Scientific Article

A Comparison of Two Meperidine/Hydroxyzine Sedation Regimens for the Uncooperative Pediatric Dental Patient

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Abstract

Purpose: The purpose of this study was to compare the safety and efficacy of submucosal-administered meperidine (SM) and oral-administered meperidine (OM). Both regimens were used in conjunction with oral hydroxyzine for the sedation of children for dental treatment.

Methods: Twenty preschool-age children, with previous histories of uncooperative behavior, were randomly assigned to first receive a sedation regimen of either SM (0.5 mg/lb), or OM (1 mg/lb), both with oral hydroxyzine (0.5 mg/lb). A cross-over design was utilized so that each child received both regimens. Safety was monitored through vital signs and side effects. Efficacy was measured with Houpt and Frankl behavior ratings.

Results: Vital signs remained stable during both treatments. Differences noted were clinically insignificant. The major side effects reported during submucosal injection included pain (58%) and edema (26%). All blinded behavior ratings, in both sedation regimens, significantly improved from presedation Frankl ratings. No significant differences existed between treatments. Success was 63% in the SM group and 80% in the OM group. The percentages were not statistically significant (P=.219).

Conclusions: Both methods of administration were found to be safe and effective for sedating uncooperative pediatric dental patients. Neither was significantly more effective or safer than the other. (Pediatr Dent 2005;27:395-400)

KEYWORDS: MEPERIDINE, HYDROXYZINE, SUBMUCOSAL, ORAL, CONSCIOUS SEDATION, PEDIATRIC DENTISTRY

Safe, effective treatment of the uncooperative child with extensive dental needs presents an ongoing challenge for the pediatric dentist. [1] Changes in parenting styles and decreasing acceptance of aggressive behavior management techniques have led pediatric dentists to search for other methods to treat uncooperative patients afflicted with dental caries. [2]

Pharmacological intervention, such as general anesthesia or conscious sedation, is a logical solution. [3] Conscious sedation is often preferred because it can be performed in-office without the increased risk and cost associated with general anesthesia. [4] No single agent or regimen is recognized as the standard for dental procedures. Meperidine and hydroxyzine are among the agents frequently reported as useful for dental sedation. [5-8]

Meperidine has euphoric and analgesic properties beneficial in patient management. [9] When orally administered for sedation of pediatric patients, meperidine has been reported to be 50% to 81% successful. [10-14] It may also be administered by other routes, such as submucosal. Hydroxyzine enhances the analgesic effect of meperidine, and it is an antiemetic. [15-19]

Although all routes of administration are used for sedation, the oral route is the method of choice for a majority of pediatric dentists surveyed. [7,8,20] It is well accepted by most patients and convenient for administration. [21] Disadvantages of the oral route include: (1) protracted waiting time for full effect; (2) erratic absorption from the gastrointestinal tract; (3) bad taste of the medication; (4) compliance of the child to drink the medication; and (5) effect of first-pass metabolism. [11]

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Orally administered meperidine (OM) serum peak plasma concentrations are reached in 45 minutes. Schmitt et al,[22] however, found submucosally injected meperidine (SM) reached peak plasma concentration in 10 minutes. SM offers several advantages over OM because it:

1. is more time efficient;
2. avoids the first-pass effect on narcotics;
3. sedates a patient who may not be willing to take the medications orally.[11]

Disadvantages of the submucosal route, however, include:

1. the administration of another injection to an already fearful child;
2. the possibility of discomfort around the injection site.[11]

There is only 1 prospective study by Lochary et al[23] using SM to sedate children for dental treatment. Lochary et al administered 2 mg/kg of SM and 2 mg/kg hydroxyzine pamoate orally to sedate 29 children ages 18 to 36 months. This study did not examine safety or efficacy, but did predict behavior. The study concluded that the consciously sedated patient exhibited quiet behavior 62% of the time.

A retrospective study by Song et al[11] examined the use of SM in 20 children. Ten patients sedated with 1 mg/lb of OM with 0.5 mg/lb of oral promethazine were compared to 10 patients sedated with 0.5 mg/lb of SM with 0.5 mg/lb of oral promethazine. Both regimens were found to be safe, with no significant difference in efficacy.

