

A PROSPECTIVE AUDIT TO INVESTIGATE THE LEVEL OF CONSCIOUSNESS OF CHILDREN REQUIRING CONSCIOUS SEDATION USING AN 'ALTERNATIVE TECHNIQUE'

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Abstract

The aim of this prospective pragmatic audit was to investigate the level of consciousness experienced by children requiring conscious sedation in a primary care sedation service, using an 'alternative technique' to avoid referral to hospital for general anaesthesia. This technique was only applied to children who were unable to accept treatment with the use of standard inhalation sedation. The technique involved titrated inhaled oxygen and nitrous oxide and titrated sevoflurane with intravenous fentanyl and titrated midazolam. The described technique was provided by an experienced team with appropriate facilities that complied with contemporary standards and guidance. During treatment and recovery the consciousness level of children was recorded using a modified Wilson's scale. Of the sample of 573 children who received the audited technique, 1.9% (11 children) scored level 5 on the modified Wilson scale (eyes closed but responsive to mild physical stimulus). Due to the fine control this technique offers, the duration of this level of consciousness was for mostly less than a minute and no more than five minutes. No children became unresponsive. The results of this audit demonstrate that the technique meets current standards and guidelines for 'alternative' conscious sedation, with a wide margin of safety and the rendering of loss of consciousness unlikely. 99% of patients who would otherwise have required general anaesthetic for dental treatment successfully completed their treatment using this technique.

Introduction

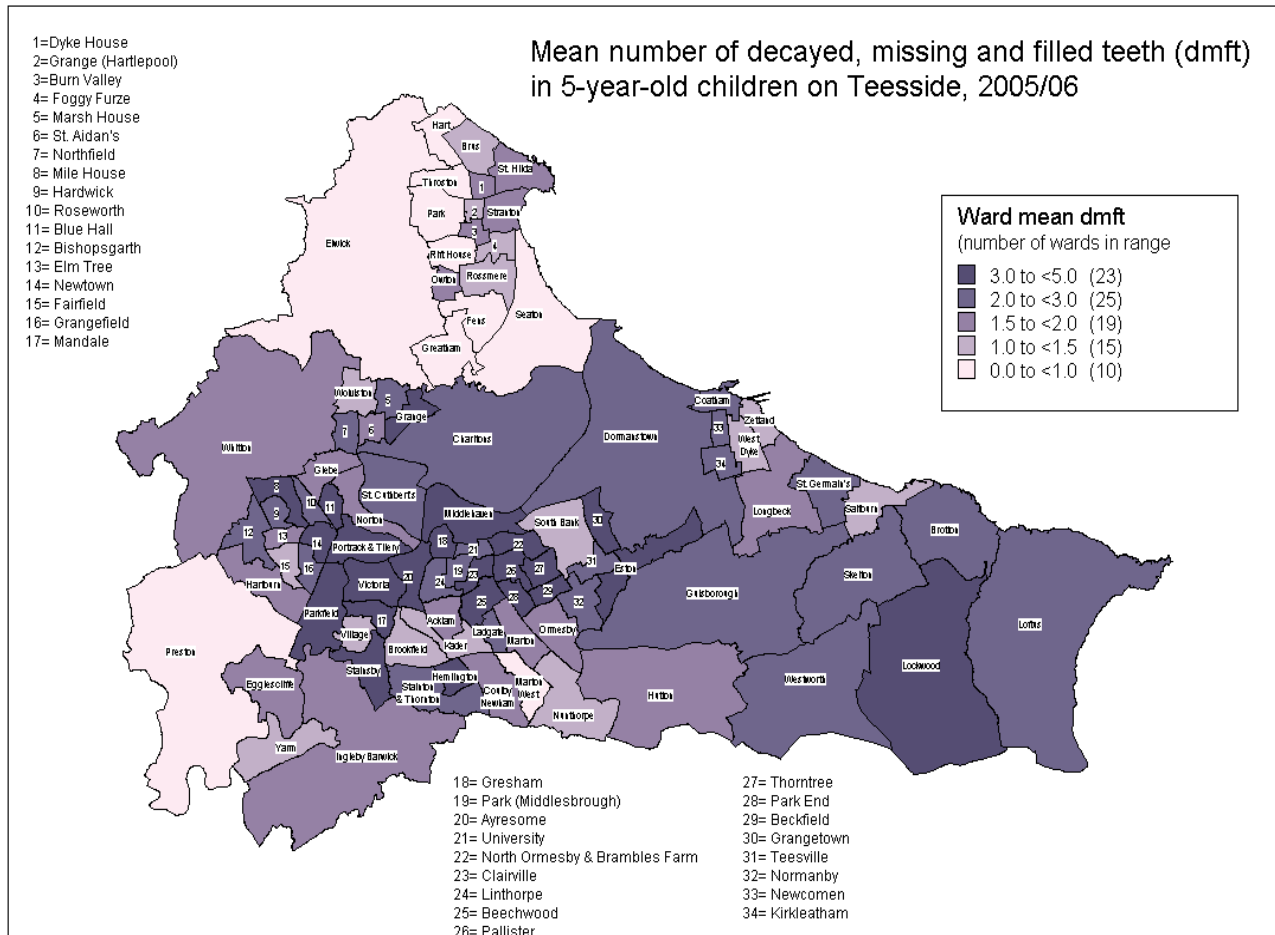
Queensway Anxiety Management Clinic (QAMC) is a primary care dental practice based in Teesside. The clinic is commissioned to provide treatment for anxious patients from across the Northeast on referral from local general dental practitioners¹.

