Scientific Article

The effects of nitrous oxide on pediatric dental patients sedated with chloral hydrate and hydroxyzine

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Abstract

Purpose: *The purpose of this prospective, double-blind, crossover study was to evaluate the effect of 50% nitrous oxide (N_2O) compared to oxygen (O_2) alone on behavioral and physiologic parameters when a standard regimen of chloral hydrate (CH) (50 mg/kg) and hydroxyzine (2 mg/kg) was administered to young children for dental procedures.*

Methods: *Twenty children (mean age 42 ± 7.3 months) were sedated, each for two appointments. At one appointment they received 100% O_2 and at the other 50% N_2O, the order randomized across patients. Physiologic parameters measured were heart and respiratory rate, systolic and diastolic blood pressure, oxygen saturation, and expired carbon dioxide. Behavior was rated using the Ohio State University Behavior Rating Scale. Physiologic and behavioral parameters were measured at eight defined procedural events.*

Results: *Results indicated differences as a function of inhalation agent were seen for crying, quiet, and struggling, but not for any physiologic parameters. Significant differences across procedures were found for systolic and diastolic blood pressure and for all behaviors (crying, movement, quiet, and struggling).*

Conclusions: *Compared to O_2, N_2O significantly modifies some behaviors but not physiologic parameters in sedated children. However, certain dental procedures did significantly modify some physiologic parameters and all behaviors. (Pediatr Dent 20:253–58, 1998)*

Combinations of sedative agents are important pharmacologic management tools of medical and dental health care providers who care for young, uncooperative children. Chloral hydrate, hydroxyzine, and N_2O is a popular combination among pediatric dentists as an adjunct to routine behavior-management techniques. In recent years, studies have been reported involving clinically popular dosages or manipulation of variables associated with these agents (e.g., with or without one of the agents) and the results have been mixed.[1-6]

The effect of N_2O is an important issue because of its potential as a separate but contributing variable in modifying children's behavior when one or more of these agents is used; however, this paradigm has been evaluated only to a limited degree.[4, 6] For example, it may be possible that, on average, chloral hydrate and hydroxyzine used together in a clinically acceptable dosage range may be efficacious in decreasing disruptive behaviors in at least 60% of young, uncooperative children. The addition of N_2O may significantly decrease the occurrence of such behaviors in a larger proportion of patients, increasing the percent of children who may be safely and economically treated.

Houpt and colleagues,[4] in an intraoperative, crossover design, used chloral hydrate (50 mg/kg) for two different appointments with a sample of patients. For half of the patients at one appointment, either 50% N_2O or 100% O_2 was administered in the first half of the appointment, then the opposite gas for the remainder of the operative appointment. For the other half of patients, the opposite sequence of administration of gases was used in the second appointment. They described intraoperative behaviors as a discreet summary value associated with specific operative procedures that occurred over a block of time for each patient. They reported that N_2O improved the sedative effects (e.g., decreased movement) approximately 50% of the time with the greatest effect notable in the first half of treatment when stimuli are relatively intense.

McCann et al.[6] studied the effects of N_2O on a regimen involving a modest dose of chloral hydrate (40 mg/kg) used with hydroxyzine (2 mg/kg). In this crossover patient design, half of the patients received 50% N_2O for the first visit and 100% O_2 on the next visit. The other half of patients received the opposite sequence of gaseous agents over two visits. They measured behaviors continuously over a block of time for defined intraoperative procedures as well as physiologic variables. Their results indicated a significantly increased percentage of crying behaviors associated with O_2 compared to N_2O. However, considerable variance in exhibited behaviors was noted. These authors suggested that higher dosages of chloral hydrate consistent with clinical practice may demonstrate a more favorable, significant change in certain behaviors when N_2O is used compared to O_2.

The purpose of this prospective, double-blind study was to evaluate the effect and relative contribution of N_2O compared to O_2 on behavioral and physiologic parameters when a clinical regimen of chloral hydrate (CH) (50 mg/kg) and hydroxyzine (2 mg/kg) is administered to young children for dental procedures.

