

A randomised controlled trial of paediatric conscious sedation for dental treatment using intravenous midazolam combined with inhaled nitrous oxide or nitrous oxide/sevoflurane

P. A. Averley,¹ N. M. Girdler,² S. Bond,³ N. Steen⁴ and J. Steele⁵

1 Principle Dentist, Queensway Anxiety Management Clinic, 170 Queensway, Billingham UK

2 Consultant and Senior Lecturer, Sedation Department, School of Dental Science and Dental Hospital, 3 Professor and Head, School of Population and Health Sciences, 4 Centre for Health Service Research, 5 Professor of Health Service Research, School of Dental Science, University of Newcastle upon Tyne, UK

Summary

Failure of dental treatment due to anxiety is a common problem in children. The aim of this study was to establish whether the use of a combination of intravenous midazolam with inhalation agents (nitrous oxide alone or in combination with sevoflurane) was any more likely to result in successful completion of treatment than midazolam alone. A further aim was to evaluate the clinical viability of these techniques as an alternative to general anaesthesia. In total, 697 children too anxious for management with relative analgesia and requiring invasive dental procedure for which a general anaesthetic would usually be required, were recruited and randomly assigned to one of three groups given the following interventions: group 1 – a combination of inhaled medical air and titrated intravenous midazolam, group 2 – a combination of inhaled 40% nitrous oxide in oxygen and titrated intravenous midazolam, and group 3 – a combination of an inhaled mixture of sevoflurane 0.3% and nitrous oxide 40% in oxygen with titrated intravenous midazolam. The primary outcome measure was successful completion of the intended dental treatment with a co-operative child responsive to verbal commands. In group 1, 54% (94/174 children) successfully completed treatment. In group 2, 80% (204/256 children) and in group 3, 93% (249/267 children) completed treatment. This difference was significant at the 1% level. Intravenous midazolam, especially in combination with inhaled nitrous oxide or sevoflurane and nitrous oxide, are effective techniques, with the combination of midazolam and sevoflurane the one most likely to result in successful treatment.

Keywords *Anaesthesia, dental. Conscious sedation. Anaesthetics: nitrous oxide, sevoflurane. Benzodiazepines: midazolam.*

Correspondence to: Dr P. A. Averley

E-mail: paul@averley.com

Accepted: 14 March 2004

Child dental anxiety is widespread [1]. Many anxious children can be satisfactorily treated using behaviour management techniques combined with relative analgesia (RA), a simple technique using inhaled nitrous oxide and oxygen, but this approach is unsuccessful for some children [2]. In such cases, control of pain and anxiety poses a significant barrier to dental care and a dental general anaesthetic (DGA) is often seen as the only option. However, not only does DGA carry its own, well

documented, risks but the dental treatment provided under DGA also tends to be more radical, with a greater proportion of extractions than fillings [3].

DGA has been successfully used when RA and behavioural management are ineffective [4], but the risks of DGA are significant. The UK Department of Health in its position document 'A Conscious Decision' recognised that although deaths were uncommon during and shortly after DGA (five deaths in dental practices in England in

the 3 years 1996–1998), they were more likely than with any other method of pain and anxiety management [5]. Despite their infrequency, deaths associated with DGA have always been difficult to accept, and in many countries are now considered unacceptable, particularly when they occur in healthy children [6]. In the UK, DGA has been banned in non-hospital settings since 2002.

Two groups of children pose a particular management problem for dentists:

- Those who are extremely anxious and are unable to cope with treatment with behavioural management or RA.
- Those who require particularly invasive or extensive dental interventions.

If RA is ineffective and the risks of DGA unacceptable, is there another option to manage the dental need of these individuals without admission to hospital?

In medical specialities, intravenous (i.v.) midazolam is gaining popularity as a conscious sedation agent in children [7, 8]. The advantages of i.v. midazolam in children are the combination of rapid onset but short duration of action as well as haemodynamic stability. The safety and tolerability profile of midazolam in children has been described as 'comparable or superior to that observed in adults' [7].

