Comparison of Three Conscious Sedation Regimens for Pediatric Dental Patients

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The aim of this study was to compare the clinical success of three conscious sedation regimens for pediatric dental patients. A clinical trial was performed wherein dental treatment was administered to pediatric patients ASA I and II under conscious sedation.. Fifty-four children were divided into three groups of 18 patients each, randomly assigned. Group A received hydroxyzine (2mg/kg 2 h before treatment and a subsequent dose of 1 mg/kg 20 min before treatment) orally; group B received 0.50mg/kg midazolam mixed with 1.5 mg/kg hydroxyzine 20 min before treatment orally; group C received chloral hydrate, 50 mg/kg mixed with 1.5mg/kg hydroxyzine 20 min before treatment orally. The Ohio State Behavioral Rating Scale (OSBRS) showed statistically significant differences between groups B and C with respect to group A. The regimens of midazolam or chloral hydrate mixed with hydroxyzine represent excellent choices for conscious sedation regimens for pediatric dental patients.

Key words: *conscious sedation, hydroxyzine, midazolam, chloral hydrate.*
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INTRODUCTION

Conscious sedation has been used as a behavior management technique for uncooperative pediatric dental patients,[1–4] using either single agents or agents in combination. The most popular sedation agents administered orally have been chloral hydrate (CH), meperidine, hydroxyzine (H), and midazolam (M).[2–8] The use of conscious sedation is preferred because it can be performed without the risk of general anesthesia. The objectives of conscious sedation are to improve the patient's behavior, reduce apprehension, minimize the negative psychological response toward treatment by reducing anxiety, maximize amnesia potential, and control behavior during dental pediatric rehabilitation.[9,10] H is one of the most popular sedatives in pediatric dentistry. Its sedative effect is due to the inhibition of some of the hypothalamic nuclei and the extension of its action to a peripheral level through the sympathetic portion of the autonomic nervous system. The only side effect is sleepiness.[9,11,12] CH is one of the sedatives most commonly used in the US. The usual dose is 20 to 75 mg/kg orally or rectally. Its main use in pediatrics is as a sedative in noninvasive procedures or as premedication. It has excellent absorption and relatively fast induction, exerting minimal effects on respiration.[7,10,13] M is a benzodiazepine characterized by prompt appearance and short duration of action, exerting an anxiolytic, anticonvulsive, muscular relaxant, and amnesic effect. It has been proven that children treated under conscious sedation will not remember the treatment being difficult or unpleasant, and these children will be cooperative.[3,8,14–17] The aim of the study was to compare the clinical success of three conscious sedation schemes for pediatric dental patients.

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MATERIALS AND METHODS

Patients for this study were selected from the Clinic for Pediatric Dentistry Posgraduate Program, Facultad de Estomatología, Universidad Autonoma de San Luis Potosi, Mexico. A controlled clinical trial was done, including 54 patients treated under conscious sedation for the accomplishment of dental treatment. Patients were randomly assigned to three groups of 18 patients each: Group A: H at a dose of 2 mg/kg 2 h before treatment and a subsequent dose of 1 mg/kg administered orally 20 min before treatment, also orally. Group B: 0.50 mg/kg of M was mixed with 1.5 mg/kg of H 20 min before treatment, administered orally. Group C: CH 50 mg/kg was mixed with 1.5 mg/kg of H administered orally 20 min before treatment.

Children needing dental care, aged 1 to 10 years and noncooperative according to the Ohio State Behavioral Rating Scale (OSBRS), ASA I and II, were included. Noncooperative behavior of the children during the dental rehabilitation included in the OSBRS were movements of the extremities and head, weeping, and physical resistance, The parameters were Q for quiet behavior without movement, C for weeping without movement, M for movement only without weeping, and S for weeping and movement at the same time.[2]

The objective of the study was explained to the parents, they were informed of the risks, and they signed a written consent form. The procedure was scheduled and the indications were given in writing. The date of the procedure was programmed, and preoperative instructions were given to the parents. On the day of the procedure the children were given the selected medication by randomization according to the three groups; the behavior of each patient was registered by an observer who was not informed of the objective of the study. The postreatment outcomes were explained and reviewed with the parents.

Statistical significance was tested with the Kruskal-Wallis test and the Wilcoxon tests where appropriate. A probability value of <0.05 was considered statistically significant. The JMP statistical program was used to analyze the data.

RESULTS

The demographic characteristics of the patients (age, gender, weight, and height) indicate that the groups were homogeneous (Table 1). The observed operating time in the groups was uniform, with a range of 15 to 30 min. A similar mean was shown for the three groups, which shows that they were homogeneous and that the operating time was not a factor that would explain differences in their behavior (Table 2).

