

# A comparison of inhalation sedation agents in the management of children receiving dental treatment: a randomized, controlled, cross-over pilot trial

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*International Journal of Paediatric Dentistry* 2010; 20: 65–75

**Aims.** First, to compare the relative effectiveness of inhalation sedation using (A) nitrous oxide and oxygen with (B) nitrous oxide, sevoflurane, and oxygen in the management of children receiving dental extractions. Secondly, to determine patient and guardian preference between the two sedation techniques.

**Materials and methods.** A randomized, controlled, double-blinded, cross-over, pilot clinical trial was undertaken. Thirty patients aged 6–15 years, ASA category I or II, who required two identical dental extractions with inhalation sedation were recruited. At the first session, patients were randomly allocated to receiving treatment with seda-

tion Method A or B. At the second session, the alternative sedation protocol was employed.

**Results.** Overall, 80% of patients successfully completed treatment at both appointments. There was no statistically significant difference between either the success rate of the two methods or in guardian preference between the two modes of sedation. There was a statistically significant difference in patient preference in favour of Method B.

**Conclusions.** The results from this pilot study would suggest no increased benefit, in terms of treatment completion, from the additional use of sevoflurane in combination with nitrous oxide and oxygen. There was, however, a small but significant patient preference in favour of nitrous oxide with sevoflurane and oxygen.

## Introduction

A significant number of children are anxious with respect to dental treatment with worldwide studies having suggested that between 3% and 43% of children exhibit dental anxiety<sup>1</sup>. The most feared dental procedures appear to be those that are invasive, such as injections and the use of 'the drill', with such types of treatment more likely to require anxiety-reducing adjuncts to facilitate treatment<sup>2–4</sup>. These adjuncts include non-pharmacological behaviour management tech-

niques (NPBMTs), conscious sedation, and dental general anaesthesia (DGA).

Although DGA facilitates treatment in virtually all patients, the morbidity and mortality risks associated with this pharmacological behaviour management technique are considerably higher compared with NPBMTs or conscious sedation<sup>5–8</sup>. As a consequence, alternative behaviour management techniques should, where possible, be attempted before resorting to a DGA (with a number of documents supporting the appropriate use of DGA<sup>9–11</sup>). Recent clinical guidelines from the British Society of Paediatric Dentistry state that the use of DGA is generally only indicated where the child needs to be fully anaesthetized to attempt treatment, or where the surgeon requires the child to be fully anaesthetized to perform treatment. Furthermore, the use of DGA for children with a carious, asymptomatic, and sepsis-free dentition is rarely justified<sup>11</sup>.

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Some of this data were presented for the Young Researcher Prize at the British Society of Paediatric Dentistry Annual Conference, London, in September 2007.

As an alternative to DGA, conscious sedation (in combination with NPBMTs) can allow patients to complete treatment without resorting to a DGA, with nitrous oxide inhalation sedation (N<sub>2</sub>O IHS) recognized as the recommended sedation technique for children in the UK<sup>8</sup>. Although N<sub>2</sub>O IHS enjoys high success rates of 83–96% treatment completion, this does indicate that N<sub>2</sub>O IHS is not successful in all cases<sup>5,12–14</sup>. It is for this reason and the need to limit the number of children being exposed to the risks of DGA that a considerable amount of research has been carried out into alternative conscious sedation techniques<sup>15–17</sup>.

One alternative conscious sedation technique that has been reported is the use of the DGA gas sevoflurane (sevo) as an IHS agent<sup>15,18,19</sup>. To date, only one randomized controlled clinical trial (based in Newcastle, UK) has investigated the use of sevo in combination with N<sub>2</sub>O for children requiring dental treatment<sup>15</sup>. This study reported a significant difference between standard N<sub>2</sub>O IHS and N<sub>2</sub>O + sevo IHS and found in favour of the latter technique. The 52% successful treatment completion rate for N<sub>2</sub>O IHS in this study, however, was comparatively low in relation to other N<sub>2</sub>O IHS studies<sup>5,12–14</sup>. Of note, the concentration of N<sub>2</sub>O to which sevo was either added to, or compared with, was 40% for all children. This 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<sup>8</sup>. The authors of the Newcastle study concluded that the use of N<sub>2</sub>O + sevo was an efficacious and safe method of IHS when administered by an anaesthetist<sup>15</sup>.

