The preoperative Frankl rating was investigated as a possible predictor of the outcome of the sedation. Table 3 shows that the preoperative Frankl was associated significantly with the effectiveness of the sedation ($P = 0.001$); i.e., the percentage of sedations rated as effective increased as the preoperative behavior was more positively rated. There was a positive association ($P = 0.04$) between the preoperative Frankl and the intraoperative Frankl rating.

The effectiveness of the various routes and combinations of chloral hydrate and hydroxyzine also are included in Table 3. The oral regimen of chloral hydrate alone or in combination with oral hydroxyzine was more effective (75.5%, 203/269) than rectal chloral hydrate alone (65.7%, 46/70), however this difference was not significant ($P = 0.09$). There was no difference in

TABLE 2. AGE AND WEIGHT ASSOCIATION WITH SEDATION EFFECTIVENESS

	Effective (N = 282)		*Ineffective (N = 100)*		
Study Variable	*Mean*	*SE**	*Mean*	*SE*	*P-Values/Comments*
Age (years)	2.69	0.04	2.48	0.60	0.01/ effectiveness significantly greater with greater age
Weight (kg)	14.15	0.12	13.75	0.25	0.16/ no significant difference

*SE = Standard error.

TABLE 3. GENDER, PREOPERATIVE FRANKL AND DRUG ASSOCIATION WITH SEDATION EFFECTIVENESS

	Effective (N = 282)		*Ineffective (N = 100)*		
Study variable	*N*	*%*	*N*	*%*	*Chi-square, P-values/comments*
Gender					
Male (N = 216)	174	80.6	42	19.4	$x^2 = 11.7$, $P = 0.001$/effectiveness
Female (N = 166)	108	65.1	58	34.9	significantly greater in males
Preoperative Frankl					
1 - definitely negative (N = 169)	110	65.1	59	34.9	$x^2 = 15.7$, $P = 0.001$/effectiveness
2 - negative (N = 77)	58	75.3	19	24.7	significantly greater the more
3 - positive (N = 67)	54	80.6	13	19.4	positive the preoperative Frankl rating
4 - definitely positive (N = 68)	60	88.2	8	11.8	
Drug and route combinations					
Oral chloral + hydroxyzine (N = 269)	75.5	203	24.5	66	$x^2 = 2.9$, $P = 0.09$/effectiveness greater for
Oral chloral alone (N = 43)	76.7	33	23.3	10	oral than rectal route, but not statistically
Rectal chloral alone (N = 70)	65.7	46	34.3	24	significant

Table 4. Percentage of patients by sex in each level of sedation (N = 382)

Level of Sedation	Female (N = 166) N	%	Male (N = 216) N	%
Heavy (N = 108)	49	45.4	59	54.6
Moderate (N = 144)	46	31.9	98	68.1
Light (N = 94)	51	54.3	43	45.4
Poor (N = 36)	20	55.6	16	44.4

Table 5. Percent effectiveness of sedations as a function of patient's and operating dentist's gender

	Male Operators N	%	Female Operators N	%
Males (N = 216)	113	81.3	61	79.2
Females (N = 166)	74	68.5	34	58.6
Totals (N = 382)	187	75.7	95	70.4

effectiveness between oral chloral hydrate alone (76.7%, 33/43) and when combined with oral hydroxyzine (75.5%, 203/269). No significant differences were found between the sedation levels for either the routes or the combinations of sedative agents used in this study.

An analysis was performed to determine whether the effectiveness ratings were influenced by any association between the sex of either the operating or monitoring dentist and the sex of the patient sedated. Male operators rated 68.5% of the female patient sedations effective compared with only 58.6% such ratings by the female operators (Table 5). This difference was not statistically significant. There was no difference between the male and female operators' ratings of the male patient sedation sessions. Similarly, no significant association was found between the sex of the monitoring dentist and the sex of the patient.

A total of 23 different dentists were involved with either performing the operative/surgical dental care or monitoring the patients and recording the data for the 382 sedations. The majority of the dentists were male (73.9%, 17/23), with a wide range of effectiveness ratings for these individuals (20.0–100%), each performing between 1 and 40 sedations. Of the operating dentists who performed a minimum of 10 sedations (57.1%, 12/21), rates of effectiveness ranged from 55.0 to 100%.

