Evaluation of morphine as compared to meperidine when administered to the moderately anxious pediatric dental patient

Susan Merlene Roberts, DDS, MS Carolyn F. G. Wilson, DDS, MSD N. Sue Seale, DDS, MSD Alton G. McWhorter, DDS, MS

Abstract

This investigation evaluated two narcotic regimens used to sedate pediatric dental patients who previously demonstrated uncooperative behavior. One consisted of submucosal morphine (0.15 mg/kg), and the other, oral meperidine (2.2 mg/kg); both were administered in combination with oral promethazine (1.1 mg/kg). *Patients 2–7 years old were sedated with one of the two regimens and videotaped during dental treatment. If* sedation was successful, the child received the other regimen at the next appointment, resulting in a total of 42 sedations in 29 children. Later, patient behavior was rated blindly by two independent observers viewing tapes of specific events during dental treatment. Fourteen of 23 (61%) patients receiving morphine and 11 of 19 (58%) patients receiving meperidine were sedated successfully. Vital signs, including pulse, respirations, blood pressure, and oxygen saturation were monitored and remained stable for both groups. ANOVA for repeated measures showed no significant differences for any vital sign in either group across time. Wilcoxon's signed rank test revealed significant improvement for the patients successfully treated in both groups when presedation behavior was compared with behavior during the events of rubber dam application, operative, restorative treatment, and exit (meperidine, P < 0.005 and morphine, P < 0.001). Improvement also was seen in the meperidine group for the event of local anesthesia (P < 0.01). Chi-square analysis showed no statistically significant differences in effectiveness or safety between the two sedative regimens. (Pediatr Dent 14:306-13, 1992)

Introduction

National surveys have concluded that meperidine and alphaprodine were the most commonly used narcotics for conscious sedation.^{1, 2} Despite its widespread use, there are surprisingly few well-designed studies in the literature documenting the safety and effectiveness of orally administered meperidine.

Meperidine is a synthetic narcotic analgesic. The therapeutic oral dosage of meperidine for sedation is 1.1 to 2.2 mg/kg (0.5 to 1 mg/lb) given orally 30 to 90 min before the beginning of the procedure.³⁻⁵ Meperidine is absorbed well by all routes, but is less effective when given orally because only 50% of the drug escapes first-pass metabolism to enter the blood stream.^{6–8} However, the oral route is considered by most pediatric dentists to be the route of choice when sedating an uncooperative pediatric dental patient, and many believe the oral route to be the safest and associated with the least potential for overdose. Peak activity from an oral dose occurs 1–2 hr after ingestion, with maximal respiratory depression occurring after 90 min.⁹ Respiratory depression is in the same order of frequency and magnitude as that observed with morphine.

Droter¹⁰ published a report on a technique on the use of orally administered meperidine hydrochloride

as a dental sedation using a dose of "50 mg for the average problem child." He reported that approximately 5% of the children receiving this drug experienced nausea or vomiting about 15 min after administration. Other reports^{11–16} describe the effects of meperidine combined with cosedatives such as promethazine, pentobarbital, scopolamine, chloral hydrate, and chlorpromazine. The doses of the meperidine in these studies ranged from 0.8–2.0 mg/kg for IM use and 0.5–0.75 mg/lb for oral administration. Success of these sedations varied from 42–100%. Although infrequent, adverse reactions include nausea, vomiting, and increased blood pressure and pulse.

The second most commonly used narcotic, alphaprodine, was withdrawn from the market by the manufacturer in 1986, and pediatric dentists have since been searching for a replacement for this more potent drug. Morphine has been suggested, as it has been quite effective in premedicating children in medicine. Recent anecdotal accounts by pediatric dentists in Texas (see footnote) indicate its current use in sedating pediatric dental patients and claim high success rates. It is disturbing to observe the increased use of morphine when there are no well-designed studies to advocate a safe, effective dose for the management of the uncooperative dental patient. Morphine sulfate is a narcotic analgesic. Morphine has been studied in the pediatric age group far more than any other opioid; therefore, its pediatric margin of safety, as well as its side effects, are established more accurately.⁸

Meperidine and morphine produce the same degree of respiratory depression when given in equianalgesic doses, and — when patients with biliary disease are excluded — both have the same contraindications.

