# Conscious sedation of pediatric dental patients: an investigation of chloral hydrate, hydroxyzine pamoate, and meperidine vs. chloral hydrate and hydroxyzine pamoate

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# Abstract

This study evaluated two oral sedative regimens for the conscious sedation of pediatric dental patients (mean age 37.0 months) unmanageable by traditional behavior management techniques. Regimen A included chloral hydrate (Noctec®-E.R. Squibb and Sons, Princeton, NJ) at 50 mg/kg with 25 mg hydroxyzine pamoate (Vistaril<sup>®</sup> — Pfizer Laboratories, New York, NY), plus meperidine (Demerol® — Winthrop-Breon, New York, NY) at 1.5 mg/kg. Regimen B included chloral hydrate at 50 mg/kg with 25 mg hydroxyzine pamoate. In a crossover research design, 10 patients were assigned randomly to receive one regimen, to be followed by the alternative regimen during the second appointment. The primary purpose of this study was to determine if meperidine would improve patient behavior, and increase the prevalence of respiratory compromise. A secondary purpose of the study was to develop an objective method to assess behavior during the conscious sedation of pediatric dental patients. Results revealed that the addition of oral meperidine to chloral hydrate and hydroxyzine pamoate resulted in improved behavior (P <0.01) during local anesthetic injection, rubber dam delivery, and the operative dental procedure. There was no increase in the prevalence of respiratory compromise with the addition of meperidine.

## Introduction

Young, uncooperative children needing extensive dental treatment present pediatric dentists with a perplexing challenge. For these children, conscious sedation or general anesthesia are the primary treatment options that allow comprehensive restorative dental care. Because of the risks and costs involved with general anesthesia, conscious sedation is often the option of first choice.

Although most pediatric dentists prefer using oral sedation (Wright and McAulay 1973), parenteral seda-

tion techniques also are popular. In recent years however, rising liability insurance costs associated with office-based parenteral sedation have caused more pediatric dentists to favor oral sedation. Consequently, the search for safe and effective oral sedation has emerged as one of the critical needs facing pediatric dentistry (Nathan and West 1987).

In previous work (Anderson and Vann 1988; Iwasaki et al. 1989), we have focused on the physiologic monitoring of children sedated for dental treatment. Our specific goal has been improving the safety of conscious sedation through improved physiologic monitoring. In this investigation, we used these monitors to focus attention on drug efficacy and safety. In addition, we developed a method for objectively evaluating the behavior of sedated pediatric dental patients.

## **Review of Literature**

Chloral hydrate is the drug of choice for conscious sedation for many pediatric dentists because it has a wide range of safety, is low in toxicity, and is relatively easy to administer orally. Chloral hydrate is a sedativehypnotic drug that causes CNS depression, resulting in a relaxed and sleepy patient. The pharmacology of chloral hydrate has been reviewed comprehensively by Moore (1984).

Many clinical trials have been undertaken using chloral hydrate for pediatric sedation (Nathan 1987). In a survey of more than 1100 pediatric dentists, the most frequent drug regimen was chloral hydrate with hydroxyzine and nitrous oxide (Houpt 1989). In our experience, chloral hydrate has been the most predictable oral drug for conscious sedation of young children for dental treatment. However, our success with this drug is not ideal, and we have continued our search for more effective sedative regimens. Nathan and West (1987) proposed a combination of meperidine with chloral hydrate orally. They chose oral meperidine as a comedicament with chloral hydrate because of meperidine's analgesic qualities. The expectation was that it would help overcome arousal resulting from noxious intraoral manipulation, typically associated with injection of local anesthesia, rubber dam clamp placement, or cavity preparation.

Meperidine, a narcotic, is structurally similar to atropine and is marketed in the United States under the trade name Demerol® (Winthrop-Breon, New York, NY). Meperidine possesses analgesic, sedative, and euphoric properties, and potentiates the action of sedatives when taken concurrently. The site of action is the CNS opioid receptors. Side effects include nausea, vomiting, and respiratory depression, with the latter being the most serious (Eckenhoff and Helrich 1958). The respiratory depression is evidenced by decreased brainstem sensitivity to carbon dioxide (Moore and Goodson 1985).

Next to alphaprodine, meperidine has been reported to be the second most popular drug for premedicating young patients (Duncan et al. 1983). Alphaprodine, however, has not been available commercially since 1986. Meperidine is approximately 10% as potent as morphine. It possesses fewer analgesic and euphoric properties than alphaprodine, and is less likely to produce respiratory depression or emesis (King and Berlocher 1979).

Meperidine is absorbed via all routes of administration, but absorption may be erratic after intramuscular injection. Following oral administration, the analgesic effects are detectable within about 15 min, reach a peak in about 2 hr, and subside gradually over several hr. Approximately 50% of the oral dose survives firstpass metabolism and is available systemically (Mather and Tucker 1976). Meperidine is metabolized chiefly in the liver. The recommended oral dose of meperidine for sedation has been derived empirically and varies according to the source. Most agree on a dose range from 1.1 to 2.2 mg/kg (Moore and Goodson 1985; Goodman and Gilman 1986; Barnhart, Physicians' Desk Reference 1989).

