ADVANCED PAEDIATRIC CONSCIOUS SEDATION: AN ALTERNATIVE TO DENTAL GENERAL ANAESTHETIC IN THE UK.

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Key Words

Paediatric dentistry, Conscious sedation, Midazolam, Sevoflurane, Fentanyl.

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Abstract

Background. Child dental anxiety is widespread, and it is not always possible to treat children using traditional methods such as behavioral management, local anaesthesia and even relative analgesia. In such cases a dental general anaesthetic (DGA) is the only option available to facilitate dental treatment in anxious children.
Aim. This study describes an advanced conscious sedation protocol which allows invasive treatment to be carried out in anxious children. It incorporates the use of titrated intravenous midazolam and fentanyl and inhalation agents, sevoflurane and nitrous oxide/oxygen, which is administered by a Consultant Anaesthetist. The aim is to produce an evidence based study which can offer a sedation technique as a safe and effective alternative to a DGA.
Study Design. Retrospective audit.
Method. 267 clinical records were audited retrospectively from a specialist sedation based clinic, for children aged between 5-15 years old. The subjects all underwent invasive dental procedures with this technique between August and November 2008 as an alternative to a DGA.
Results. 262/267 (98%) of the subjects were treated safely and successfully and without the loss of verbal communication using this technique. This included many treatments requiring four quadrant dentistry, with both restorations and extractions as necessary being carried out in one visit. 5 subjects (2%) did not tolerate treatment and had to be referred for a DGA. No medical emergencies occurred.
Conclusions. Based on the evidence for this group of patients, this advanced conscious sedation technique utilising inhalation sevoflurane and nitrous oxide/oxygen and intravenous midazolam and fentanyl, offers a safe and effective alternative to DGA when carried out in a dedicated, specialist environment.

Introduction and Background.

Dental anxiety in children is widespread and the problem of treating extremely anxious children, other than by a hospital admission for DGA, is an area which has seen progressive research [Averley et al., 2004a]. Many new techniques researched include the use of oral and transmucosal benzodiazepines, intravenous propofol, inhaled sevoflurane, and ketamine, all of which are considered to be acceptable for anxiety management in children [Averley et al., 2004a; Gilchrist et al., 2007; Hosey, 2002; Mikhael et al., 2007; Millar et al., 2007; Wilson et al., 2006; Wilson et al., 2007].

This audit was carried out at Queensway Anxiety Management Clinic (QAMC) in Billingham, Cleveland, UK. It is a clinic which provides a unique, specialist, dental referral centre for children and adults who cannot be managed in normal general practice with behavioral and local anaesthetic techniques alone. Treatment here is carried out by a professional team of 12 dentists, each of who have postgraduate training/qualifications in conscious sedation. This is in conjunction with six Consultant anaesthetists who provide full-time management and cover for patients, six days a week. QAMC delivers dental care for more than 8000 children and adults per year [Averley et al., 2004b], using a range of sedation techniques which are each specific to the individual and their needs. These techniques range from simple Relative Analgesia (RA) using inhaled nitrous oxide/oxygen in combination with local anaesthesia (LA), to a more complex procedure of advanced conscious sedation, which incorporates inhalation and intravenous techniques.

Dental practitioners who are both appropriately trained and experienced in conscious sedation assess patients in line with current Standards for Conscious Sedation in Dentistry guidelines [SDAC, 2003], and the Standards for Conscious

Sedation in Dentistry: Alternative techniques guidance [Standing Committee on Sedation for Dentistry, 2007]. Following these guidelines, as a first line of management, inhalation sedation with nitrous oxide (RA) is offered to both adults and children. If this treatment does not meet the requirement of the individual then adults and children over 16 years old are offered treatment with intravenous midazolam as a lone sedative, or with the possibility of additional RA to help decrease their anxiety. For the more anxious or uncooperative children (generally under 16 years of age) where experience dictates that they would not be able to tolerate treatment under RA, or for those who have previously failed RA, then these children are offered an alternative to DGA and are invited to be treated using advanced conscious sedation techniques. Express written consent is gained and these children are sedated in line with current guidelines [SDAC, 2003; Standing Committee on Sedation for Dentistry, 2007] and treated using a combination of titrated intravenous midazolam and fentanyl, with the addition of inhaled sevoflurane (0.3%) and nitrous oxide (40%). These drugs are administered by a specialist trained consultant anaesthetist in conjunction with a dedicated team who carry out all necessary dental treatment, generally in one visit. This audit was implemented to assess the success of the outcomes with this sedation technique, in the treatment of anxious paediatric dental patients as an alternative treatment method to DGA.

