Abstract

Purpose: The purpose was to evaluate two sedation protocols during dental sessions in anxious children.

Materials and Methods: It was a randomized and double-blind study, with each individual being his/her own control within each protocol. Furthermore, the two protocols were compared. Twenty children (36 to 84 months old) who exhibited “definitely negative” behavior according to the Frankl scale were assigned to receive oral chloral hydrate (40 mg/kg) (Group I) or Diazepam® (5 mg) (Group II). Behavior during local anesthesia, application of rubber dam, cavity preparation, restorative procedures was evaluated, considering the degree of sleep, body movement, crying and overall behavior. Vital signs were assessed at three different times. The Wilcoxon, Mann-Whitney, Exact Fisher’s and Spearman correlation tests were used to analyze the data.

Results: Group I presented higher scores for sleep during the CH session than placebo session during rubber dam application ($P = 0.0431$) and restoration ($P = 0.0431$). In Group II there was no statistically significant difference ($p > 0.05$). There were no statistically significant differences between sessions and groups in the evaluation of body movement, crying and vital signs. Overall behavior in the placebo session was better than in the CH session during local anesthesia, but there was no difference between the two drug regimens. There was influence of age during anesthesia and cavity preparation in Group I and during rubber dam application in Group II.

It was concluded that oral diazepam and chloral hydrate had no influence on the behavior management for dental treatment with the studied sample.

Key words: Behavior control, chloral hydrate, conscious sedation, diazepam

Introduction

For many years, conscious sedation has been a popular pharmacological approach in the management of young uncooperative children who need invasive dental and medical procedures but cannot be treated using basic behavior management techniques (BBM), such as tell-show-do, positive reinforcement, controlled expectations, distraction, modeling and suggestion.

The real intention is to apply BBM to create an environment that will facilitate development of the child's confidence and allow the dentist to carry out procedures with minimal disruption and maximum safety and to provide quality dental care when using behavioral management strategies. Normally, fear of the dentist is fairly common in children, having been reported in 7% of children 4-11 years of age, while behavior management problems have been found in 8-11% of children when BBM was used alone. For them, pharmacological intervention (sedation or general anesthesia) becomes an important alternative for the dentist to adopt to manage dental anxiety, to help children cope with the stress of dental treatment and to avoid unpleasant and unproductive confrontation with the child.

The pediatric dental literature contains numerous reports on various medications (e.g., nitrous oxide, opioids, benzodiazepines, chloral hydrate, barbiturates and antihistamines) which have been administered alone or in combination. However, the search for a predictable, safe and efficacious sedative protocol is still the main goal of therapeutic health care procedures for children.

Frequently, chloral hydrate and diazepam have been used to manage an uncooperative child in a dental setting. Their pharmacological effects are as different as their reported success rate as sedative agents. Chloral hydrate is considered to be a hypnotic sedative whose effect on the cerebral hemisphere causes only minimal depression of the respiratory system and has minimal effect on blood pressure. It has a wide margin of safety, being detoxified in the liver and eliminated by the kidneys. On the other hand, diazepam is a benzodiazepine, which produces mild muscle relaxation and has anticonvulsant properties. It is a drug that is relatively lipid soluble and water insoluble and when taken orally, its availability is about 100%.

The purpose of this study was to make a random, double-blind comparison of the sedative, behavioral, dental procedures and vital signs in anxious children who had received oral chloral hydrate 40 mg/kg or diazepam (Diazepam® - 5 mg).
medicine was used to modify the behavior of uncooperative children in order to provide comprehensive dental treatment.

Materials and Methods

The study included 20 children ranging in age from 36 to 84 months (mean weight 16 kg). Otherwise, the children were healthy and they all needed two visits of restorative dental care. Written and verbal consents were obtained from each child’s parents/guardians after they were informed about the procedures, possible discomforts or risks, as well as the possible benefits; their informed consent was obtained prior to the investigation. The research was reviewed and approved by the institutional review board.

The children were seen for their initial exam and it was determined that they definitely exhibited “definitely negative” behavior according to the Frankl scale. The subjects were randomly assigned to one of the two experimental groups: Group I - chloral hydrate (40 mg/kg, not exceeding 1g) or placebo; and Group II diazepam (5 mg) or placebo, with the alternative regimen administered during the second appointment. A member of the research team other than the operator; or the independent evaluators, trained nurse, offered the medication to the patient in a plastic cup in order to ensure that the operator and the child were blind to the regimen. Following drug administration, the child remained with the parent in an appropriate room for approximately 60 minutes and after that the dental treatment was performed. All sessions were videotaped (VHS) to verify the reliability of the rating scales that had previously been established. The nurse did not participate in dental sessions.