Few studies have examined meperidine as an oral sedative agent for pediatric dental patients. Moore et al. (1981) report success of an oral sedative combination including meperidine and scopolamine for patients from the ages of 24–96 months. The results showed that 42% of the sedations were rated as excellent, while all patients had stable physiological vital signs throughout the procedure.

Nathan and West (1987) examined the effectiveness of low doses of meperidine with chloral hydrate for management of highly resistive pediatric dental patients. Subjects received an oral dose of chloral hydrate (50 or 70 mg/kg) and 25 mg hydroxyzine pamoate, or chloral hydrate (50 or 70 mg/kg) and 25 mg hydroxyzine pamoate and 1.5 mg/kg meperidine. Nitrous oxide analgesia, ranging from 10-50%, was used when the oral medications failed to produce adequate sedation. The sedation was 46% more successful when meperidine was added, regardless of the chloral hydrate dose. In addition, there was no suggestion of respiratory compromise.

## Analysis of Child Patient Behavior During Conscious Sedation

Studies involving conscious sedation in pediatric dentistry have focused primarily on two topics physiologic parameters and behavior. Most data from physiologic parameters are objective and amenable to statistical analysis. Evaluation of child patient behavior has been more subjective, making statistical analysis difficult, cumbersome, or impossible.

Most pediatric sedation studies have relied upon a dichotomous rating scale (satisfactory vs. unsatisfactory) for evaluating child patient behavior during conscious sedation for dental treatment. A dichotomous scale can provide valuable information for a practitioner, but the two parameters must be defined carefully to be useful, since behavior occupies a full spectrum of possibilities. What may be satisfactory child behavior to one operator may not be satisfactory to another. A dichotomous scale allows for good inter- and intraexaminer reliability; however, it is insensitive to subtle differences in behavior.

Houpt et al. (1985) used a more sophisticated analysis of behavior by developing rating scales for movement, crying, and overall behavior. Ordinal numbers were assigned to specific sets of behaviors so that the data were appropriate for sophisticated statistical analysis. Another objective rating scale that facilitates statistical analysis of subtle behavioral changes is the North Carolina Behavior Rating Scale (NCBRS). The NCBRS was developed by Chambers et al. (1981) to assess disruptive behavior for children undergoing dental treatment without sedation. This scale included four categories of behaviors that could be analyzed by specific appointment segments for frequency and duration. This scale generated data that were amenable to powerful parametric statistical analyses, and intraexaminer reliability confirmed that the scale was stable over time.

## **Purpose of the Present Study**

The purpose of this investigation was to use a new objective method of evaluating behavior during conscious sedation of pediatric dental patients. The following questions were examined. When oral meperidine is added to oral chloral hydrate and hydroxyzine pamoate:

- 1. Is there an improvement in patient behavior during the dental appointment?
- 2. Are there differences in physiologic measures of respiration between the two drug regimens?

## Materials and Methods

Patients selected were 28-48 months old and reguired conscious sedation for behavior management during two restorative dental appointments. All were referred by general dentists or other pediatric dentists who determined that the children required sedation for dental treatment. The decision to recommend conscious sedation was made after a screening examination, when behavior was evaluated and dental needs were assessed. All children were unmanageable with conventional behavior management techniques, and fit into the category of young and highly resistive. All participants were required to be healthy children with negative medical histories and Class I anesthetic risks as defined by the American Society of Anesthesia (ASA). All were required to undergo a presedation health evaluation by a physician. The sample population included 10 children.

#### **Preliminary Procedures**

The parent was informed of the proposed dental treatment and alternatives to sedation. The risks of conscious sedation were explained to the parents. Also, they were informed that the appointment would be videotaped for research purposes. Written parental consent was obtained for all procedures, including videotaping of the appointment. All sedation procedures were conducted in strict accordance with the *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Patients* (AAPD, Pediatric Dentistry 1985).

#### Sedation Appointments

Parents were given oral and written preoperative instructions, and patients were scheduled for two restorative dental appointments. The patients arrived 1 hr before the dental procedure to receive the oral medications, and were required to have been NPO since the previous midnight. The sedation was cancelled if there was any symptom or condition that could compromise patient safety (upper respiratory tract infection or violation of the NPO restriction).

The principle investigator (PI) recorded baseline physiologic data, including weight. The PI then randomly assigned the patient to one of two sedation regimens for the first appointment, with the alternative regimen assigned for the second appointment. All drugs were administered orally using a 12-cc syringe, followed by 10 cc of water. The PI delivered all medications and monitored patients from then until dismissal.