In this study, the dose of meperidine was doubled for the OM group because of the first-pass effect. The purpose of this investigation was to evaluate the safety and efficacy of 2 sedation regimens for uncooperative pediatric dental patients:

1. submucosally administered meperidine (0.5 mg/lb) with oral hydroxyzine (0.5 mg/lb);
2. orally administered meperidine (1 mg/lb) and hydroxyzine (0.5 mg/lb).

Methods

This study evaluated:

1. overall success rates of OM and SM;
2. Frankl and Houpt scores before and after the procedures;
3. differences in vital signs between the first and second appointments;
4. side effects from the different sedation regimens;
5. the ability of the patients to cooperate, depending on whether radiographs could be obtained prior to treatment;
6. the effects of the order of drug administration;
7. success related to prestudy Frankl scores;
8. which patients had success with both regimens, with 1 regimen, or with neither.

The study was granted approval by the Institutional Review Board at Baylor College of Dentistry, Dallas, Tex, and was conducted by a team of 6 pediatric dentists. This study utilized a blind, randomized, cross-over design. Twenty children were recruited from the patient pool at Baylor College of Dentistry. Inclusion criteria required that each child be 30 to 66 months of age, weigh less than 50 lbs, and have documented negative behavior (Frankl scores=1 or 2)[24] at the initial oral exam appointment. Each child must have had a tonsillar assessment of +2 or less, as specified by Brodsky,[25] and a dental treatment plan with a minimum of 2 sextants of dentistry requiring at least 1 stainless steel crown in each sextant. Medical histories were updated in the dental record. Each child was examined by the primary investigator (PI) and classified as American Society of Anesthesiologists (ASA) I or II.[26] No child was admitted into the study with known contraindications for the use of meperidine, hydroxyzine, lidocaine, or nitrous oxide or with a prior history of dental sedation.

After each child met inclusion criteria for the study, informed consent was obtained from the parent/legal guardian. Presedation instructions were given to ensure both patient safety and standardization of the procedure. Instructions included fasting times of 5 hours or more for solid foods and 3 hours for clear liquids prior to the appointment.

Patients were scheduled to arrive 1 hour before treatment for assessment of the health and compliance with presedation instructions. The PI recorded baseline vital signs:

1. oxygen saturation and heart rate were measured by a pulse oximeter;
2. expired CO_2 levels were monitored with a capnograph;
3. blood pressure was assessed with an automatic blood pressure cuff.

Respiratory rate, temperature, weight, and tonsillar assessment were evaluated by the PI. A computer-generated random number list was used to determine the route of administration he/she would receive first.

Initial procedures for the submucosal meperidine (SM) group

Children assigned to receive SM first were given 0.5 mg/lb of oral hydroxyzine and waited with the parent. After 30 minutes, monitors were reapplied. One coinvestigator continuously monitored the child's vital signs every 10 minutes during the appointment. Nitrous oxide and oxygen were administered at 50% each throughout the appointment. Topical anesthetic was applied for 1 minute at the site of the submucosal injection.

The child received SM at a dosage of 0.5 mg/lb in the maxillary vestibule, on the side opposite that in which the child was to have dental work performed. If the child was uncooperative, restraint was used only for the injection. The PI recorded pain and tissue irritation/edema experienced during treatment.

Similar to the study by Schmitt et al,[22] 4 categories were recorded for pain and or tissue response: (1) none; (2) mild; (3) moderate; and (4) severe. The pain response was assessed by the PI during the submucosal injection, and the tissue response was assessed 10 minutes after the injection and at the end of treatment. The patient remained in the dental chair for 10 minutes while the SM was absorbed before treatment started.

Initial procedures for the oral meperidine (OM) group

Children assigned to receive OM first received oral hydroxyzine at a dosage of 0.5 mg/lb, while simultaneously receiving oral meperidine at a dosage of 1 mg/lb. After ingesting the medications, each child waited with his/her parent(s). After 45 minutes, each child was seated in the dental chair and monitors were reapplied. One coinvestigator continuously monitored the child's vital signs every 10 minutes during the appointment. Nitrous oxide and oxygen were each administered at 50% throughout the appointment.