Each appointment was divided into four intervals as follows: (1) injection of local anesthesia - 5 minutes; (2) application of rubber dam - 5 minutes; (3) cavity preparation - 10 minutes; (4) restoration - 5 minutes. If the predetermined time of the appointment was exceeded, the procedure was considered to be not fulfilled. One pediatric dentist performed all dental procedures. If at any time during treatment, the child became so uncooperative that the dental procedures could not be carried out or if the child seemed to be in a state where injury might occur, the remaining treatment was aborted. In such cases, the parent or legal guardian was given an opportunity to fix a new appointment for the child with the alternative sedation regimen or withdraw the child from the investigation.

Patients’ behavioral responses throughout the treatment were evaluated by three specialists in Pediatric Dentistry, using a scoring system established by Houpt et al.,[21] and modified by Badalaty et al.,[7] considering the degree of sleep, body movement, crying and overall behavior. Ratings were made during the four operative procedures mentioned above (Table 1). The rating dentists were independent of the operator and they were trained for this purpose. The score values were progressive according to the quality of the behavior. The highest values corresponded to the best behaviors. If the subject did not cooperate and the procedure was not completed, the child was given the lowest score. The mean scores of the three dentists were considered.

The nurse monitored vital signs, viz, arterial blood pressure (mmHg), heart rate (beats/min), respiratory rate (mov./min) and body temperature (°C), at three different times: (a) 5 minutes after patient’s arrival, (b) 60 minutes after drug administration and (c) 5 minutes after ending dental care procedure as recommended by the AAPD guidelines for the elective use of pharmacologic conscious sedation and deep sedation in pediatric dental patients.

Data analysis

The study was designed so that each patient served as his/her own control, within each group, with time of day and type of procedure being relatively constant between the two treatment visits. The data were analyzed to determine whether there were differences between the sessions with and without medication within the evaluated parameters. Since the rating scales used the ordinal scales of measurement with related samples, the Wilcoxon matched-pairs signed-rank test was used at the 95% level of significance. The Mann-Whitney test was applied to determine whether the mean scores of the session with CH were significantly different from the scores of the session with diazepam. In addition, the exact Fisher’s test was used for comparison of the overall effectiveness of the drug regimens. Analysis of variance was applied to verify the differences in vital signs during the three evaluation times. Spearman coefficients were applied

| Table 1: Behavior rating criteria |
|----------------------------------|
| **Rating scale**                 |
| Sleep                            |
| 1. Fully awake, alert            |
| 2. Drowsy, disoriented           |
| 3. Asleep                         |
| Body movement                    |
| 1. Violent movement that interrupts treatment |
| 2. Continuous movement that makes treatment difficult |
| 3. Controllable movement that does not interfere with treatment |
| 4. No movement                   |
| Crying                           |
| 1. Hysterical crying that interrupts treatment |
| 2. Continuous persistent crying that makes treatment difficult |
| 3. Intermittent, mild crying that does not interfere with treatment |
| 4. No crying                     |
| Overall behavior                 |
| 1. Aborted - no treatment rendered |
| 2. Poor - treatment interrupted, only partial treatment completed |
| 3. Fair - treatment interrupted but eventually all completed |
| 4. Good - difficult, but all treatment performed |
| 5. Very good - some limited crying or movement |
| 6. Excellent - no crying or movement |
between age and the score values in order to verify if the tendency to cooperate increased with age.

**Results**

This study involved 20 patients, who participated in 40 dental appointments. All children were previously classified as having “definitely negative” behavior. Clinical success was defined as the ability to perform the planned operative treatment without significant opposition from the child. An overall behavior rating of 4 or better was considered a success. Clinical failure was defined as the inability to complete planned treatment. An overall behavior rating of 3 or less was representative of failure.

The mean rating for each drug regime and operative procedures are shown in Tables 2 and 3. There was 80% agreement among the ratings of the three dentists, demonstrating reasonable reliability.