Since the majority of both the operating and monitoring dentists were dental residents, two analyses were performed to investigate if experience affected effectiveness. Fig 1 illustrates the effectiveness rating of the sedations as a function of when the sedation was performed during the calendar year. May through June and September through November demonstrated the lowest effectiveness ratings, while April demonstrated the highest. In the second analysis, only the sessions of the 12 operating dentists who performed at least 10 sedations were included. The effectiveness of the first

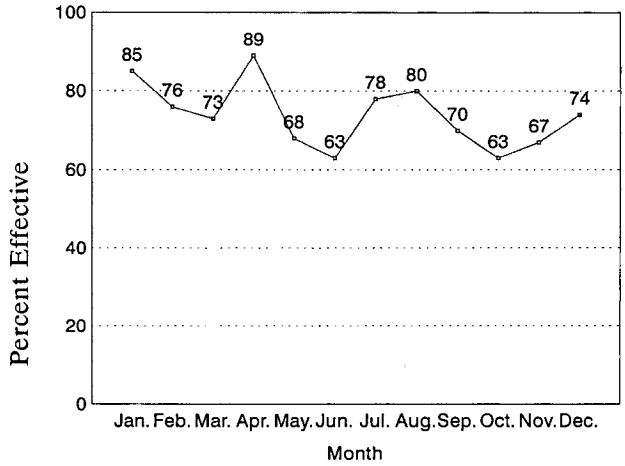

Fig 1. Sedation effectiveness by month.

half of the sedations performed during the time period of the study was compared to the last half of the sessions. When the first- and second-half sedation sessions were grouped together for all 12 operators, no significant difference in effectiveness was found.

In the multiple logistic regression analysis, sedation effectiveness was considered as the dichotomous dependent variable. Independent variables included in the model were age, gender, weight, preoperative Frankl, drug combinations, and routes of administration. Only two factors — patient gender and the preoperative Frankl rating — were found to be significantly associated ($P < 0.05$) with the effectiveness of the sedation session. Odds ratios calculated from the analysis indicated that girls were 44% less likely to have an effective sedation session than boys. Also, children who had a negative preoperative Frankl rating were 42% less likely to have an effective sedation.

Induction time, operative time, and dental procedures

The average induction time was 66.6 min (SD = 39.6). There were no significant differences in the induction time based on the various levels of sedation of the children or the effectiveness rating of the sedation sessions. The average operative time for the effective sedations was significantly longer (31.9 min) than the ineffective sessions (24.3 min) ($P < 0.001$). Similarly, the operative time increased significantly with greater levels of sedation; i.e., 23.8 min for the poorly sedated group, 27.2 min for the light/alert group, 31.1 min for the moderately sedated group, and 32.9 min for the heavily sedated group ($F = 4.77$; $P = 0.003$).

At least some treatment was accomplished in 92.1% (252/382) of the sedations, including all of the sedations rated as effective (282/282) and 70% (70/100) of the ineffective sedations. The average number of sextants receiving treatment was significantly greater (1.45) for the effective sedations than for the ineffective sedations (1.02) ($P = 0.001$). Table 6 shows the percentage of children receiving various types of procedures during both

the effective and ineffective sedations. Although most restorative procedures were more likely to be performed during effective sedations, only resin procedures were performed more often with statistical significance ($P < 0.001$). Extractions were more likely to be performed during the ineffective sedations ($P = 0.02$).

Complications and vital signs

Vomiting occurred intraoperatively in 8.1% (31/382) of the sedations. Children who received the oral regimens had a higher prevalence of vomiting (8.7%, 27/312) than those receiving rectal chloral hydrate (5.7%, (4/70), but this difference was not significant. When the prevalence of vomiting was analyzed comparing the oral chloral hydrate alone (4.6%, 2/43) with the combination of oral chloral hydrate and hydroxyzine (9.3%, 25/269), no significant difference was found.

Table 7 shows the mean SaO_2, pulse and respiration rates, as well as the percentage of patients experiencing O_2 desat episodes for the four levels of sedation. The pulse rate significantly increased as the level of sedation decreased ($P < 0.001$), while SaO_2 and respiratory rates did not vary significantly. The percentage of children experiencing at least one O_2 desat episode varied as a function of the level of sedation, but these differences did not reach significance. The moderately sedated group experienced the highest percentage of children having at least one O_2 desat episode (43.3%), followed by the heavy (29.8%), light (20.9%), and poor (6.0%) levels of sedation. When all the physiologic parameters were analyzed solely as a function of effective versus ineffective sedation, only the pulse rate was found to be significantly higher for the ineffective sedations ($P < 0.001$).

