# Evaluation of the effect of nitrous oxide and hydroxyzine in controlling the behavior of the pediatric dental patient

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## Abstract

*This study evaluated and compared the effect of three different sedation combinations on the young dental patient: hydroxyzine alone, hydroxyzine with nitrous oxide, and nitrous oxide alone. Nineteen uncooperative children with mean age of 37 months needing at least three restorative visits were selected for this study. Crying, alertness, and general behavior were evaluated during the dental procedure. The combination of hydroxyzine and nitrous oxide was more effective than the others for the majority of the sessions in terms of controlling crying and alertness. The results in the present study indicate that the sedative effect of hydroxyzine on children's behavior is enhanced by the addition of nitrous oxide. (Pediatr Dent 14:167–70, 1992)*

## Introduction

Behavior management of the uncooperative pediatric patient who requires comprehensive dental treatment is enhanced frequently by using sedation. Oral and inhalation routes of sedative administration are the most convenient for use in children, and are the most popular among pediatric dentists.[1–4] Hydroxyzine and nitrous oxide are used solely or in combination by many pediatric dentists.[1, 2, 5] Both medications are remarkably safe and have no serious side effects.[6] Lang [7] reported on a controlled double blind study of pediatric patients with a mean age of 6 years, 4 months. In this study, 50 mg of hydroxyzine were administered to the patients of the test group 1 hr before the treatment. The results showed that "hydroxyzine reduced significantly the behavioral difficulties exhibited by pediatric patients." Stewart[8] reported a 97% success rate when using hydroxyzine combined with nitrous oxide to reduce preoperative anxiety and produce a state of subdued emotional response in the children treated. He suggested that hydroxyzine alone may suffice in a few patients, but is most valuable for controlling the apprehension of the patient when used in combination with nitrous oxide. Stewart[8] used an initial dose of 10 mg of hydroxyzine for children younger than 4 years of age and 20 mg for those older than 4. The drug was administered 45 min before the appointment. In this study, the medications were given routinely to all his patients and the criteria for behavior evaluation were not provided. The possible advantages of combining the nitrous oxide with hydroxyzine have not been evaluated adequately in a controlled study.

The present study was conducted to evaluate and compare the effect of three different sedations: hydroxyzine alone, hydroxyzine with nitrous oxide, and nitrous oxide alone.

## Methodology

Patients were children who visited the emergency clinic in the Department of Pediatric Dentistry of the Hadassah School of Dental Medicine in Jerusalem shortly before the study was conducted. Children selected for this study had to be in good health (ASA 1), and in need of at least three restorative visits. They were screened by a senior pediatric dentist not involved in the study, to determine if they were difficult-to-manage patients who needed to be treated under sedation. All of them were identified as being negative or definitely negative toward dental treatment (ratings 1 and 2 as defined by Frankl et al.[9]). The children ranged in weight from 11 to 19.5 kg with a mean weight of 14 kg. Nineteen children, 12 boys and seven girls between the ages of 25 and 45 months, with a mean age of 37 months participated in this study.

Medications: Three sedation combinations were evaluated:

1. Combination A: Hydroxyzine syrup 50 mg + nitrous oxide 50%
2. Combination B: Hydroxyzine syrup 50 mg + oxygen
3. Combination C: Placebo syrup + nitrous oxide 50%.

The hydroxyzine and the placebo were administered as oral suspensions and both had the same pineapple flavor.

The study was based on a "within subject" design, whereby all three combinations were administered to each patient. At each visit, patients were administered a different combination. The order of administration of the three combinations was determined randomly for each patient.

A treatment plan was prepared by a senior pediatric dentist for each patient. The procedure, possible discomforts or risks, as well as possible benefits, were explained fully to the parents of the children involved, and their informed consent was obtained before the investigation. The patients received the syrup in the dental clinic after being kept NPO for 4 hr and were kept in a quiet area with the parents for 45 min. The patients then were taken to the operatory and placed in a restraint device (Papoose Board , Olympic Medical Group, Seattle, WA). A precordial stethoscope monitored pulse and respiratory rates which were recorded at the beginning of each session and subsequently every 15 min until the end of the treatment. The treatment period was divided into two phases: the preparatory phase, in which local anesthesia was administered and mouth prop and rubber dam were placed, and the treatment phase, in which the restorative procedure was performed. The first quadrant to be treated was chosen by the operator according to urgency of treatment needs. If no such need existed, the upper posterior area was treated first.

The two principal investigators (JS and GH) independently assessed the behavioral responses of the first five sessions when a consensus rating was made to establish reliability. Neither the operator nor the evaluator were aware of the sedation combination used, since the medications and the nitrous oxide/oxygen were administered by a third person.

