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Comparison of two different dosages of hydroxyzine for sedation in the paediatric dental patient

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Aim. This study compared the effect of two different dosages of hydroxyzine supported by 50% nitrous oxide inhalation sedation in child patients.

Subjects and methods. Thirty uncooperative healthy children with an age range of 31–120 months were included in this study. Patients were randomly assigned into two groups. The patients in group 1 were given 20 mg of hydroxyzine (Atarax) 24 h preoperatively and on the operation day, 3.7 mg/kg hydroxyzine was administered orally. The patients in group 2 received 3.7 mg/kg hydroxyzine orally only on the operation day. All patients also received 50% nitrous oxide inhalation sedation. The child's behaviour was evaluated every 5 min by using Houpt Sedation Rating Scale. The oxygen saturation and heart rates were also followed.

Results. The mean age of the children in the study was 61.9 months (SD 11.9) for group 1 and 53.7 months (SD 12.8) for group 2. Evaluation of the results showed that there were no significant differences ($P < 0.05$) between behavioural attitudes and sedation degree of the patients.

Conclusions. Twenty milligrams of hydroxyzine administered 24 h preoperatively has no significant benefit on sedation of the child.

Introduction

Fearful children are one of the major problems in paediatric dentistry. When behaviour management techniques are insufficient, it is unavoidable to use a safe and inexpensive technique such as sedation. Pharmacological sedation is employed as an adjunct to behaviour management techniques. Oral and inhalation routes of sedative administration are the most convenient for use in children and are the most popular among paediatric dentists[1,2].

Several drugs are being used for conscious sedation. Oral hydroxyzine is one of the popular sedative agents, which is usually used in combination with other drugs like chloral hydrate, meperidine, or midazolam[3–8]. However, dosages and schedules for oral administration of hydroxyzine have varied widely in clinical reports, ranging from 20 to 60 mg taken 45 min to 1 h before treatment[9–12]. Lang[12] reported that 50 mg of hydroxyzine administered 1 h before treatment was effective in sedating children. Shapira *et al.*[9] administered 50 mg of hydroxyzine and found that success was better when hydroxyzine is used in combination with inhalation sedation. Some studies suggest that weight of the child must taken into account and 3.7 mg/kg dosage must be given[9,10].

The purpose of this study was to evaluate the effectiveness of sedation using two different dosages of hydroxyzine with nitrous oxide inhalation sedation.

Materials and methods

The Ethics Committee of the Faculty of Dentistry at University of Ankara approved this study. The procedures, possible discomforts or risks, as well as benefits were explained fully to the parents of the children and signed informed consent was obtained from the parents prior to the sedation procedures.

The study sample consisted of patients who were referred to the Clinic of Pedodontics at the Faculty of Dentistry, University of Ankara. Thirty uncooperative, fearful children aged between 31 and 120 months (mean age 58 months) participated in the study. The patients

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had required pharmacological management for treatment, because of a 'definitely negative' or 'negative' rating according to the Frankl Behaviour Rating Scale. All children were in good health (ASA I). Subjects with any systemic or chronic diseases, upper respiratory infections, cold, nasal obstructions, or children who failed to drink the drug were excluded from the study.

Subjects were assigned randomly to one of two oral sedation treatment groups. All patients were NPO (nil per os) for 6 h before scheduled procedure. The patients in group 1 received 20 mg/kg hydroxyzine (Atarax, UCB Pharma A.S., Istanbul, Turkey) 24 h prior to the sedation procedure. The drugs given at home were administered to the child by the parents. The patients in group 2 received oral hydroxyzine at the clinic on the day of the sedation procedure. All patients in both groups were weighed and received 3.7 mg/kg oral hydroxyzine. The drug was administered at the clinic by the assistant. The children remained in a quiet room after drug administration, under observation of a parent and a nurse. After an hour, all patients were carried to the dental unit and restrained using a pediwrap to prevent significant movement during treatment. An oxisensor probe (Datex-Ohmeda, TuffSat, Lousville, CO, USA) was attached to the toe. In addition to the oral hydroxyzine, 50% nitrous oxide/oxygen was administered via nasal mask during the entire procedure. Nasal mask was placed over the patient's nose and N_2/O_2 was administered at 50% ± 10% at 3–4 litre/min during the entire procedure. The required dental procedures was begun and completed by one experienced paediatric dentist who was blinded to the subject group assignment. Local anaesthetic (Ultracaine® D-S Forte, Aventis, Pharma San, Istanbul, Turkey) injection was administered in cases of tooth extraction or endodontic treatment. Local anasthesia was administered to 5 patients in Group 1 and to 8 patients in Group 2.

Heart rate and blood oxygen saturation level were continuously monitored using a pulse oximeter placed on the patient's toe.

The monitoring dentist using Houpt Sedation Rating Scale (Table 1) recorded the degree of sleep, movement, crying, and overall behaviour at 5-min intervals.