By contrast, intravenous midazolam has not been readily accepted as a means of conscious sedation for child dental patients, certainly in the UK and a number of other developed countries. The concerns are twofold. Firstly, it is argued that deeper levels of sedation than intended may be produced, and secondly, that the reaction of children to i.v. sedation may be unpredictable [9]. The evidence to support these concerns is limited and of low quality. Oral midazolam is, however, gaining popularity and is proving to be both safe and effective [10–12], but is not a realistic alternative to intravenous methods for the most anxious children. Given its successful use in other medical specialities [7, 8, 13], i.v. midazolam may be an important alternative, allowing conscious sedation for the child dental patient when DGA is considered the only other option.

Another possible solution to this clinical problem is the use of sevoflurane, a volatile anaesthetic agent with a sweet, non-pungent odour that can also be used for conscious sedation. It has a low blood-gas coefficient of 0.40 [14], allowing the depth of sevoflurane inhaled conscious sedation to be carefully controlled when used in subanaesthetic concentrations [15]. The sedative properties of inhaled sevoflurane have been investigated [15–19] whilst the use of inhaled sevoflurane in lower concentrations (0.1–0.3%) in addition to 40% nitrous oxide has been demonstrated to be successful as a

paediatric conscious sedation technique with no adverse events [20, 21]. Like midazolam, sevoflurane may provide another option for conscious sedation in dentistry as an alternative to DGA.

Given the large variation in the needs of children, one conscious sedation technique is not enough to manage the needs of all anxious children. With the restriction in availability of DGA services in the UK and several other European countries, there is now an urgent need to develop and test a range of conscious sedation techniques for the large number of children who would otherwise require a DGA in a hospital setting. This study seeks to evaluate intravenous midazolam used in three different conscious sedation techniques. If effective and safe, these techniques have the potential to become part of the sedation armamentarium for a primary care setting, allowing the treatment of children who would otherwise require referral to a hospital for DGA.

The aim of this trial was to establish whether combinations of sedation agents, including intravenous midazolam, were any more likely to effect successful completion of treatment than midazolam alone when using conscious sedation techniques for the dental treatment of anxious children unsuitable for conventional behaviour management and RA techniques. A secondary aim was to assess the success of all of the techniques employed in the context of the only realistic alternative: a DGA in a hospital setting.

Materials and methods

This study tests the efficacy of three conscious sedation techniques. Completion of the planned dental treatment was the primary outcome measure. Secondary outcome measures were the poorest level of co-operation during treatment, the recovery time in minutes, the dose of midazolam used, the child's perceptions of anxiety and pain and the parent's satisfaction with the procedure.

The study was conducted in Queensway Anxiety Management Clinic (QAMC) in the North-East of England. This is part of a large primary care dental practice with a professional team of 10 dentists and six part time consultant anaesthetists who provide full time cover, 6 days a week. QAMC delivers dental care for more than 3000 children per year using a range of conscious sedation techniques. Appropriately trained and experienced dentists administer inhalation sedation with nitrous oxide or, if required for children over the age of 16 years, intravenous midazolam. For more anxious children who require complex techniques not suitable at present for general practice, operator sedation is not employed. These children are sedated in dedicated

facilities with the addition of an appropriately trained and experienced consultant anaesthetist, an anaesthetist's assistant and a recovery nurse as part of the team [22].

Approval from the local research ethics committee and a licence from the medicines control agency were obtained prior to the start of the trial. Professionals involved in the study (dentists, anaesthetists, nurses and administrative staff) were formally trained in the study protocol and the use of its clinical scales before clinical work was undertaken. A pilot study to check procedures, refine criteria and to allow a power calculation for the main trial was undertaken [23].

Population and sample

Children were recruited aged between 6 and 14 years, who were referred by their general dental practitioner to QAMC for dental treatment using anxiety management. All children were assessed by one of 10 dentists experienced in the management of anxious children, and were entered into the trial if one or more of the following criteria were met (Fig. 1):

- The child's self-expressed level of anxiety scored four or more using the 10-point visual scale described by Wong & Baker [24].

- The dentist's assessment of the child's co-operation scored three or more using the six-point co-operation behavioural scale described by Venham & Quatrocelli [25].

- The invasiveness of the planned dental procedure (for one visit) scored 10 or more using a numerical scale where one point is scored per quadrant of the mouth being treated, one point is scored per primary tooth treated, and two points are scored per permanent tooth treated.

Children were also required to have an adequate degree of comprehension and understanding regarding the treatment (if necessary with the support of interpretation services). They were also required to accept topical anaesthetic cream (EMLA[®]) applied to the dorsum of their hand prior to treatment and a nasal hood for the procedure. Any history of hypersensitivity to benzodiazapines, sevoflurane, nitrous oxide or local anaesthetics (all are very rare) resulted in exclusion from the trial.