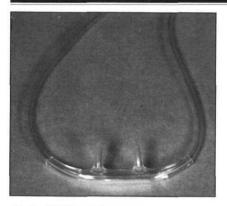
The two drug regimens were: A) chloral hydrate (Noctec®—E.R. Squibb and Sons, Inc., Princeton, NJ) at 50 mg/kg with 25 mg hydroxyzine pamoate (Vistaril® — Pfizer Laboratories, New York, NY) and meperidine (Demerol) at 1.5 mg/kg, F and B) chloral hydrate at 50 mg/kg with 25 mg hydroxyzine pamoate. After administration of the medication, the patient was supervised by the parent and PI for 30 min in a quiet room. Neither the dental operator nor the dental assistant knew which drug regimen had been given to the child; only the PI knew this information.

After 30 min in a quiet room, the patient was carried into the dental operatory and placed in a Papoose Board® (Olympic Medical Group, Seattle, WA) restraint. The chest restraint was avoided when possible to allow for unrestricted chest movement during respiration, and to better see the child's chest movement. A shoulder roll was placed under the patient's neck and shoulders to aid in maintaining a patent airway. A precordial stethoscope was placed and secured in the best position to maximize auscultation of respiratory and cardiac sounds.

A Criticare POET<sup>™</sup> (CSI, Waukesha, WI, Fig 1) was used to assist with patient monitoring and collect physiologic data. POET is the acronym for pulse oximeter/end tidal carbon dioxide monitor. Child nasal prongs (Salter Labs, Arvin, CA, Fig 2, see next page) were used with the capnometer. The pulse oximeter probe was placed on the great toe of the left foot. Data obtained from the Criticare POET included oxygen saturation of hemoglobin (SaO2), end tidal carbon dioxide (EtCO<sub>2</sub>), pulse rate, and respiratory rate. These were printed at 30-sec intervals during periods in which any of the physiologic parameters fluctuated and at 5min intervals during stable periods (SaO<sub>2</sub> > 96%), and also was visible as a digital reading on the POET.



Fig 1. Criticare POET™ unit.



Supplemental 100% oxygen (O2) was administered throughout each appointment via a Frazier-Harlake nasal nitrous oxide mask, to ensure the best possible oxygenation for each child. Anytime the SaO<sub>2</sub>

Fig 2. Child nasal prongs.

fell below 96%, the operator was instructed to reposition the patient's airway immediately. Mechanical monitoring was continuous throughout the dental appointment, and was discontinued after completion of the restorative procedures. Data from the entire procedure were printed in graphic form for SaO<sub>2</sub>, EtCO<sub>2</sub>, pulse rate, and respiratory rate.

All sedation appointments were videotaped using a Sony video camera (Model #CV-0001) wall-mounted 20 ft from the dental chair. Taping commenced from the time the patient was restrained in the Papoose Board and continued until patient dismissal from the dental chair.

Children were released to their parents only when they were alert, communicative, and ambulatory. The parent was given oral and written instructions for postoperative care.

#### Study Design

The study was designed to minimize as many potentially confounding variables as possible. Using a crossover design, each patient received both drug combinations. The sequencing of regimens was randomized to control for learning effects that the child may have experienced from the first to the second appointment. Nitrous oxide analgesia was not used as a comedicant in this study because it had the potential to confound the behavioral and physiologic comparisons of the two regimens. It was recognized that supplementation with 100% oxygen might influence the oxygen desaturations for both regimens. In fact, a previous study (Dilley et al. 1989) suggested that oxygen supplementation reduced desaturations in sedated pediatric patients. For purposes of data analysis, we planned to compare the two regimens even though the absolute number of desaturations may be reduced via oxygen supplementation. The decision to include oxygen supplementation was based on the evidence that such supplementation may enhance patient welfare.

Appointments were scheduled at the same hour to control for time-of-day variability in patients' behavior.

An attempt also was made to schedule patients with the same operator for both appointments. As noted previously, neither the operator nor assistant knew which regimen the child received at which appointment.

#### Analysis of Behavioral Data

All behavioral data were recorded on audio-videotapes that included on-screen time data. The patient, Papoose Board, and dental chair were in full view of the camera, with only the dentist's and assistant's hands visible.

Each tape was rated from start to finish by a trained and unbiased rater using the NCBRS, as described by Chambers et al. (1981). The four behaviors that were considered undesirable were foot movement, torso movement, head movement, and crying. Hand movement, a behavior usually included in the NCBRS, was not examined because the patients' hands were restrained in the Papoose Board. All behaviors were recorded and counted by the Automated Coding System (Version 1.0, JAGTECH, Rockville, MD 1987). The behavior codes were Q, A, U, and Z (Table 1).

TABLE 1. Behavioral Codes

Code	Behavior Criteria Quiet — patient quiet and/or asleep with only extraneous, inconsequential movements.				
Q					
A	Annoyed — patient cooperative allowing treatment to proceed easily, but with one to two of the undesirable behaviors present.				
U	Upset — patient noticeably disturbed, with two to three undesirable behaviors present, making treatment difficult but possible.				
Z	Zoo — patient extremely defiant with presence of foot movement, torso movement, head movement, and crying to the extent that treatment was extremely difficult.				

