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Efficacy of Inhaled Sevoflurane Sedation Compared with Nitrous Oxide in Managing Children Undertaking Dental Extraction: A Randomized Controlled Trial

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Abstract

Background: For many years dental anxiety is considered as a major problem in behavior management. Nitrous Oxide Inhalation sedation can be used to reduce anxiety and manage children during treatment, but it is not successful in all cases. The aim of this study was to compare the relative effectiveness of inhalation sedation using nitrous oxide(A) with new inhalation sedation technique using sevoflurane (B), in management of children receiving dental extractions.

Methods: A randomized, controlled clinical trial was undertaken. forty children who are anxious aged between (8- 10) years, ASA category I, They were randomly allocated to have inhalation sedation with method (A) or (B), the level of anxiety has been evaluated using Venham Anxiety Scale.

Results: There was no statistically significant difference between the success rate of the two methods of sedation. Both methods were effective in reducing the anxiety in children during dental extraction. No adverse cardiorespiratory effects were reported in either method , and there were no significant differences in oxygen saturation, heart rate, or time of recovery between the two methods.

Conclusions: The sevoflurane inhalation sedation can be a suitable alternative method to the nitrous oxide inhalation sedation in the management of children.

Keywords: Inhalation sedation, Nitrous Oxide, Sevoflurane, Children, Extraction.

Introduction

Children fear from dental services is one of the main concerns in dental clinics [1]. Appointments with dentist is stressful for most children [2].While anxiety can be modified by non-pharmacological behavior management techniques (NPBMTs), in many instances pharmacological approaches (conscious sedation, and dental general anaesthesia (DGA)) are required [3,4]. Although DGA facilitates treatment in virtually all patients, the morbidity and mortality risks associated with this technique are considerably higher compared with NPBMTs or conscious sedation [5-7]. As a consequence, alternative behavior management techniques should, where possible, be attempted before resorting to a DGA.

The use of conscious sedation in primary dental care reducing the need for DGA, particularly for children, is consistent with public expectations and professional concerns [8]. Although Nitrous oxide inhalation sedation (N_2O IHS) is commonly used in dentistry practice and it has impressive safety and is excellent for providing conscious sedation for apprehensive dental patients [9], it is not successful in all cases [8,10-12]. So a considerable amount of research has been carried out into other sedation techniques acceptable to those patients who are not suitable or who fail to cope with nitrous oxide sedation [13]. One alternative conscious sedation technique that has been reported is the use of the gas sevoflurane (sevo) as an IHS agent [13-16].

Sevoflurane is a safe and versatile inhalational anesthetic, non-pungent odor, lack of irritation to airway passages compared [17-19]. It has unique properties of rapid uptake and elimination. For children it is the most widely accepted and tolerated anesthetic drug in outpatient anesthesia [19].

Limited literature is available on the use of sevoflurane alone as a form of conscious sedation for pediatric dental patients. Further investigation is required to investigate the effectiveness of its use as an IHS technique when compared with N2O IHS. Consequently, the aim of the study was to investigate and compare the relative effectiveness of two titrated IHS Methods, Nitrous oxide method (A) and sevoflurane method (B), for the extraction of primary molars under local anesthesia in children aged 8–10 years in both methods. So, further research will be required for other age groups.

Materials and Methods

Ethics

This study has been approved by a specific Review Board.

Sample size

A study sample size of 40 patients was chosen based on the program GPower 3.1.6, after a pilot study.

Recruitment

All patients attending the Department of Pediatric Dentistry at faculty of dentistry in Damascus University, who were on the IHS waiting list, are considered suitable for trial inclusion. Each child had been assessed at a pediatric dentistry consultant-led pre-sedation assessment visit and had been deemed to be both suitable for and to require dental treatment with HIS. Patients were deemed eligible for trial inclusion who met the following inclusion criteria:

1) Children who are anxious aged between 8 and 10 years; ASA category I; no patient or family history of malignant hyperpyrexia or hypersensitivity to sevo
2) Those who required to extract their upper primary molars indicated from radiographic examination. Having fulfilled the selection criteria, the child and his/her guardian(s) were invited to attend appointment for extraction to be completed as part of the trial using method (A) or method (B).

Randomization

The type of sedation was randomized among these two groups. This was achieved by employing random numbers, generated from random-number tables, which were placed and sealed inside consecutive opaque envelopes numbered 1–40. This randomization process was carried out by an individual not directly involved in the clinical aspect of the study. Individual patient envelopes were opened directly before treatment by the consultant anesthetist (CA) delivering the sedation agents.

Blinding

The patient, external assessor and guardian were blind to the sedation agent used at the time of appointment. The CA recorded the type of IHS used in a separate log book, which was stored in a locked cupboard. The IHS machine, with a covering canvas, was positioned to prevent the patient, external assessor, and guardian from inadvertently observing the type of inhalation sedation agents used.