In view of the limited evidence currently available for N<sub>2</sub>O + sevo IHS, further investigation is required to confirm the reported greater effectiveness of its use as an IHS technique when compared with N<sub>2</sub>O IHS. Consequently, the primary aims of this study were to investigate and compare the effectiveness of two titrated IHS techniques, Method A

(oxygen with nitrous oxide) and Method B (oxygen with nitrous oxide and sevo), used in the management of children deemed to require inhalation sedation for dental extractions and determine patient preference. Secondly, to determine guardian preference between the two inhalation sedation techniques.

The primary outcome measures of the study were successful treatment completion and patient preference between sedation agents.

Secondary outcome measures included:

- guardian preference between sedation techniques;
- patient behaviour during treatment;
- adverse events.

To achieve these aims and assess these outcome measures, a randomized, controlled, double-blinded, cross-over, pilot clinical study was undertaken.

## Materials and methods

### Ethics

This study was approved by the Tayside Committee on Medical Research Ethics in January 2006 (Ref. No. 05/S1401/57) and by the Research and Development Department, Tayside Research Consortium in February 2006 (Project No. 2005DE02).

### Sample size

An attempt at the calculation of sample size was undertaken, but given the paucity of previous work, this was not possible and, as such, following statistical advice, a pilot study sample size of 30 patients was chosen.

### Recruitment

All patients attending the Department of Paediatric Dentistry at the Dundee Dental Hospital, who were on the IHS waiting list, were potentially suitable for trial inclusion. Each child had been assessed at a paediatric dentistry consultant-led pre-sedation assessment visit and had been deemed to be both suitable for and to require dental treatment with IHS. The dental records of patients were reviewed

by the principal investigator (PI) and patients were deemed eligible for trial inclusion who met the following inclusion criteria:

English spoken as a first language; aged between 6 and 15 years; ASA category I or II; no patient or family history of malignant hyperpyrexia or hypersensitivity to sevo; identical extractions on contralateral sides of the dental arch deemed from radiographic examination to be of similar extraction difficulty.

Having fulfilled the selection criteria, a recruitment pack (including a cover letter, an age-related patient information leaflet, a guardian information leaflet, and a positive-response slip) was posted to the guardians of all possible subjects between March and November 2006. No reminders were posted and, as such, recruitment continued until 30 patients had opted into the study. On receipt of a positive-response slip, the patient and his/her guardian(s) were invited to attend two appointments for extractions to be completed as part of the trial using Method A at one visit and Method B for the other visit. Any additional extractions required thereafter were to be carried out using standard N<sub>2</sub>O IHS. The same guardian had to be able to attend both visits, which were to be a minimum of 1 week apart.

### *Randomization*

Both the type of sedation and side of extraction at the first visit were randomized. This was achieved by employing random numbers, generated from random-number tables, which were placed and sealed inside consecutive opaque envelopes numbered 1–30. 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 anaesthetist (CA) delivering the sedation agents.

### *Blinding*

The PI, dental nurse (DN), patient, and guardian were blind to the sedation agent used at all appointments. 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 PI, DN, patient, and guardian from inadvertently observing the type of inhalation sedation agents used.

### *Sedation and treatment protocol*

Following both verbal and written consent for involvement in the study and the proposed treatment, pre-operative questionnaires were completed by the PI, the patient, and the guardian. Prior to the placement of a well-fitting nasal hood, all children were asked to complete an Eve's test. This was a test of spatial awareness in which the child was asked to close their eyes and touch the tip of the nose with his/her forefinger. This was recorded as either successfully or unsuccessfully completed.