The appointment was divided into five discrete time blocks, which are shown in Table 2 (see next page).

The rater who performed the behavioral assessment of the videotapes using the NCRBS was trained by viewing and studying videotapes of typical sedation appointment procedures. Only one behavior code could be entered at a time (Q,A,U,Z), and each code was mutually exclusive. The Automated Coding System (ACS) computed the total time of each behavioral code for the entire appointment. After practice and calibration, the rater assessed the videotapes from the study in random order.

#### TABLE 2. Time Blocks

Time Block	Description		
Preoperative	Started when all monitors had been attached to the patient and ended with topical anesthetic application.		
Local anesthetic delivery	Started with topical anesthetic application and ended with rubber dam clamp placement.		
Rubber dam placement	Started with rubber dam clamp placement and ended when the bur penetrated the tooth.		
Operative	Started when the bur penetrated the tooth and ended with rubber dam removal.		
Postoperative	Started with rubber dam removal and ended when the child was sitting upright in the dental chair.		

To examine intraexaminer reliability for the study, the rater rated sample tapes from five patients at three different times: one week before the study, at the start of the study, and near the conclusion of the study. Each tape was rated for the amount of time spent in Q, A, U, and Z. In this setting (a random effects model), a natural measure of intrarater reliability (Neter 1985) was the ratio r:

r – between subject variance

between subject variance and within subject variance

When there is perfect reliability (WS Var = 0), r = 1. When r is near 0, there is poor reliability. Generally an r near 0.80 is considered good. For our data set, a calculation of r for each behavior type was performed.

After the rater completed the behavioral ratings for all tapes, the frequency and duration of each behavior were converted into per cent occurrences for each of the five discrete time blocks. This provided data for statistical analyses to determine whether there was a difference between the two treatment groups, in the per cent occurrences of any of the four behaviors during the five time blocks. An analysis of variance procedure (ANOVA) was used for that determination.

#### Analysis of Physiologic Data

The SaO<sub>2</sub> and EtCO<sub>2</sub> were preserved on hard copy printouts while respiratory rate was monitored continuously throughout the appointment and recorded every 5 min. Appeic episodes of at least 25 sec were recorded as were episodes when the respiratory rate was less than 15 breaths/min.

The physiologic research question was: Did the treatment groups differ in the prevalence of respiratory compromise, as defined by SaO2 desaturations of less than 96%, apnea for at least a 25 sec duration, or occasions when the respiratory rate dropped to less than 15?

## Results

The sample size included 10 child patients (five females and five males), ranging in age from 28–48 months. The random assignment resulted in six patients who received Regimen A first, while four received Regimen B first, so patient age and weight differed very slightly for the two restorative appointments. The mean age was 37.0 months for Regimen A and 37.2 months for B. The patients' mean weight for Regimen A was 15.0 kg (range, 11–19 kg) and 15.1 kg (range, 11–19 kg) for Regimen B. A summary of patients' gender, age, and weight is presented in Table 3 (see next page).

#### **Behavioral Findings**

Using Coefficients of Reliability, the r values for intraexaminer reliability were as follows: Q = 0.84, A = 0.62, U = 0.46. The prevalence of Z behavior was too infrequent to calculate meaningful r values.

To assist with the statistical analysis of the behavioral findings, variables were created to reflect the per cent of total time that a particular behavior or combination of behaviors occurred during a particular time block. For example, per cent quiet (%Q) was constructed for each time block as follows: %Q = total time quiet divided by total time quiet plus total time annoyed plus total time upset plus total time zoo. In this manner, variables were created for %Q, %A, %U, and %Z. For purposes of statistical analysis, the cells were collapsed in such a way as to yield larger cells for more valid analysis: Specifically, %Q and %Z were maintained to represent extremes in behavior, while %QA and %UZ represent intermediate behaviors (Table 4, see next page). This comparison is illustrated more graphically in Figs 3 and 4 (page 437).

For each variable and combination of variables created, an ANOVA was performed at each time block to detect sources of variation among three factors: sequence of drug, subject, and drug regimen (A vs. *B*). Least square means were generated for the dependent variable in each model to show the direction and magnitude of differences for levels of drug. The greatest source of variation, consistent across all models, was the drug regimen; those patients receiving Regimen A exhibited far more favorable behavior. The sequence of drug administration and subject explained little of the variation, indicating that the drug effect was consistent across all subjects and both visits.