Sedation and treatment protocol

Full verbal and written explanation of the study was provided, and written informed consent and pre-operative medical questionnaires were completed by child's parents or guardian with the help of the dentist. Age, gender, body weight, heart rate and oxygen saturation for all children were also recorded at the time of treatment.

As mentioned before all children were randomly allocated method (A) or method (B) based on randomization. The minimum alveolar concentration of sevoflurane in 100% oxygen is approximately 2% [21] and that of nitrous oxide in 100% oxygen is 110 [22]. An alveolar concentration of 1% sevoflurane is known to be equipotent with 50% nitrous oxide in oxygen [14].

The anesthetic gases and oxygen were delivered via an anesthetic circuit with a vaporizer (Drager Vapour 2000) and a nasal mask. All children under study get familiarized with the mask and nasal breathing with 100 percent oxygen alone for one to two minutes followed by titration nitrous oxide was introduced at a concentration of 10% and increased by 10% every 30 s up to 50% [4] Method (A). A similar titration of sevoflurane was introduced at a concentration of 0.2%sevoflurane and increased by 0.2% every 30 seconds up to 1% in Method (B) treatment group.

During the procedure the dentist chatted with the child using hypnotic suggestion and imagery, to reassure the child is doing well and distract attention. Before the planned dental extraction the child was given topical anesthesia, and 2 min later followed by a local anesthetic (standardized—lidocaine 2% with adrenaline 1:80 000) was injected by the dentist. Local anesthetic quantity was always maintained below the maximum dose for each patient's weight.

All sedation was administered by one anesthetist and all extraction procedures were performed by one experienced pedodontic. Throughout the procedure an external assessor evaluated of the degree of anxiety during injection of local anesthesia and during extraction by recorded videos using the six-point Venham scale [20] (Table 1).

Each patient was monitored clinically by the dentist, and CA throughout treatment. Continual clinical observation of the patient's responsiveness, color, and respiratory rate and rhythm and level of consciousness was performed [4]. Pulse-oximetry was also carried out which, although not a mandatory requirement

Table 1: The six-point Venham Scale [20]

Relaxed	Smiling, able to converse, best possible working conditions. Displays the behavior desired by the dentist spontaneously
Uneasy	Concerned. During stressful procedure may protest briefly and quietly to indicate discomfort. Child willing and able to interpret
Tense	Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, quiet crying, hands tense and raised but not interfering much. Child interprets situation with reasonable accuracy and continues to cope with his or her anxiety. Protest more distracting and troublesome. Child still complies with request to co-operate. Continuity is undisturbed
Reluctant	Tends to reject the treatment situation, difficulty in assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop the procedure. Protest out of proportion to threat, or is expressed well before the threat. Copes with situation with great reluctance. Treatment proceeds with difficulty.
Anxious	Anxiety interferes with ability to assess situation. General crying not related to the treatment. Prominent body movements, needing restraint on occasion. Child can be reached through oral communication, and eventually with reluctance and great effort begins to cope. Protest disrupts procedure.
Out of Contact	Fails to grasp the reality of the threat, hard loud crying. Screaming, swearing. Unable to listen to oral communication. Regardless of age reverts to primitive flight responses. Actively involved in escape behavior. Treatment impossible to complete

for N_2O IHS, monitoring and recording of pulse-oximetry readings were carried during injection of local anesthesia and during extraction by the CA for all patients.

On completion of procedure, all gases were withdrawn and 100% oxygen was given through the nasal hood for 5 min.

If the patient exhibited either signs or symptoms of still being sedated following this, the patient was monitored clinically and further care provided as appropriate, e.g., supplemental oxygen, until such time as the patient was fully recovered (able to walk unaided in a straight line across the room and complete a target test) [23].

During recovery the level of anxiety and cooperation using the six-point Venham scale assessed by the dentist; time to recovery; adverse events, oxygen saturation and heart rate were also recorded [20] and the patient subsequently discharged. The guardian was contacted by telephone approximately 24 h post-operatively to allow any side effects experienced by the patient following sedation and dental treatment to be recorded.

Data were analysed using Student's t-test and Mann–Whitney U-test. In all cases, $P<0.05$ was the criterion for statistical significance. The computer package used for all calculations was SPSS (version 17).

Results

The characteristics of all the children under study are summarized in Table 2. The technique was effective in 17 of the 20 children (85%) in the nitrous oxide treatment using method (A),and in 16 of the 20 children (80%) in the sevoflurane treatment using method (B).

During the procedure the external assessor assessed the level of anxiety and cooperation using the Venham scale in the nitrous oxide group method (A). 10 children (50% had a score of 1 (relaxed), 3 (15%) had a score of 2 (uneasy) and 4(20%) had a score of 3 (tense). 3 failed to co-operate had a score of 4 (reluctant). For the other arm with Sevoflurane treatment group method (B), 9 children (45%) had a score of 1 (relaxed), 4 (20%) had a score of 2 (uneasy) and 3(15%) had a score of 3 (tense) in which 4 failed to cooperate. Of these, 3(15%) children scored 4 (reluctant), 1 scored 5 (anxious). Analysis of Venham scores for methods (A) and (B) as recorded by the external assessor during the procedure revealed no statistically significant difference between the two methods of sedation (Table 3).