**Evaluation of sleep**

When the four operative procedures were considered together, there was statistically significant difference between the scores of the CH session and the respective placebo session (p = 0.028) [Table 2, Figure 1]. In Group I, the mean ratings for sleep in the CH session were significantly higher statistically than in the placebo session during rubber dam application (p = 0.043) and restoration (p = 0.043). In Group II there was no statistically significant difference. Only one child who received CH was asleep by the end of the restorative procedure, whereas no patient who received diazepam was asleep during any procedure [Tables 2 and 3].

**Evaluation of body movement**

The results indicate that while there was some movement with all drug groups, no statistically significant differences were evident in overall session and in operative procedures between sessions and between groups despite the children from Group I having presented lower scores than those from Group II [Tables 2 and 3, Figure 2].

**Evaluation of crying**

In Group I the scores were less than 3, except for anesthesia in the session with placebo, meaning that crying was always present, disturbing the procedures. There was no statistically significant difference between the sessions. For Group II, the results indicate that there was some minimal or moderate crying in the sessions with and without diazepam, but there was no statistically significant difference between the respective scores [Tables 2 and 3, Figure 3].

**Evaluation of overall behavior**

During local anesthesia the mean scores from placebo session were significantly higher than those from the CH session (p = 0.043), meaning that in the placebo session, behavior was better than in the CH session. Between the two drug

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**Table 2: Overall mean rating for each drug regime and operative procedures for Group I**

| Group I (Chloral hydrate) | Sleep | Movement | Crying | Overall behavior |
|---------------------------|-------|----------|--------|-----------------|
| Local anesthesia          |       |          |        |                 |
| Session CH                |       |          |        |                 |
| Session placebo           |       |          |        |                 |
| Placebo                   | 1.222 | 1.519    | 2.963  | 3.407           |
| (0.276)                   | (0.475)| (1.414)  | (0.894)| (1.444)         |
| Rubber dam                |       |          |        |                 |
| Session CH                |       |          |        |                 |
| Session placebo           |       |          |        |                 |
| Placebo                   | 1.167 | 1.481    | 2.222  | 2.333           |
| (0.284)                   | (0.475)| (1.379)  | (1.333)| (1.501)         |
| Cavity preparation        |       |          |        |                 |
| Session CH                |       |          |        |                 |
| Session placebo           |       |          |        |                 |
| Placebo                   | 1.204 | 1.481    | 2.333  | 2.611           |
| (0.281)                   | (0.475)| (1.369)  | (1.364)| (1.501)         |
| Restoration               |       |          |        |                 |
| Session CH                |       |          |        |                 |
| Session placebo           |       |          |        |                 |
| Placebo                   | 1.189 | 1.630    | 2.385  | 2.348           |
| (0.256)                   | (0.696)| (1.409)  | (1.148)| (1.448)         |

*Significant difference - P < 0.05 using Wilcoxon matched-pairs signed-rank test

**Table 3: Overall mean rating for each drug regime and operative procedures for Group II**

| Group II (Diazepam) | Sleep | Movement | Crying | Overall behavior |
|---------------------|-------|----------|--------|-----------------|
| Local anesthesia    |       |          |        |                 |
| Session diazepam    |       |          |        |                 |
| Session placebo     | 1.530 | 1.530    | 3.152  | 3.379           |
| (0.427)             | (0.476)| (0.947)  | (0.882)| (0.934)         |
| Rubber dam          |       |          |        |                 |
| Session diazepam    |       |          |        |                 |
| Session placebo     | 1.576 | 1.621    | 3.167  | 3.455           |
| (0.449)             | (0.427)| (1.067)  | (1.014)| (1.041)         |
| Cavity preparation  |       |          |        |                 |
| Session diazepam    |       |          |        |                 |
| Session placebo     | 1.576 | 1.530    | 2.848  | 3.333           |
| (0.449)             | (0.435)| (1.149)  | (0.978)| (1.078)         |
| Restoration         |       |          |        |                 |
| Session diazepam    |       |          |        |                 |
| Session placebo     | 1.576 | 1.591    | 3.636  | 3.636           |
| (0.449)             | (0.443)| (0.924)  | (0.924)| (0.932)         |
regimens, there was no statistically significant difference in overall behavior scores [Figure 4].