#### TABLE 3. Summation of Patients

				Regimen A		Regimen B		
Patient	Sex	Age (mo)	Weight (kg)	Dosage* (mg)	Age (mo)	Weight (kg)	Dosage* (mg)	
1	F	37	14	F-25 H, 700 CH, 21.0 M	39	15	S-25 H, 750 CH	
2	м	36	14	F-25 H, 700 CH, 21.0 M	36	14	S-25 H, 700 CH	
3	м	46	17	F-25 H, 850 CH, 25.5 M	46	17	S-25 H, 850 CH	
4	м	33	16	S-25 H, 800 CH, 24.0 M	33	16	F-25 H, 800 CH	
5	F	33	15	F-25 H, 750 CH, 22.5 M	34	15	S-25 H, 750 CH	
6	F	40	15	S-25 H, 750 CH, 22.5 M	39	15	F-25 H, 750 CH	
7	м	28	11	F-25 H, 550 CH, 16.5 M	29	11	S-25 H, 550 CH	
8	м	47	19	S-25 H, 950 CH, 28.5 M	46	19	F-25 H, 950 CH	
9	F	33	16	S-25 H, 800 CH, 24.0 M	33	16	F-25 H, 800 CH	
10	F	37	13	F-25 H, 650 CH, 19.5 M	37.2	13	S-25 H, 650 CH	
Mean		37.0	15.0		37.2	15.1		

\* CH = Chloral Hydrate

H = Hydroxyzine Pamoate

M = Meperidine

F = First Appointment

S = Second Appointment

#### **Physiologic Findings**

A desaturation event was defined as a period of time when the SaO<sub>2</sub> fell below 96% during 100% O<sub>2</sub> supplementation. Desaturations were classified (Iwasaki et al. 1989) as mild (90–95% SaO<sub>2</sub>) or moderate (less than 90% SaO<sub>2</sub>). All desaturation data were recorded on hard copy printouts that printed automatically at 30-sec intervals. Over the 10 appointments, for Regimen A, there were seven desaturations in the 90-95% range, and two desaturations at less than 90% (one was 89%; the lowest was 85%) (Table 5, see next page). For Regimen B, there were 13 desaturations in the 90–95% range, and none less than 90% (Table 6, see next page). The prevalence of desaturations was low and the trends were similar for both regimens, supporting no differences in Regimen A vs. B.

Measurement error for desaturations was felt to be minimal. Foot movement was infrequent, and when it occurred, the POET displayed a decrease in pulse signal amplitude and no change in saturation values.

The range of respiratory rates for Regimen A vs. Regimen B was very similar. There were no episodes of apnea that lasted 25 sec for either regimen. Over the 10 appointments, Regimen A patients had six occasions

#### TABLE 4. Behavioral Data

Time	%Q	%QA*	%UZ*	%Z*
Block	A∕B	A/B	A∕B	A/B
1 (preop)	99.1/54.3	99.1/72.9	0.9/27.1	0.6/6.4
2 (inj)	69.5/16.5	90./47.8	9.1/52.1	0.3/6.5
3 (rd)	78.2/14.7	96.1/50.0	3.9/50.0	0.0/9.8
4 (op)	88.3/41.8	94.9/65.6	5.1/34.4	0.4/4.0
5 (postop)	78.7/40.5	81.8/91.2	18.2/8.8	3.2/0.3

A = Regimen A; B = Regimen B

%Q = total time quiet (Q) divided by total time quiet (Q) plus total time annoyed (A) plus total time upset (U) plus total time zoo (Z)

%A =total time A divided by (Q + A + U + Z)

%U = total time U divided by (Q + A + U + Z)

%Z =total time Z divided by (Q + A + U + Z)

Please note: In reality, %Q + %A + %U + %Z = 100%

%QA = total time Q + total time A divided by (Q + A + U + Z)

UZ =total time U + total time Z divided by (Q + A + U + Z)

\*Cells were collapsed to provide larger cell sizes to facilitate statistical analyses; %Q and %Z are illustrated as the extremes in patients' behaviors.

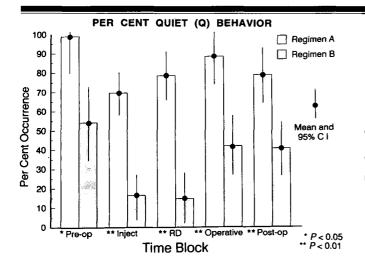


Fig 3. Percentquiet(Q) behavior.

when the respiratory rate dropped to less than 15 breaths/min while Regimen B patients had seven.

## Discussion

The use of narcotics during conscious sedation of pediatric dental patients has been controversial for many years. This concern was reflected by the recent removal of the narcotic alphaprodine (Nisentil<sup>®</sup> --Hoffmann-LaRoche, Nutley, NJ) from commercial availability (1986). Risks and misadventures using narcotics for pediatric sedation have been well docu-

TABLE 5.	Patient	Desaturations	for	Regimen A	(CH)	.H.D)

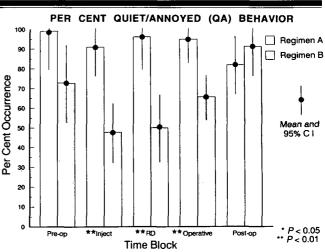


Fig 4. Per cent quiet/annoyed (QA) behavior.

mented (Goodson and Moore 1983; Moore and Goodson 1985). Interestingly, almost all reported mishaps involved parenteral administration of a narcotic.