Despite adverse side effects, physicians have used morphine quite effectively in medicating children for a variety of reasons, including relief of moderate-to-severe acute or chronic pain. Morphine is used preoperatively to sedate the patient, allay apprehension, facilitate induction of anesthesia, and reduce the anesthetic dosage.¹⁷ Effective sedation with morphine usually occurs 10-30 min following intramuscular (IM) or subcutaneous administration. The recommended pediatric dosage of morphine sulfate is 0.1-0.2 mg/kg (up to 15 mg) when given every 4 hr IM or subcutaneously.^{7, 17, 18} O'Hara et al.¹⁹ compared oral morphine (0.15 mg/kg) given every 4 hr to IM meperidine (1 mg/ kg) given every 3 to 4 hr in children during the first 48 hr after orthopedic surgery. Their assessment favored morphine because there was a significantly higher number of pain-free children during the first two postoperative days with no significant differences in the side effects of the two regimens.

In the supine position, therapeutic doses of morphine have no major effect on blood pressure or cardiac rate and rhythm. Morphine is absorbed readily from the GI tract, nasal mucosa, lung and after subcutaneous or IM injection. Maximal respiratory depression correlates with the pharmacokinetics of morphine and occurs 7 min after an IV dose, 30 min following IM injection, and 90 min after subcutaneous administration.^{7, 8}

There is only one published article in the dental literature dealing with the use of morphine sulfate for sedating the apprehensive child for dental procedures.²⁰ Schneider reported nine years of data, 4,363 episodes, from patients in his private pediatric dental practice for whom he used morphine sulfate in combination with hydroxyzine pamoate and nitrous oxide to alleviate apprehension during extensive dental procedures. The IM dose of morphine was described as "1 mg/year of age, provided the patient was not underweight." When used with hydroxyzine, he advocated reducing the morphine dose by one-third. Nitrous oxide:oxygen was used, but no concentrations were given. All patients were restrained, and he occasionally supplemented the original dose of morphine if the patient became restless. Many of the children fell asleep during treatment, and no vital signs were monitored. He reported complications including vomiting, hyperactivity, and five patients having convulsions during treatment. Schneider's results showed that the sedation regimen worked best for the 3- to 7-year-old group. His findings justify further investigation into the use of morphine for sedation of the pediatric dental patient.

The pediatric dental practitioners using morphine in Texas have selected the same types of patients they sedated in the past with alphaprodine. Doan reported using 0.15 mg/kg of morphine administered submucosally 15 min after 1.1 mg/kg promethazine had been administered orally. Nitrous oxide:oxygen was administered by nasal hood at a ratio of 50:50% for 5 min before the administration of morphine, and then reduced to a ratio of 20:80% for the remainder of the treatment. When sedating patients 1.5 to 8 years old, he reported a success rate of 85%. Hatton used the same dosage as Doan without oral promethazine, and he routinely reversed the morphine with submucosal naloxone at the end of the appointment. He reported that before using naloxone reversal, he had numerous patients with nausea. Hatton reported using morphine sedation in patients 3 to 5 years old with a success rate of 90%.

Because oral meperidine is the most commonly used narcotic sedation technique among pediatric dentists and morphine injection is increasing in popularity, this study was conducted. The purposes of this study were to: 1) determine the effectiveness and safety of meperidine in combination with promethazine in managing the moderately uncooperative pediatric dental patient; 2) determine the effectiveness and safety of morphine in combination with promethazine in managing the moderately uncooperative pediatric dental patient; and 3) compare these two agents for effectiveness and safety.