Verbal and written information about the study was given to the parents of recruited children. Written informed consent/assent was obtained from recruited

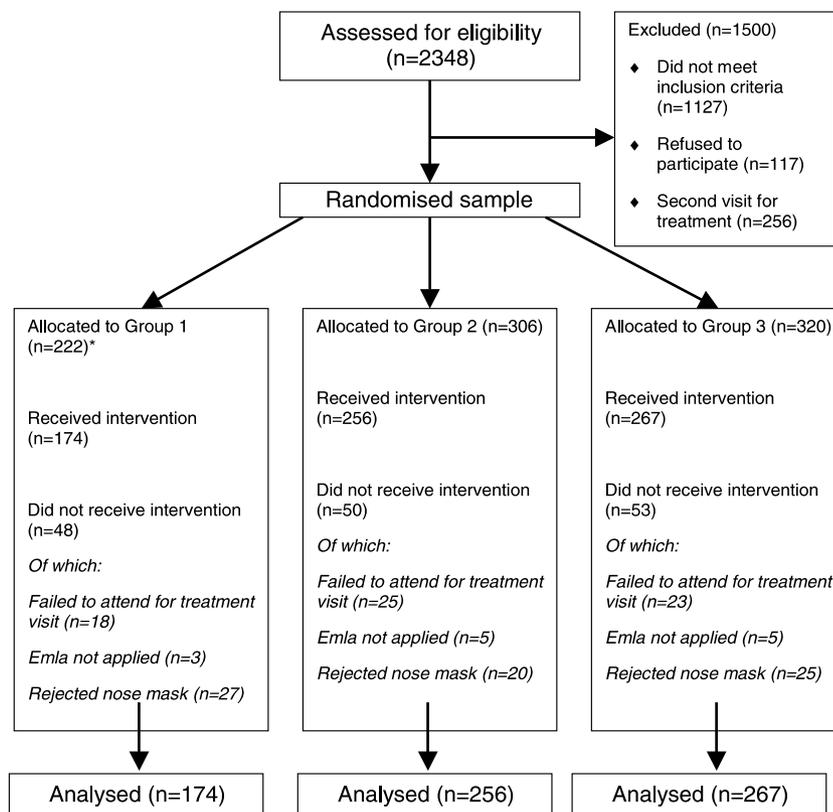


Figure 1 Flow diagram of the process through phases of the trial (enrolment, intervention allocation and data analysis). *Allocation to this group was stopped on the advice of the Data Monitoring Committee.

children/parents and EMLA[®] was supplied. Finally, a treatment appointment was arranged.

Randomisation and sedation technique

The children recruited were randomly allocated to one of three groups using the Newcastle Centre for Health Services Research web based randomisation service. Randomisation was carried out by a nurse not connected with the study. A note of group allocation was placed in the patient record card in preparation for the appointment.

Had there been no practical constraints, randomisation would have been carried out on the occasion of the visit for treatment after it had been ascertained that EMLA[®] cream had been applied, that the child would sit in the dental chair and accept the nose mask. For practical reasons, this was not possible and randomisation was carried out before the child's arrival for treatment. Children for whom treatment was not possible for the above reasons, or who failed to attend their treatment appointment, were not included in the analysis. The reason for withdrawal could not be influenced by the group allocation. For the purpose of the analysis, acceptance of the nose mask was regarded as the virtual point of randomisation and from that point on, all children were retained in the analysis on an 'intention to treat' basis.

The three groups were:

- *Group 1:* Inhaled medical air at 6 l.min^{-1} for 2 min, followed by 0.5 mg of i.v. midazolam per minute, titrated to reach a clinical end point (Level 3 on the consciousness scale) [26].
- *Group 2:* Inhaled 40% nitrous oxide in oxygen at 6 l.min^{-1} for 2 min, followed by i.v. midazolam 0.5 mg.min^{-1} , titrated to reach a clinical endpoint as described above.
- *Group 3:* Inhaled combination of 0.3% sevoflurane and 40% nitrous oxide in oxygen at 6 l.min^{-1} for 2 min, followed by midazolam 0.5 mg.min^{-1} titrated to reach a clinical endpoint as described above.