Methods

Patients

Patient selection in this institutionally approved study was based on the following criteria. All children were between the ages of 24 and 60 months and were healthy (ASA I). Each patient needed at least two mandibular quadrants of restorative dentistry and had no previous sedation experience involving dentistry.

The children were previously screened by pediatric dentists or pediatric dental residents and found to exhibit uncooperative behaviors. These behaviors may have included, but were not limited to, any of the following: failure to open mouth voluntarily; active attempts to escape from the dental chair; extraneous flailing of arms and/or legs and excessive interfering head movements; and extreme crying and struggling. Because of these behaviors and their lack of modification through routine behavioral intervention techniques (e.g., tell-show-do or voice control), it was deemed necessary to sedate the patient in order to complete the restorative dentistry. Children meeting the criteria for participation were identified and their parents were given informed consent. Preoperative instructions were given, including dietary restrictions consistent with the American Academy of Pediatric Dentistry (AAPD) sedation guidelines.[7]

Procedures

Prior to the sedation appointments, patients were randomly assigned (flip of a coin) to 1 of 2 groups (A or B) for use in a double-blind, crossover design. CH and hydroxyzine pamoate were used for both groups at a dose of 50 mg/kg and 2 mg/kg, respectively. N_2O in combination with O_2 was administered at a concentration of 50% at 6-L/min flow delivered through a nasal hood to group A at their first appointment and to group B at their second appointment. For each group, the patients received 100% O_2 on their alternative visits, respectively.

Physiologic monitoring was done using the following machines: Critikon Dinamap Vital Signs Monitor, 1846SX (blood pressure [BP]); Nellcor pulse oximeter model N-100 (heart rate [HR] and peripheral oxygen saturation); Datex Carbon Dioxide Monitor, model 223 (expired carbon dioxide concentration). The Porter MXR N_2O delivery system was used.

At each appointment, the medical history and NPO status were reviewed again with the parent. All sedation appointments were scheduled at 7:30 in the morning and patients had an NPO status of at least 8 h. The child's baseline vital signs were taken, including BP, HR, respiratory rate, and peripheral oxygen saturation. If the child was sufficiently cooperative, expired carbon dioxide (CO_2) was also obtained. The child was weighed, the dose of oral sedatives calculated, and the drugs administered per oris. Uncooperative children received the drug slowly in the buccal vestibule via a large needleless syringe.

After receiving the oral sedatives, the patient was observed for a 45-min latency period before being separated from their parents and taken to a private operatory. Each patient was placed unrestrained on a Papoose board, monitors were attached, a nasal hood placed over the nose with the technique of tell-show-do, and the appropriate gas was administered depending on the group. The separation and initial phases of gas administration were usually done by one of the investigators (SW) who also concealed the N_2O/O_2 machine from view. The primary operator (AMM) who entered the operatory after gas administration was started and the assistant were blind to the conditions of the study. A videotape recording of each appointment was started as the child was brought into the room.

Physiologic parameters were manually recorded throughout the treatment session by the assistant at specified pretreatment procedures and at 5-min intervals during treatment. Continuous monitoring of all parameters was carried out, except for BP, which was set to record automatically every 5 min. Use of a precordial stethoscope allowed the operator to continuously monitor respiratory and heart sounds.

Treatment was limited to operative or extraction procedures in posterior mandibular quadrants based on the operator's clinical judgment and radiographs, if available. Treatment time averaged approximately 45 min per session. Monitoring and videotaping were stopped following completion of operative procedures and the patient was reunited with the parent. Patients were observed postoperatively until discharge criteria were met. Postoperative instructions were given to the parents.