There have been very few studies involving oral administration of narcotics for conscious sedation of pediatric dental patients. Nathan and West (1987) found that the potentiating effects of oral meperidine added to oral chloral hydrate showed a statistically significant improvement in behavior, with or without nitrous oxide. The study was retrospective, and the experimental design did not permit patient exposure to all four experimental variables. Also, the criterion for

Patient	# of SaO <sub>2</sub> 90-95%	# of SaO <sub>2</sub> > 90%*	Appointment Duration (min)
1	0	0	85
2	0	0	45
3	0	0	110
4	1	1	45
5	0	0	70
6	2	0	65
7	0	0	60
8	4	1	120
9	0	0	62
10	0	0	70
Total	7	2	
Mean			73.2
Range			45-120

1

**TABLE 6.** Patient Desaturations for Regimen B (CH,H)

Patient	# of SaO <sub>2</sub> 90-95%	# of SaO <sub>2</sub> > 90%*	Appointment Duration (min)
1	0	0	95
2	0	0	40
3	0	0	80
4	1	0	38
5	3	0	105
6	5	0	75
7	3	0	40
8	1	0	77
9	0	0	65
10	0	0	90
Total	7	2	
Mean			70.5
Range			38-105

\* There were no desaturations < 75%

CH = Chloral Hydrate

H = Hydroxyzine Pamoate

M = Meperidine

\* There were no desaturations < 75%

CH = Chloral Hydrate

H = Hydroxyzine Pamoate

successful sedation was an indirect and gross measure of patient behavior — the sedation was considered successful only when harsh physical restraint was not needed to overcome persistent behavioral interference. Finally, while there was no incidence of detectable loss of protective reflexes or respiratory depression, the methods of physiologic monitoring were less precise than today's newer methods. In spite of these criticisms, the Nathan and West (1987) study generated very interesting findings that stimulated our interest in undertaking the present study.

We selected an oral dosage of 50 mg/kg chloral hydrate with 25 mg Vistaril, because that combination is one of our standard regimens for pediatric dental sedation and one which we have had reasonable success. We selected 1.5 mg/kg meperidine, because authorities agree on a dosage within 1.1–2.2 mg/kg, and also because 1.5 mg/kg was used with success and safety by Nathan and West (1987).

#### **Behavioral Findings**

The traditional dichotomous measure of behavior during sedations as either a success or a failure is wrought with ambiguity and confusion. We tried to develop a more objective means of evaluating child patient behavior by utilizing video technology, the NCBRS, and the ACS. Videotapes of the sedation appointments were reviewed by a trained observer, using specific behavioral categories. Therefore, objective behavioral assessment was achieved to provide meaningful results for the pediatric dental practitioner.

The r values for Q and A (0.84 and 0.62, respectively) revealed good intraexaminer reliability. There were low r values for U and inadequate data to calculate values for Z. An examination of the raw data revealed that these low reliability values resulted from the lower prevalence of the U and Z behaviors. Because of the poor intraexaminer reliability for the U and Z categories, we have drawn no conclusions from those findings. Rather, we have focused our discussions on the Q and QA findings because of our confidence in their validity. Finally, we acknowledge that a problem in this study, like many pediatric dental sedation studies, is a small sample size. For that reason, we have attributed little significance to findings unless we observed a statistical significant of a P < 0.01.

Our first research question was whether there was any behavior difference between the two treatment groups throughout treatment. In general, the addition of meperidine resulted in significantly improved behavior during all five time blocks. This improvement was dramatic during the more invasive periods, such as the local anesthetic injection or rubber dam application. During the preoperative period, the children demonstrated a mean %Q of 99.1% for Regimen A vs. 54.3% for Regimen B (P = 0.013). The greatest difference in %Q was during local anesthetic injection and rubber dam placement (Fig 3). During injection, the children were quiet 69.5% of the time for Regimen A vs. 16.5% for Regimen B, a fourfold difference (P = 0.001). The mean %Q for rubber dam application was 78.2% for A vs. 14.7% for B, a fivefold difference (P = 0.001). These large differences can be explained in at least two ways. Because local anesthesia and rubber dam application occurred approximately 1 hr after drug delivery, this may have coincided with peak plasma concentrations of meperidine. Another explanation may be that these procedures can be the most painful and stimulating the addition of meperidine may have provided better analgesia. The mean %Q behavior for the operative and postoperative periods followed the pattern of significantly improved behavior with Regimen A, a two-fold difference in improvement in each period.

The mean %QA behavior also demonstrated an improvement in behavior with Regimen A. The more invasive local anesthesia, rubber dam application, and operative periods showed significantly (P < 0.01) improved with behavior with Regimen A (Fig 4).

In summary, the differences in behavior in Regimen A vs. Regimen B appear to support strongly that meperidine exhibited both its narcotic and/or sedative effects during the more painful and stressful phases of the dental treatment.