The average cardiac rate in the three groups indicates a descending variation from group A to C, with group A having the highest average and group C, the lowest, because the cardiac rate is directly related to the patients' behavior (Table 3).

Figure 1 shows that the type of behavior in group A falls mainly in M(3) and S(4), compared with what was observed in groups B and C, which showed levels of behavior between Q(l) and C(2). Group A began between levels C(2) and M(3) and progressed to M(3) and S(4). Group C presented a higher level of samples in Q(1) than groups A and B, although with significant statistical differences only with respect to group A.

Oxygen saturation of the hemoglobin did not change significantly throughout the course of sedation but was constant within the three groups (95%–97% on average). Further, they do not show any significant statistical differences ($P > 0.05$).

The cardiac rate did not vary significantly throughout the sedations, and it was consistent within the three groups (120–160 on average), although there were no significant statistical differences found. However, after 10 min it was observed that the cardiac rate was slightly lower in group C, which is directly linked to the behavior ($P < 0.05$, Wilcoxon test, Figure 2).

DISCUSSION

The handling of patients' behavior depends on the interaction between child, parent, and dentist. Unfortunately, there are noncooperative patients, whether it be because of their mental growth, fear transmitted by parents, unpleasant dental treatment, or unpleasant hospital experiences, in which cases behavioral control techniques1[3,18,19] do not work; therefore dental rehabilitation is best accomplished through sedation.20 The classification system of behavior that we used is the Ohio State Behavioral Rating Scale (OSBRS), [2,6,16] featuring parameters easy to measure.

Monitoring of pediatric patients treated under sedation is especially important in nonhospital environments. Malviya *et al* [5] reported some adverse events such as oxygen saturation, bradycardia, hypotension in patients sedated with CH, as opposed to our study, wherein only one patient presented oxygen saturation below 90%. This might have been because we included only patients ASA I and II, whereas in Malviya's study ASA III patients were included. Also, they used CH ranging from 38 to

Table 1. Summary of Demographic Characteristics

		Age	Gender	Weight	Height
Group	N	Mean (Range)	Male/Female	Mean (Range), Kg	Mean (Range), Cms
A	18	3.90 (4–6)	11/7	18.10 (0.9–22.0)	104.8 (85.2–112.0)
B	18	2.83 (1–8)	11/7	15.00 (10.4–22.5)	93.6 (85.0–110.0)
C	18	2.94 (1–10)	10/8	16.33 (10.4–20.0)	94.5 (83.5–109.0)

N, sample size; A, hydroxyzine group; B, midazolam with hydroxyzine group; C, chloral hydrate with hydroxyzine group.

Table 2. Treatment Time

Group	N	Mean (Range) Min
A	18	23.50 (15–30)
B	18	22.50 (15–30)
C	18	23.67 (15–30)

P > 0.05 Kruskal-Wallis; N, sample size; A, hydroxyzine group; B, midazolam with hydroxyzine group; C, chloral hydrate with hydroxyzine group.

Table 3. Cardiac Rate

Group	N	Mean (Range)
A	18	152.3 (140.4–159.8)
B	18	146 (140.4–159.8)
C	18	136.9 (125.7–142.4)

P > 0.05 Kruskal-Walli;, N, sample size; A, hydroxyzine group; B, midazolam with hydroxyzine group; C, chloral hydrate with hydroxyzine group.

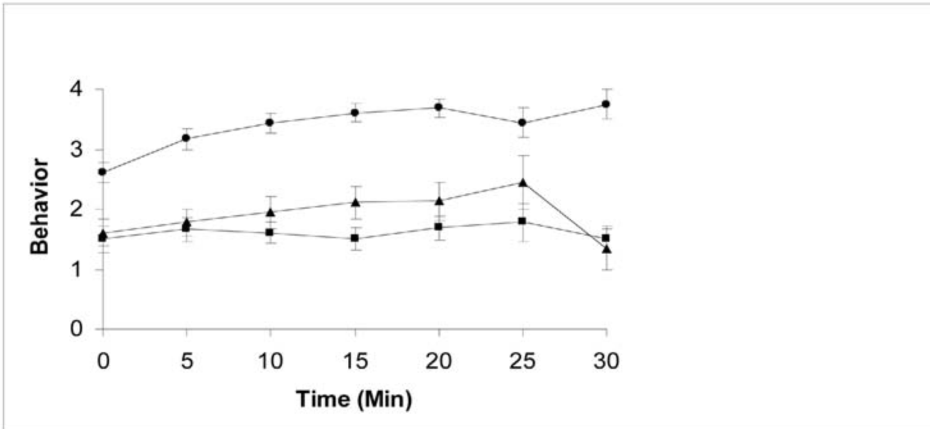

Figure 1. Behavior between the groups through time.