Teesside is a deprived, largely non-fluoridated area where decay rates in children are rising at a significant rate. For example, in 1999 decay experience in five-year-old children in Gresham ward (Middlesbrough) was 2.90 decayed, missing and filled teeth (DMFT) compared with 4.18 in 2006. This represents an increase of 44%. Worryingly, there is also an upward trend in the proportion of untreated dental decay across the area². The location of QAMC means there is a high need for dental treatment and a large population of potentially anxious, uncooperative patients, especially young children, who historically have been managed through the use of general anaesthetic services.

Figure 1. Map of the mean number of decayed missing and filled teeth in five-year-old children across Teesside (BASCOD 2005/6)

There is consensus that the use of dental general anaesthesia should be considered as a last resort, with the use of conscious sedation as an alternative for anxious patients³. Following the advent of local commissioning of services in 2006, local commissioners have been given guidance in order to further develop sedation services⁴. In Teesside this has meant a reduction in the number of

Figure 1



children requiring general anaesthetic, the latter of which has been shown to be more expensive from a commissioning perspective⁵.

QAMC has a team of experienced dentists who have completed their Diploma in Conscious Sedation. These dentists deliver 'standard' sedation techniques⁶. In addition, a team of consultant anaesthetists are employed who are trained and experienced in the 'alternative' conscious sedation techniques employed⁶. The practice, therefore, is able to provide a range of both standard and alternative conscious sedation techniques to cope with a range of patients.

The practice works to the current UK definition of conscious sedation and follows the most recent guidelines from the Royal Colleges⁶. These state that sedation is:

'A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which

verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely. The level of sedation must be such that the patient remains conscious, retains protective reflexes and is able to understand and respond to verbal commands.'

The guidelines continue to state that:

"Deep sedation" in which these criteria are not met must be regarded as a general anaesthetic. In the case of patients who are unable to respond to verbal contact even when fully conscious the normal method of communication must be maintained.'

The practice also follows the Standing Dental Advisory Committee (SDAC) guidance in conscious sedation in the provision of dental care – standard techniques 2003⁷. This includes providing safe, effective care adhering to the

definition of conscious sedation.

The aim is to deliver appropriate techniques matched to individual patient needs in a timely manner at a convenient location. Careful, accurate clinical assessment of patient needs is made at a separate appointment in relation to pain and anxiety management.