The dental procedure was divided into 15-min periods. The child's behavior in each period was evaluated using two behavioral variables: crying and alertness (Table 1). At the conclusion of each session the general behavior of the child was rated 1 to 6 (Table 2), following a modified scale developed by Houpt et al.[10] The effect of each combination on the patient's general behavior was considered a "success" when it was scored 4 to 6 and a "failure" when it was scored 1 to 3.

The mean of all the readings was calculated separately for each variable and for each sedation combination. The means of the different sedation combinations were compared using the ANOVA and the Student-$t$-test.

## Results

In all sessions, the preparatory phase lasted between 5 and 15 min. During this phase, the vital signs and the behavior variables were recorded only once. The dental procedure phase lasted between 20 and 45 min with an average of 30 min per session.

### Evaluation of General Behavior

Eighty-nine per cent of the sessions (Table 3, next page) were considered a "success" (score 4 to 6). Only

six sessions of 57 were considered a "failure" (score 1 to 3). Of the six failures, four children were sedated with combination B (hydroxyzine + oxygen), one with combination A (hydroxyzine + nitrous oxide) and one with combination C (nitrous oxide + placebo). The one-way ANOVA procedure showed no significant difference between the three sedation combinations. No statistical difference (using the multiple regression test) was found between the patient's scores for general behavior in the first, second or third visit ($P > 0.07$).

### Evaluation of Crying

The distribution of the readings for crying are presented in Table 4, next page. In 44 of 56 (79%) readings there was no crying at all (score 4) when hydroxyzine + nitrous oxide sedation (combination A) was used, compared with 51 and 58%, respectively, when hydroxyzine or nitrous oxide was administered. Hysterical cry (score 1) was never associated with combination A, but was found in 10 and 4 % of the readings, respectively, when hydroxyzine alone and nitrous oxide alone, respectively, were used. The mean for combination A was compared to that of combination B and combination C. The differences were found to be significant ($P < 0.004$). Comparing combination B to C did not reveal a significant difference ($P > 0.5$).

**Table 1. Rating scale to evaluate crying and alertness**

| Score | Crying | Alertness |
|---|---|---|
| 1 | Hysterical crying | Fully awake, alert |
| 2 | Continuous or strong crying | Drowsy, disoriented or asleep |
| 3 | Intermittent or mild crying | — |
| 4 | No crying | — |

**Table 2. Rating scale to evaluate general behavior**

| | | |
|---|---|---|
| 1 | Aborted | No treatment rendered. |
| 2 | Poor | Treatment interrupted, only partial treatment rendered. |
| 3 | Fair | Treatment interrupted, but eventually all completed. |
| 4 | Good | Difficult, but all treatment performed. |
| 5 | Very good | Some limited crying or movement, e.g. during anesthesia or movement. All treatment performed. |
| 6 | Excellent | No crying or movement. All treatment performed. |

**Table 3. Distribution of the scores for overall behavior by the sedation combinations**

| Score | A No. | A % | B No. | B % | C No. | C % | Total No. | Total % |
|---|---|---|---|---|---|---|---|---|
| 3* | 1 | 5 | 4 | 21 | 1 | 5 | 6 | 11 |
| 4 | 1 | 5 | 2 | 11 | 5 | 26 | 8 | 14 |
| 5 | 7 | 37 | 9 | 47 | 4 | 21 | 20 | 35 |
| 6 | 10 | 53 | 4 | 21 | 9 | 47 | 23 | 40 |
| Total | 19 | | 19 | | 19 | | 57 | 100 |
| Mean | 5.40 | | 4.70 | | 5.10 | | | |
| SD | 0.83 | | 1.06 | | 0.99 | | | |

*Sedation Combination* header spans columns A, B, C.

* No session was scored for 1 or 2.

## Evaluation of Alertness

The distribution of the readings for alertness is presented in Table 5. When combination A was used, the children were found to be drowsy or asleep in 45 of 56 (80%) readings, compared to only 53 and 51% of the readings when using combinations B or C. The differences between combination A and B, and combination A and C were significant ($P < 0.02$). There was no significant difference between combinations B and C ($P > 0.8$).

## Discussion

In our study design, the selection of subjects was based upon the Frankl Scale[9] utilizing behavior criteria. The children selected for this study presented a negative attitude toward the dental examination. Putting the children in the dental chair wrapped in a Papoose Board to establish a baseline for this study seemed unjustified. Therefore, their defiant behavior, associated with strong or hysterical cry, in the emergency clinic shortly before the first operative session, served as the baseline for their evaluation during the study.