Methods and Materials

Thirty patients (15 males and 15 females) treated in the graduate pediatric dental clinic at Baylor College of Dentistry constituted the sample for this study. The patients ranged in age from 31–95 months (mean 58 \pm 2.8) and were healthy with no systemic, physical, or neurologic disorders. One of the primary investigators, a faculty member previously calibrated for participation in numerous sedation studies, selected patients based on negative behavior at a prior appointment. For uniformity of the patient population only patients rated as a 2 on the Frankl Scale²¹ were included. Twentyseven of the 30 patients were selected at an initial appointment; the remaining three were selected at a subsequent operative visit. Upon identification of a child as a candidate for the study, the procedures,

Doan D: Personal communication, 1990.

Hatton C: Personal communication, 1990.

possible discomforts and risks, and possible benefits were explained fully to the parents of the subjects involved, and their informed consent was obtained. The parent was given presedation instructions that the child must be NPO for 12 hr before the time of the appointment and informed of the need to cancel if the child was ill.

The patients were divided randomly into two groups. Group A received the sedation regimen consisting of morphine sulfate injection (Elkins-Sinn, Inc., Cherry Hill, NJ) and promethazine hydrochloride (Phenergan Svrup Fortis[®] — Wyeth Laboratories, Inc., Philadelphia, PA) and Group B received the sedation regimen of meperidine (Demerol hydrochloride Syrup[®]) Winthrop-Breon Laboratories, New York, NY) and promethazine hydrochloride. The dosage of morphine was based on a currently used technique but was consistent with the recommended pediatric IM and subcutaneous dosages.^{7, 17–19} This dosage was chosen to provide a starting point in data collection on which future studies may be based. The oral route was chosen for meperidine because it is the most commonly used route of administration by private practitioners and dosage was consistent with recommended pediatric dosages.^{3–5} A crossover design was planned for all patients who demonstrated successful cooperation at the first visit in both groups. At the sedation appointment, a pulse oximeter (N100-Nellcor[®] — Nell Corp., Hayward, CA) and automatic blood pressure cuff (Dinamap[®] - Critikon, Tampa, FL) were attached to the child's upper limbs. Baseline vital signs, including blood pressure, respirations (rate, depth, and quality by visual monitoring and stethoscope), hemoglobin oxygen saturation (SaO₂) and pulse rate, were recorded for all patients.

Initial Procedures for Group A (Morphine and Promethazine)

Oral promethazine was administered at a dosage of 1.1 mg/kg. Vital signs were monitored and recorded every 10 min from that point until the patient was dismissed. After 15 min, nitrous oxide:oxygen (3L:3L) was administered for 5 min. Topical anesthetic was placed on the mucosa above the second primary molar on the side opposite the proposed local anesthetic injection site for 1 min; then the calculated dosage (0.15 mg/ kg) of morphine was injected submucosally. The two primary investigators rated patient behavior at the time of the morphine injection. Nitrous oxide:oxygen was discontinued, and the patient was allowed to sit quietly in the chair for 15 min. Nitrous oxide:oxygen was reinstituted at 3L:3L for 5 min. Topical anesthesia was achieved and local anesthetic was injected into the areas appropriate for the planned operative procedure.

Initial Procedures for Group B (Meperidine and Promethazine)

An oral suspension of meperidine (2.2 mg/kg) and promethazine (1.1 mg/kg) was administered to the patient, and behavior was rated by the primary investigators. The patient waited quietly for 1 hr to allow peak sedation activity to occur. The patient returned to the operatory and the pulse oximeter and automatic blood pressure cuff were reattached. Vital signs were then recorded every 10 min. Nitrous oxide:oxygen (3L:3L) was administered, topical anesthesia was achieved, and the local anesthetic was injected.