Sedation techniques approved by the Royal Colleges fall into two categories: 'standard' and 'alternative'. QAMC uses both 'standard' and 'alternative' techniques. These techniques include:

Standard techniques:

Inhalation sedation using nitrous oxide/oxygen
Intravenous sedation using midazolam alone.

Oral/transmucosal benzodiazepine provided adequate competence in intravenous techniques has been demonstrated.

The transmucosal administration of conscious sedation is regarded by some sedationists as falling within the category of standard techniques. Nevertheless, it is essential that strict protocols are in place.

Alternative techniques:

Any form of conscious sedation for patients under 12 years of age other than nitrous oxide/oxygen inhalation sedation
Benzodiazepine plus any other intravenous agent, for example: opioid, propofol, ketamine
Propofol either alone or with any other agent, for example: benzodiazepine, opioid or ketamine
Inhalation sedation using any agent other than nitrous oxide/oxygen alone
Combination (non-sequential) routes, for example: intravenous and inhalation agent (except the use of nitrous oxide/oxygen during cannulation).

As a consequence of the high need and demand for sedation services in Teesside, together with the desire to reduce the number of patients receiving general anaesthetics, QAMC has developed a range of techniques that it has sought to evidence^{5, 8-10}.

Care pathway

Following referral from a general dental practitioner, the patient's journey begins with an assessment appointment with one of the experienced dentists (this is at a separate visit prior to the treatment visit). The patient will be considered for a range of treatment options, taking

account of their medical history, treatment need, age, level of cooperation and anxiety level. Treatment offered may be by using local anaesthetic only or local anaesthetic with the support of the following conscious sedation alternatives: oral sedation and local anaesthetic, relative analgesia with nitrous oxide, intravenous midazolam or treatment with an alternative technique. In cases of extreme anxiety, especially in very young children with high treatment needs, patients may be referred for treatment under general anaesthetic. This audit will focus on those patients deemed too anxious for treatment with the standard sedation techniques offered at QAMC, who were treated using an alternative technique to avoid the need for general anaesthetic. Consent is completed at the initial assessment and treatment is provided at a separate appointment. Following completion of treatment, patients are referred back to their own general dental practitioners.

Research has previously been undertaken at the practice to look at the effectiveness and safety of an alternative technique using intravenous midazolam combined with inhaled nitrous oxide or nitrous oxide and sevoflurane^{5, 9, 10}. The results of this research showed this technique met the definition of conscious sedation, having a wide margin of safety and the rendering of the loss of consciousness unlikely. 93% of patients treated using this technique managed to successfully complete their treatment and were referred back to their general dental practitioners.

To try to build on the 93% success of this technique, intravenous fentanyl has now been supplemented to the technique. The addition of fentanyl aims to improve success rates, improve patient comfort and acceptance of local anaesthetic due to fentanyl's analgesic affect and to reduce the required dose of midazolam due to its synergistic effect.

This audit of the amended technique was undertaken to investigate whether the amended alternative technique meets current sedation guidelines rendering the loss of consciousness unlikely and ensuring a wide margin of safety.

Aims and objectives

The audit aim was to establish the incidence of 'oversedation' in children undergoing dental treatment under conscious sedation using a combination of inhalation and intravenous drugs. Its objective was to carry out a pragmatic prospective audit of patients receiving 'alternative' conscious sedation, delivered in a dedicated sedation environment with well trained and experienced teams.

Audit standard

The technique being audited must meet the definition of conscious sedation in the UK following the most recent guidance from the Royal Colleges⁶.

The modified Wilson scale¹¹ was used to assess the level of consciousness during treatment and recovery. A score of 5 or above is considered to be in breach of the UK definition.

Modified Wilson scale⁴

1. Fully awake and orientated
2. Drowsy
3. Eyes open and responsive to speech (partial ptosis and/or slurred speech)
4. Eyes closed and responsive to speech
5. Eyes closed and responsive to mild physical stimulation
6. Unresponsive to mild physical stimulation.

The technique to be audited was an alternative technique comprising a combination of inhalation and intravenous sedation.

