Physiologic response and adverse reactions in pediatric dental patients sedated with promethazine and chloral hydrate or meperidine

Deirdre R. Sams, DDS, MS Carl M. Russell, DMD, MS, PhD

Introduction

Drug combinations for premedication are used to allay apprehension and to counter adverse reactions such as nausea and vomiting, but drug combinations potentially increase the risk of other adverse reactions. Monitoring is very important, and the *Guidelines for elective use of conscious sedation* of the American Academy of Pediatric Dentistry[1] recommend assessing heart rate and respiratory rate at various intervals during and after the sedation. Cardiopulmonary function should be assessed continuously at regular intervals during pediatric dental sedations. Pulse oximetry assists in the early detection of any oxygen saturation changes by measuring oxyhemoglobin levels.[1,2]

Reported side effects with chloral hydrate include gastric irritation, excitation, and respiratory depression. This drug is contraindicated in patients with renal or hepatic impairment.[3] Nausea, vomiting, dizziness, and respiratory depression frequently are reported adverse reactions when meperidine is used as a sedative agent.[3-5] A comprehensive survey of narcotic sedations indicates that the risk of adverse reactions is approximately 1:5,000 compared to 1:30,000 for non-narcotic techniques. Also a higher risk exists with a narcotic agent and promethazine versus a narcotic and hydroxyzine combination, and that risk is increased with the addition of a local anesthetic.[6]

This study evaluated physiological changes and incidence of adverse reactions for oral sedations combining promethazine with chloral hydrate or with meperidine.

Methods

Twenty-four children were ASA Class I, ranged in age between 18 and 48 months, and preoperatively exhibited definitely negative behavior in accordance with the Frankl Scale.[7] An informed consent was obtained and this study met requirements of the Institutional Review Board. Patients were assigned randomly to one of two oral sedation treatment groups and received either 50 mg/kg chloral hydrate (CH) (Barre National, Inc., Baltimore, MD) and 1 mg/kg Phenergan® (PH) (Wyeth Lab Inc., Philadelphia, PA) or 1 mg/kg for Demerol® (DE) (Winthrop Pharmaceuticals, New York, NY) and (PH).

Each patient was NPO for at least 8 hr, received medication, and remained in a quiet room for approximately 60 min after drug administration. All patients were placed in a Papoose Board® (Olympic Papoose Board, Olympic Medical Corp., Seattle, WA), received a local anesthetic (not < 1.8 ml or > 3.6 ml 2% Xylocaine with 1:100,000 epinephrine), and were monitored for physiologic vital signs. Nitrous oxide was administered to 21 of the 24 study patients. (One patient displayed excellent behavior and the other two exhibited severe body movements that made stabilization of the nasal mask difficult.) The concentration of nitrous oxide did not exceed 50%. Vital signs (blood pressure, heart rate, respiration, temperature, oxygen saturation) were recorded preoperatively; for treatment procedures—injection phase, 15, 30, and 45 min after the injection; and postoperatively 30 min after treatment. Hypoxemia was based on oxygen saturation below 95%.[8] At least 6 hr after treatment, a telephone interview was conducted with the parent to assess postoperative complications such as nausea, vomiting, fever, pain, increased anxiety/irritability, lightheadedness, and skin rash. Parents were given Crystaline™ (Sharn Inc., Tampa, FL) skin temperature strips to monitor temperature.

The mean values for the vital signs during pre-, intra-, and postoperative treatment phases and mean differences from the preoperative baseline were analyzed by a 2-sample *t*-test with an alpha level of 0.05.

Results

The mean age, weight, and duration of the sedations are recorded in Table 1. There were no statistically significant differences between the drug regimens with respect to age, weight, or duration of treatment. All patients were responsive throughout the sedation procedures.

There were no differences between the drug regimens for any vital signs differences from preoperative baseline values in the physiological parameters studied (Table 2). Preoperatively, there was a statistically significant difference between the regimens for diastolic blood pressure (DBP) ($P = 0.0259$) and respiratory rates ($P = 0.0487$). The mean DBP was higher, 61.6 (± 13.8 SD) for DE/PH compared with CH/PH, which had a value of 50 (± 10.0 SD). Postoperatively, there

Table 1. Mean values for sedations

Drug Regimen	*Mean Age (months)*	*Mean Weight (kg)*	*Mean Treatment Time (minutes)*
Chloral hydrate / Phenergan	31.0 ± 8.6	13.3 ± 2.7	50.8 ± 13.3
Demerol/ Phenergan	35.8 ± 10.6	13.4 ± 3.3	50.9 ± 17.6

was a statistically significant difference for oxygen saturation ($P = 0.04$) with DE/PH having a 99.2% (± 1.0 SD) saturation compared to 98.2% (± 1.2 SD) for CH/PH ($P = 0.34$).

There were no episodes of emesis in this study. Verification of adherence to diet/NPO instructions occurred before drug administration. All patients were compliant with these preoperative instructions. Two female patients, 24 months in age, sustained oxygen saturation readings between 90–95%. One patient was sedated with 475 mg CH and 9.5 mg PH. The other patient was sedated with 12.3 mg DE and PH.

The CH/PH sedations were associated with two cases of postoperative pain, six of increased anxiety/irritability, and two of fever. No temperature values were given by the parents. With the DE/PH sedations, fever was not reported postoperatively, but one patient was reported to have increased anxiety/irritability, and two had episodes of postoperative pain.