In addition to evaluating behavior by the NCBRS, a more subjective assessment of patient behavior was made by requesting all operators to rate each sedation as either a success or a failure, using their personal definitions. Regimen A was rated 100% successful vs. a 30% success rate for B. As noted previously, the operator was always blind to the drug regimen. Even though this was a highly subjective assessment because the criteria for success or failure was not defined, this is a measure often reported in other sedation trials. These subjective findings lend support to our behavioral data collected by the more sophisticated objective methods.

## **Physiologic Findings**

We suspected that the addition of meperidine to chloral hydrate and hydroxyzine pamoate would result in increased respiratory depression as exhibited by a decreased rate and depth of breathing and perhaps by a higher prevalence of apnea. However, patients in both regimens exhibited surprisingly little evidence of respiratory compromise. There were no apneic periods that lasted 25 sec. The two regimens were very similar in the prevalence of respiratory rate drops to 15 breaths/ min — 6 for Regimen A vs. 7 for Regimen B, with four patients exhibiting drops to 15 with both regimens. Over the 10 appointments, Regimen A had a total of only seven desaturations in the 90–95% range vs. 13 such desaturations for Regimen B. Many desaturations, especially in Regimen B, were associated with crying. A similar association was observed by Iwasaki et al. (1989), who reported a high prevalence of SaO<sub>2</sub> below 96% for children who exhibited crying and breathholding. This physiologic phenomenon still is not understood completely but may be secondary to venous congestion (Kim et al. 1986).

Iwasaki et al. (1989) studied chloral hydrate at 75 mg/kg with no O<sub>2</sub> supplementation and reported 11.8 desaturations (< 96%) per appointment and 1.3 desaturations (< 90%) per appointment — a prevalence of desaturations more than 10 times greater than we observed. On the basis of our findings, we cannot conclude that supplemental oxygen reduced desaturations in our study, but this is our hypothesis. We speculate that we observed so few desaturations because the supplemental 100% O2 rendered the patients hyperoxic. In the hyperoxic range (high  $PaO_2$ ), brief periods of respiratory compromise may not reduce a decrease in  $SaO_2$  because  $SaO_2$  is related to  $PaO_2$  by a nonlinear curve; despite large decreases in  $PaO_2$  on the flat portion of the oxygen hemoglobin disassociation curve ( $PaO_2 > 100\%$ ), the SaO<sub>2</sub> does not decrease significantly.

#### Potential Concerns With the Use of Oral Meperidine

Although these results are encouraging, the addition of meperidine to an oral regimen for children has potential liabilities. We experienced no episodes of nausea or vomiting, but emesis is a reported side effect of meperidine; aspiration of vomitus can be a life-threatening situation. NPO requirements must be enforced strictly to avoid potential problems.

A second concern is the possibility of respiratory depression when a narcotic is administered. We recommend strongly that practitioners use O2 supplementation when narcotics are used for pediatric conscious sedation; in fact, the prudent practitioner should consider using supplemental  $O_2$  with any conscious sedation drug regimen for pediatric patients. Also, one should always have Narcan® (DuPont Pharmaceuticals, Inc., Manati, Puerto Rico) and positive pressure  $O_2$  available for emergency situations if narcotic sedatives are used.

Finally, although not measured in this study, it was our impression that children receiving meperidine experienced a longer period of postoperative drowsiness and disorientation. This needs further study so recommendations regarding recovery protocols can be made. If the recovery period is too long, this sedation regimen may not be popular with private practitioners in busy practice settings.

## Conclusions

In this study, Drug Regimen A included chloral hydrate, hydroxyzine pamoate, and meperidine. Regimen B included chloral hydrate and hydroxyzine pamoate. Under the conditions of this study, the following conclusions were made:

- 1. Using video technology, the NCBRS was combined with a new computer program (ACS) to yield a valid and reliable analysis of the behavior of pediatric patients undergoing restorative treatment under conscious sedation
- 2. As compared to Regimen B, Regimen A resulted in a significant improvement in pediatric patient behavior during the injection, the rubber dam application, and the operative periods. There was a trend toward more cooperative behavior for Regimen A during the preoperative and postoperative periods
- 3. Both regimens A and B resulted in little respiratory compromise as defined by the prevalence of SaO2 desaturations < 96%, apnea of at least 25 sec, or respiratory rates of less than 15 breaths per min.

This investigation was supported by NIH Grant #2-S07-RR05333. The authors express their appreciation to several others who helped make this study possible: Doctoral Candidate Jamie Grady and Dr. Gary Koch in the Biometrics Laboratory of the University of North Carolina School of Public Health, Chapel Hill, NC; Dr. Meg Lockery our behavior examiner; and to the faculty and staff of the Frank Porter Graham Child Development Center, for sharing the Automated Computing System software technology.