Sedation agents were delivered via an unscented, fitted nasal hood using a customized Boyle International 2 Selectatec SM anaesthetic machine with Ohmeda Quantiflex N<sub>2</sub>O/O<sub>2</sub> mixer (Datex-Ohmeda, Helsinki, Finland). This machine permitted a maximum of 2% sevo to be delivered in conjunction with a maximum of 70% N<sub>2</sub>O, the remaining gas flow being oxygen. A standard IHS tubing system with a one-way expiratory valve attached to an active scavenging system was also used. The sedation techniques used were as follows:

*Method A: nitrous oxide only technique.* Each patient was initiated on 100% oxygen at a patient-titrated flow rate with incremental introduction of N<sub>2</sub>O up to a maximum of 30%. Sedation agent administration and gas flow rate was controlled by the CA with the concentration of sedation agent being determined by the PI; this was titrated to the lowest concentration that comfortably facilitated treatment for the child; *Method B: nitrous oxide and sevo technique.* Inhalation sedation was administered and titrated as above with a combination and incremental introduction of either (i) 10% N<sub>2</sub>O and 0.1% sevo, (ii) 20% N<sub>2</sub>O and 0.2% sevo, or (iii) 30% N<sub>2</sub>O and 0.3% sevo.

During all treatment sessions, the PI and DN employed a range of NPBMTs with attention given to each individual patient's requirements. These NPBMTs included a steady flow of semi-hypnotic suggestion, guided imagery, and distraction techniques, all of which were used for all patients. Attention of the dental team was fully focussed on the child with a tell-show-do approach used throughout the procedure. The verbal description of the treatment to be completed was tailored according to patient age, maturity, and level of understanding/co-operation.

With the child sedated, a standard procedure was used for topical (20% Benzocaine Ointment; Utradent Products Inc., Utah, USA) and local anaesthesia placement (Lidocaine 2%, Adrenaline 1 : 80,000; Xylocaine®; AstraZeneca, Sweden). Where insufficient anaesthesia was attained, Prilocaine 3% with Octapressin (Citanest®; AstraZeneca) was employed as a supplemental anaesthetic agent. Local anaesthetic quantity was always maintained below the maximum dose for each patient's weight.

Each patient was monitored clinically by the PI, DN, and CA throughout treatment. Pulse-oximetry was also carried out which, although not a mandatory requirement for N<sub>2</sub>O IHS, was employed at both visits in order to maintain the blindness of the study. Monitoring and recording of pulse-oximetry readings were carried out every 5 min by the CA for all patients. Venham patient behaviour scores were recorded by the PI, DN, and CA at 5 min intervals throughout treatment<sup>20</sup>.

On completion of treatment, or where treatment was abandoned due to lack of patient co-operation, all patients received 100% oxygen for a minimum of 2 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 an Eve's test). Post-operative questionnaire sections were then completed (including PI, DN, and CA record of Frankl and Houpt patient

behaviour ratings<sup>21,22</sup>) 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 collection*

Questionnaires were designed by the PI to allow data collection by the PI, DN, CA, patient, and his/her guardian. The following main parameters were measured to facilitate the comparison of the techniques (further study information is available from the authors directly).

Pre-operatively: age, gender, and weight; heart rate and oxygen saturation; previous dental history of both patient and guardian.

Intra-operatively: heart rate and oxygen saturation monitored continuously and recorded every 5 min; Venham patient behaviour score as recorded by PI, DN, and CA every 5 min<sup>20</sup>.

Post-operatively: treatment completion success; overall Houpt and Frankl score as recorded by PI, DN, and CA<sup>21,22</sup>; patient and guardian preference of sedation method at second appointment only; time to recovery; adverse events.

The subjective assessment of each patient's behaviour by the PI, DN, and CA was completed and recorded without any collaboration between individuals. In total, one PI, one DN, and two CAs were involved in the study. In addition, collaboration between the guardian and child was prevented, where possible, to prevent either individual from influencing the other regarding preference of IHS method. Patient and guardian questionnaires were completed with no or minimal assistance from the various medical/dental professionals involved; where necessary, the PI provided clarity to the parent/guardian or patient on any aspect of the questionnaires, which was not clear.