Discussion

All patients in this study maintained stable vital signs throughout the dental procedures. All sedations were successful. Preoperatively, the patients sedated with DE/PH showed statistically significant differences with respect to diastolic blood pressure values, but the clinical significance is questionable. Fluctuations in heart rate values were noted during treatment; however, no statistically significant differences were evident. These findings are consistent with other investigators.[9,10]

Oxygen desaturation occurred in two of the 24 patients. Both patients were females younger than 30 months old with oxygen hemoglobin saturation levels between 90 and 95%. Mueller et al.[8] and Hasty et al.[4] reported episodes of desaturation and these—as well as those in the current study—were managed by repositioning the head.

Respiratory means indicated a statistically significant difference for preoperative values prior to drug administration with patients selected to receive DE/PH having a lower rate. This difference was attributed to chance since this study did not measure vital signs before randomization. Patients sedated with CH/PH

Table 2. Effect of Phenergan with chloral hydrate or Demerol on vital signs monitoring

Parameters Evaluated	*Preoperative Measurement*	*Injection Phase*	*15 Min Postinjection*	*30 Min Postinjection*	*45 Min Postinjection*	*Postoperative Measurement*
BP-systolic						
Chloral hydrate	101.8 ± 18.5	107.8 ± 32.0	102.3 ± 22.3	110.0 ± 24.4	92.1 ± 6.2	106.0 ± 19.0
Demerol	108.6 16.0	116.7 16.0	113.6 21.0	129.1 16.0	117.2 25.0	100.0 12.0
BP-diastolic						
Chloral hydrate	50.0 10.0	59.7 28.1	49.0 15.2	55.7 28.4	42.6 5.1	57.8 9.3
Demerol	61.6 14.0*	55.4 14.0	56.1 22.0	55.5 24.0	54.8 16.0	58.0 14.1
HR						
Chloral hydrate	110.6 24.0	97.2 35.0	101.8 20.0	105.6 19.0	102.5 22.2	15.7 31.2
Demerol	112.3 22.1	103.9 42.0	117.0 32.0	103.5 23.0	127.0 31.3	119.6 31.4
RR						
Chloral hydrate	24.5 5.0					29.69 29.2
Demerol	21.5 2.0*					21.54 3.0
O_2 saturation						
Chloral hydrate	99.1 1.3	98.4 2.0	99.5 1.2	98.8 2.2	99.0 1.1	98.2 1.2
Demerol	99.3 1.0	99.0 1.3	99.2 1.4	99.3 2.0	99.6 1.0	99.2 1.0*
Temperature						
Chloral hydrate	94.5 1.0	94.7 1.1	94.8 1.3	94.9 2.1	95.0 2.4	94.8 1.5
Demerol	94.7 ± 2.0	95.0 ± 2.0	95.4 ± 1.0	95.5 ± 1.0	96.2 ± 1.3	95.0 ± 1.0

* Significant difference at 0.05 level between the two regimens for this parameter.

had a higher respiratory rate postoperatively, while the rate was the same before and after the procedure for the DE/PH sedations. There were no episodes of emesis in this study. The addition of an anti-emetic may decrease the potential of emesis during sedations.

Fever occurred in two patients who were sedated with CH/PH, but the parents did not define fever in numerical terms and did not use the strips provided. Parents also reported increased anxiety/irritability and/or pain as other postoperative symptoms. Many of these patients experienced their first invasive dental procedure, so pain could have been associated with the procedures performed and/or the diminishing effect of the local anesthetic.

This project was submitted in partial fulfillment of the requirements for the degree of Master of Science in the Department of Community and Public Health Dentistry in the Graduate School at The University of Alabama at Birmingham. Special recognition goes to the dental operators, Drs. Araya Phonghanyudh and Claudia Tomaselli, and to the dental clinic staff of The Children's Hospital of Alabama.

Dr. Sams is assistant professor, Department of Pediatric Dentistry, and Dr. Russell is associate professor, Office of Biostatistics and Department of Oral Diagnosis and Patient Services, Medical College of Georgia, Augusta.

1. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatr Dent 7:334–37, 1985.
2. Iwasaki J, Vann WF, Dilley DCH, Anderson JA: An investigation of capnography and pulse oximetry as monitors of pediatric patients sedated for dental treatment. Pediatr Dent 11:111–17, 1989.
3. Troutman KC: Pharmacologic management of pain and anxiety for pediatric patients. In Pediatric Dentistry: Total Patient Care, Wei SHY, ED. Philadelphia: Lea & Febiger, 173–77, 1988.
4. Hasty MF, Vann WF Jr, Dilley DC, Anderson JA: Conscious sedation of pediatric dental patients: an investigation of chloral hydrate, hydroxyzine pamoate and meperidine vs. chloral hydrate and hydroxyzine pamoate. Pediatr Dent 13:10–19, 1991.
5. Poorman TL, Farrington FH, Mourino AP: Comparison of chloral hydrate/hydroxyzine combination with and without meperidine in the sedation of pediatric dental patients. Pediatr Dent 12:288–91, 1990.
6. Aubuchon RW: Sedation liabilities in pedodontics. Pediatr Dent 4:171-80, 1982.
7. Frankl SN, Shiere FR, Fogels HR: Should the parent remain with the child in the dental operatory? ASDC J Dent Child 29:150–63, 1962.
8. Mueller WA, Drummond JN, Pribisco TA, Kaplan RF: Pulse oximetry monitoring of sedated pediatric dental patients. Anesth Prog 32:237–40, 1985.
9. Roberts SM, Wilson CFG, Seale NS, McWhorter AG: Evaluation of morphine as compared to meperidine when administered to the moderately anxious pediatric dental patient. Pediatr Dent 14:306–13, 1992.
10. Saravia ME, Currie WR, Campbell RL: Cardiopulmonary parameters during meperidine, promethazine, and chlorpromazine sedation for pediatric dentistry. Anesth Prog 34:92–96, 1987.