Inhalation: titrated nitrous oxide in oxygen with titrated sevoflurane (with a maximum expired end-tidal concentration of sevoflurane of no greater than 0.3%).

Intravenous sedation: fentanyl up to a maximum of 0.75µg/kg (max 50µg) with titrated midazolam at 0.5mg increments.

Sedation was administered by a consultant anaesthetist experienced in the technique, with full essential monitoring.

Method

The protocol for the prospective audit was agreed amongst dental practitioners and anaesthetists working in the primary care setting at QAMC. This was a pragmatic study to test a technique that was in current use. The practice environment meets with current guidelines for safe practice^{4,6,7}, all its staff are trained and experienced in providing dental sedation for children and all staff hold relevant postgraduate qualifications. When using an alternative technique a dedicated sedationist (a consultant anaesthetist) is present throughout the procedure.

Sedation technique

Each child was assessed according to their level of cooperation, their level of anxiety and the invasiveness of the intended procedure by an experienced dentist. Where possible, children were offered the standard inhalation sedation technique of titrated nitrous oxide in oxygen and introduced to an inhalation sedation nose mask. As part of the assessment, written informed consent was obtained, written information and advice was given and topical anaesthetic cream (Emla[®]) was supplied, to be placed on the dorsum of the child's hand one hour prior to the sedation visit.

At the treatment appointment the child was asked to sit in the dental chair and tolerate breathing through a nasal mask. An inhaled combination of up to 0.3% sevoflurane and up to 40% nitrous oxide in oxygen at 6l/min was titrated for 2 minutes. This was followed by intravenous cannulation using a Teflon-coated in-dwelling cannula. Intravenous administration of fentanyl followed up to a maximum of 0.75µg/kg (max 75µg) with titrated midazolam at 0.5mg increments. Sedation was administered by a consultant anaesthetist experienced in the technique, with full essential monitoring.

A Drager 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.

Once the clinical end point of conscious sedation was reached, topical anaesthetic was then applied to the gum. Two minutes later the dentist injected 2% lignocaine with 1:80,000 adrenaline. During the procedure, the dentist maintained verbal contact and ensured the child remained responsive to verbal commands. The dentist chatted to the child using calming suggestions and imagery, to reassure and to distract attention.

If necessary, the concentration of sevoflurane or nitrous oxide was reduced during the procedure if the child showed signs of oversedation. Throughout the procedure the established protocols of good sedation practice were employed by the team.

The anaesthetist continuously monitored oxygen saturation, heart rate, ECG, capnography, fractional inspired sevoflurane and end-tidal sevoflurane and formally recorded them at five-minute intervals during treatment. Blood pressure was recorded once the clinical end point of sedation had been reached.

The intended dental treatment was carried out unless limited by the maximum dosage for local anaesthetic. If additional treatment was required a second visit was arranged; this visit was not included in the study.

After treatment, 100% oxygen was delivered through the nasal hood for two minutes before transfer on a trolley to the recovery room. The child was monitored during recovery by an appropriately qualified nurse.

Inclusion criteria

Patients included in the audit were all children aged between 3 and 16 with an ASA of 1 or 2, had consented and were deemed fit to undergo conscious sedation following pre-assessment with the described alternative technique.

Exclusion criteria

Children who were too uncooperative to proceed with treatment (failed sedation). Children with ASA 3 or above or children deemed too anxious for conscious sedation at pre-assessment appointment.

Audit protocol

During treatment and recovery the conscious sedation record sheet was completed and copied for the purpose of the audit. All patients meeting the inclusion criteria and treated using the alternative technique being evaluated were collected from 1 October 2007 and 26 January 2008.

Data recorded included: patient's name, sex, date of birth, ASA classification, the operating dentist and anaesthetist, patient's weight, any relevant medical history, time of last food and drink, time of start and end of procedure, the technique and drugs used, cooperation and consciousness levels during procedure and consciousness levels during recovery, time of discharge, method of transport and escort, treatment provided and finally the treatment outcome.

Pre-operative starvation requirement was equivalent to that for general anaesthesia.