When the overall evaluation data was dichotomized to represent success or failure of the sedative technique, success was defined to include the ratings “excellent” and “very good” (scores 6 and 5 respectively). Four of the nine administrations of CH (44.4%) and seven of the eleven administrations of diazepam (63.6%) were rated as “excellent” or “very good.” These results demonstrate no statistically significant difference in overall effectiveness if success of the sedation is defined to include these two ratings (Fisher exact test \( p > 0.05 \)). If the treatment were to be considered successful if it was completed despite there being some movement or crying, the rating “good” also would be included, but there was also no statistically significant difference between drug regimens (Fisher exact test \( p > 0.05 \)). Two children from Group I received score 1 or 2; thus the treatment was not performed in either of the two sessions and one allowed treatment only in the placebo session - the overall behavior being rated as 3 (fair). In Group II one child received score 3 for overall behavior in both sessions.

Correlation between age and behavioral scores
The significant correlations between age and scores are presented in the Table 4. There were no correlations between age and sleep scores in the two groups, as well as for crying in Group II.

Vital signs
In general, vital signs remained stable throughout the evaluation time. There was no statistical difference in the score ratings between sessions in the two groups [Table 5].

Discussion
The important purpose of sedation is to prevent negative experiences for the dental care patient, as well as for the family and the dental team.[2] It is also to encourage change in the child’s behavior, to help children develop their own coping skills and to promote acceptance of the dental environment.[22]

In this study, diazepam was selected for the reason that it has sedative effects on patients undergoing surgical procedures. Secondly, the 5 mg dose was chosen because it is more effective in larger doses than oral administration of 0.2 or 0.3 mg/kg, which produced inadequate sedation for the dental treatment of uncooperative children.[23,24] Chloral hydrate 40 mg/kg was chosen because it is a common regimen in
Table 4: Significant spearman coefficients ‘r’ and ‘P’ values between age and rating scores

|                | Movement  | Crying   | Overall behavior |
|----------------|-----------|----------|------------------|
|                | Session   | Session  | Session          | Session   | Session  |
|                | placebo   | medication | placebo | medication | placebo | medication |
| Group I (CH)   | Local anesthesia | r | 0.750 | 0.729 | - | 0.729 | - | 0.838 | 0.678 |
|                | r | P | 0.020 | 0.026 | - | 0.026 | - | 0.005 | 0.045 |
|                | Cavity preparation | r | 0.838 | 0.820 | 0.744 | 0.852 | 0.002 | 0.004 | 0.004 | 0.018 |
|                | r | P | 0.005 | 0.007 | - | - | - | - |
| Group II (Diazepam) | Rubber dam | r | - | 0.779 | - | - | - | 0.643 | 0.033 |
|                | r | P | - | 0.005 | - | - | - |

Table 5: Mean value of vital signs (standard deviation) at the three evaluation times

|                | Session | Group I | | Group II | | |
|----------------|---------|---------|---|---------|---|
|                | a | b | c | a | b | c |
| HR Placebo     | 67.7 (7.5) | 68.7 (7) | 67 (8.3) | | 65.2 (6.3) | 64 (6.1) | 63.6 (5.6) |
| Chl/oral cort/m | 66.8 (5.2) | 68.1 (5.6) | 67.8 (6.2) | | 65.4 (7.6) | 61.8 (7.5) | 62.2 (11.6) |
| RR Placebo     | - | - | - | 22.4 (3.3) | 22.4 (2.0) | 21.3 (2.5) | 21 (2.7) |
| Chl/oral cort/m | 20.8 (4) | 21.5 (2.8) | 20.8 (3) | | 21.6 (2.4) | 22.6 (3.2) | 21.2 (1.8) |
| T Placebo      | 36.4 (0.2) | 36.3 (0.1) | 36.3 (0.3) | | 36.6 (0.4) | 36.5 (0.4) | 36.6 (0.4) |
| Chl/oral cort/m | 36.2 (0.2) | 36.6 (0.3) | 36.4 (0.2) | | 36.5 (0.4) | 36.3 (0.4) | 36.4 (0.4) |
| BP Placebo     | 100/64 (5.5/4.2) | 101/64 (7.4/4.2) | 102/67 (9.1/3.3) | | 97/62 (11/3.8) | 102/62 (5/5) | 102/61 (18/5.5) |
| Chl/oral cort/m | 106/65 (11/5.6) | 98.2/63 (15/11) | 99.1/64 (12/9.5) | | 106/67 (16/8.5) | 96.9/53 (3/12.5/6) | 98/60 (11/3.4) |

