Institution: Newcastle University

Unit of Assessment: UoA3

Title of case study:
A second-line option for conscious sedation of children during dental procedures

1. Summary of the impact

Anxiety before dental procedures is common in children, and is usually managed by conscious sedation of the patient. Previously, nitrous oxide inhalation was the only method widely used in primary care, so patients who could not be thus sedated were referred for general anaesthesia. In 2010, NICE published the first national guideline on medical sedation, which states that administration of midazolam should be considered alongside the standard technique of nitrous oxide inhalation for sedation of children. That recommendation is based on robust evidence, the majority of which came from a series of randomised controlled clinical trials carried out by researchers at Newcastle University. Midazolam is now deployed as a second-line sedation option across the UK.

2. Underpinning research

Key Newcastle University researchers

- Professor Nick Girdler, initially a Senior Lecturer, then from 2006 a Professor of Sedation Dentistry
- Dr Katherine Wilson, Honorary Clinical Tutor in the Department of Dental Sciences. Wilson was co-supervised by Professor Richard Welbury (University of Glasgow during the research period), who helped plan five of the clinical trials.

Background

A study published in 2011 of 552 child patients who underwent extractions and minor surgery found that two-thirds of patients reported being anxious or very anxious before treatment (Lourenco-Matharu and Roberts, 2011, PMID: 21701471). When invasive procedures need to be performed, most children are given relative analgesia, which involves managing the child's behaviour and inducing mild conscious sedation by passing a combination of nitrous oxide and oxygen through the nose.

Previously, in cases where relative analgesia failed (estimates vary, but approximately 15-20% of child sedations), child patients were usually referred for general anaesthesia. However, because general anaesthesia is a more complex and higher risk intervention than conscious sedation (the former may only be carried out in hospital) and is much more expensive, there was a pressing need for another conscious sedation option.

Underpinning research

Over a six year period (2002–7), Newcastle researchers published six papers (R1–6) detailing the results of clinical trials of the drug midazolam for conscious sedation of children during dental procedures (although in one study midazolam was used in combination with nitrous oxide (R4)). The comparator in each of the studies was either nitrous oxide combined with oxygen or nitrous oxide combined with oxygen and sevoflurane. Indicators of patient health during treatment (blood pressure, heart rate, arterial oxygen saturation), sedation scores, patient anxiety levels and post-operative satisfaction were recorded. Midazolam was administered orally (R1, R2 and R5), intravenously (R3, R4) or via the oral transmucosal route (R6). Subjects were children between 10 and 16 years of age in four studies (R1, R2, R3, R6), and slightly younger on average in two others (6–14 years, R4; 5–10 years, R5).

The studies showed that intravenous, oral and buccal (transmucosal) midazolam, in the hands of fully experienced practitioners, could be used safely and effectively during dental procedures for conscious sedation of child patients.

3. References to the research (Scopus citation data as at 31/7/13, Newcastle researchers in **bold**)

R1. **Wilson KE**, Welbury RR, **Girdler NM** (2002). A Randomised, Controlled, Crossover Trial of Oral Midazolam and Nitrous Oxide for Paediatric Dental Sedation. *Anaesthesia*. 57(9):860-867. DOI: 10.1046/j.1365-2044.2002.02784.x **23 citations.**

R2. **Wilson KE**, Welbury RR, **Girdler** NM (2002). A Study of the Effectiveness of Oral Midazolam Sedation for Orthodontic Extraction of Permanent Teeth in Children: a Prospective, Randomised, Controlled, Crossover Trial. *British Dental Journal*. 192(8):457-462. DOI:10.1038/sj.bdj.4801400 **10 citations.**

R3. **Wilson KE, Girdler NM**, Welbury RR (2003). Randomized, Controlled, Cross-Over Clinical Trial Comparing Intravenous Midazolam Sedation With Nitrous Oxide Sedation in Children Undergoing Dental Extractions. *British Journal of Anaesthesia*. 91(6):850-856. DOI: 10.1093/bja/aeg278 **27 citations.**