Procedure for Both Groups After Administration of Local Anesthetic

After the local anesthetic injection, the nitrous oxide:oxygen ratio was reduced (1.5L:4.5L). A rubber dam was placed when appropriate and operative procedures were performed. All operative treatments were provided by one principal investigator while the other assisted at chairside and monitored the patient.

Procedures for Evaluating Behavior

All aspects of the appointment were videotaped. The investigators reviewed and edited all tapes for evaluation by two independent observers. The tapes were shortened to the following brief episodes:

- 1. Entry (30 sec) Group A 15 min after the patient received promethazine, before morphine administration; Group B 1 hr after the patient had the meperidine-promethazine mixture
- Nitrous oxide:oxygen initial 30 sec of administration
- 3. Local anesthetic administration
- 4. Rubber dam application
- 5. Operative (30 sec) 5 min into procedure; (30 sec) every 10 min thereafter
- 6. Restoration placement (30 sec) 5 min into procedure; (30 sec) every 10 min thereafter
- 7. Exit 30 sec.

Care was taken to omit taped segments showing the delivery of medications to the patient and all verbal references to the narcotic used.

Standardization of Raters — Two independent observers (pediatric dentists) were asked to simultaneously view 23 short taped scenarios showing a variety of behaviors, but record their ratings of the different patient behaviors separately and independently. During this attempt to standardize the observers, it was discovered that the Frankl Scale was inadequate for accurately describing behavior of a sedated patient. For example, sedated patients with rubber dams in place cannot interact actively, and consequently, cannot be given a 4 on the Frankl Scale, even though their behavior may be perfect.

Table 1. Comparison of Frankl scale with modified Frankl scale

Frankl Scale		6
Category #1	Definitely negative. Examples of this are the child's refusal of treatment, crying forcefully, fearful, or any overt evidence of extreme negativism.	t a ł
Category #2	Negative. The child may be reluctant to accept treatment and have some evidence of negative attitude (not pronounced).	c i
Category #3	Positive. The child is accepting of treatment but may be cautious. The child is willing to comply with the dentist, but may have some reservation.	t s
Category #4	Definitely positive. This child has a good rapport with the dentist and is interested in the dental procedures.	t ł
Category #4		nd

Modified Frankl Scale

Category #1	Definitely negative. Examples of this are the child's refusal of treatment, crying forcefully, fearful, or any overt evidence of extreme negativism.
Category #2	Negative. The child may be reluctant to accept treatment and have some evidence of negative attitude (not pronounced).
Category #3	Positive. The child is accepting of treatment but may be cautious. The child willing to comply with the dentist, but may have some reserva- tion. He may need reminders to keep mouth open or hands down, and may whimper.
Category #4	Very cooperative. This child is as good as he can be whether actively communicating or sitting quietly. The child shows no signs of resistance to treatment or negativism.

The Frankl Scale (Table 1) was modified to allow the observers to assess the sedated child's behavior more accurately. The modification affected only the positive ratings, allowing patients exhibiting perfect cooperation to receive a 4, although they did not interact with the operator. Since the modification did not affect the rating used to determine the patient selection for the study, it was felt that the modified Frankl Scale remained comparable to the original Frankl Scale.

Using the modified Frankl Scale, the independent observers again viewed the short taped scenarios, and were coincident in 21/23 ratings for an interrater reliability of 91%. The other two ratings were, however, in the same broad category — positive or negative.

Evaluation — The observers then viewed the edited study tapes in a blind study method and independently rated each child's behavior, at the predetermined times, according to the modified Frankl Scale. The operative and restorative events had from one to seven timed segments which were rated individually and averaged to give one overall rating for that event for analysis. The two observers' ratings for each event then were averaged to provide a single rating for each event for each child. This averaging was performed so that an isolated good or bad behavior did not overly skew the rating for an event.