### *Data analysis*

Data analysis was carried out using Microsoft® Office Excel 2003 and SPSS Version 15.0



(SPSS Inc., Chicago, IL, USA). Given the size of the sample, nonparametric tests were employed as follows.

Wilcoxon signed-rank test was used for paired data: Venham, Houpt, and Frankl scores reported by the PI, DN, and CA ( $n = 26$ ); time to recovery ( $n = 26$ ).

The McNemar test was used with respect to: treatment completion (intention-to-treat analysis) ( $n = 30$ ); side effects reported at 24 h post-treatment for patients attempting both methods of sedation with data available ( $n = 25$ ).

Kendall's coefficient of concordance was used for paired data for: Venham, Houpt and Frankl scores reported by PI, DN, and CA ( $n = 26$ ).

## Results

Thirty patients were recruited to the study of which 26 patients attended both appointments. The mean age of recruited children was 10.6 years old (SD 2.1, range 7–14.5) with a mean weight of 35.9 kg (SD 11.4). The female : male ratio was 3 : 2. Twenty-five children were ASA I and five were ASA II.

Extractions were undertaken for orthodontic purposes, caries or orthodontic purposes and caries in 40%, 33%, and 27% of patients respectively. The type of extraction completed at each appointment is presented in Table 1. Of note, one patient at visit 2 reported pain of an acute nature in a permanent tooth not planned for extraction within the study, although planned for extraction at a subsequent nonstudy appointment. This complaint was reported directly following extraction of the 'study-tooth' while the patient was still sedated. The problematic tooth was therefore also extracted after the first extraction with no break in treatment and the CA asked to employ N<sub>2</sub>O IHS only if this was not already the case. This was deemed to be in the patient's best interests. Questionnaire results for only the 'study-tooth' were recorded by the PI, DN, and CA. The patient and parent were asked to comment on treatment for the 'study-tooth' only.

**Table 1. Treatment completed at visits 1 and 2 ( $n = 30$ ).**

	Visit 1 ( $n = 30$ )	Visit 2 ( $n = 30$ )
One primary canine	3 (10)	3 (10)
One primary molar	4 (13)	3 (10)
One first permanent molar	12 (40)	9 (30)
One permanent premolar	4 (13)	4 (13)
Two permanent premolars	3 (10)	3 (10)
One first permanent molar and one primary canine	1 (3)	1 (3)
Two first permanent molars	0	1 (3)
Placement of local anaesthetic only	2 (7)	2 (7)
No treatment permitted by patient	1 (3)	0
Patient failed to attend for further treatment	0	1 (3)
Patient failed treatment at visit 1 and no visit 2 arranged	NA	3 (10)

Values within parenthesis represent percentages.

The outcome of all patients recruited to the study is presented in Fig. 1. In total, 26 patients attempted both methods of sedation. Of these patients, all of whom had successfully completed treatment at visit 1, one individual failed to complete their second treatment appointment using Method A and one patient failed to complete their second treatment appointment using Method B.

A total of 29 patients attempted treatment under N<sub>2</sub>O IHS with 26 patients completing treatment (90%). Twenty-six patients attempted N<sub>2</sub>O + sevo IHS with 25 patients completing treatment (96%). When data were analysed on an intention-to-treat analysis, assuming failure of treatment at visit 2 in those who either failed to complete visit 1 or failed to attend visit 2, there was no difference in successful treatment completion between the sedation methods [87% N<sub>2</sub>O IHS, 83% N<sub>2</sub>O + sevo IHS ( $\chi^2 = 0.33$ ,  $P = 1.00$ , McNemar test)].