R4. Averley PA, **Girdler NM**, **Bond S**, **Steen N**, **Steele J** (2004). A Randomised Controlled Trial of Paediatric Conscious Sedation for Dental Treatment Using Intravenous Midazolam Combined With Inhaled Nitrous Oxide or Nitrous Oxide/Sevoflurane. *Anaesthesia*. 59(9):844-852. DOI: 10.1111/j.1365-2044.2004.03805.x **15 citations.**

R5. **Wilson KE, Girdler NM**, Welbury RR (2006). A comparison of oral midazolam and nitrous oxide sedation for dental extractions in children. *Anaesthesia* 61(12):1138-44. DOI: 10.1111/j.1365-2044.2006.04835.x **15 citations.**

R6. **Wilson KE**, Welbury RR**, Girdler NM** (2007). Comparison of Transmucosal Midazolam With Inhalation Sedation for Dental Extractions in Children. A Randomized, Cross-Over, Clinical Trial. *Acta Anaesthesiologica Scandinavica*. 51(8):1062-1067. DOI: 10.1111/j.1399-6576.2007.01391.x **6 citations.**

Relevant funding award

2002–2006. The Department of Health £401,689. *Developing the Evidence Base for Effective Paediatric Conscious Sedation Techniques: An Alternative to General Anaesthesia.*

4. Details of the impact

The need

In the past few years, 50,000–60,000 dental sedation procedures have been carried out each year on children in England and Wales (data from FOI request to the NHS Business Services Authority). The majority of those were standard inhalation sedations with nitrous oxide and oxygen, which induces a mild state of conscious sedation in patients. The technique is called relative analgesia; it has been used for a long time and has a very good safety record – hence it is the first-line option for sedation. However, in a proportion of child patients, inhalation sedation is not adequate due to non-compliance and dental treatment cannot be performed. A study published in 2002 reported that in a cohort of children receiving inhalation sedation within the community dental service of one primary care trust, 16% of dental procedures failed due to problems with sedation (Bryan (2002) PubMed ID: 12452982).

Previously, the only alternative to nitrous oxide for sedating children had been dental general anaesthesia, an unsatisfactory situation. Since 2002, general anaesthesia has been prohibited in a primary care setting and must be carried out in hospital. A hospital visit for dental work is both an unpleasant experience for the patient and is costly to the health service. In 2010, the cost of a dental general anaesthetic in hospital (staff and consumables) was estimated to be £719.90, more than 2.5 times the cost of a sedation procedure carried out by a primary care referral service (£273.01): see NICE clinical guideline 112: www.nice.org.uk/nicemedia/live/13296/52185/52185.pdf.

Guidelines on dental sedation

In 2010, NICE published the guideline *Sedation for diagnostic and therapeutic procedures in children and young people* (Ev a). It states:

"For a child or young person who cannot tolerate a dental procedure with local anaesthesia alone, to achieve conscious sedation consider: nitrous oxide (in oxygen) or midazolam" (pg 19).

The full-length guideline development document, which accompanies the concise guideline, shows that all five trials considered by the Guideline Development Group which involved a direct comparison between nitrous oxide and midazolam were from Newcastle University (Ev b).

The results of a sixth clinical trial performed at Newcastle University (R4), which compared intravenous midazolam plus nitrous oxide with nitrous oxide plus sevoflurane was also examined by the guideline development group – although combination techniques are not explicitly recommended in the guideline.

The NICE guideline applies to all NHS dental services in England and Wales. Dental practices in Scotland follow the Scottish Dental Clinical Effectiveness Programme guideline on dental sedation of adults and children, which was updated in June 2012. On child sedation, the updated guideline states:

"…*intravenous sedation* [midazolam is recommended earlier as the drug of choice] *of paediatric dental patients has been reported as a safe and effective technique…"*

and

"…intravenous sedation for children is appropriate in a minority of cases." (Ev c)

Two studies are cited as supporting this, both of which were carried out at Newcastle University and involved use of midazolam (R3 and R4).

The guidelines also state (citing R2, a trial of oral midazolam):

"Oral and transmucosal sedation is appropriate in a minority of cases" but only where *"titratable techniques (inhalation and intravenous sedation) are deemed to be inappropriate."* (Ev c).

The President of the Society for the Advancement of Anaesthesia in Dentistry (SAAD) confirms that "*a large majority* [of SAAD members] *now apply the current guidelines.*" (Ev d).