Data Interpretation — Average ratings for each event were used to determine the effectiveness of each agent in improving patient behavior at each event. Success was defined as the ability to complete treatment on the child without use of restraint or harsh techniques. This criterion was chosen for two reasons. First, if restraint had to be used following drug administration, there was not sufficient alteration in behavior or mood for the sedation to be considered successful. Second, due to changing attitudes which consider restraint of children for multiple nonemergent restorative appointments to be unacceptable, necessity for restraint following sedation was considered a failure. All children were managed with appropriate nonaversive techniques throughout the

appointment including T-S-D, directive guidance, questioning for feeling, and reinforcement. Those children for whom treatment had to be stopped and subsequently completed under general anesthesia were considered to be unsuccessful sedations. For those children for whom the sedative regimen was considered successful, the average rating given for each event was compared with the presedation rating of a Frankl 2 using Wilcoxon's signed rank test to determine significant differences between events. The analyses compared the events for the patients within Group A and within Group B to determine the effectiveness of the agents tested during the various procedural events. To determine the differences in effectiveness between the two sedation regimens, Mann-Whitney-U was used to compare the ratings for each event for all successful patients in Group A with the same events for all successful patients in Group B. Overall success of the sedation technique was determined by the percentage of successful patients in each sedation regimen group, whereas Chi-square analysis was used to determine whether the differences in percentage of success for each regimen was statistically significant.

Vital signs were examined at the various time intervals by ANOVA for repeated measures to determine any statistical differences within Groups A and B.

Results

This study was conducted to determine the effectiveness and safety of two regimens currently used to sedate moderately uncooperative pediatric dental patients. A partial crossover design resulted in 30 patients undergoing 44 appointments. The crossover design involved 13 patients who received both sedation regimens. One patient was

Table 2. Wilcoxon's sign	ed rank analysis o	f cooperation rating	s for successful sedations

Group A: Morphine and Promethazine Group				
Event I	Mean Stan. Er.	Event 2	Mean Stan. Er.	Behavior
Pre	2 ± 0	LA	2.49 ± .25	No improv.
Pre	2 0	RD	3.71 .16•	+
Pre	2 0	Oper	3. 7 9 .11•	+
Pre	2 0	Rest	3.86 .14°	+
Pre	2 ± 0	Exit	$3.98 \pm .02^{\circ}$	+

• P < 0.001 Pre = Rating given prior to sedation; LA = Local anesthesia administration; RD = Rubber dam application; Oper = Operative treatment; Rest = Restoration; Exit = Exit.

dropped from the study due to inadequate data collection, resulting in a final sample of 29 patients and 42 sedation appointments.

Group A: Morphine and Promethazine Sedation Regimen

Morphine and promethazine were used to sedate 23 patients. During morphine injection, the patient's behavior was rated by the investigator. Seven patients were cooperative; 16 patients were uncooperative and cried or had to be restrained to successfully complete the injection. For the treatment portion of the study, 14 (61%) cooperated sufficiently to be completed in the clinic, and nine became so uncooperative that treatment was completed at a later appointment under general anesthesia. Two patients never calmed down sufficiently after the morphine injection to receive local anesthetic. The seven remaining unsuccessful patients were so uncooperative for local anesthetic injection that treatment was aborted. The patient ages of the failed sedations ranged from 32–74 months (mean 51 \pm 4.7).

For the 14 patients who were able to undergo the planned treatment, the average ratings of the independent observers for the five events following nitrous oxide:oxygen administration were analyzed. The only ratings which had to be averaged were in the operative phase for three patients where their behavior differed between the 5 and 15 min ratings. The rating for each event was compared to the presedation rating (Frankl 2) to determine the degree of improvement. Data from Wilcoxon's signed rank test (Table 2) revealed significant improvement in behavior when the presedation event was compared to all other events except local anesthetic injection (P < 0.001).

Vital signs were evaluated and analyzed statistically at baseline, before morphine injection, and every 10 min thereafter. Measurements recorded during the sedation appointments showed that oxygen saturation never dropped below 95%. Respiration rate showed only very slight variations (2/min for 18 patients and 4/min for five patients). ANOVA for repeated measures revealed no significant differences among the various measurements for the systolic or diastolic blood pressures or pulse rates across time.