EMLA[®] cream was applied to the dorsum of both hands of each child by a parent or guardian 1 h before treatment. At the start of the procedure, the child was asked to perform a baseline Eve's test (a simple test of spatial awareness in which the child touches the tip of his or her nose with a forefinger with eyes closed) and then to breathe through a nasal mask. The anaesthetist then opened the envelope inside the record card identifying the technique randomly allocated and commenced its administration for 2 min prior to cannulation. Whilst all three groups received intravenous midazolam, the positioning of the anaesthetist and his/her equipment meant that the dentist was blind to the gases being administered.

Once the clinical endpoint was reached, a red car toy was shown to the child for 5 s. The child was asked to recognise the object and memorise it for later in order to assess amnesia.

Topical anaesthetic was then applied to the gum. Two minutes later the dentist injected lidocaine. During the procedure, the dentist maintained verbal contact and ensured the child remained responsive to verbal commands. The dentist used calming suggestions and imagery to reassure the child and to distract him/her. At 5 min intervals, the treating dentist made a formal assessment of the child's co-operation using the six-point co-operation scale [25] and the child's level of consciousness using a six-point consciousness scale [26]. Children were maintained between level 3 (eyes open and responsive to verbal commands) and level 4 (eyes closed and responsive to verbal commands) on the consciousness scale. If necessary, the concentration of sevoflurane or nitrous oxide was reduced during the procedure if the child showed signs of over sedation (over level 3 on the consciousness scale) [26]. Throughout the procedure, the QAMC protocols of good sedation practice were employed [22].

A Draeger Julian anaesthetic machine monitored pulse oximetry, automatic non-invasive blood pressure and ECG. The nasal hood was adapted to incorporate a probe to measure fractional inspired and end-tidal oxygen, carbon dioxide, nitrous oxide, and sevoflurane. The anaesthetist continuously monitored oxygen saturation, heart rate, ECG, capnography, fractional inspired sevoflurane and end-tidal sevoflurane and formally recorded them at 5 min intervals during treatment. Blood pressure was recorded once the clinical endpoint of sedation had been reached.

If a child's level of co-operation rose to level 4 or greater ('reluctant' or worse) during treatment, the technique was deemed to have failed for the purposes of the study as at this point it becomes difficult to provide effective dental care. The child then received appropriate anxiety management according to the QAMC protocols and the nature of the child's anxiety management subsequently employed was recorded. The intended dental treatment was carried out, limited only by the maximum dosage for local anaesthetic. If additional treatment was required, because of the extent of the treatment, a second visit was arranged but this visit was not included in the study.

After treatment, 100% oxygen was delivered through the nasal hood for 2 min before transfer on a trolley to the recovery room. The child was monitored during recovery by a nurse, who recorded a range of physiological and secondary outcome variables. The time taken to perform an Eve's test was recorded at 5-min intervals, as was the

time taken to walk unaided across the recovery room with close supervision. Before discharge, the child was asked to recall seeing the toy, to assess their level of amnesia. The child's level of anxiety and experience of pain was reassessed using the visual analogue scales previously reported [24]. Finally, the parent's opinion of the overall management of the child was recorded on a simple 5-point scale (1 = poor, through to 5 = excellent).

All data were recorded contemporaneously in ink on the anxiety management record sheet and the data stored in a locked cupboard prior to data entry.

Analytic strategy

An intention to treat analysis was performed. For each variable considered, initially all three groups were compared simultaneously to test the hypothesis that there were differences between the groups against the null hypothesis that there were no differences. For the key outcome measure (co-operation leading to successful completion of dental treatment) and for other binary variables, a Chi-squared test was undertaken. For continuous variables, a one-way analysis of variance with a standard *F*-test was undertaken. When the overall test indicated that the differences between groups were significant at the 5% level, groups were then compared pair-wise. For binary variables a 95% confidence interval for the relative risk (of success) between groups was calculated. For continuous variables, a 95% confidence interval for the difference in mean scores between the groups was calculated.

A fully independent Study Data Monitoring Committee, comprised of a statistician, a clinician and a lay member, was set up to monitor the progress of the trial. Their role was to ensure good practice by ensuring data quality during the trial and that the demographic breakdown of the groups supported random allocation. In addition, they monitored the outcome data and could

advise the cessation of any arm of the trial on an ethical or statistical basis if the outcome was clearly less effective than those the other arms.