Procedures for both treatments

All dental treatment was performed by the PI. Dental treatment began with the administration of 2% lidocaine with 1:100,000 epinephrine, never exceeding 2 mg/lb of lidocaine. Each child had 1 sextant of dental treatment completed when possible. If the child became too uncooperative for quality dental work to be performed, the sedation appointment was aborted and regarded as a failed sedation.

The child was monitored and discharged to the parent when the AAPD sedation guidelines for discharge were met[27] and an Aldrete score of 9 or greater was achieved. This score is an objective measurement for alertness/sedation.[26] Recovery time was recorded for each child. Each parent received: (1) postoperative instructions; (2) 24-hour emergency telephone numbers; and (3) an appointment for the alternate treatment. The PI contacted the parent the next day and recorded if the child had any postoperative adverse reactions or side effects.

The PI rated patient behavior for the entire procedure at the end of each appointment using the modified overall Houpt scale[5] (Table 1) and the modified Frankl scale[24] (Table 2). In addition to this, every appointment was videotaped in its entirety. Later, predefined, 30-second segments were copied to another tape for evaluation of behavior by blinded raters. The 30-second segments were copied at the following standard intervals:

1. N_2O administration (10 minutes after SM administration. 45 minutes after OM administration);
2. radiographs (if attempted);
3. local anesthetic administration;
4. rubber dam application;
5. operative treatment start and every 10 minutes thereafter;
6. restoration placement (cementation of SSC or curing of strip crown);
7. exit.

After all videotapes were edited, 2 pediatric dentist raters who were not otherwise involved in the study were calibrated by viewing videotaped segments of similar patients. Using the Houpt scale, the raters scored: (1) body movement; (2) crying; (3) head and oral resistance; (4) sleep; (5) verbalization; and (6) overall behavior. The

Table 1. Modified Houpt Behavior Rating Scale*
Body movement
1 – Violent, uninterrupted movement
2 – Continuous, making treatment difficult
3 – Controllable, does not interfere with treatment
4 – No body movement present
Head/oral resistance
1 – Turns head, refuses to open mouth
2 – Mouth closing, must request to open
3 – Choking, gagging, spitting
4 – No crying present
Verbal
1 – Verbal abuse, threats
2 – Verbal protest
3 – Statement of discomfort
4 – Occasional talking or silence
Overall
1 – Aborted: No treatment performed
2 – Poor: Treatment interrupted, all treatment completed
3 – Fair: Difficult, all treatment completed
4 – Good: Some limited crying or movement
5 – Excellent: No crying or movement

*Modified from Houpt et al by Cathers et al.

"sleep" component could not be accurately judged because the rubber dam and nitrous oxide mask obstructed the patient's face. Therefore, the Houpt scale was modified for use (Table 1). The modified Frankl scale used to score patient behavior was previously modified in another sedation study by Roberts et al.[12] Spearman rank correlation results from the calibration exercise found high interrater reliability (r=.94; $P<.001$). After calibration, the 2 raters simultaneously viewed the segments of each appointment and independently rated behavior.

All children were managed with appropriate nonaversive techniques throughout the appointment. This study defined safe and successful sedation as follows:

1. physiological parameters remained within clinically acceptable ranges;
2. oxygen saturation remained at 90% or greater;
3. overall behavior was at least a modified Houpt 4 and a modified Frankl 3 rating;
4. no use of restraint for dental treatment.

Several statistical tests were used to evaluate the data: (1) Friedman 2-way analysis of variance; (2) Wilcoxon signed rank test; (3) paired t test; (4) Mann Whitney-U Test; (5) McNemar test; (6) Spearman rank correlation; and (7) Fisher's exact test.