Table 2: Characteristics of 40 children as mean (SD)

Method(A) Method (B)	(n=20)	(n=20)
Age in years	9.1(0.9)	8.9(0.7)
Weight in kg	20.9(9.1)	20.2(8.2)
Male : Female	10:10	9:11
Sedation time; min	19.41 (4.74)	18.58 (4.44)
Recovery time; min	2.95 (1.1)2.55 (1.2)	

During recovery the dentist assessed the level of anxiety and cooperation using the Venham scale. In the nitrous oxide group method (A). 11 children (55%) had a score of 1 (relaxed), 7 (35%) had a score of 2 (uneasy) and 2(10%) had a score of 3 (tense). Andin the sevoflurane group method (B).11 children (55%) had a score of 1 (relaxed), 6 (30%) had a score of 2 (uneasy) and 1had a score of 3 (tense). 2 failed to cooperate had a score of 4 (reluctant). Similarly, there were no significant differences in scored children s' degree of anxiety by the dentist during recovery (post-operatively) with the two sedation methods (Table 3).

During the procedure or recovery, there were no episodes of cardiovascular or respiratory instability and the oxygen saturation was > 97% in all cases. The time of recovery with sevoflurane was comparable to nitrous oxide. In this study, all patients were able to sit up unaided and walking unaided in next 2-3 min after cessation of sedation. The mean (SD) time to discharge in the sevoflurane group was 7.2 (3.1) min compared with 7.8 (3.8) min in the nitrous oxide group.

Table 3: Mean of six-point Venham Scale for measures Level of anxiety recorded by external assessor and the dentist

	During the procedure	In recovery
Method (A) (*n*=20)	1.2 (1-4)	0.73(0-2)
Method (B) (*n*=20)	1 (1-5)	0.55 (0-3)

Side-effects

Side effects reported by the patients' guardians within the 24 h post-HIS (N_2O as well as sevo), included nausea (1; 0), headache (3; 2), patients complained of pins and needles of the fingers (2; 0), mild dizziness (1; 1).

Discussion

This study has shown that both sevoflurane and nitrous oxide were effective in reducing anxiety in children and produced comparable and satisfactory sedation for the extraction of primary molars with local anesthesia. Moreover, there were no adverse events related to either sedation method that required termination of treatment or administration of any emergency medications. This is in agreement with The only comparative report of N_2O , sevo IHS for dental treatment (in a sample of 17), reported a satisfactory and reliable success in both two inhalational sedation regimens during third molar surgery[14].

This study's success rates are similar to previously reported N2O IHS success rates and would suggest that the investigators' identification of suitable IHS patients and their management thereafter was at least similar to other workers [5,10,15,24].

This study's success rates are higher for the N_2O group in contrast to that reported by the Newcastle study (add reference), successful treatment completion was reported for 52% of patients [13]. There are a number of potential reasons for the differences between this study and the Newcastle study, it may be due to this study's small sample size, unknown differences in the sample Population. however, that inhalation sedation is more likely to fail in those who are younger [5], in Newcastle study the children was aged 3–10 years and those are younger than the children This study. These may include differences in operator management of patients, differences in patient base between the units, the concentration of N2O was (40%) used for all children. Fixed sedation regime would appear to contravene current guidelines regarding the need to titrate the concentration of inhaled sedative agent to the individual child's needs; the concentration of sedation agent required to facilitate treatment may differ from

patient to patient and appointment to appointment [25].

In this study The time of recovery and the recovery profile with sevoflurane was comparable to nitrous oxide All children were able to sit up unaided and walking unaided in 2-3 min after cessation of sedation. Speed of recovery is important for outpatient procedures. Rapid recovery is one of the advantages of inhalational sedation with nitrous oxide [23].

This study's side effects were recorded at 24 h post-operatively. This is substantially different from The Newcastle study in which no adverse incidents during or directly after treatment. the differences between the two studies may be due to the longer period of patient assessment in this study , may explain the increased number of minor adverse events in this study [13]. Certainly, the side effects in this study were similar to previous reports, e.g., headache within the 24 h post-N2O IHS in 15% of patients compared with 10% of patients within the same time period in a previous study [15].

In summary, both sevoflurane and nitrous oxide gave good sedation, and were effective in reducing anxiety in children during dental extraction, with no significant difference in these two inhalational sedation methods.

Sevoflurane has two major advantages over nitrous oxide because it has not been reported to interfere with vitaminB12 metabolism or associated with abortion. Because of these advantages, sevoflurane offers an attractive alternative method of sedation for children undergoing dental extraction.

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