Q (Quiet) = 1; C (crying .without moving) = 2; M (moving without crying) = 3: S (crying and struggling) = 4. —= group A, hydroxyzine; – = group B, midazolam with hydroxyzine; —— group C, chloral hydrate with hydroxyzine.

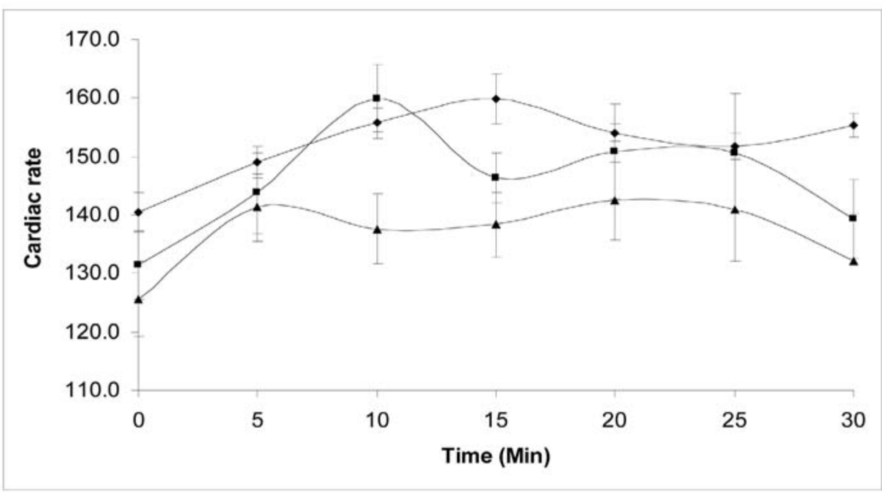

Figure 2. Mean cardiac rate.

—= group A, hydroxyzine; ——group B, midazolam with hydroxyzine; —= group C, chloral hydrate with hydroxyzine.

83 mg/kg; this could be an important factor in their findings since events of oxygen saturation with doses of 60 mg/kg have been reported.[19,21,22]

We agree with the findings of Chowdhury and Vargas[4] that behavior is directly related to cardiac rate. Therefore, the cardiac rate increases as more measurements are found in M or S, whereas it decreases when both measurements Q and C fall between normal parameters. According to the recommendations of Coté *et al* [19] regarding possible adverse effects, it is necessary that the dental pediatrician be assisted by an anesthesiologist or trained personnel. In our study, we carried out the sedation procedures according to the recommendations of the American Academy of Pediatrics (AAP) and the American Society of Anesthesiologists (ASA),[5,23] since it is reported that 80% of sedation deaths have been due to untrained medical personnel. In this study we used H, M, and CH, which have been reported to be used alone or combined.[2,6,8,11,16,20,24] It has been demonstrated that H enhances the sedative effects of CH, according to reports by Avalos-Arenas *et al* [16] in a study made at the Children's Hospital in Mexico; however, in contrast to our study they used oxygen concentrations below 90%, possibly because of having used a dose of 70 mg/kg of CH and 2 mg/kg of H. In our study, only one patient demonstrated an oxygen concentration below 90%; in this patient we used an average dose of 0.50 mg/kg of CH and 1.5 mg/kg of H. Chowdhury and Vargas4 had better results from CH than M, even though they changed the CH with H and meperidine, and both with nitrous oxide. This raises the question that they might have had better results using four drugs instead of two, that is, the level of sedation was perhaps better because the drugs enhanced each other when combined. Singh *et al* [8] compared M, triclofos, and prometazine, finding better results for M using a dose of 0.50 mg/kg, the same dose used in our study. M has several praiseworthy characteristics, including its safety range, quick action, and its potential to obtain a certain degree of amnesia. Another characteristic is its use in emergency procedures due to its short duration, with a satisfactory clinical effect of 20 minutes—ideal in dental pediatrics.[2,7,8,25,26]

CONCLUSION

Based on our findings, we conclude that the behavior of patients during dental treatment under conscious sedation with hydroxyzine alone is not controllable; however, when it is combined each with midazolam and chloral hydrate, it enhances their effects, although there are no significant statistical differences between the two combinations. Because of this property, both represent excellent options for treating such patients under conscious sedation.

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