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A Comparison of Oral Sedation-related Events for Three Multi-Agent Oral Sedation Regimens in Pediatric Dental Patients: A Pilot Study

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Introduction

One of the main challenges pediatric dentists face is managing children's behavior and obtaining cooperation during dental treatment. This is particularly true for for pre-cooperative children with early childhood caries and severely anxious children.[1,2] Although the majority of children can be treated using non-pharmacological behavioral guidance techniques, a portion of children will need advanced behavioral management modalities to help ensure delivering quality dental care.

An advanced behavioral management technique is oral conscious sedation(OCS). This approach is defined as a drug-induced depression of consciousness in which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.[3] No intervention necessary to maintain an open airway and spontaneous ventilation is adequate while cardiovascular function is maintained.[3,4]

Oral conscious sedation technique utilizes different medications to achieve the required sedation level. Common medication classes used in oral sedation in children include benzodiazepines, antihistamines and opioids. The use of these medications has been described individually or in combination for oral sedation in pediatric dentistry.[4] Currently, No single agent or regimen is recognized as the standard for dental procedures.[5]

Although OCS can be very beneficial to pediatric dentists, some limitations exist. One drawback is the inability to titrate the medications to the desired effect.[6-8] Much of the sedation research does not address the rates of agitation, irritability, intra-operative and post-operative behavior.[9-10] Adverse events might be expected from the time of drug administration until after the patient is discharged from the office.

This Purpose of this pilot study is to the compare the post sedation events from three different multi-drug oral sedation regimens in order to help pediatric dentists determine the best course of action for their patients and prepare parents appropriately and caution them about the expected effects.

Hypothesis

No significant difference exists in the incidence of adverse sedation-related events at different time points up to 24 hours when using Midazolam (MZ), Meperidine (M), and Hydroxyzine (H) (3 drug regimen) compared to Midazolam, Hydroxyzine, and Meperidine, Hydroxyzine, (2 drug regimen) when used in combination with nitrous oxide and local anesthesia.

Methods

In this randomized clinical trial pilot study, fifteen healthy (ASA I) patients, ranging from three to eight years of age, were selected to be included in the study.

The patients were independently scheduled to undergo oral sedation in Loma Linda University's pediatric dental clinic. Exclusion criteria consisted of children who have taken any medication within the two weeks prior to dental treatment, presented for emergencies, have been sedated previously by other providers or in other institutes, had a BMI greater than the 95th percentile for their age and gender, and who failed to drink the entire amount of medication dispensed.

Informed consent was obtained upon arrival of the parent, or legal guardian, and child to their sedation appointment. The standard sedation protocol of the pediatric dentistry clinic at Loma Linda University and guidelines of the AAPD and were followed in each case. The patients were randomly divided into one of three groups, using a randomization bag. All treatments were done in conjunction with nitrous oxide.

- The first group, five patients, received a three-medication cocktail of Midazolam, Meperidine and Hydroxyzine (MZ/M/H)
- The second group, five patients, received a two medications cocktail of (MZ/H)
- The third group, five patients, received a two medications cocktail consisting of (M/H)

Once treatment was completed, data was collected in the form of 3 survey sets. The first survey was filled by the dentist performing the sedation. The second and third surveys were completed by the parents via a phone interview at two time points after discharge. The surveys consisted of questions addressing common adverse sedation events.

All responses were entered into an excel spreadsheet and analyzed using SPSS 26 (SPSS Chicago, IL). Data Analysis include descriptive statistics and inferential statistics utilizing the chi-square. The significance level will be set as p less than 0.05.

Results

A total of 15 subjects were enrolled in this study. Ten subjects (66.7 %) were female, and 5 (33.3 %) were male. Ages ranged from three to eight years old, and the mean age was 66±22.5 months.

Three surveys were collected for each of the 15 patients. A total of 45 surveys were collected. Analysis in survey 1 (responses of treating dentists about behavior during treatment) showed no significant difference between the three sedation regimens.

In Survey 2 (parental survey about patient's behavior-1st time point), no statistical significance differences was found in any of the adverse categories studied. Among parents who reported giving pain medication postoperatively (26.3%), all reported mild dental soreness as the indication for the medication.

In Survey 3 (parental survey about patient behavior-2nd time point), no significant difference between the three sedation regimens was found.

It is worth nothing the incidence of multiple adverse events (such as snoring and stomach upset) was found to be higher in patients who received the three-medication regimen (MZ/M/H); these findings, however, was not significant (figure 2).

No significant correlations were found between age, sex or BMI of the patient and incidence of adverse events.

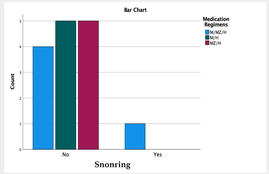

Figure 1

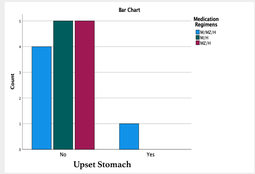

Figure 2

Discussion

Currently, no single agent or combination of agents or has been recognized as an optimal regimen for sedation in the pediatric population requiring dental treatment.[5] Each sedative administered, alone or in combination, can produce a variety of outcomes and side effects.[11] When selecting a sedation regimen for the patient considers both the efficacy of the regimen in providing enhanced behavior control as well as the pharmacodynamics of the agents used and their possible associated risks of adverse events.

When investigating the association between age, gender, and BMI of the patient and the incidence of adverse sedation related events, no significant correlations were found between the age, sex or BMI of the patient. This is in contrast to a previous study that reported a positive correlation between the BMI of the patient and incidence of adverse sedation-related events.[9] The author of this paper stated that as the BMI of the child increased, there was an increase in CNS-related events prior to discharge.[9]

An interesting finding of this pilot is that parents whose children received the three-medication regimen (MZ/M/H) reported more adverse related events. The non significance of this finding may be attributed to the small sample size and warrants further exploration.

Although no major differences were found in the adverse effects between the three regimens, it was noted that the incidence of adverse sedation-related events was greatest within the first eight hours after discharge. Therefore, it is the responsibility of the clinician to assess each patient's individual needs and situation and choose an appropriate regimen for each patient. For example, if the clinician's pre-sedation assessment shows a child with larger tonsils or a history of snoring, it may be prudent to select a sedation regimen with a shorter half-life and a lower incidence of postoperative sleeping, while also taking extra precautions, or no sedation at all depending on the potential for sleep apnea.

Conclusion

Based on this pilot study's results, the following conclusions can be made:

1. No significant differences between three medication combinations were found among all categories up to 24 hours after discharge
2. No significant correlations were found between age, sex or BMI of the patient and incidence of adverse events.
3. The pediatric dentist providing sedation should counsel parents on the expectations of unwanted side effects based on the regimen of sedative agents used.

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