Results

All 20 children completed OM, and 19 completed SM. One child did not return following the first visit (OM), and the parents could not be contacted. This same child refused to drink most of the OM, and the sedation had to be aborted due to poor behavior. All children were between the ages of 30 and 66 months, with a mean age of 50 months and a mean weight of 38 lbs. There were 11 males and 9 females. Payer source varied: (1) 7 had Medicaid; (2) 3 had State Children's Health Insurance Program (SCHIP); and (3) 10 were private pay. Eight patients presented with a Frankl 1 rating, and 12 patients had Frankl 2 ratings. Radiographs were unobtainable for 11 children, and 3 patients had dentistry attempted before participation. Random selection assigned 12 children to receive OM first and 8 SM first.

Spearman rank correlation found high interrater reliability of the 2 blinded ratings of the study videotaped segments (r=.98; P<.001) and significant correlation between the Frankl ratings of the PI and the blinded raters for both the OM (r=.778; P<.001) and SM ratings (r=.85; P<.001). Spearman rank correlations found significant correlation between the overall Houpt ratings of the PI and the blinded raters for both OM (r=.84; P<.001) and SM (r=.86; P<.001).

The blinded raters found overall success for SM to be 63%, whereas the overall success for the OM was 80%, as rated by blinded raters (Table 3).

A Wilcoxon signed rank test was used on both groups (SM and OM), which compared the prestudy Frankl ratings to Frankl ratings of the blinded raters—indicating a statistically significant improvement in behavior for both groups (P<.002).

Paired sample t tests were used to evaluate differences between OM- and SM-blinded rater Houpt and Frankl scores, due to greater than 50% ties when the Wilcoxon signed rank test was conducted. There were no differences between the blinded rater overall SM Houpt (mean=3.58±1.87 SD) and OM Houpt (mean=4.16±1.46; P=.206). Likewise, no differences were noted between the SM (mean=2.89±1.41) and OM (mean=3.32±1.08) Frankl scores (P=.226).

A Friedman test evaluated differences in medians among each of the sets of vital signs recorded during each visit. Statistical differences were found in the SM and OM groups. None of these differences were clinically significant, however, because all recordings were within 20% of baseline values. No patient ever dropped below 95% oxygen saturation.

Wilcoxon signed rank tests and paired samples t tests were conducted between each child's OM and SM vital signs at the different measurements. There were statistically significant changes in vital signs. None of these differences were clinically significant, however, because all recordings were within 20% of baseline values.

One SM patient experienced nausea/vomiting during the car ride home. The SM caused pain or a burning sensation in 11 children. Minor edema was seen in 3 children at the time of the injection, and 2 more patients reported edema at the follow-up phone call.

It was found that SM success was related to:
1. the patient's ability to cooperate for radiographs during the initial visit prior to the sedation appointment;
2. the order that the patient received the sedation regimen.

Of the children who cooperated for radiographs, 89% were successfully sedated with the SM regimen, while only 40% of those without previous radiographs were successfully sedated with the SM regimen (Fisher's exact test; P=.057). This was not found, however, with the OM group. Of the 8 children who received SM first, 38% had successful sedations, while 82% of those who received OM first had successful SM sedations at the second appointment (Fisher's exact test; P=.074).

In the OM group, success was related to the prestudy Frankl score. Patients rated as Frankl 1 had 63% successful

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Table 2. Modified Frankl Scale*

1 – Definitely negative

Examples of this are the child's refusal of treatment, crying forcefully, fear, or any overt evidence of extreme negativism.

2 – Negative

The child may be reluctant to accept treatment and exhibits some evidence of negative attitude (not pronounced).

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. He/she may need some reminders to keep mouth open or hands down, and may whimper.

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.

*Modified by Roberts et al.[12]

Table 3. Comparison of Overall Success in the Submucosal and Oral Regimens Rated by the Houpt Scale*

Overall behavior rating	Submucosal	Oral
1 – aborted	6	4
2 – poor	0	0
3 – fair	1	0
4 – good	1	4
5 – excellent	11	12
Total		
% aborted	32%	20%
% failure	37%	20%
% success	63%	80%

*A Houpt rating of 4 or 5=a successful sedation.

completion with OM, whereas those who rated a Frankl 2 had 92% successful completion with OM (Fisher's exact test; P=.255). This was not found in the SM group.

Overall sedation success found: (1) 11 children successfully sedated with both treatments; (2) 2 unsuccessful with either; (3) 5 successful with OM only; and (4) 1 successful with SM only (Table 3). A McNemar test of dependent proportions found no significant difference (P=.219) between successful completion of OM (80%) and SM (63%).