Monitoring during the procedure included electrocardiogram, end arteriole oxygen saturation, fractionated inspired and expired gases (oxygen, nitrous oxide and sevoflurane, end-tidal CO₂ and non-invasive blood pressure monitoring.

Consciousness using the modified Wilson scale¹¹ and cooperation using the Venham scale¹² were monitored and recorded on the sedation record sheet every five minutes during the procedure. Consciousness was recorded every five minutes while in recovery.

The consciousness and cooperation score was agreed by the dentist and the anaesthetist and recorded as an average value every five minutes.

If responsiveness to verbal commands was lost, its incidence and duration was recorded.

Oversedation was considered to have occurred if a score of 5 or 6 on the Wilson scale was recorded.

The audit was prospective, so training and discussion of protocols and agreed scales for levels of consciousness and cooperation was undertaken. Anaesthetists, dentists and nursing staff involved in data recording were trained and calibrated to reduce operator bias.

Results

Results were transferred from the data sheets to a spreadsheet by an independent single operator using an agreed key to standardise the input of the recorded data.

Results analysis revealed that during the audit period there were 9 dental operators and 7 consultant anaesthetists who worked in the clinic, with each clinician treating a similar number of patients.

During the audit period, 752 patients received treatment. Of these the age was recorded on the data sheet for 581 patients, of whom 9 were over the age of 16 and were therefore excluded from the analysis, giving a sample size of 743 patients. The youngest patient treated was 1 year old. The average age was 8.3 years old. 491 patients were male and 253 patients were female.

ASA was recorded for all patients: 628 were ASA 1, 112 were ASA 2 and 3 were ASA 3.

Nitrous oxide was received by 94.9% of patients; 1.6% of patients received 30% nitrous oxide, 0.13% received 35%, 86.7% received 40%, 4.4% received 50%, 1.89% received 60%, and 0.13% received 65%.

Sevoflurane was received by 93.3% of patients; 0.13% of patients received 0.1% inspired sevoflurane, 19.3% received 0.2%, 71.6% received 0.3%, 2% received 0.4% and 0.13% received 0.5%.

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Fentanyl was administered to 95% of the patients; the range was 10µg to 75µg, 35% of patients were given 25µg, 1% had 20µg and 26.5% had 50µg.

Titrated intravenous midazolam was received by 95% of patients. The range was between 0.5mg and 8mg. The average dose was 1.67mg.

Of the 743 patients, 573 received the audit protocol technique of titrated doses of nitrous oxide, sevoflurane, fentanyl and midazolam. One hundred and one patients were excluded from this part of the analysis because they received oral sedation prior to treatment or propofol (4 patients) or flumazenil (3 patients). The remaining 62 were excluded because they had not received all the agents in the protocol technique.

Of the 573 patients, 570 successfully completed treatment and were referred back to their own general dental practitioner, 1 patient was referred for a general anaesthetic and 2 failed to complete treatment, being referred back to their own GDP as they did not meet local general anaesthetic referral guidelines.

The average length of the procedure was 20.1 minutes, with a range of 5 minutes to 85 minutes. The average length of the recovery period was 30 minutes.

The number of teeth treated during the single visit ranged from 1 to 16 teeth, the average patient having 4.8 teeth treated.

Of the 573 patients treated with the technique without modification, 11 patients had a consciousness score of 5. No one had a consciousness score of 6. For these 11 patients the duration of a consciousness score of 5 or more was for 1 minute or less for 7 patients, 2 minutes for 3 patients and 5 minutes for 1 patient.

All of the 11 patients who had a consciousness score of 5 during treatment experienced uneventful recovery periods. There were no signs of minor morbidity, none had oxygen saturation below 95% and none received flumazenil. All 11 patients managed to complete their treatment and were referred back to their GDP. Of these 11 patients, 7 patients were male and 4 patients were female. The patients' ages were 2 patients aged 5, 1 patient aged 6, 1 patient aged 7, 1 patient aged 10, 2 patients aged 12, 1 patient aged 13, 1 patient aged 14, 1 patient aged 15 and for 1 patient the age was not recorded. The ASA was 1 for 8 patients and 2 for 3 patients.