TABLE 6. COMPARISON OF THE PERCENTAGE OF CHILDREN RECEIVING VARIOUS PROCEDURES FOR ALL, EFFECTIVE, AND INEFFECTIVE SEDATIONS

	Sedations			
Procedure	*All (N = 353)*	*Effective (N = 278)*	*Ineffective (N = 75)*	*P-Value**
Resin	53.8	58.6	36.0	<0.001
Extraction	50.4	47.1	62.7	0.02
Amalgam	26.1	27.0	20.0	0.18
Stainless steel crown	7.9	9.0	4.0	0.16
Pulpotomy	4.8	5.0	4.0	0.71
Sealant	1.1	0.72	2.67	0.16

*Two-sided *t*-test.

TABLE 7. MEAN INTRAOPERATIVE PHYSIOLOGICAL PARAMETERS AS A FUNCTION OF LEVEL OF SEDATIONS

Level of Sedation	*% O_2 Saturation (N = 317)*	*% Patients with O_2 Desats (N = 67)*	*Pulse Rate (N = 326)*	*Respiration Rate (N = 301)*
Heavy	98.3	29.8	107.9	24.5
Moderate	98.2	43.3	115.1	25.4
Light	98.3	20.9	130.6	25.1
Poor	98.0	6.0	131.5	25.7

Discussion

Overall effectiveness

The overall success rate of 73.8% of the sedations in this study is similar to the findings of other studies using the same drug combination in addition to nitrous oxide.[7,9–11] Readers should be cautious when comparing the effectiveness of sedation studies that use different methodologies and definitions of success. Our study was retrospective and used a dichotomous measurement of success (effective versus ineffective). Most similar studies are prospective in design and use multiple and finer measurements of patient behavior (e.g., the Houpt Scale[10]) to determine effectiveness both prior to and during the sedation.

Studies using dosages of chloral hydrate higher than the 55 mg/kg used in our population reported only a slightly greater (2–6%) effectiveness.[6,16] In addition to higher drug dosages used, these reports included subjects with broader age ranges (1.7–10.5 years),[6] as well as smaller sample sizes (N = 17, N = 51).[6,16] The validity of the effectiveness rate reported in this study is strengthened by the substantial sample size (N = 382) and the large number of operating and monitoring dentists (N = 23) employed in the sedative sessions.

When investigating sedation effectiveness prospectively, standardization of observations with respect to measurements made is possible. In this retrospective study such standardization was not possible, however, the effectiveness ratings were consistent with the independent variable of level of sedation — lending validity to the outcome measurement. Our study relied upon a more clinical and practical definition of effectiveness and agreement of both the operating and monitoring dentists in classifying a sedation session as effective or ineffective. Moreover, the large number of operators and their varied previous experience with sedations strengthen the predictive accuracy of the effectiveness of the sedative regimens used in our study. The only chloral hydrate/hydroxyzine study using more than a few operators or monitors was Nathan and West,[8] which included 10 different operators, eight of whom were postdoctoral pediatric dentists.

The dentist's experience or ability to use other behavioral management techniques may have had a significant impact on the effectiveness of this sedation regimen. Proper use of nonpharmacologic behavioral management techniques can affect sedation outcomes. For example, knowing when to persevere through a seemingly failed sedation and ultimately succeed can be gained only with previous experience. Many inexperienced operators do not realize that a

crying, refractory patient who has received the sedative drugs may eventually calm down. Nitrous oxide at a higher levels (50–70%) for short periods of time also can help calm the patient to allow the sedative effects of the drugs to begin to take effect.

In an attempt to evaluate if prior experience affected the outcome, two different analyses were performed with conflicting results. Dramatic variations in effectiveness of the sedations were noted when evaluated as a function of the month of the year in which the sedation was performed; ranging from a low of 63% effectiveness for June and October, to a high of 89% for April. This may be explained by the dentist's previous experience with both patient management and sedations at any one particular time of the year. The majority of dentists performing the sedations were residents who start to participate in sedations toward the end of the first year of their two-year residency (May–June), having recently completed a prerequisite anesthesia rotation. This time period coincides with the lowest effectiveness ratings (68% and 63% respectively) in this study. By the beginning of the second half of their final year of the program (January) they had had at least 8 months' experience with sedations. This time period coincides with some of the higher success rates reported, and culminates in the highest rating of 89% in April. This reinforces the idea that operators do not rely solely on sedative drugs. This experience effect, however, was not observed when effectiveness was evaluated for the first and second half of sedations performed by individual operators.