Behavioral assessment

Measurement of behavioral patterns was done by videotaping each session and later analyzed using the Ohio State University Behavior Rating Scale (OSUBRS) and the Automated Counting System (ACS, Version 1.0 JAGTECH, Rockville, MD). This scale has been shown to be reliable in other studies.[8–10]

One trained research assistant, using the OSUBRS, reviewed the videotape and rated the behavior of each treatment session. This scale used four behavior categories with each being designated by a letter: q = quiet behavior, no movement; c = crying, no bodily movement; m = movement with struggling, no crying; s = crying and struggling concurrently. Rating occurred at set time periods of the treatment session (Table 1). These time periods are as follows: 1) initial placement

TABLE 1. DEFINITION OF TIME PERIODS OF EACH PATIENT VISIT DURING WHICH PATIENT BEHAVIOR WAS RATED

Event		*Definition*
Baseline	start	Placement of nasal hood on patient
	stop	2 min after "start"
Topical	start	Insertion of cotton swab into patient's mouth
	stop	Removal of cotton swab from patient's mouth
Local	start	Insertion of local anesthetic syringe into oral cavity
	stop	Removal of syringe from oral cavity
Rubber dam	start	Placement of mouth prop into mouth
	stop	Removal of dam forceps from oral cavity
Treatment initiation	start	Entry of dental handpiece into oral cavity, or placement of acid etch if sealant was placed first
	stop	2 min after "start"
5 min after treatment	start	5 min after initiation of treatment
	stop	2 min after "start"
10 min after treatment	start	10 min after initiation of treatment
	stop	2 min after "start"
15 min after treatment	start	15 min after initiation of treatment
	stop	2 min after "start"

of nasal hood and continuing for 2 min; 2) topical anesthetic placement; 3) local anesthetic injection; 4) rubber dam placement; 5) start of operative procedure; 6) 5 min after start of treatment; 7) 10 min after start of treatment; and 8) 15 min after start of treatment. Each of the time periods was rated for a total of 2 min. For example, the behaviors during the time period designated as "5 min after start of treatment" was rated during the time block of 5–7 min following the initiation of restorative treatment.

A description of the ACS has been previously reported, but will be briefly summarized here.[6, 8–10] The ACS is a computer software program designed to measure the duration and frequency of occurrence of defined events. It was used in this study to quantify the duration of each behavioral category during each treatment procedure or phase. Each defined behavioral category was recorded on the computer by pressing the key on the keyboard which corresponded to the behaviors (i.e., q, c, m, s). As behaviors changed during recording periods, a new key was pressed. The computer thus provided data as to the frequency and duration of each behavior (if they occurred) during each of the defined procedures or treatment phases. Intrarater reliability was done by having the rater maintain 90% or higher association in the rating of each of the behavioral categories over a minimum of five videotaped sessions at the beginning and midway through the study.

Additionally, because the depth of sedation of the AAPD sedation guidelines is based, in part, on a behavioral assessment of the patient, the level of sedation was estimated by the operator for each procedure or treatment phase. The assistant recorded the estimated level of sedation for later analysis. Finally, using categorical measures, the operator rated the difficulty of sedation (ranging from "mildly challenging" to "intensely challenging") based on the operator's opinion of how difficult the child was to manage during the sedation and size of tonsils (ranging from "none present" to "> than 50%") based on a clinical examination of the airway. The amount of planned treatment completed was based on the number of restorations (e.g., alloy) or procedures (e.g., extraction) done.

The mean, standard deviation, and frequency distribution were used to characterize the age and sex of the sample population. ANOVA was used to determine differences in behavior and physiologic parameters as a function of procedure and inhalation agent. Intrarater reliability was assessed using a Student's *t* test to determine differences in time of rated behaviors, comparing the first to the second rating of five selected sessions for each behavioral category.

Results

The study population consisted of 13 males and seven females who ranged in age from 28 to 59 months (mean = 42 ± 7.3). The weights of patients ranged from 10.0 to 18.6 kg (mean = 14.3 ± 2.2). The mean dose of sedatives administered was 715 mg of CH and 28.6 mg hydroxyzine.

Physiologic measures

A repeated-measures ANOVA was used to determine significance in physiologic parameters across the time periods and as a function of inhalation agent for patients. The only physiologic variables showing a statistically significant change across the eight time periods (phases) were systolic and diastolic BP ($F = 3.237$, $P < 0.003$; $F = 2.802$, $P < 0.009$, respectively). The most notable change occurred around the local injection phase when a definitive increase in BP was observed. There was no statistical difference between N_2O and O_2 visits in physiologic parameters although, on average, the BP was higher during O_2 administration.