The weight was not used as criterion for determining hydroxyzine dose: instead, the 50-mg dose was selected. Several pediatric dentists[7, 11, 12] recommended the administration of only one dose of 50 mg of hydroxyzine, 1 hr before the treatment. Lampshire,[11] in his discussion on "balanced medication" based on his experience of more than 2000 administrations, found that 50 to 75 mg of hydroxyzine is the usual dose for an extremely hyperemotive 2-year-old child. Linenberg[13] reported on the use of 50 mg of orally administered hydroxyzine in adults and wrote, "since by means of a clinical trial it was determined that 50 mg are just enough to reduce apprehension and nervousness." Although the effectiveness of medication may be increased if administered in divided doses,[12, 14] we found this to

be impractical. It may create a long-lasting unnecessary tension, and parents seem to find it inconvenient.[8] Lang[7] concluded his study by stating that a single dose of 50 mg, 1 hr before the appointment, proved to be effective and convenient for the parents. It also was found that after a single orally administered dose of the drug, the mean peak concentration of hydroxyzine in the serum occurred at a mean time of 2 hr.[15] This finding enhanced the earlier suggestion that the appropriate time for the pediatric dentist to start the dental treatment is about 1 hr after drug administration. At that time, the drug concentration in the blood is rising.

When the same dose of hydroxyzine is administered to children of different body weight, the mg/kg ratio is lower in the high-weight children. In our study, "general behavior" was considered to be "failure" in six children who were among the 10 heaviest participants. Furthermore, in four of the six sessions considered "failures," the children were premedicated

**Table 4. Distribution of the scores for crying by the sedation combinations**

| Score | A No. | A % | B No. | B % | C No. | C % |
|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 5 | 10 | 2 | 4 |
| 2 | 3 | 5 | 7 | 13 | 11 | 21 |
| 3 | 9 | 16 | 14 | 26 | 9 | 17 |
| 4 | 44 | 79 | 27 | 51 | 31 | 58 |
| Total | 56 | | 53 | | 53 | |
| Mean | 3.73 | | 3.19 | | 3.30 | |
| SD | 0.56 | | 1.00 | | 0.93 | |

*Sedation Combination* header spans columns A, B, C.

**Table 5. Distribution of the scores for alertness by the sedation combinations**

| Score | A No. | A % | B No. | B % | C No. | C % |
|---|---|---|---|---|---|---|
| 1 | 11 | 20 | 25 | 47 | 26 | 49 |
| 2 | 45 | 80 | 28 | 53 | 27 | 51 |
| Total | 56 | | 53 | | 53 | |
| Mean | 1.80 | | 1.53 | | 1.51 | |
| SD | 0.40 | | 0.50 | | 0.50 | |

*Sedation Combination* header spans columns A, B, C.

with hydroxyzine alone (combination B). This finding suggests that the mg/kg ratio of hydroxyzine may influence the child's behavior. This stands in contradiction to Kopel's[14] belief that "age and weight are not used as prime factors when determining hydroxyzine dose, instead, greater consideration is given to the physical, mental, and emotional state of the patient."

An ideal sedative agent or a sedative combination significantly reduces the number of disruptive behaviors caused by a difficult-to-manage child. It includes fewer vocalizations, and more drowsiness and sleep. Nitrous oxide augmented the sedative effect of hydroxyzine. Hydroxyzine as a sole medication was found to be less effective in controlling the child's behavior, compared to its combination with nitrous oxide — as indicated by the patients' crying and sleep.

Are the results of this study comparable to similar studies? As mentioned earlier, we used a modification of behavior evaluation criteria, design and age groups of children, as in Houpt's[16] study, except that Houpt investigated the effect of nitrous oxide on chloral hydrate sedation. He defined success of sedation as "the lack of crying or movement which interrupted treatment." According to this definition, 84% of the treatment sessions in his study were considered successful. In the present study, using the same definition for success, 89% of the sessions were successful. Only six sessions of 57 were defined as unsuccessful.

No significant difference between the three sedation combinations was found when analyzing the patients' overall behavior, despite the fact that the combination of hydroxyzine with nitrous oxide had a significantly better effect on the control of crying and alertness. This can be explained by the fact that the rating scale of "overall behavior" was based not only on the crying or alertness of the patients, but also on the completion of all dental treatment.

## Conclusions

1. The effect of the combination of nitrous oxide and hydroxyzine on the child's crying and alertness was found to be better than the effect of each of them separately.
2. There was no difference between the overall behavior of the patients in the first, second, and third sessions.

3. When the dose of hydroxyzine is calculated, the body weight of the patient should be taken into consideration along with the child's behavior.

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