Sedation in practice

Sedation with midazolam, usually administered intravenously and sometimes in combination with other drugs, is now the main alternative to nitrous oxide for conscious sedation of children. The group that developed the 2010 NICE guideline stated in their report that: "*the use of midazolam alone in dental procedures in adolescents and in oesophago-gastroscopy is common."* (Ev b).

The NHS Business Services Authority does not centrally record data on the *types* of dental sedations paid for by the NHS in the UK (FOI response 3449), and there is no recently published audit of sedation practice containing that information. Nevertheless, we have statements from several sedation providers, **two of which* were named by the NHS Business Services Authority as belonging to the top ten providers** of dental sedations to children on referral in the UK in 2011–12, which indicate that sedation with intravenous midazolam is widespread.

- [Text removed for publication]* (Ev e).
- [Text removed for publication]* (Ev f).
- The Queensway Dental Clinic, Billingham, Teesside is one of the larger specialist sedation clinics in England. It has received around 9,000 referred patients per year over the last few years, and in the year 2012–13 approximately 3,621 children were sedated there with intravenous midazolam in combination with nitrous oxide, sevoflurane and/or fentanyl where appropriate (Ev g).
- Cumbria Partnership NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust and Newcastle upon Tyne Hospitals NHS Foundation Trust have all acknowledged in responses to FOI requests that they carry out child dental sedations with intravenous midazolam where appropriate (Ev h).

Sedation training

In the UK, professional training in paediatric conscious sedation has adapted to reflect that midazolam is now the standard alternative to nitrous oxide.

The UCL Eastman Dental Institute is the largest postgraduate dental school in Europe and is a world-leading academic centre for dentistry. They have confirmed in a statement that their Paediatric Dentistry DDent programme includes both teaching and practical experience with intravenous midazolam sedation (Ev i). Also, in December 2011 the Independent Expert Group for Training Standards on Sedation in Dentistry (whose members overlap those of SAAD) released a training syllabus on advanced conscious sedation techniques which include use of midazolam in children (Ev j). While sedation courses provide dentists with the underpinning knowledge for alternative conscious sedation of children, SAAD strongly advises that substantial clinical experience should be acquired before independent practice. To facilitate this, SAAD and the Dental Sedation Teachers' Group provide a mentor list that details the contacts of around 50 experienced sedation dentists (almost all in the UK, a few elsewhere in Europe) who can supervise trainees. In the 2011 list, 13 of the mentors were listed as able to supervise and train dentists in intravenous sedation of children (Ev g).

5. Sources to corroborate the impact

Ev a. Sedation for diagnostic and therapeutic procedures in children and young people (concise guideline). National Institute for Health and Clinical Excellence, December 2010. (Quotation from page 19.) http://www.nice.org.uk/nicemedia/live/13296/52130/52130.pdf

Ev b. Sedation for diagnostic and therapeutic procedures in children and young people (full guideline, with working of guideline development group). National Clinical Guideline Centre, December 2010. (Table from page 236.) http://www.nice.org.uk/nicemedia/live/13296/52124/52124.pdf

Ev c. Conscious Sedation in Dentistry: Dental Clinical Guidance. Scottish Dental Clinical Effectiveness Programme, June 2012. Quotations from Section 4: Conscious sedation for children. http://www.sdcep.org.uk/index.aspx?o=2331

Ev d. Statement from the President of the Society for the Advancement of Anaesthesia in Dentistry

Ev e. Statement from [text removed for publication]

Ev f. Statement from [text removed for publication].

Ev g. Statement provided by a Managing Partner at the Queensway Dental Clinic, Teesside. (Also provided the 2011 list of sedation mentors published by SAAD and the dstg.)

Ev h. Freedom Of Information responses from Cumbria Partnership NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust and Newcastle upon Tyne Hospitals NHS Foundation Trust.

Ev i. Statement from Unit Head, UCL Eastman Dental Institute.

Ev j. Advanced conscious sedation techniques for paediatric dental patients. Training syllabus. Independent Expert Group on Training Standards for Sedation in Dentistry (December 2011). http://www.dstg.co.uk/wp-content/uploads/2012/09/Paediatric-syllabus-for-website.pdf