Results

The sample of 697 children was recruited over a 9-month period; their demographics, by test group, are shown in Table 1. Primary and secondary outcomes, by test group, are shown in Table 2. Children were generally healthy, 664 children were classed as American Society of Anaesthesiology (ASA) I and 33 children were ASA II. The cases were well distributed in terms of age, assessment of co-operation and the invasiveness of the procedure undertaken, with no statistically significant differences between the three groups. There was an even distribution of dentists across the trial arms. There was a slight imbalance with respect to anxiety at assessment. Children were less anxious in Group 1, with a mean anxiety score of 5.6 (SD 2.0) than in Group 2 (6.1 (SD 1.7)) or Group 3 (6.0 (SD 1.9)). There was also an imbalance with respect to gender (see Table 1).

At the recommendation of the independent Study Data Monitoring Committee, an interim analysis of data was carried out by the committee and independent from the research team. It was decided by the committee that due to the high failure rate of Group 1, this arm of the study should be discontinued and the trial proceed with only Groups 2 and 3. As a result, the numbers of children recruited into Group 1 are lower than in Group 2 or 3.

Table 2 shows the results for both primary and secondary outcome measures. For the primary measure of outcome, 54% (94/174 children) successfully completed treatment in Group 1, 80% (204/256 children) in Group 2 and 93% (249/267 children) in Group 3. The Chi-squared test indicated that differences between

Table 1 Baseline characteristics of the study groups.

Variable	Group 1: Air (<i>n</i> = 174)	Group 2: Nitrous oxide (<i>n</i> = 256)	Group 3: Sevoflurane (<i>n</i> = 267)	Overall test of difference between groups	Pair-wise comparison of groups		
					2 v 1	3 v 1	3 v 2
Sex (male); <i>n</i> (%)	81 (47%)	127 (50%)	103 (39%)	$\chi^2_2 = 6.79$; <i>p</i> = 0.03	RR: 1.07 (0.87, 1.30)	RR: 0.83 (0.67, 1.03)	RR: 0.78 (0.64, 0.95)
Age; mean (SD)	9.1 (2.7)	9.5 (2.7)	9.6 (2.5)	$F_{2,693} = 2.20$; <i>p</i> = 0.11			
Weight; mean (SD)	36.3 (13.4)	37.8 (14.1)	37.7 (14.0) (<i>n</i> = 251)	$F_{2,689} = 0.69$; <i>p</i> = 0.50			
Invasiveness of treatment; mean (SD)	8.9 (4.1)	9.7 (4.5) (<i>n</i> = 256)	9.8 (4.2) (<i>n</i> = 265)	$F_{2,692} = 2.65$; <i>p</i> = 0.07			
Anxiety at baseline assessment	5.6 (2.0)	6.1 (1.7)	6.0 (1.9)	$F_{2,694} = 5.05$; <i>p</i> = 0.01	0.55 (0.21, 0.90)	0.44 (0.07, 0.80)	-0.16 (-0.42, 0.19)
Co-operation at baseline assessment	2.6 (1.2)	2.8 (1.1)	2.6 (1.2)	$F_{2,694} = 2.11$; <i>p</i> = 0.12			

Table 2 Primary outcomes and secondary outcomes for successful cases.