Behavior

Table 2 shows the mean values of each behavioral category as a function of gas administered. A repeated measures ANOVA indicated a significant difference in the percent of crying, quiet, struggle, and movement across the eight time periods studied ($F = 4.90$, $P < 0.001$; $F = 12.6$, $P < 0.001$; $F = 8.16$, $P < 0.001$; $F = 3.48$, $P < 0.002$, respectively). The differences were most notable during the injection phase of treatment when crying, struggling, and movement were increased during O_2 administration compared to N_2O.

There was a significant effect of N_2O compared to O_2 on the percent of crying, quiet, and struggling behaviors, but not movement ($F = 4.97$, $P < 0.03$; $F = 7.66$, $P < 0.01$; $F = 4.23$, $P < 0.04$; $F = 0.049$, $P = 0.83$, respectively). N_2O caused a significant reduction in crying and struggling behaviors while increasing quiet behaviors. There were no interactive effects between the eight time periods and the gas administered for any of the behavioral variables.

Several significant correlations, at the 0.01 probability level, were observed between behavior and physiologic parameters using a two-tailed Pearson correlation. As the percent of crying increased so did HR (0.299), systolic (0.216), and diastolic (0.224) BP. As the percent of struggle time increased so did the heart rate and blood pressure (HR = 0.313, systolic BP = 0.179, diastolic BP = 0.259). An inverse relationship was seen with percent quiet and these same parameters (HR = –0.394, systolic BP = –0.241, and diastolic BP = –0.314) thus, as the percent of quiet time increased the HR and BP decreased.

Over the time periods assessed, each physiologic parameter had significantly more data missing during O_2 than N_2O trials because of disruptive behaviors of the patient causing less opportunity to measure each of the parameters (e.g., motion artifacts interfering with oxygen saturation measurement). The order, from most to least, of physiologic parameters in which data were missing as a function of gas administered was CO_2 ($\chi^2 = 21.19$, $P < 0.001$), respiratory rate ($\chi^2 = 7.82$, $P < 0.005$) diastolic and systolic BP ($\chi^2 = 8.03$, $P < 0.005$), and HR and O_2 saturation ($\chi^2 = 5.88$, $P < 0.015$).

Of the 20 sedations completed with N_2O, the operator rated six as not challenging, eight as mildly challenging, four as moderately challenging, and one as intensely challenging. For 19 patients, 100% of planned treat-ment was completed, with 50% completed on the remaining patient's visit.

The operator rated the 20 O_2 visits as follows: one was not challenging, 10 were mildly challenging, eight were moderately challenging, and one was intensely challenging. Furthermore, 100% of planned treatment was completed on 17 visits, between 70–100% for two patients, and less than 70% for one. In all cases, the tonsil size never exceeded half the airway diameter.

TABLE 2. PERCENT BEHAVIOR BY EVENT FOR OXYGEN AND NITROUS OXIDE VISITS

Event	*Visit*	*Behavior % (± SD)*			
		Cry	*Movement*	*Quiet*	*Struggle*
Baseline	O_2	25% (29.5)	7% (16.0)	55% (40.9)	13% (21.9)
	N_2O	17% (26.6)	7% (10.5)	70% (32.1)	6% (12.5)
Topical	O_2	23% (29.8)	4% (7.8)	57% (43.9)	17% (23.5)
	N_2O	10% (23.2)	3% (6.3)	79% (36.4)	8% (18.9)
Local	O_2	42% (32.7)	2% (6.8)	24% (35.1)	31% (30.5)
	N_2O	24% (26.2)	3% (4.3)	44% (40.6)	29% (28.6)
RD*	O_2	26% (35.8)	3% (7.4)	66% (38.3)	4% (10.7)
	N_2O	4% (10.3)	2% (4.3)	89% (25.3)	5% (17.1)
Treatment	O_2	22% (28.9)	1% (2.3)	65% (44.3)	13% (22.4)
	N_2O	6% (18.1)	1% (3.0)	88% (30.5)	6% (15.4)
5 min	O_2	8% (18.7)	3% (6.3)	74% (39.5)	15% (31.4)
	N_2O	10% (25.6)	3% (7.3)	82% (35.5)	4.7% (13.6)
10 min	O_2	15% (22.6)	1% (1.3)	67% (40.6)	17% (29.4)
	N_2O	9% (19.8)	1% (1.3)	91% (20.2)	0% (0.0)
15 min	O_2	17% (30.8)	3% (4.3)	67% (43.6)	14% (27.0)
	N_2O	13% (26.3)	1% (2.0)	81% (35.1)	5% (15.4)

*Rubber dam.