The 11 patients with a consciousness score of 5 or above were treated by 6 different dentists and 6 anaesthetists. All

patients received 40% nitrous oxide, 10 patients had 0.3% sevoflurane and 1 patient had 0.4% sevoflurane. The fentanyl dose range was 15–50µg relative to the weight of the patients. The length of procedure ranged from 15–40 minutes with an average of 20 minutes. The time in recovery before discharge ranged from 20–50 minutes with an average of 35 minutes. The number of teeth treated ranged from 1 to 13.

Recovery consciousness scores for the 573 patients receiving the audited technique revealed 2 patients had a score of 5 or above during the recovery period. Each consciousness score of 5 had a duration of less than 5 minutes. The overall recovery time was 50 and 60 minutes respectively, the patients were aged 11 years and 13 years and both had treatment completed successfully. Both had received 40% nitrous oxide, 0.3% sevoflurane, 50µg fentanyl and 4mg of midazolam.

The consciousness score was recorded during the treatment for the 170 patients excluded from the main analysis. A consciousness score of 5 was recorded for 3 patients; of these, 2 patients had a duration of 1 minute and the third patient had a duration of 2 minutes. All 3 patients had received oral sedation prior to cannulation and received all four sedative agents. One of these patients received flumazenil. During the recovery period a further 4 patients had a consciousness score of 5 or more while the duration was noted as 5 minutes.

All of these patients successfully completed their treatment, did not have oxygen saturations below 95% and were discharged uneventfully. No patient, at any point during treatment or recovery, was overly uncooperative.

Discussion

QAMC provides dental care for anxious patients in the deprived area of Teesside, where there is not only a high need but also great demand for dental treatment with conscious sedation. A range of sedation techniques is used at the clinic, each carefully tailored to suit the individual patient's needs.

QAMC aims to complete treatment for patients with the minimum dose and least number of sedative agents following the principle of minimum intervention.

This audit has focused on the cohort of patients who were deemed too anxious for treatment with standard sedation techniques and were therefore treated using alternative techniques in order to avoid the need for referral to hospital for general anaesthetic.

For the 743 patients managed with a dedicated sedationist during the audit period the alternative technique was tailored to the individual patient's requirements on the day of treatment but always within the definition of conscious sedation. Of these, 101 patients required oral sedation prior to treatment as they would not sit in the dental chair to allow inhalation sedation to be administered prior to cannulation, and 4 patients received propofol as an additional agent to the audit protocol. The technique was modified to reach the level of sedation required for individual patients and 62 patients did not require all protocol drugs in order to cooperate and complete their treatment.

Of the 743 patients 573 were treated with the audit protocol without modification and were treated with a titrated dose of inhaled oxygen, nitrous oxide, sevoflurane and titrated intravenous fentanyl and midazolam.

570 of these patients, who would otherwise have required general anaesthetic, successfully completed their treatment using this technique. Two patients were unable to tolerate treatment and were referred for treatment under general anaesthetic, and one patient failed to complete their treatment but did not meet local referral guidelines and was referred back to their general dental practitioner.

These results indicate an improved success rate, with the addition of fentanyl to the previous research technique, from 93% to 99%.

1.9% of patients treated with this technique experienced a consciousness level of 5 (eyes closed, responsive to mild physical stimulation). For all of these patients the duration was less than 5 minutes and they did not experience a drop in oxygen saturation. They had no minor morbidity nor untoward incident and all recovered uneventfully. A consciousness score of greater than 5 (unresponsive to mild physical stimulation) was not recorded for any patients during the audit period. This suggests the alternative technique fits the UK definition of conscious sedation as verbal contact is maintained and there is a margin of safety wide enough to render the loss of consciousness unlikely.

In conclusion this audit indicates that this alternative technique was tolerated by 99% of patients who would otherwise have required general anaesthetic for their dental treatment with increased costs and risks. This technique also meets the UK definition of conscious sedation.

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