All patients remained fully conscious and there were no adverse reactions for any patient.

Group B: Meperidine and Promethazine Sedation Regimen

Meperidine and promethazine were used to sedate 19 patients. Ratings given by the investigator for behavior during administration of the oral sedation suspension showed 18 patients to be cooperative. One patient was uncooperative and was coerced into drinking the solution. For the treatment, 11 (58%) cooperated sufficiently to be completed in the clinic, and eight were so uncooperative that treatment was completed later under general anesthesia. Of these eight patients, two were never cooperative enough to receive local anesthetic, and five were so uncooperative during local anesthetic injection that treatment was aborted. One patient had operative commence, but a temporary restoration had to be placed due to uncontrollable movements. The patient ages of the failed sedations ranged from 43–72 months (mean 54 ± 4.1).

For the 11 patients who were able to undergo the planned treatment, the average ratings of the independent observers for the five events following nitrous oxide:oxygen administration were analyzed. The only ratings that had to be averaged were for one patient during the operative phase (his behavior differed at the 25-min rating) and for two patients during restoration placement (their behavior differed between the 5- and 15-min ratings). The five rated events were compared to the presedation rating (Frankl 2) to determine the degree of improvement. Data from Wilcoxon's signed rank test (Table 3, page 311) revealed significant improvement for local anesthetic injection (P < 0.01) and all events following local anesthesia when compared to the presedation behavior (P < 0.005).

Vital signs were evaluated and statistically analyzed at baseline, start of treatment (1 hr after oral meperidine),

Table 3. Wilcoxon's signed rank analysis of cooperation ratings for successful sedations

Group B: Meperidine and Promethazine Group				
Event I	Mean Stan. Er.		Mean Stan. Er.	Behavior
Pre	2 ± 0	LA	$3.05 \pm .24^{\circ}$	+
Pre	2 0	RD	3.68 .19 ⁺	+
Pre	2 0	Oper	3.76 .18 ⁺	+
Pre	2 0	Rest	3.66 .27*	+
Pre	2 ± 0	Exit	$3.86 \pm .10^{+}$	+

• P < .01; † P < 0.005. Pre = Rating given prior to sedation; LA = Local anesthesia administration; RD = Rubber dam application; Oper = Operative treatment; Rest = Restoration; Exit = Exit.

and every 10 min thereafter. Vital sign measurements recorded during the sedation appointments showed that oxygen saturation never dropped below 96%. Respiration rate showed only very slight variations (2/min for 17 patients and 4/min for two patients). ANOVA for repeated measures revealed no significant differences among the various measurements for the systolic or diastolic blood pressures or pulse rates across time.

All patients remained fully conscious; however, two patients vomited.

Comparison of Group A With Group B

All successful first appointment patients were included in the crossover study. Originally 17 patients qualified, but four were unable to complete the study for a variety of reasons. Both sedation regimens were received by 13 patients. Four received morphine first and meperidine second, and nine received meperidine first and morphine second. The number that received morphine first was so small that it was decided not to analyze the crossover group as a separate subset, but rather use all patients from Groups A and B (crossover and noncrossover) in the group comparisons.

The ratings given for the events of local anesthesia, rubber dam, operative, restorative, and exit for all successful patients in Group A were compared with the ratings for successful patients in Group B (Table 4). Mann-Whitney-U analysis showed no statistical differences for any event when the groups were compared. However, there was a trend for local anesthesia behavior ratings of patients in Group B to be more positive than for the patients in Group A.

Overall success, as determined by the ability to complete treatment, was 61% (14/23) for the sedation regimen of morphine and promethazine, and 58% (11/19) for the regimen of meperidine and promethazine. Chisquare analysis revealed no significant differences between the success rates for the two sedation regimens.