Table 1. Houpt Sedation Rating Scale.

	Score
Sleep	
Fully awake, alert	1
Drowsy, disoriented	2
Asleep	3
Movement	
Violent movement interrupting treatment	1
Continuous movement making treatment difficult	2
Controllable movement that does not interfere with treatment	3
No movement	4
Crying	
Hysterical crying that demands attention	1
Continuous, persistent crying that makes treatment difficult	2
Intermittent, mild crying that does not interfere with treatment	3
No crying	4
Overall behaviour	
Aborted	1
Poor – treatment interrupted, only partially completed	2
Fair – treatment interrupted, but eventually all completed	3
Good – difficult, but all treatment performed	4
Very good – some limited crying or movement	5
Excellent – no crying or movement	6

Following sedation session, the child was taken to a quite room, waited until fully awakened, and discharged according to the discharge criteria mentioned in the AAPD guidelines[13]. The patients were discharged approximately 20 min postoperatively. Appropriate postoperative instructions were given to parents.

The mean and standard deviations of all readings was calculated separately for each variable. The means were compared using analysis of variance (ANOVA) and Mann–Whitney *U*-test at the 95% level of significance.

Results

The study population consisted of 14 girls and 16 boys with an age range of 31–120 months. The mean age of the children in the study was 61.9 months (SD 11.9) for group 1 and 53.7 (SD 12.8) months for group 2. The overall sedation success rate was 90% regardless of group. The mean scores according to Houpt Sedation Rating Scale are shown in Tables 2–5. There were no statistically significant differences between Groups 1 and 2.

Table 2. Houpt Sedation Rating Scale (Sleep).

	Group 1		Group 2		
	Mean	SD	Mean	SD	
Baseline	1.1	0.9	1.2	0.8	n.s.*
Nitrous oxide	1.5	0.6	1.5	0.8	n.s.*
5 min	1.6	0.5	1.5	0.6	n.s.*
10 min	1.4	0.9	1.3	0.9	n.s.*
15 min	1.5	0.9	1.4	1.0	n.s.*
20 min	1.5	1.0	1.4	1.4	n.s.*
25 min	1.6	0.8	1.4	0.7	n.s.*

*Statistically nonsignificant differences.

Table 3. Houpt Sedation Rating Scale (Movement).

	Group 1		Group 2		
	Mean	SD	Mean	SD	
Baseline	3.2	0.9	3.7	0.8	n.s.*
Nitrous oxide	3.7	0.6	3.7	0.8	n.s.*
5 min	3.7	0.5	3.7	0.6	n.s.*
10 min	3.3	0.9	3.0	0.9	n.s.*
15 min	3.5	0.9	3.2	1.0	n.s.*
20 min	3.4	1.0	2.7	1.4	n.s.*
25 min	3.6	0.8	4.0	0.0	n.s.*

*Statistically nonsignificant differences.

Table 4. Houpt Sedation Rating Scale (Crying).

	Group 1		Group 2		
	Mean	SD	Mean	SD	
Baseline	3.2	1.0	3.7	0.8	n.s.*
Nitrous oxide	3.6	0.9	3.8	1.0	n.s.*
5 min	3.7	0.5	3.7	0.6	n.s.*
10 min	3.3	0.9	2.9	1.0	n.s.*
15 min	3.4	1.0	3.2	1.0	n.s.*
20 min	3.4	1.0	3.0	1.3	n.s.*
25 min	3.6	0.8	3.7	0.5	n.s.*

*Statistically nonsignificant differences.

Table 5. Houpt Sedation Rating Scale (Overall behaviour).

	Group 1		Group 2		
	Mean	SD	Mean	SD	
Baseline	4.9	1.4	5.6	1.3	n.s.*
Nitrous oxide	5.5	1.2	5.6	1.3	n.s.*
5 min	5.7	0.5	5.4	1.2	n.s.*
10 min	4.9	1.4	4.8	1.1	n.s.*
15 min	5.1	1.5	4.8	1.7	n.s.*
20 min	5.2	1.5	4.6	1.6	n.s.*
25 min	5.4	1.0	6.0	0.0	n.s.*

*Statistically nonsignificant differences.

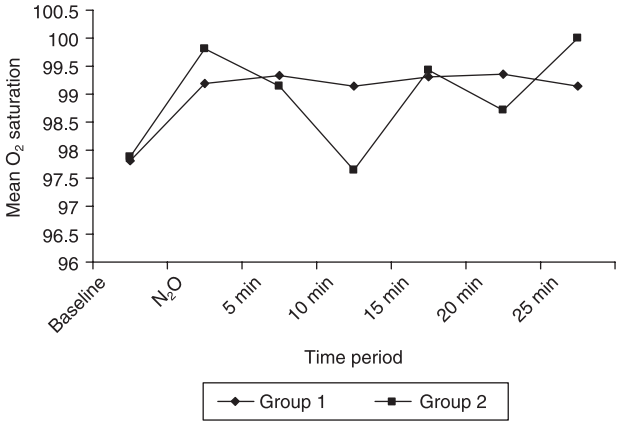

Fig. 1. Mean oxygen saturation.