Maximum Venham scores recorded for Methods A and B by the PI, CA, or DN found no significant difference between the two sedation methods ( $P = 0.889$ ;  $P = 0.657$ ;  $P = 0.368$  respectively; Table 2). Using Kendall's coefficient of concordance, the three observers were found to significantly disagree on the maximum Venham score ( $P = 0.001$ ), with the PI and CA perfectly agreeing (mean rank score = 2.18;

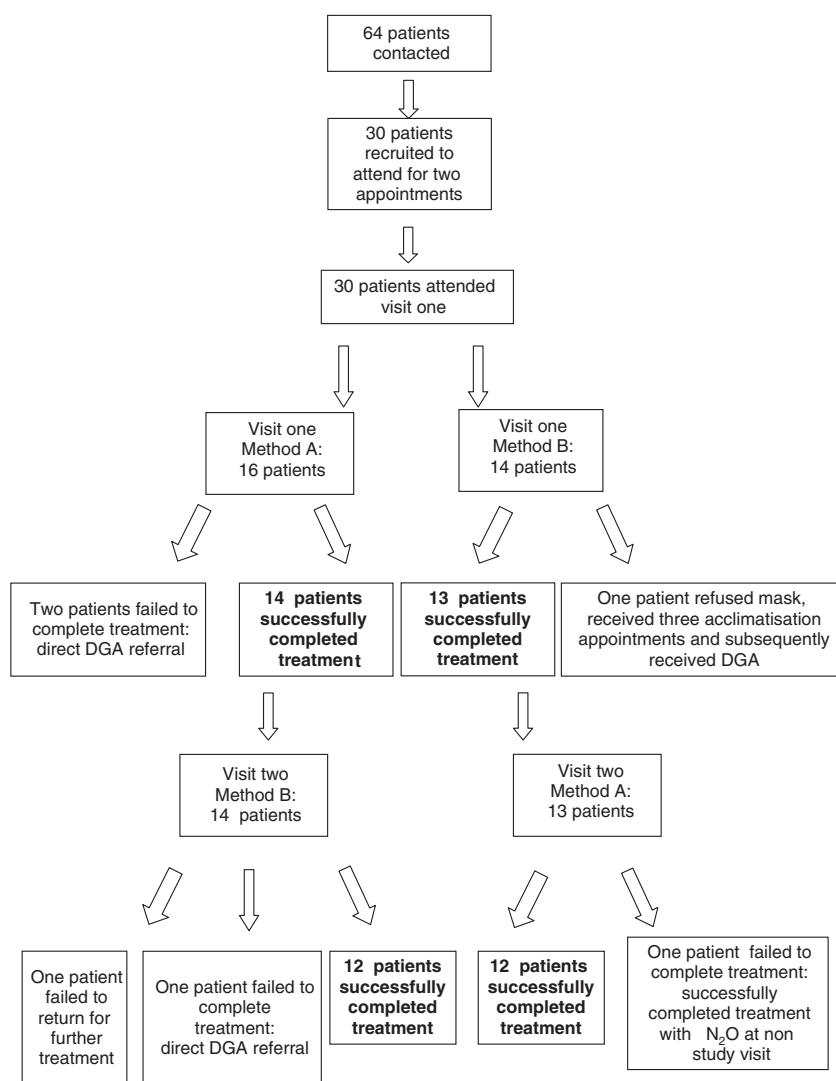


Fig. 1. Patient flow through the trial.

mean rank score = 2.18 respectively) and the DN being significantly different (mean rank score = 1.63).

Analysis of Houpt scores for Methods A and B as recorded by the PI, CA, and DN revealed no statistically significant difference between the two methods of sedation ( $P = 0.316$ ;  $P = 0.980$ ;  $P = 0.593$  respectively; Table 2). Using Kendall's coefficient of concordance, there was no significant disagreement in observer scores ( $P = 0.440$ ).

There were no statistically significant differences in Frankl scores between  $N_2O$  and  $N_2O + sevo$  as recorded by the PI, CA, and DN ( $P = 0.168$ ;  $P = 0.577$ ;  $P = 0.822$  respectively; Table 2). Using Kendall's coefficient

of concordance, there was no agreement between observer scores ( $P < 0.001$ ).