Vital sign measurements of systolic and diastolic blood pressures and pulse for both regimens revealed no significant differences when analyzed across time by ANOVA for repeated measures. The oxygen saturation and respiration rates were similar for both sedation regimens at all measurement intervals. Therefore, both regimens were found to be equally safe.

Discussion

This investigation was designed to provide data on the efficacy and safety of two sedative regimens currently used in pediatric dentistry.

One objective of this study was to contribute to the literature a well-designed study to support a narcotic sedation technique, oral meperidine and promethazine, which is most commonly used in private practice. There are few controlled studies investigating an effective, standardized dosage or using defined criteria for patient selection, success, and safety of this sedation regimen.

An important goal in conducting this project was to use defined criteria for determining success of the agents. The goal of sedative regimens used in pediatric dentistry is to improve patient behavior so that treatment can be completed. Overall success for this study was based on the ability of the investigator to complete the prescribed treatment for the child without the use of restraint or harsh management techniques. The success rates of 58% for the meperidine group and 61% for the morphine group are comparable to success rates reported for some investigators for conscious sedation regimens in children, ^{12, 14, 15} but lower than others previously reported.¹¹ To be able to document improvement in behavior as a result of the sedation regimen, the patient's behavior had to be rated at the time of selection for purposes of comparison with ratings for sedated behavior. For uniformity, the criteria for patient selection in our study were very stringent and specific. Only patients exhibiting frank evidence of in-

Table 4. Mann-Whitney-U analysis: cooperation ratings
between groups — successful sedations

Event	Group A	Group B	Signif
LA	2.49 ± .25	3.05 ± .24	NS
RD	3.71 .16	3.68 .19	NS
Op	3.79 .11	3.76 .18	NS
Rest	3.86 .14	3.66 .27	NS
Ex	$3.98 \pm .02$	$3.86 \pm .10$	NS

LA = Local anesthesia administration; RD = Rubber dam application; Op = Operative treatment; Rest = Restoration; Ex = Exit; Mean and SE; NS = Nonsignificant. ability or unwillingness to cooperate, or a Frankl 2 rating, were candidates for the study. Although success was based on the ability to complete treatment, statistical analyses of the present data (behavior ratings at five events) determined that there were significant improvements in behavior at all events for the group deemed to be successful.

The alternative sedation regimen evaluated in our study consisted of submucosally administered morphine in combination with oral promethazine. There is only one study in the dental literature to which this regimen could be compared. Schneider²⁰ published a nine-year study in which morphine, administered IM at a dose of "1 mg/year of age," was examined in a population of pediatric dental patients. Based on data provided in Schneider's tables, it is assumed that the dose averaged about 0.2 mg/kg. The dose in our study was somewhat lower (0.15 mg/kg), and was based on personal communication with private practitioners known to the investigator (see footnote). Schneider did not report a success rate for comparison to the 61% success rate of this study. He reported complications of vomiting, hyperactivity, and convulsions during treatment. Due to the fact that no vital signs or local anesthetic dosages were recorded, hypoxia and/or local anesthetic overdose cannot be ruled out as the cause. Vital signs proved to be very stable in our study and no patients exhibited any complications. Schneider also reported that many of his patients slept during treatment, whereas in this study, no patients slept at any point during treatment.

In comparing the two regimens examined in this study, the route of drug administration must be evaluated. Orally administered meperidine and promethazine was received cooperatively by 95% of the children. Only 30% (7/23) of the patients receiving morphine were cooperative during the injection while the remainder were uncooperative and cried forcefully or had to be restrained. Therefore, the two regimens caused very different responses to the administration of the agents. This aspect of the study appears to be associated with patient acceptance of the local anesthetic injection. In the analysis of data for the ratings of the patient's behavior at each event, the event of local anesthesia was different for the two regimens. Those patients receiving the submucosal injection of morphine demonstrated no improvement in behavior for the local anesthesia event when compared to the presedation rating. Therefore, improvement in behavior was not evident until after this event. The local anesthetic event in the group receiving oral meperidine was significantly different in a positive direction when compared with the presedation rating. It appears that the morphine injection may either sensitize the patients to the local anesthetic injection or

be less effective than meperidine in elevating the pain threshold. The former is the more likely since those patients appeared to anticipate the second injection and have a more difficult time accepting it. Oral administration for the meperidine group seems more advantageous than the submucosal route for the morphine group with respect to patient behavior during subsequent local anesthesia administration.