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- American Academy of Pediatric Dentistry: Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatr Dent 7:334–37, 1985.
- Anderson JA, Vann WF: Respiratory monitoring during pediatric sedation: pulse oximetry and capnography. Pediatr Dent 10:94– 101, 1988.
- Barnhart ER ed: Physicians' Desk Reference, 43rd Edition. Oradell, NJ: Medical Economics Co. Inc., pp 2245–46, 1989.
- Chambers WL, Fields HW, Machen JB: Measuring selected disruptive behaviors of the 36 to 60-month-old patient. Part 1: Development and assessment of a rating scale. Pediatr Dent 3:251–56, 1981.
- Dilley DC, Vann WF, Anderson JA, Iwasaki J: Pulse oximetry and capnography monitoring of pediatric sedation patients. J Dent Res 68 (Special Issue): 198, Abstract #133, 1989.
- Duncan WK, Pruhs RJ, Ashrafi MH, and Post AC: Chloral hydrate and other drugs used in sedating young children: A survey of American Academy of Pedodontics Diplomates. Pediatr Dent 5:252–56, 1983.

Eckenhoff JE, Helrich M: Study of narcotics and sedatives for use preanesthetic medication. JAMA 167:415–22, 1958.

- Gilman AG, Goodman LS, Gilman A: Goodman and Gilman's: The Pharmacologic Basis of Therapeutics. New York, NY: Macmillan Publishing Co., pp 513–16, 1985.
- Goodson JM, Moore PA: Life-threatening reactions after pedodontic sedation: An assessment of narcotic, local anesthetic, and antiemetic drug interaction. J Am Dent Assoc 107:239–45, 1983.
- Houpt MI: Report of project USAP: The use of sedative agents in pediatric dentistry. ASDC J Dent Child 56:302–9, 1989.
- Houpt MI, Sheskin RB, Koenigsberg SR, Desjardins PJ, Shey Z: Assessing chloral hydrate dosage for young children. ASDC J Dent Child 52:364–69, 1985.
- Iwasaki J, Vann WF, Dilley DC, Anderson JA: An investigation of pulse oximetry and capnography as monitors of pediatric patients sedated for dental treatment. Pediatr Dent 11:111–17, 1989.
- Kim J-M, Arakawa K, Benson KT, Fox DK: Pulse oximetry and circulatory kinetics associated with pulse volume amplitude measured by photoelectric plethysmography. Anesth Analg 65:1333–39, 1986.

- King DL, Berlocher WC: Premedication in pedodontics: attitudes and agents. Pediatr Dent 1:251–57, 1979.
- Mather LE, Tucker GT: Systemic availability of orally administered meperidine. Clin Pharmacol Ther 20:535–40, 1976.
- Moore RL, Carrel R, Binns WH: A balanced oral sedation technique. J Dent Child 48:364–67, 1981.
- Moore PA: Therapeutic assessment of chloral hydrate premedication for pediatric dentistry. Anesth Prog 31:191–95, 1984.
- Moore PA, Goodson JM: Risk appraisal of narcotic sedation for children. Anesth Prog 32:129–39, 1985.
- Nathan JE: Management of the refractory young child with chloral hydrate: Dosage selection. ASDC J Dent Child 54:22–29, 1987.
- Nathan JE, West MS: Comparison of chloral hydrate-hydroxyzine with and without meperidine for management of the difficult pediatric patient. ASDC J Dent Child 54:437–44, 1987.
- Neter J: Applied Linear Statistical Models, 2nd Edition. Homewood, IL: Irwin Press, 642–47, 1985.
- Wright GZ, McAulay DJ: Current premedicating trends in pedodontics. ASDC J Dent Child 40:185–87, 1973.

# Puerto Ricans run highest infant mortality risks among Hispanics in U.S.

Babies born to Puerto Rican parents run the highest neonatal and postnatal infant mortality risks among Hispanics in the U.S. and Puerto Rico, according to a study published in the *Journal of the American Medical Association*.

Compared with the infant mortality risks of non-Hispanic whites, among all Hispanic groups, the neonatal (less than 28 days old) mortality risk was higher among Puerto Rican islanders, according to this study by José Becerra, MD, MPH, of the Centers for Disease Control, Atlanta, GA, and colleagues. The postnatal (28 to 364 days) mortality risk was highest among continental Puerto Ricans.

The authors examined 1983 and 1984 Linked Birth and Infant Death data sets of singledelivery infants of Hispanic descent, and compared them with those of non-Hispanic whites. Infants who had a Hispanic identifier marked on their birth certificate, or who were born to a woman who was born in Mexico, Puerto Rico, or Cuba were defined as Hispanic. A total of 828, 579 live Hispanic births were examined.

Neonatal mortality risks among all other Hispanic groups were not significantly different from those among non-Hispanic whites, according to the authors. Postnatal mortality risks (PNMR) for Puerto Rican and Mexican-Americans were the same as non-Hispanic whites. PNMRs for Cuban-Americans were below those of non-Hispanic whites.

The authors believe that their study underscores the heterogeneity of the Hispanic population in the United States, and the need to consider these differences in the planning and implementation of ethnic-specific interventions to prevent infant mortality.