Materials and Methods

The combination of intravenous midazolam and fentanyl is not a new technique for use in paediatric care in the hospital environment [Mamula and Markowitz, 2004; Sury, 2004;]. From this concept, an anxiety management technique for treating paediatric dental patients was developed for use at QAMC by the Consultant anaesthetists and dental teams, which also included the addition of inhalation sevoflurane and nitrous oxide/oxygen.

Audit Design

The design of this audit is retrospective and was achieved by extracting quantitative data from patient record cards and extrapolating it onto data collection sheets over a three month period commencing from 1st August 2008.

Population and sample

In total, 420 clinical records were inspected between 1st August 2008 and 31st October 2008, producing 267 viable inclusions for the audit. (Table 1)

Inclusion criteria for study data collection:

- Children deemed to be ASA (American Society of Anesthesiology) I – II for treatment
- Children aged 5-15 years old who will agree to sit in the dental chair at assessment and are able to tolerate an examination.
- Children, who when assessed by dentists experienced in the management of anxious children, were unable to accept treatment under LA alone or in combination with RA.
- Children deemed to have an adequate degree of comprehension and understanding regarding the treatment (if necessary with the support of an interpreter).
- Children deemed to be able to accept breathing through a nasal hood and able to have EMLA® (lidocaine and prilocaine) topical anaesthetic

cream applied to the dorsum of the hand.

Exclusion criteria for study data collection:

- Children ASA III or above for treatment
- Children with hypersensitivity to benzodiazepines, sevoflurane, nitrous oxide, LA or fentanyl.
- Children aged below 5 years old, or 15 years old or above.
- Children who had refused the nasal hood, or who would not sit in the dental chair prior to, or at the start of treatment on the day. This would have resulted in non-cannulation with no intravenous drugs being given, and treatment therefore being abandoned.
- Children who had failed to attend (FTA) or who had cancelled their appointments
- Children who were on their second visit for the same course of treatment and had experienced fentanyl before.
- Children who had no record of drug increments in their clinical notes

Sedation technique

The patient is assessed for treatment in line with current sedation guidelines [SDAC, 2003; Standing Committee on Sedation for Dentistry, 2007], which includes a full medical history and weight measurement. Valid written consent is then gained by the legal parent/guardian for the treatment of the patient and fasting instructions and attendance instructions are given both in written form and verbally to the parent/guardian, who will also be acting as their supervisor. An appointment is made and topical anaesthetic cream (EMLA® cream) is given to the patient to apply before their appointment. This cream is applied to the dorsum of the hand an hour before treatment is due to commence to prevent pain upon intravenous catheter insertion. Once the patient is in the chair a correctly fitting MATRX M® scavenging nasal hood is placed on the child and 0.3% sevoflurane and 40% nitrous oxide is inhaled for approximately two minutes at a flow rate of 6 litres/minute. This is to help settle the patient’s anxiety and to allow cannulation to take place. After successful cannulation has been obtained by the anaesthetist, fentanyl is added intravenously (0.5µg /kg) followed by 0.5mg of midazolam per minute. The midazolam is titrated by the anaesthetist to a clinical end point where the patient is sedated to an appropriate level to allow treatment to commence. The patient is always able to maintain verbal contact in accordance to current UK General Dental Council requirements [GDC, 2005].

A Drager- Julian anaesthetic machine, manufactured in 1998, is used to administer the inhalation sedation agents and also monitor oxygen saturation, blood pressure and other tracings (see below). The nasal hoods used had been specially adapted to incorporate a probe to measure fractional inspired and end-tidal, oxygen, carbon dioxide, nitrous oxide and sevoflurane. The anaesthetist continually monitored oxygen saturation, heart-rate, blood pressure, capnography, fractional inspired sevoflurane and end-tidal sevoflurane on a written record sheet. These variables were recorded every five minutes, along with the increments of drugs and the outcome of the treatment for each patient.

Data Collection

The parameters recorded were: age, weight, sex, drug dosage regime and outcome of the treatment. A non-successful outcome was deemed as the child having accepted cannulation and titration of drugs, but being too uncooperative to complete treatment successfully. If treatment was abandoned at this stage then the procedure was classed as a failure with an unsuccessful outcome recorded, and the patient referred for a DGA. All data from the clinical records were recorded onto a data collection sheet using the patients' clinical number only to allow for complete confidentiality. Data were then entered into Microsoft® Excel® spreadsheet for analysis.