HR - Heart Rate; RR - Respiratory rate; T - Body temperature; BP - Blood pressure, (a) 5 minutes after patients’ arrival; (b) 60 minutes after drug administration; (c) 5 minutes after ending dental care procedure

pediatric dental literature.[1,21] A total dose not exceeding 1 mg was chosen in an attempt to avoid toxicity. Nitrous oxide supplementation was not used due to the authors’ desire to eliminate any synergistic drug effects from the study. The findings of this study showed that in Group I the ratings for sleep during the rubber dam application and restorative procedures were statistically higher in the CH session. These findings could be explained by the kind of procedures, since they are performed in shorter time and do not involve discomfort and noise, as happens with anesthesia and cavity preparation respectively. Nevertheless, during the placebo session, children from Group I presented higher ratings in overall behavior for anesthesia than during the CH session, probably due to the crying and the movement in this operative procedure. In the studied sample, CH does not contribute to behavior management, since three children did not allow the treatment to be completed in the CH session; and in the placebo session, two of them behaved in the same way, but it is not possible to draw definitive conclusion due to the small number of evaluated children. Croswell et al.[25] reported a 66% success rate in 44 patients using CH (mean age 39 months). In addition, a 5-year retrospective study by Leelataweedwud and Vann[1] reported a 72% success rate for chloral hydrate regimen and only one incident of nausea/vomiting.

In order to verify if the cooperation was associated with age, the correlation was done with the rating scores in all clinical procedures. The correlations that were found [Table 4] evidenced the influence of age during the most difficult procedures, as are the anesthesia and cavity preparation in Group I. This finding could be explained by the fact that small children may not be expected to behave too cooperatively in the chair. Significant correlations were observed also in Group II between age and scores for movement in session with diazepam and in both sessions for overall behavior during rubber dam application. Although nausea, vomiting and respiratory depression are common adverse reactions for both chloral hydrate and diazepam,[26] in this study no adverse effects were observed at any time during the procedure. In this respect, Hasty et al.[27] also reported no vomiting with Ch MH/O 2 for the 20 sedations in their study. In contrast, Needleman et al.[28] reported 8.1% vomiting intraoperatively using chloral hydrate/hydroxyzine/nitrous oxide/O 2. For diazepam, our findings were similar to Yanase et al.[29] Badalaty et al.[7] found one occurrence of vomiting for one administration of chloral hydrate and diazepam.

In this study diazepam appears to be safe and it produces sedative effects comparable to chloral hydrate, which is in agreement with the findings of Badalaty et al.[7] Differences in intra- and inter-operative behaviors were not noted between the two drug regimes for any of the parameters evaluated, as observed by Reeves et al.,[9] who compared two different regimes of associated drugs (chloral hydrate/hydroxyzine vs. Midazolam/acetaminophen). Nevertheless, Wilson et al.,[20] used chloral hydrate in association with others drugs; meperidine and hydroxyzine produced significantly quieter and better sleeping behaviors than benzodiazepines. Reinemer et al.,[29] who also assessed efficacy and safety of ketamine associated with diazepam, observed 87% clinical success in terms of modifying behavior of young children,
suggesting that the diazepam or chloral hydrate sedative effects occur with different drug associations.

According to its pharmacological characteristics, the sedative level of diazepam is attained some 30 minutes after oral administration, with the deepest sedative effects occurring after 60-90 minutes. The chloral hydrate peak of concentration after administration is at 20-60 minutes. Therefore, waiting in a quiet room has been reported to produce a similar outcome as taking the sedatives at home prior to the appointment, in the present study, a 30- to 60-minute wait in a quiet and appropriate room for children was adopted, as previously reported in order to control the dosage and monitor the children. On the other hand, the waiting time should be carefully analyzed because it could be an important factor in predicting sedation success, as it would be expected to arouse greater fear and anxiety in children who are already fearful.

A significant limitation of many previous conscious sedation studies has been the method by which behavior was evaluated. The Frankl Scale has been used for its simplicity. Broad, nondescriptive behavior assessments of all physiological variables being within normal limits for blood pressures, heart rates and oxygen saturation for 4 minutes, that diazepam and chloral hydrate, as drug regimens only, had no influence on the behavior management during dental treatment of the evaluated children. Further study with increased sample size with the current procedures and making a direct comparison of each drug within each patient should be carried out, since the outcomes of this preliminary study must be interpreted with caution, due the number of children and the influence of age on the recorded results.

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