All patients were able to complete an Eve's test satisfactorily both prior to sedation and within 2 min of cessation of inhalation sedation. Median time to discharge at visit 1 was 7.0 min [interquartile range (IQR) 6.0–8.0] and 7.0 min (IQR 6.0–9.0) at visit 2. For those receiving Method A, the median was 7.0 min (IQR 6.0–8.0) and for those receiving Method B the median was 7.0 min (IQR 6.0–8.0). There was no statistically significant difference between the recovery time and sedation method employed ( $P = 0.669$ ). All patients had oxygen saturation levels of  $>98\%$  throughout

**Table 2.** Maximum intra-operative Venham, Houpt, and Frankl scores as reported by the PI, DN, and CA for all patients attempting treatment (IQR).

	Method A (n = 29)			Method B (n = 26)		
	PI	DN	CA	PI	DN	CA
Venham	2 (1–3)	2 (1–2)	2 (1.5–3)	2 (2–2)	2 (1–2)	2 (2–2)
Houpt	5 (5–6)	5 (5–6)	5 (4.5–6)	5.5 (5–6)	5 (5–6)	5 (5–5)
Frankl	4 (3–4)	3 (3–4)	3 (3–3)	4 (3–4)	3 (3–4)	3 (3–3)

Values are given as median (IQR, interquartile range).

PI, principal investigator; DN, dental nurse; CA, consultant anaesthetist.

their treatment. Heart rates were all within 17% of the baseline readings.

Side effects reported by the patients' guardians 24 h post-IHS ( $N_2O$ ;  $N_2O$  + sevo), included nausea (5; 0), vomiting (1; 0), headache (3; 2), drowsiness (8; 1), and increased sleeping (5; 5) respectively. Although anecdotally there was a difference between the two methods regarding drowsiness and nausea, statistical analysis revealed no significant difference between the two methods of sedation in relation to these side effects ( $P = 0.063$ ;  $P = 0.070$ ).

Regarding preference of IHS technique, of the 26 patients who attended both visits, only 10 patients stated a preference between the two methods: nine preferred  $N_2O$  + sevo and one preferred  $N_2O$ . The remainder reported that both methods of IHS were the same (10), or that they were unsure as to their preference (6). The probability of patients preferring  $N_2O$  + sevo was 0.346 with an approximate 95% confidence interval 0.163–0.529. The probability of patients preferring  $N_2O$  was 0.038 with an approximate 95% confidence interval 0–0.112. Reasons for patient preference included 'last visit was easier', 'it tasted juicier', 'it wasn't too sore', and 'it felt more relaxing'.

In total, 13 guardians stated a preference between the sedation methods: five preferred  $N_2O$  + sevo and eight preferred  $N_2O$ . The remainder reported that both methods of IHS were the same (7), or that they were unsure as to their preference (6). The probability of guardians preferring  $N_2O$  + sevo was 0.192 with an approximate 95% confidence interval 0.041–0.344. The probability of guardians preferring  $N_2O$  was

0.308 with an approximate 95% confidence interval 0.130–0.485.

## Discussion

The results of this pilot study would suggest that inhalation sedation with oxygen and  $N_2O$  + sevo IHS was as successful as inhalation sedation with oxygen and  $N_2O$  IHS alone with respect to successful treatment completion. Moreover, there were no adverse events related to either sedation method that required termination of treatment or administration of any emergency medications.

It is important to first highlight the main limitations of this study. This is primarily the small sample size used, i.e., a pilot study of 30 patients. This pilot study was carried out to facilitate a sample size calculation and to allow refinement of the methodology prior to any full-scale studies being planned, if needed. In view of the small size of the sample, the resultant limitations of the statistical analysis and conclusions from which these are drawn must be fully appreciated. Regarding sample size calculation, statistical advice would suggest that approximately 350 patients would be required to show a difference of 6% successful treatment completion between  $N_2O$  (90%) and  $N_2O$  + sevo IHS (96%), as found in this pilot study (power = 0.8,  $P = 0.05$ ).

The small number of sedation team members involved in this study, namely one SpR, one DN, and two CAs facilitating the sedation could also be seen as a limitation and, as a result, the findings are not generalizable. Successful treatment completion, or otherwise, is therefore closely related to the behav-

behaviour management/clinical skills of the individual SpR and DN involved in this study.