Analytic strategy

The main outcome measurement for the audit was to establish whether the use of this advanced conscious sedation technique was safe, successful and met without incidence. Using a Microsoft® Excel® spreadsheet, results were drawn up giving percentages, means and standard deviations. A Chi-squared test was undertaken to compare the successful completion of dental treatment using this technique against a previous study that omitted fentanyl.

Results

Gender

267 children classed by the American Society of Anesthesiology grading for ASA grades I and II were included in the audit. Amongst these children the gender was approximately even with 52% being male and 48% being female (Table 2).

Age

The age in years of population treated (Table 2) shows a mean of 8.8 (+/-2.7).

Weight

The weight in Kg of the population treated (Table 2) shows a range between

15 – 97, with a mean of 33.4 (+/-15.4).

Intravenous Midazolam dosage.

The mean dosage of intravenous midazolam (mg) given per individual for treatment (Table 2) was 1.8 (+/-1.1).

Intravenous Fentanyl dosage.

The range of intravenous fentanyl (µg) given to the population (Table 2) is between 12.5 and 85 with a mean of 33.2 (+/-13.7).

Primary outcome measures.

The primary outcome measures (Table 3) show that 98% (262/267) of children successfully completed their treatment with this advanced conscious sedation technique.

Comparison of previous studies.

A comparison of studies carried out at the same centre (table 4) show that 98% (262/267) of children successfully completed their treatment with the addition of fentanyl, compared with 93% (249/267) of children with the omission of fentanyl [Averley et al., 2004a]. This was shown to be statistically significant (P=0.012).

Complications

All children included in the audit were responsive to verbal commands once sedated and throughout the duration of the treatment and during recovery. No child lost consciousness and no adverse events were encountered during treatment that required emergency medical intervention or hospitalisation. Of post-operative complications recorded, three children suffered from post-operative vomiting and were given an anti-emetic (ondansetron). A further child, who was feeling dizzy and disorientated after treatment, was reversed with flumazenil to aid recovery. The clinical records taken showed that all children remained well saturated with no patient falling below 95% oxygen saturation during treatment or in recovery. The children were discharged to their supervisors once they had satisfactorily completed a series of subjective tests for recovery and were judged by the anesthetist/dentist to be clinically recovered.

Discussion

The advanced conscious sedation technique that has been described and analysed in this study is not in common use in the UK and is not used for every child needing dental treatment at QAMC. The advanced conscious sedation technique is used once it has been established that the patient will not accept conventional behavioral with local anaesthetic or RA for their dental treatment. Without this advanced conscious sedation technique, the only other option open for treatment of these children is via a DGA. Subsequently, it is clinically vital to acquire further knowledge about the safety and success of the conscious sedation techniques used, in order to protect these patients who may be offered this option for their treatment. It is also important to ensure that the conscious sedation techniques being developed and being used fit with current UK guidance on conscious sedation [SDAC, 2003; Standing Committee on Sedation for Dentistry, 2007].

Whilst this audit is necessary to evaluate current practice at QAMC, it cannot adequately assess the full frequency of possible adverse events which may occur outside a specialist setting. It is very encouraging however, that the results presented show clearly that the administration of intravenous fentanyl and midazolam, along with the gaseous inhalation of sevoflurane and nitrous oxide resulted in a very safe and comprehensive success rate of treatment in these children, whose only other option was a DGA. This was statistically more so when compared against a previous study carried out in the same centre in 2004, using only intravenous midazolam, sevoflurane and nitrous oxide/oxygen. It also recorded that a high proportion of these procedures carried out were to address multiple carious lesions, generally in four quadrants and requiring both extractions and/or restorations. The clinical significance is that when this technique is delivered in a specialist care setting with the involvement of consultant anaesthetists and specially trained dental teams, then this technique is shown to be both safe and effective, while also reducing the dependency on dental general anaesthesia for children. Following this, it is still important that further studies and controlled trials are undertaken in order to supplement and support the results from this audit especially when safety is paramount. Adverse events recorded that only

4 children out of 267 children treated (1.5%) required the attention of the consultant anaesthetist during recovery. None of these children ever lost consciousness or experienced a drop in their oxygen saturation, but it still highlights that best practice for advanced sedation is one that should be carried out in a dedicated environment with the necessary collection of training, equipment and personnel to deal with any medical emergencies that may occur. Subsequently, it is a remit of QAMC that the whole dental team is efficient and well rehearsed in the management of medical emergencies with an up-to date emergency protocol which is evidence based, clear and easy to follow. Therefore it must be mandatory that further

postgraduate training be undertaken to ensure that this advanced sedation technique remains safe and does not result in the fateful consequences of DGA which occurred in dental practice. However, there is still a place for DGA in dentistry, as children are extremely unpredictable and for some, treatment with conscious sedation will still fail.