Effectiveness and sex of patient

The most striking result of this study was the strong association between the sex of the children with both the effectiveness ratings and level of the sedation, with male sedations having a 15.5% greater success rate than female (80.6% versus 65.1% respectively). This difference remained even after accounting for potentially confounding factors such as age, weight, and sex of the operating and monitoring dentists.

Few reports associate gender differences in humans with the effectiveness of sedative or analgesic drugs. Tsinidou et al. (1992)[14] did report findings similar to ours in their study using oral chloral hydrate and hydroxyzine to sedate children for dental restorative treatment. The overall behavior of the nine boys in their sample was significantly better than the 11 girls; however, this was only true at the first 15-min interval of treatment. Other human studies have similarly reported that males are more responsive to certain sedative or analgesic drugs than females.[17–23] In addition, numerous animal studies using rodents (rats or mice) demonstrate sexual dimorphism with regard to responsiveness to certain painful stimuli or drugs in the same direction as our findings.[25, 26]

Developmental and cognitive differences between boys and girls may be an alternative explanation for the different responses to sedative agents. It is ironic that girls, who are often thought to mature at a younger age, should be more disruptive than boys. By 13 months old, females seem to be more aware of contextual relationships and thus more aware of what is occurring.[24] It has been observed in preschool children that with greater understanding and with the growing ability to imagine, new fears arise.[27] This may result in more fearful, resistant, disruptive behavior for girls than for boys. In a study by Aho and Erickson,[28] elementary age children exhibited gender differences in their frequency and intensity of medical fears, with girls expressing more and stronger fears than boys. Consistent with these hypotheses and findings is the recognized, but not well understood, difference between boys and girls that some objects may arouse fear more rapidly in girls than in boys.[29] Additionally, cultural differences may influence the way in which male and female children are taught to react to stress, pain, and unfamiliar situations. Because of such possible differences in gender expectations, girls may develop less impulse control and may be more sensitive to separation from their mothers than boys.[24]

Effectiveness and Frankl ratings

Both the preoperative and intraoperative Frankl ratings were strongly associated with the effectiveness rating outcome. The child's preoperative behavior during the physical examination and compliance with requests to take the oral medication were good predictors of the effectiveness of the sedation session to follow. The intraoperative Frankl evaluation was associated with the final outcome as it rates the child's behavior during the procedure, which is associated with the final rating of effectiveness.

Effectiveness and drug and route combinations

Moody et al.[7] reported that the rectal administration of chloral hydrate (50 mg/kg) was more effective than the oral administration of an equivalent dose. The results of our study contradict this finding since our sedations involving rectal administration were found to be 11% less effective than the oral administration, although this difference ($P = 0.09$) did not reach statistical significance. In our study, rectal administration of the sedative agent was based on previous parental experience with their child's acceptance of oral medications and/or the patient's refusal to take oral medication preoperatively. Thus, the characteristic of defiant preoperative behavior probably resulted in a selection bias. The more difficult patients were placed in the rectal administration group, probably accounting for their lower effectiveness rating.

When comparing alternative oral drug regimens, Moody et al.[7] reported that the oral administration of chloral hydrate alone was as effective as the combination of chloral hydrate with hydroxyzine. Similarly, our study failed to show any significant difference in effectiveness when hydroxyzine was added to oral chloral

hydrate. Perhaps our dosage of 1 mg/kg of hydroxyzine was insufficient to alter the effectiveness of the sedation. Since the average weight of our study children was 14.1 kg, the average dose of hydroxyzine was 14.1 mg. This dose is almost half the standard 25 mg dose of hydroxyzine used in most other studies employing the combination of chloral hydrate and hydroxyzine[6–12, 14] and half the dosage of 2.0 mg/kg used by Tafaro et al.[13] Nevertheless, our success rate of 73.8% compares favorably with those using this greater dosage of hydroxyzine and similar doses of chloral hydrate. It would be interesting to increase our dosage of hydroxyzine to 1.5–2.0 mg/kg and evaluate any changes in effectiveness. A recent animal study by Gladney et al.[30] concluded that there was no advantage in using a combination of chloral hydrate and hydroxyzine to increase anxiolytic (anti-anxiety) activity over the use of chloral hydrate alone. The authors demonstrated that hydroxyzine has weaker anxiolytic activity than chloral hydrate and suggested that only when extremely high doses of hydroxyzine are used would significant anxiolytic and sedative effects be demonstrable.