Reliability

A Student's t test for intrarater reliability revealed no significant difference for each of the behaviors studied between the first and second rating sessions of the selected five test sessions (crying, $t = -0.007$, $P = 0.99$; movement, $t = 0.75$, $P = 0.45$; quiet, $t = -0.22$, $P = 0.82$; and struggle, $t = 0.37$, $P = 0.71$). This suggests that the rater was consistent in rating behaviors throughout the study.

Level of sedation

The distribution of the levels of sedation defined by the AAPD sedation guidelines as a function of gas administered can be seen in Table 3. A chi-square analysis indicated a significant difference in the distribution of levels of sedation as a function of gas administered ($\chi^2 = 12.4$, $P < 0.002$). Generally, N_2O increased the depth of sedation with a majority of the distribution involving level III (noninter-

TABLE 3. DISTRIBUTION OF SEDATION LEVELS* DETERMINED DURING ALL RATING PERIODS AS A FUNCTION OF GAS ADMINISTERED

Sedation Level	O_2	N_2O
Anxiolysis	43	21
Interactive	57	55
Noninteractive; arousable with mild to moderate stimuli	56	82
Noninteractive; arousable with intense, repeated stimuli	0	0

*Sedation levels defined by American Academy of Pediatric Dentistry sedation guidelines.[7]

active, but arousable with mild-to-moderate stimuli such as local anesthetic administration). At no time was a patient noted to be in level IV, which is characterized as noninteractive and arousable only to repeated, intensely noxious stimuli (i.e., deep sedation).

When the distribution of levels of sedation are assessed as a function of the eight time periods and cross-tabulated with the gas administered, a statistically significant difference in distribution of sedation levels was found ($\chi^2 = 25.5$, $P < 0.029$). Two notable patterns were seen. First a slightly deeper level (mainly level II or "interactive sedation") was seen for the N_2O administration compared to O_2 during the first phases of treatment up to and including local anesthetic administration and rubber dam isolation. Secondly, a later shifting occurred in the distribution to deeper levels (i.e., level II to level III) for the N_2O administration compared to O_2 during the initiation and restorative phases of treatment.

Discussion

The main findings of this study were that N_2O administration does produce significant changes in behavior but not in physiological measures when used in combination with chloral hydrate and hydroxyzine. The primary changes observed include a mean percent decrease in struggling and crying behaviors and a mean percent increase in quiet behaviors when N_2O is administered compared to O_2. These changes in behavior generally were modestly associated with minor (i.e., within physiologic limits for the patient sample ages) and expected changes in some physiologic parameters such as HR, expired CO_2, and BP. The disruptive behaviors also accounted for more missing data during O_2 administration compared to N_2O. This suggests that the oral agents alone resulted in a less favorable experience for the child and poorer working conditions for the dental team.

The range of physiologic measures were consistent with normal values associated with the age of the children studied and no statistically significant effects were noted as a function of inhalation agent. Nonetheless, under conditions of N_2O administration compared to O_2, BP statistically was less elevated across procedures, suggesting that N_2O increased the sedative effect of the drug combinations. In fact, when O_2 was used, the elevated physiological values of HR and BP associated with crying and struggling tended to be consistent with states of emotional excitement and anger.[11] Thus, N_2O generally tends to ameliorate the stress burden placed on the child. These findings are generally consistent with those of other investigators.[4,6]

Also consistent with other reports is the change in physiologic and behavioral responses of patients associated with specific dental procedures, particularly, the time and events surrounding the injection of local anesthesia.[5,6,11] This finding is expected and constitutes one of the primary reasons for why young, uncooperative children who have significant numbers and degrees of carious destruction of teeth are not good candidates for tolerating routine delivery of dental care unless they are managed, to some degree, pharmacologically.