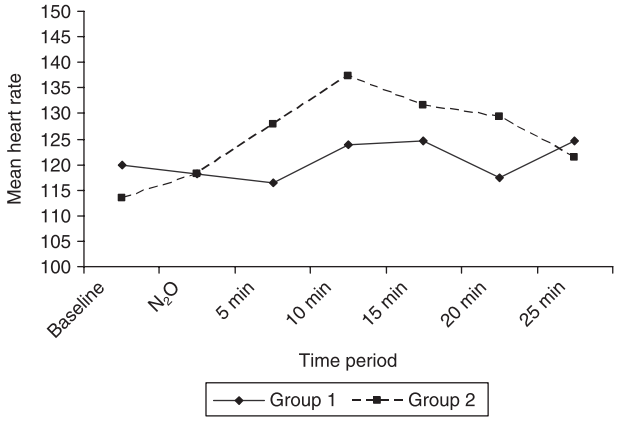

Fig. 2. Mean heart rate.

The mean SaO_2 (blood oxygen saturation) and mean heart rates are shown in Figs 1 and 2. SaO_2 rates were over 94% throughout all sedation procedures for both groups. At 10 min of the sedation procedure, there was a slight difference between groups for SaO_2 and heart rates; however, the difference was statistically significant ($P < 0.05$). The SaO_2 rate of group 2 was significantly lower than group1, whereas, mean heart rate was significantly higher for group 2 ($P < 0.05$). However, all readings were above 94%, which was not clinically significant.

Discussion

Various drugs, alone or in combination, are widely used via oral, nasal, intravenous, or intramuscular routes for conscious sedation[3,14]. Because of the easy use and safety, oral route is mostly preferred.

Oral hydroxyzine administration is a safe and inexpensive technique for the sedation of uncooperative child. Aside from its anti-emetic and saliva secretion-reducing properties, it has minimal effects on the circulation system and has little or no side-effects. For these reasons, it has been used for many years in sedation procedures of paediatric patients[3,4,6,11]. However, it is usually used in combination with other drugs, such as chloral hydrate or midozalam. There are only a few studies reporting the results of hydroxyzine used in combination with nitrous oxide[9,10]. In these studies, oral hydroxyzine was administered in different dosages and there was no certainty about the dosage that would be effective. Stewart[16] reported a higher success rate when using hydroxyzine combined with nitrous oxide. Shapira *et al.*[9] used the 50-mg dose, but they concluded that 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; therefore, the child's weight must be taken into consideration. The effectiveness of the medication may be increased if administered in divided doses[17]. In this study, the weight of the patient was used as a criterion for determining the dose of hydroxyzine and 3.7 mg/kg was administered, and for group 1, a preoperative dose of 20 mg was administered.

The Houpt Sedation Rating Scale was used to assess efficacy because of its demonstrated reliability and frequent use in other studies[18]. The crying, sleep, movement, and overall behaviour were similar for both groups.

All physiological variables were within normal limits for the children. The only significant difference between the two dosages was observed in SaO_2 and heart rates at 10 min. Wilson *et al.*[7] observed dramatic increase in heart rate following the administration of local anaesthetic, which was also associated with struggling behaviours. In a study by Poiset *et al.*[19], the largest increase in pulse rate was observed during the post-injection period, the 6-s period after the needle was removed from the tissue. Possible explanations for the increase in pulse rate may be the pain or the expansion of the connective tissue by the anaesthetic fluid[19]. There were no statistically significant changes in the SaO_2 and heart rates except at 10 min. The increase observed in pulse rate in group 2 might be due to the local anaesthetic injection and pain as local anaesthetic injection was administered around the 10th min of the procedure.

The success rates in sedation studies range from 70 to 89%[3,8,9]. It is difficult to compare the outcomes between sedation studies, because of the different methodologies and criteria of success used. Also, the age of the patient, experience of the dentist and even caries prevelance may effect the results. The overall success rate in this study was 90% regardless of the dose used. This result was similar to the study in which Shapira *et al.*[9] reported 89% success rate using hydroxyzine and nitrous oxide.

In conclusion, there was no significant benefit of 20 mg hydroxyzine administered 24 h preoperatively for the effective sedation of fearful and uncooperative children.

What this paper adds

- Hydroxyzine 24 h preoperatively has no significant effect for the conscious sedation of paediatric dental patients.

Why this paper is important to paediatric dentists

- Effective sedation could be performed with hydroxyzine within combination with nitrous oxide.

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