	Group 1: Air (n = 174)	Group 2: Nitrous oxide (n = 256)	Group 3: Sevoflurane (n = 267)	Overall test of difference between groups	Pair-wise comparison of groups		
					2 v 1	3 v 1	3 v 2
<i>Primary outcome</i>							
Successful completion of treatment; n (%)	94 (54%)	204 (80%)	249 (93%)	$\chi^2 = 9.64$; p < 0.001	RR: 1.47 (1.27, 1.72)	RR: 1.73 (1.50, 1.99)	RR: 1.17 (1.09, 1.25)
<i>Secondary outcomes of successful cases</i>							
Secondary outcomes of success	n = 94	n = 204	n = 249				
Total dose in mg of midazolam: mean (SD)	3.7 (1.8)	3.2 (1.8)	2.6 (1.6)	$F_{2,544} = 16.1$; p < 0.001	-0.46 (-0.90, -0.03)	-1.08 (-1.47, -0.69)	-0.62 (-0.93, -0.31)
Poorest level of co-operation during treatment; mean (SD)	2.4 (0.7) (n = 93)	2.3 (0.8) (n = 203)	2.3 (0.7) (n = 248)	$F_{2,541} = 0.73$; p = 0.48			
Recovery time in min; mean (SD)	8.2 (5.6);	7.4 (3.5);	7.9 (4.2) (n = 247)	$F_{2,542} = 1.36$; p = 0.26			
Child's perception of pain; mean (SD)	0.4 (1.1)	0.4 (1.2)	0.4 (1.4)	$F_{2,544} = 0.05$; p = 0.95			
Anxiety reported by child; mean (SD)	0.8 (1.3)	0.8 (1.3)	0.8 (1.3)	$F_{2,544} = 0.02$; p = 0.98			
Parent's satisfaction	4.7 (0.7)	4.8 (0.6)	4.8 (0.5)	$F_{2,544} = 0.70$; p = 0.50			
Any recall: n (%)	22 (24%) (n = 91)	27 (14%) (n = 194)	25 (10%) (n = 241)	$\chi^2 = 10.4$; p = 0.005	RR = 0.58 (0.35, 0.95)	RR = 0.43 (0.26, 0.72)	RR = 0.75 (0.45, 1.24)
Successful cannulation; n (%)	124 (71%)	245 (95%)	262 (98%)	$\chi^2 = 101.4$; p = 0.001	RR = 1.34 (1.22, 1.48)	RR = 1.38 (1.25, 1.52)	RR = 1.02 (0.99, 1.06)
Failed treatment after successful cannulation; n (%)	30 (24%) (n = 124)	41 (17%) (n = 245)	13 (5%) (n = 262)	$\chi^2 = 31$; p = 0.001	RR = 0.69 (0.45, 1.95)	RR = 0.21 (0.11, 0.38)	RR = 0.30 (0.16, 0.54)

groups was significant at the 0.001% level. Given successful cannulation, the odds of successful treatment in Group 2 were not significantly greater than those in Group 1, with an odds ratio of 1.61 (95% CI: 0.96, 2.72). In this case, the p-value did not reach statistical significance (p = 0.075) and on the basis of the interval estimate of the odds ratio, we cannot exclude the possibility of a clinically important difference between the two treatment modes. Given successful cannulation, the odds of successful treatment in Group 3 were significantly greater than those in Group 1, with an odds ratio of 6.33 (95% CI: 3.18, 12.65). Given successful cannulation, the odds of successful treatment in Group 3 were significantly greater than those in Group 2, with an odds ratio of 3.94 (95% CI: 2.06, 7.52).

Of the 151 failed treatments shown in Table 3, 59 children in Group 1 and 24 children in Group 2 were successfully treated with the addition of sevoflurane and nitrous oxide in oxygen. A further 34 children (including Group 3 failures) were managed with an alternative conscious sedation technique (by administration of additional sedation agents), ensuring at all times that consciousness did not drop below level 4 on the consciousness scale [26]. Eighteen children who could not be managed using conscious sedation techniques were

referred back to their own general dental practitioner as they did not meet the clinic referral protocol for a DGA because there was no need for urgent treatment. Sixteen children required referral to a hospital setting for DGA.

The analysis of secondary outcomes is restricted to subjects who underwent a successful procedure (Table 2). There were significant differences between groups (p < 0.001) in the amount of midazolam required. The dose of midazolam was not weight determined but titrated to a clinical endpoint, and the pair-wise comparisons indicate children who received sevoflurane (Group 3) needed less midazolam than children in the other two groups. There was no difference (p = 0.48) between the Groups for the poorest level of co-operation recorded amongst those who were treated successfully. Differences in recovery times were not statistically significant (p = 0.26). There was no statistical significance in child perception of pain (p = 0.95) and anxiety in recovery (p = 0.98) or parent's satisfaction (p = 0.5).