In comparing the two regimens with respect to changes in physiological parameters and safety, there appear to be no differences. For both groups, the heart rate and systolic and diastolic blood pressures fluctuated slightly during treatment, usually in association with environmental stimulation. However, statistical analysis showed no significant variation between baseline and treatment recordings. Hemoglobin oxygen saturation did not drop below 95% in any patient in either group and respiratory rate never varied more than 4/min. Saravia et al.¹⁴ reported that following IM sedation with meperidine, promethazine, and chlorpromazine, 47% of the patients experienced a decline in oxygen saturation. This was not observed in our study.

Comparison of the complications associated with the two sedative regimens in the our study showed that vomiting was a complication associated with meperidine. Two patients vomited, one 10 min after administration and one after treatment was completed. No vomiting occurred after morphine administration.

A comparison of the success rates of the two regimens indicated that one was not superior to the other in improving behavior. The advantages of one regimen over the other, therefore, would be relative to aspects other than successful behavior modification. Because the patient can be restrained for the injection, the morphine may have the advantage in administration to a totally noncompliant patient or one who will not, or cannot, swallow. Additionally, morphine would be expected to have a more reliable response, because submucosal administration allows for more complete uptake of the drug. The meperidine regimen would appear to have the advantage of a less noxious route of administration and, therefore, would not sensitize the patient to the local anesthetic injection.

The success rates of these two drug regimens, as determined in this study, are very similar. This is surprising, in that it was anticipated that morphine would have a superior success rate when considering the anecdotal reports. In fact, neither morphine nor meperidine can be considered a panacea. Both drug regimens were equally safe at the recommended dosages as determined by the stability of the vital signs. It is our opinion that, at the recommended dosages, meperidine is preferred to morphine for the patient who is able and willing to swallow the sedation mixture. However, additional dose-response studies are needed to determine if a higher dose of morphine would increase success.

Conclusions

- 1. The sedation regimen consisting of a combination of 0.15 mg/kg of morphine sulfate administered submucosally and 1.1 mg/kg of promethazine administered orally was successful 61% of the time in modifying the behavior of the moderately uncooperative pediatric dental patient sufficiently to allow completion of treatment.
- 2. The sedation regimen consisting of a combination of 2.2 mg/kg of meperidine and 1.1 mg/kg of promethazine administered orally was successful 58% of the time in modifying the behavior of the moderately uncooperative pediatric dental patient sufficiently to allow completion of treatment.
- 3. There was no statistically significant difference in the effectiveness of the two sedation regimens studied with respect to modifying the behavior of the moderately uncooperative pediatric dental patient.
- 4. There was more negative behavior for the event of local anesthesia in the patients receiving the sedation regimen using a submucosal injection of morphine in combination with orally administered promethazine as compared to the other regimen.
- 5. The physiologic parameters of hemoglobin oxygen saturation, respiratory rate, and blood pressure did not change significantly at any interval for either of the sedation regimens studied.

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Dr. Roberts is in private practice in Dallas, TX. Dr. Wilson is associate professor, Dr. Seale is professor and chair, and Dr. McWhorter is assistant professor in the Department of Pediatric Dentistry, Baylor College of Dentistry, Dallas, TX. Reprint requests should be sent to: Dr. Carolyn Wilson, Baylor College of Dentistry, Department of Pediatric Dentistry, 3302 Gaston Ave., Dallas, TX 75246.

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