Conclusion

The evidence from this audit concludes that by adhering strictly to the SDAC Alternatives Techniques guidance [Standing Committee on Sedation for Dentistry, 2007], advanced paediatric conscious sedation utilizing multiple intravenous and inhalational sedative agents can, and does work extremely well for patients at QAMC, and is a very effective and safe alternative to DGA.

References

Averley PA, Girdler NM, Bond S, Steen N, Steele J. A randomised controlled trial of paediatric conscious sedation for dental treatment using intravenous midazolam combined with inhaled nitrous oxide or nitrous oxide/sevoflurane. Anaesthesia. 2004; 59:844-52

Averley PA, Lane I, Sykes J, Girdler NM, Steen N, Bond S. An RCT pilot study of the effects of intravenous midazolam as a conscious sedation technique for anxious children requiring dental treatment -an alternative to general anaesthesia. Br. Dent. J. 2004: 197; 553-8.

Department of Health. A conscious decision. A review of the use of general anaesthesia and sedation in primary dental care. London: DoH. 2000.

General Dental Council. Standards for Dental Professionals. London: GDC, May 2005.

Gilchrist F, Cairns AM, Leitch JA. The use of intranasal midazolam in the treatment of paediatric dental patients. Anaesthesia. 2007; 62:1262-5.

Hosey MT. UK National Clinical Guidelines in Paediatric Dentistry. Int. J. Paed. Dent. 2002; 12:359-72.

Mamula P, Markowitz JE. Safety of intravenous midazolam and fentanyl for pediatric GI endoscopy. J. Pediatr. Gastroenterol. Nutr. 2004; 39:S359.

Millar K, Asbury A, Bowman AW, Hosey MT, Martin K, Musiello T, Welbury RR. A randomised placebo-controlled trial of the effects of midazolam premedication on children's postoperative cognition. Anaesthesia. 2007; 62:923-30.

Mikhael MS, Wray S, Robb ND. Intravenous conscious sedation in children for outpatient dentistry. Br. Dent. J. 2007; 203:323-31.

Standards for Conscious Sedation in Dentistry: Alternative Techniques. A Report from the Standing Committee on Sedation for Dentistry 2007.

Standing Dental Advisory Committee. Conscious Sedation in the Provision of Dental Care: Report of an expert group on sedation for dentistry. DoH.2003.

Sury MRJ. Paediatric sedation. Continuing Education in Anaesthesia, Critical Care & Pain 2004; Volume 4 Number 4 2004 © The Board of Management and Trustees of the British Journal of Anaesthesia 2004.

Wilson KE, Girdler NM, Welbury RR. A comparison of oral midazolam and nitrous oxide sedation for dental extractions in children. Anaesthesia 2006; 61: 1138-44.

Wilson KE, Welbury RR, Girdler NM. Comparison of transmucosal midazolam with inhalation sedation for dental extractions in children. A randomised, cross-over, clinical trial. Acta Anaesthesiologica Scandinavica 2007; 51:1062–7.

TABLES

Exclusions for Audit	Number (n = 420)	% of records inspected
Refused nasal hood	7	1.7%
Not required age	58	18.6%
Failed to Attend Appointment	40	9.5%
Cancelled	11	2.6%
Attending second treatment session	17	4%
Total Exclusions	153	36.4%
Total Inclusions	267	63.6%
Total records viewed	420	

Table 1: Total number of clinical records inspected and the percentage of exclusions.

Primary Outcome Measurements	n	%	SD	(+/-)
male	140	52%		
female	127	48%		
age (years)			8.8	(2.7)
weight (Kg)			33.4	(15.4)
mean dose midazolam (mg)			1.8	(1.1)
mean dose fentanyl (μg)			33.2	(13.7)

Table 2: Summary of results for audit population.

Comparison of Success Rate

Treatment Outcome	n	%
Success count within population	261	97.8
Failure count within population	6	2.2
Total count within population	267	100

Table 3. Success rate of completion of treatment for audit population.

Comparison of Success Rate

Primary Outcome of Group Cross tabulation

	2004	2008	TOTAL
Success count % within group	249 93.3	261 97.8	510 95.5
Failure count % within group	18 6.7	6 2.2	24 4.5
Total count % within group	267 100	267 100	534 100

Chi square
the difference between groups was significantly different at 5% level:

chi = 6.282
p = 0.012 ($p < 0.05$)

Table 4: Comparison of success rate of completion of treatment between 2004 (without fentanyl) and 2007 (with fentanyl) sedation technique studies.