From the clinician's perspective, the administration of N_2O in combination with CH and hydroxyzine may be viewed with mixed considerations when these agents are used in acceptable levels and dosages, respectively. On one hand, this combination will increase the likelihood of more acceptable and easily manageable behaviors of very young, uncooperative children who require restorative procedures. Thus, the obvious advantages would include the provision of higher quality care with less intense stress on the child and dental team. Also, the possibility exists for longer working times resulting in an increase in the number of procedures completed—with the caveat that the maximum dose of local anesthesia is not exceeded. The results of this study support such a notion.

On the other hand, any sedative drug, whether used alone or in combinations with or without N_2O, requires an appropriate level of monitoring. When N_2O is added to a sedative drug regimen, the likelihood of a deeper level of sedation also increases the need to anticipate and prepare for managing adverse events should they occur. Thus, this situation includes an increased need for monitoring and emergency equipment, preparedness for emergency management, and practitioner training and skills. Economic and time-management issues are prominent considerations as well.[12] These issues may be viewed by some as a distinct clinical disadvantage in the private office.

The results of this study lend support for the anecdotal bias of many clinicians that this particular regimen of agents does not render the child patient into a physiologically unstable state from which arousal is not easily attained. None of the patients were noted at any time in this study to have attained level IV seda-

tion (i.e., deep sedation) requiring repeated, painful stimuli to arouse the patient. Also, no significant untoward trends were noted in the physiologic parameters measured corresponding to different levels of sedation in the study. As this regimen is one of the most popular[1, 13] among pediatric dentists and extrapolation of published data[1] would suggest that approximately 120 000 such sedations are done annually by pediatric dentists alone, the safety of this regimen, as tested under the conditions of this study, seems quite acceptable. Increased depth of sedation, according to AAPD guidelines, requires increased attention on the part of the dental team to monitoring the patient clinically and electronically on a more frequent basis.[7]

The technique of rating behavior in this study deserves some comment. Although videotaping and subsequent analysis using a continuous means of categorizing behaviors, as was done in this study, is extremely labor intensive, it has salient features that can be useful to clinicians and researchers. The technique has been repeatedly demonstrated to afford 1) a reasonably high reliability,[8–10] 2) a fairly unlimited set of behaviors that can be assessed which increases the flexibility of the system (i.e., behaviors other than those used in this study or those involving different sets of combinations can be used), and 3) data constituting the accumulated occurrence of behaviors continuously over defined time periods. The latter consideration is important because 1) more powerful statistical analyses can be done compared to that of categorical data summarized as a single value over a time period (i.e., summarized, categorical ratings contain unaccountable gaps during which changes in behavior may have occurred and are lost to analysis); 2) the likelihood is lessened that the rater will be influenced by prominent and exaggerated behaviors resulting in formulation of a bias (e.g., shrill screaming compared to mild, low-intensity crying); 3) valid percentages of different behaviors can be reported and compared which is important when the appointment periods vary from patient to patient; and 4) in using this format, the clinician can gain a sense of anticipated expectations in any given clinical scenario. These problems have been addressed elsewhere.[14]

One shortcoming of this study should be addressed briefly. The circumstances and design of this study did not permit determination of the exact category of sedation defined by AAPD guidelines and for an obvious reason (viz., to purposefully stimulate a peacefully resting and physiologically stable child with a noxious stimulus to assess the child's reaction *at each time period* is not conducive to sound clinical delivery of care). Logically and pragmatically, more emphasis should be placed on monitoring patient physiology for stability within expected ranges and trends of values than on determining the exact category of sedation.

Conclusions

Based on the design and constraints of this study, we concluded the following:

1. N_2O does significantly modify the behavior during a standard sedation regimen of CH (50 mg/kg) and hydroxyzine (2 mg/kg). In clinical studies its impact must be controlled to eliminate its confounding effects.
2. Physiologic parameters are not significantly influenced by 50% N_2O compared to 100% O_2.

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