Discussion

This study's results indicated that SM was statistically as safe as OM at the recommended dosages, as determined by stability of vital signs and side-effect profiles. Although statistically significant fluctuations in vital signs occurred, none were clinically significant. Oxygen saturation never dropped below 95% in any patient. The SM group, however, had additional side effects caused by the injection. Signs of edema were evident after 5 of 19 submucosal injections. This is less than reported by Schmitt et al,[22] where 100% of adult patients had mild to moderate tissue changes. A mild to severe pain response was observed in 60% of patients, possibly due to the low pH of the meperidine solution.

Both OM and SM improved behavior significantly. Frankl scores documented after SM and OM were significantly higher than the prestudy Frankl scores. While not significantly different, success is almost 20% higher for OM (80%) than SM (63%). The 63% success rate of SM in this study closely matched the results of Lochary et al,[23] who reported a quiet behavior rating of 62%.

A retrospective study by Song et al[11] reported a higher success rate of 90% for the SM group. Fifty percent of patients, however, had Frankl ratings of 3 prior to being sedated.

The success of SM was also related to the order of the 2 regimens and the ability to achieve preoperative radiographs. Patients who received OM first were twice as likely to have a successful SM sedation. Again, it is possible that, since the SM agitated the patient more than the OM during the first treatment, it may have decreased the likelihood that the second treatment would be completed. An indication of this is the fact that the SM regimen caused increases in heart rate, systolic, and diastolic blood pressure. SM group patients who demonstrated negative behavior during the initial exam, but successfully completed radiographs, were twice as likely to have a successful sedation. This was not found in the OM regimen.

The success rates of 63% for SM and 80% for OM are comparable to success rates reported in the literature.[10-14] Active restraint has commonly been used in sedation studies. The need for active restraint in this study was regarded as failed sedation. The use of restraint precludes accurate evaluation of sedated behavior.

A weakness of this study was that it was not double-blind, which constitutes a bias with internal validity and makes it less powerful scientifically. To double-blind this study, the OM group must be injected with a noxious stimulus similar to that of SM. This would be technically difficult and ethically questionable and may decrease the clinical relevance.

The cross-over design decreased sample variability by comparing patients to themselves, and the quantity of dentistry performed on each patient was standardized to ensure equality in the sample. The route administered was randomized to ensure that any effects due to administration order could be detected, since both orders (SM/OS, OM/SM) occurred randomly. Strict criteria for determining success and failure were followed. The raters were blinded to the method used to sedate the patient to decrease bias. The blinded-rated Frankl scores were compared to the PI-rated Frankl scores to determine if a score based only on fragments of the sedation was comparable to the score given for the entire sedation experience. No discrepancy was indicated. Nitrous oxide was used on all patients and, thus, was not a variable.

Since OM and SM were found to improve behavior to a similar degree, practitioners should evaluate both routes. Based on this study's results, a practitioner should consider the clinical situation and the advantages and disadvantages of each route of delivery before deciding whether to use OM or SM sedation.

Advantages of the OM include: (1) high acceptance by most patients; and (2) convenient administration. Disadvantages include: (1) protracted waiting time for full effect; (2) erratic absorption from the GI tract; (3) bad taste of the medication; (4) compliance of the child to drink the medication; and (5) effect of first-pass metabolism.

SM offers several advantages to OM. It: (1) is more time efficient; (2) avoids the first-pass effect on narcotics; and (3) sedates patients not willing to take the medications orally. SM disadvantages include: (1) administration of another injection to an already fearful child; and (2) possibility of discomfort around the injection site.

It is the investigators' opinion, however, that, at the recommended dosages, OM is preferred to SM for the patient who is able and willing to swallow the sedation medication. Additional dose-response studies are needed to determine if a higher dose of SM would increase success.

Conclusions

Based on this study's results, both the oral regimen and the submucosal regimen were found to be equally safe and effective for sedating uncooperative pediatric dental patients. Neither was significantly more effective than the other.

Acknowledgments

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