A further limitation is the use of a wide age-range of patients and variety in extractions attempted, i.e., primary and/or permanent tooth extractions, which may have influenced the results. It may then be advisable that future sedation studies should be carried out in narrower age ranges of patients and/or types of extraction so as to identify factors influencing successful treatment completion.

While accepting the limitations of this study, it nonetheless provides valuable further evidence regarding this relatively new method of IHS and can be compared with similar studies previously reported, of which there are few. The first such report of N<sub>2</sub>O + sevo IHS for children receiving dental treatment (in a sample of 75), reported a high success rate of 92%<sup>23</sup>. The subsequent full-scale randomized controlled trial, by the same workers based in Newcastle, compared 40% N<sub>2</sub>O sedation with 40% N<sub>2</sub>O + 0.1–0.3% sevo in two separate groups of patients. Successful treatment completion was reported for 52% and 89% of patients respectively<sup>15</sup>.

If the data in this study were to be analysed as two separate groups of patients, namely a N<sub>2</sub>O group and a N<sub>2</sub>O + sevo group (including only those who attempted treatment at either visit), then successful completion rates would be 90% and 96% respectively. This would suggest both a marginally higher rate of success for the N<sub>2</sub>O + sevo group and a considerably higher success rate for the N<sub>2</sub>O group in contrast to that reported by the Newcastle study. Furthermore, when data were analysed based on an intention-to-treat basis, it can be seen that although the N<sub>2</sub>O + sevo success rate is slightly lower (83%) than that reported in the Newcastle study, the success rate for N<sub>2</sub>O was still considerably higher at 87%. This study's success rates are similar to previously reported N<sub>2</sub>O 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<sup>5,12–14</sup>. The reasons for the differences between this study and the Newcastle study are unclear,

although it may be due to this study's small sample size, unknown differences in the sample population, and/or alternative techniques available locally in Newcastle, e.g., intravenous midazolam or a variation in the utilization of NPBMTs techniques.

Although a substantial amount of data were recorded regarding previous dental and medical experiences from both patients and guardians, due to small sample numbers and no statistically significant differences in success rates between the two sedation methods, an analysis could not be made regarding contributing factors to the failure of individual sedation methods. It has previously been reported, however, that inhalation sedation is more likely to fail in those who are younger, poor attenders, and who are having multiple extractions compared with those having orthodontic extractions<sup>5</sup>. The results from this study would appear to support this with all those who attempted but failed to complete treatment having reported to be irregular attenders. Five of the six patients who failed to complete treatment had a history of previous DGA extractions with all their guardians also having had previous experience of dental extractions. In contrast, all those who required orthodontic extractions successfully completed treatment.

Regarding patient behaviour during sedation, multiple behaviour scoring tools (Venham, Frankl, and Houpt) were employed to facilitate comparison with previous sedation studies that have used an array of different scoring systems<sup>23</sup>. In the Newcastle study, Venham scores were notably different between the two methods of sedation, with those patients who had received N<sub>2</sub>O + sevo IHS reported as having been more relaxed than those who received N<sub>2</sub>O IHS<sup>15</sup>. This is in comparison with this study where there did not appear to be any significant difference in behaviour between the two methods of sedation. There are a number of potential reasons for the differences in Venham scores between these two studies. These may include differences in operator management of patients, a higher untitrated dose of N<sub>2</sub>O (40%) used for all patients in the Newcastle study, and differences in patient base between the units.



Overall, there did appear to be considerable variation in the assessment of patient behaviour by the different members of the sedation team. Lack of inter-observer agreement is perhaps not surprising as all members of the sedation team had different levels of experience and the CA had less experience of dental treatment in the conscious child than the DN and PI. This highlights what others have previously found: that there are difficulties with scoring systems regarding patient behaviour and that as yet there is no perfect method of assessing patient behaviour<sup>24,25</sup>. This is not surprising in view of the subjective nature of such assessments and highlights the need for further work to develop a more objective assessment tool with respect to patient behaviour. The use of video-taped treatment sessions and observation of these by independent, trained observers may be a method that could help overcome such limitations.