Induction time, operative time, and dental procedures

Classification of the types of treatment rendered and the average working time for both the effective and ineffective sedations were revealing. The effective sedation group yielded 7.6 min greater average working time and included 0.4 more sextants of dentistry than the ineffectively sedated children. The effectively sedated group was more likely to receive restorative treatment such as placement of resins in the anterior dentition. Conversely, patients in the ineffective group were twice as likely to receive extractions (39%) than pateints in the effective group (17.0%). Certainly, patient cooperation favors placement of technically demanding resin restorations, while lack of the same favors extraction of primary anterior teeth.

Complications and vital signs

Ease of administration, relative safety, and effectiveness of chloral hydrate and hydroxyzine appear to account for their continued popularity. Our findings corroborate this belief since all 382 sedations were completed without serious complications.

Intraoperative vomiting occurred in 8.1% of our sedations. This low prevalence of vomiting is similar to other studies using both chloral hydrate and hydroxyzine.[6–14] Only Nathan and West[8] reported a lower frequency of vomiting (5.3%, 4/75). Although hydroxyzine was included in this regimen for its antiemetic properties, it did not appear to significantly alter the prevalence of intraoperative vomiting. Perhaps if the dosage were increased to aid in the effectiveness of the regimens as previously suggested, it might also decrease the prevalence of vomiting. The addition of hydroxyzine however, does aid the palatability of the oral chloral hydrate suspension. As expected, rectal administration was associated with a lower frequency of vomiting (5.7%), however this decrease was not statistically significant.

Mean pulse rate was 116.6 beats/min. This is similar the 121 rate reported by Moody et al.[7] and the 117 rate reported by Meyer et al.[10] and Poorman et al.[11] who used the same sample population. Pulse rates did increase significantly with poorer levels of sedation and in the ineffectively sedated children, clearly a result of patient agitation. We reported a mean SaO_2 of 98.2%, which is similar to the 98.6% reported by Moody et al.[7] and the 98.7% reported by Meyer et al.[10] and Poorman et al.[11] Twenty-one percent of our patients experienced at least one O_2 desat less than 95%. In the study by Whitehead et al.,[9] two of their 12 patients had episodes of O_2 desats (90% and 92%), both improving with head repositioning. Hasty et al.[12] reported 13 O_2 desat episodes during the sedation of the 10 patients in their study. All of their episodes ranged between 90–95% and most were associated with crying. Iwasaki et al.[31] observed that a high prevalence of O_2 desats below 96% are associated with crying. Kim et al.[32] suggested that this might be secondary to venous congestion during the crying episode. Tsinidou et al.[14] reported that three of their 20 cases demonstrated O_2 desats below 90% and were due to obstruction hypoxemia. In all three cases the SaO_2 improved with raising of the mandible. The number of O_2 desats occurring during any one sedation session was more likely to be associated with the moderately and heavily sedated levels, indicating that airway obstruction was the likely cause of the episode. We agree with previous studies that many of the O_2 desats can be caused by patient movement or crying. However, operating and monitoring dentists must make sure that well-sedated patients who desaturate are not obstructed, and should reposition the mandible in an initial attempt to reverse the hypoxemia.

Conclusions

1. Seventy-four percent of 382 sedation sessions of uncooperative pediatric dental patients using chloral hydrate (55 mg/kg), hydroxyzine (1 mg/kg), and nitrous oxide were rated as effective.
2. Boys had a significantly higher rate of effective sedation sessions (80.6%) than girls (65.1%) ($P = 0.001$). Similarly, boys were more likely to be rated as moderately and heavily sedated than girls ($P = 0.002$).
3. The preoperative Frankl behavior rating was significantly associated with the effectiveness of the sedation session ($P = 0.001$).
4. The oral regimen of chloral hydrate alone or in combination with oral hydroxyzine was more effective (75.5%) than rectal administration of chloral hydrate alone (65.7%) ($P = 0.09$).
5. There was no difference in the effectiveness when chloral hydrate was administered orally alone or in combination with oral hydroxyzine.

6. Those sedation sessions rated as effective had longer operative times, included more sextants of treatment, were more likely to include restorative treatment, and were less likely to include extractions than the ineffective sedations.
7. Vomiting occurred in 8.1% of the sedation sessions and its prevalence did not vary significantly with either the route of administration or with the inclusion of hydroxyzine in the oral regimen.
8. Pulse rates were significantly higher for children in the ineffective sedation sessions ($P < 0.001$).
9. Twenty-one percent of the patients experienced at least one O_2 desat below 95%.

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