All children were responsive to verbal commands throughout the duration of the procedure and during recovery (no children scored greater than 4 on the consciousness scale). No significant adverse events were encountered during the study. One child in Group 1 suffered a vaso-vagal attack during cannulation, and six

Variable	Group 1: i.v. midazolam & air (n = 174)	Group 2: i.v. midazolam & nitrous oxide (n = 256)	Group 3: i.v. midazolam & nitrous oxide & sevoflurane (n = 267)
Addition of sevoflurane and nitrous oxide allowing completion of treatment	59	24	n/a
Addition of other i.v. agent (maintaining consciousness level 4) allowing completion of treatment	10	13	11
Referral back to own dentist	6	8	4
Referral for General anaesthetic	5	7	4
Total number of failures	80	52	19

Table 3 Outcome techniques for failed treatments under initial sedation technique.

children in Group 3 vomited clear fluids after treatment. All children remained well saturated and within acceptable limits for conscious sedation during treatment and in recovery. In total, 98% of children had an oxygen saturation of 98% or above. The lowest saturation of 94% was recorded in one child in Group 1. Heart rates and blood pressure remained $\pm 20\%$ of normal base values throughout treatment and recovery for every patient.

Children in all groups exhibited good amnesia as would be expected with the use of midazolam. However, 30/124 children (24%) in Group 1, 27/194 children (14%) in Group 2 and 25/241 children (10%) in Group 3 had some recall of the dental procedure. This difference was significant between the groups ($p = 0.005$).

There were significant differences between groups ($p < 0.001$) when the level of co-operation during cannulation was compared. In Group 1, 71% (124/174) co-operated to allow successful cannulation compared with 95% (245/256) in Group 2 and 98% (262/267) in Group 3.

Discussion

The findings from this single centre randomised control trial clearly show that inhalation support provided by a combination of inhalation sedation and intravenous midazolam rather than intravenous midazolam alone, improves co-operation during cannulation, improves the level of co-operation during the dental procedure, resulting in a higher rate of successfully completed treatment, reduces the dose of midazolam required and produces good amnesia. Delivered in a primary care setting with involvement of anaesthetists, these techniques are effective and apparently safe. The clinical significance of this is that it potentially reduces the need for hospital referral for a DGA.

Adverse events are rare in dental anaesthesia, and a definitive evaluation of safety requires a long history of

treatment using a given technique. Whilst a trial of this size cannot assess the frequency of possible adverse events, the results presented here indicate a safe technique. The conscious sedation techniques practised ensured co-operation and consciousness throughout the procedure and full control of protective reflexes. This is in stark contrast to DGA, and also in contrast to the practice of 'deep sedation'.

Only minor adverse events were recorded, and the only ones that had clinical relevance were six cases where children vomited clear fluids, all of which occurred in the midazolam/nitrous oxide/sevoflurane group. While the numbers are too small for comparative analysis, they suggest that there may be a greater risk of vomiting where these agents are used in combination. This occurred in just over 2% of such cases so the overall prevalence is very low. Nevertheless, where more than one agent is used we would recommend that the patient is starved before the procedure as a precautionary measure in accord with the protocol used in this study.

It is widely accepted that conscious sedation is safer than general anaesthetic [2, 23, 26–30]. However, poorly controlled conscious sedation may result in 'deep sedation' or even general anaesthesia with all its attendant risks [2, 31]. The sedationist must be able to exert a fine control over the level of sedation and the margin of safety between sedation and anaesthesia must be wide enough to prevent unintended loss of consciousness occurring. Such techniques are not particularly difficult and can be appropriate for a primary care setting, but do need to be practised by trained personnel. Children requiring more complex techniques for effective sedation, involving combinations of drugs such as those used in this trial, should be treated in specialist centres with appropriately trained and experienced teams where a trained anaesthetist is present. However, treatment does not need to be undertaken in a hospital setting and does not require admission.

The evidence from this trial suggests that, provided proper care and attention are exercised, intravenous sedation in combination with inhaled agents may be a useful alternative to DGA. The results of this trial adds to the evidence base for sedation techniques which can be used to help children who fail to accept dental treatment using local anaesthetic alone or supplemented with conventional relative analgesia sedation. The development of guidelines on paediatric conscious sedation needs to be an ongoing process based on new evidence such as that presented in this paper [2, 32].

Acknowledgements

We thank all the patients involved in this study. We are grateful for the support of an NHS R & D National Primary Care Researcher Developers Award (2002). Thanks to dental surgeons: Dr M. Hanlon, Dr I. Lane, Dr R. Hobman, Dr U. Mansoor, Dr B. Smith, Dr J. Sykes and A. Weston for their valuable contribution. In addition to consultant anaesthetists Dr S. Gooneratne, Dr G. Lahoud, Dr H. Mohan and Dr I. Riddle for their support and advice. We thank all the staff at QAMC for their hard work and Abbott Laboratories for providing the sevoflurane.

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