The Newcastle study reported no adverse incidents or side effects with either the N<sub>2</sub>O or N<sub>2</sub>O + sevo IHS methods, although this was limited to side effects noted during or directly after treatment<sup>15</sup>. This is substantially different from this study, in which adverse side effects were recorded not only intra- and post-operatively, but with a further record of side effects at 24 h post-operatively. This longer period of patient assessment, albeit as reported by the guardian via telephone, may explain the increased number of minor adverse events in this study<sup>15</sup>. In this study, the guardians reported that their child demonstrated greater drowsiness following the N<sub>2</sub>O IHS visit compared with N<sub>2</sub>O + sevo IHS. With the pilot sample size, it is difficult to determine if this drowsiness was related to the sedation method employed, the extraction procedure duration/difficulty, or other unknown factors, e.g., lack of sleep the previous night due to anxiety (which was reported anecdotally by a number of patients and their guardians). Certainly, other side effects in this study were similar to previous reports, e.g., patients' parents reported vomiting within the 24 h post-N<sub>2</sub>O IHS in 3% of patients compared with 7.4% of patients within the same time period in a previous study<sup>12</sup>.

Although less than half of the patients stated any preference between the two agents, there would appear to be a patient preference in favour of N<sub>2</sub>O + sevo. The majority of patient comments regarding preference of sedation agent, however, referred to positive or negative aspects of the procedure rather than the sedation sensation, suggesting that it may be difficult for children to assess objectively the sedation sensation experience as a separate entity from the treatment experience.

The questionable patient preference when employing N<sub>2</sub>O + sevo with no apparent difference in treatment completion rates perhaps makes the use of N<sub>2</sub>O + sevo difficult to justify when considering the extra costs associated with its use, namely that of the additional equipment, the sevo gas costs (on average, £3.40 per patient at the time of the study), and the need for CA manpower. At the present time, sevo can only be administered by a CA due to the potential risk of malignant hyperpyrexia and its subsequent management<sup>26</sup>. Until such time as the need for a CA to be present when carrying out N<sub>2</sub>O + sevo IHS is removed, the financial viability of such a method of IHS with questionable patient-reported benefits, particularly in the light of already limited resources within the UK's National Health Service, is unlikely to be practical.

## Conclusions

Overall, the results from this pilot study would suggest that although both N<sub>2</sub>O IHS and N<sub>2</sub>O + sevo IHS are safe and effective methods of IHS for providing dental care in the paediatric dental population, there appears to be no increased benefit in terms of treatment completion from the additional use of sevo. Less than half of the patients and their guardians noted a preference regarding the sedation method used. Where a preference was made, a majority of patients selected nitrous oxide in combination with oxygen and sevo, with a much smaller majority of guardians preferring nitrous oxide with oxygen.

**What this paper adds**

- Further evidence base for the inhalation sedation technique of nitrous oxide with sevoflurane within a paediatric dental population.
- Further evidence to support high success rates with the use of nitrous oxide inhalation sedation.
- Evidence which suggests that the additional use of sevoflurane to nitrous oxide inhalation sedation does not increase successful treatment completion.

**Why this paper is important to paediatric dentists**

- This pilot study would suggest no increased benefit from the additional use of sevoflurane with nitrous oxide inhalation sedation in terms of treatment completion, patient behaviour, and guardian preference.
- Patient preference for inhalation sedation method was found to be in favour of sevoflurane with nitrous oxide sedation. This preference, however, appears to be influenced by the treatment process itself. This influence should be borne in mind for future sedation studies.

**Acknowledgements**

Sincere thanks to Mrs M Long for nursing support, Drs C Cumming and M Checketts for all anaesthetic support, and Mrs R Inglis for assistance with data entry. Thanks also to Prof. T Wildsmith for advice during the early stages of study design and Dr GE Thomas for statistical advice. Funding was provided by the Tattersal Scholarship, University of Dundee.

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