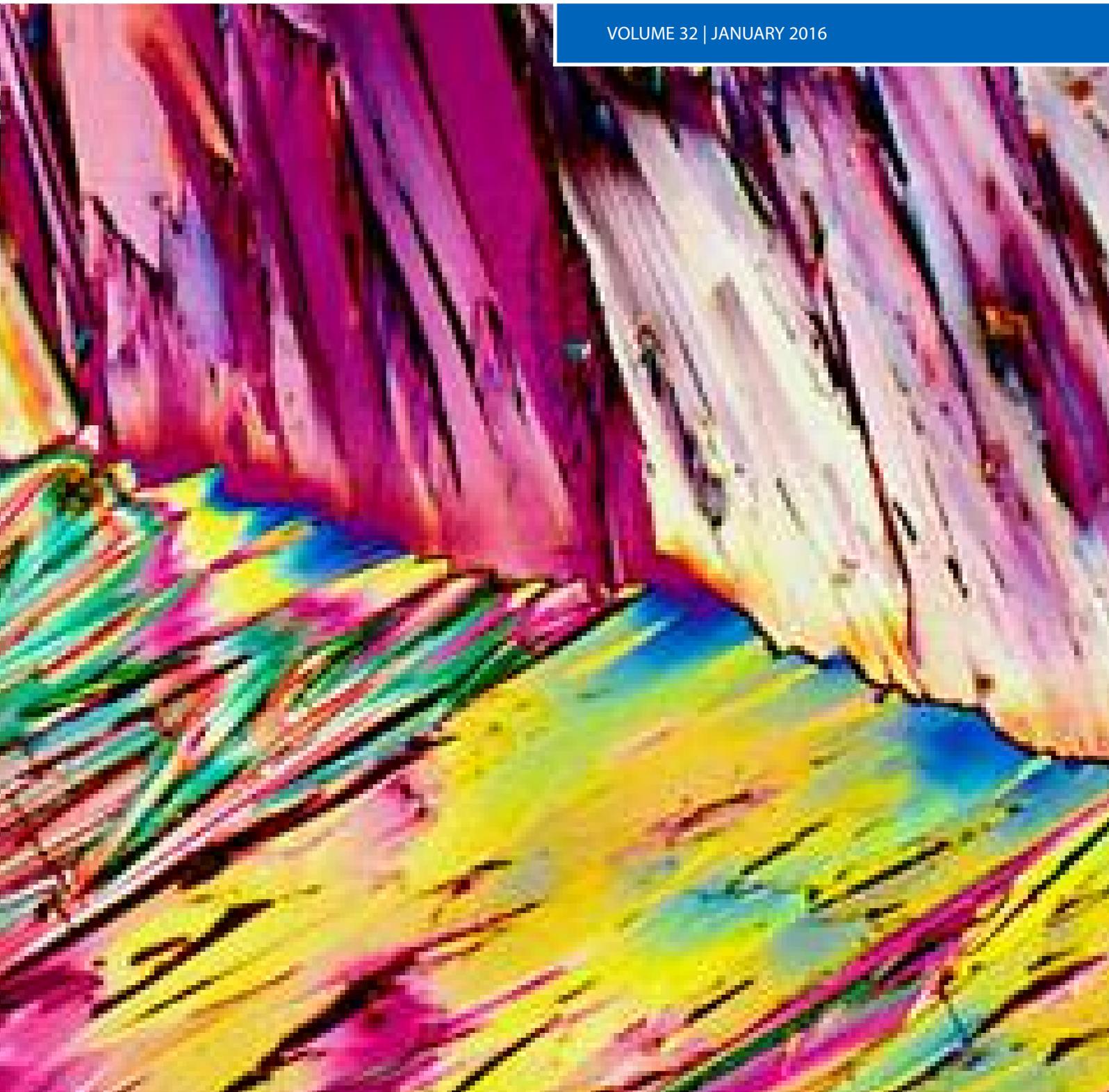




SAAD DIGEST

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Consent | Teaching of LA | Oral Midazolam | IV Escorts

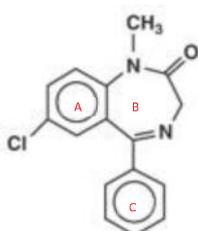
Allergy and Propofol | Defining Over Sedation | NAP5 Results | Clinical Audit

STORY BEHIND THE COVER

DIAZEPAM

Leo Sternbach discovered benzodiazepines. Being a Jewish chemist in wartime Europe, he had to evade the Nazis, and he joined Roche in the United States in 1941. Chlordiazepoxide was his first benzodiazepine in 1960 and Diazepam began its long career in 1963. These two, their trade names being Librium and Valium, quickly supplanted barbiturates and became the standard treatment for anxiety. There was a lot of anxiety in those days apparently. The peak year for Diazepam was 1978 when 2.3 billion doses were sold in the US. Most patients benefited but if taken for too long Diazepam had serious withdrawal effects. An overdose was surprisingly safe unless other drugs and alcohol were combined. One patient swallowed 2000mg became comatose but walked out of hospital without harm two days later.

No-one then knew how a benzodiazepine worked, but now students are expected to know the basic molecular structure; it is not difficult to learn. A core benzene ring (A) is attached to a diazepine ring (B) which usually has another sub-unit benzene ring at its 5th position (C): by the addition of more sub-units other benzodiazepines are created. The sub-units require specific metabolic breakdown pathways and therefore drugs with certain sub-units have similar half-lives. The potency and absorption, however, are related to the sub-unit positions and combinations. Benzodiazepine receptors are found in the frontal cortex, the limbic system and brainstem. They are integral within Gamma-aminobutyric acid (GABA) receptors, and since GABA is the major inhibitory central neurotransmitter, the anxiolytic, sedative and anti-convulsant actions of benzodiazepines are linked to the modulation of GABA.



Diazepam

Intravenous (IV) Diazepam, as used for dental sedation, occasionally caused excessively deep sedation. The dose varied considerably: a reasonable dose in an adult might be 10mg but this would be too much in frail and sick patients. Even though it could be titrated to effect, it had a delayed effect and consequently patience was needed to avoid excessive sedation. As dentists learned its subtle

effects it came to be considered a safe and reliable method of achieving a calm patient who would respond easily to command ~ the state known as conscious sedation and the expression "a wide margin of safety" were born.

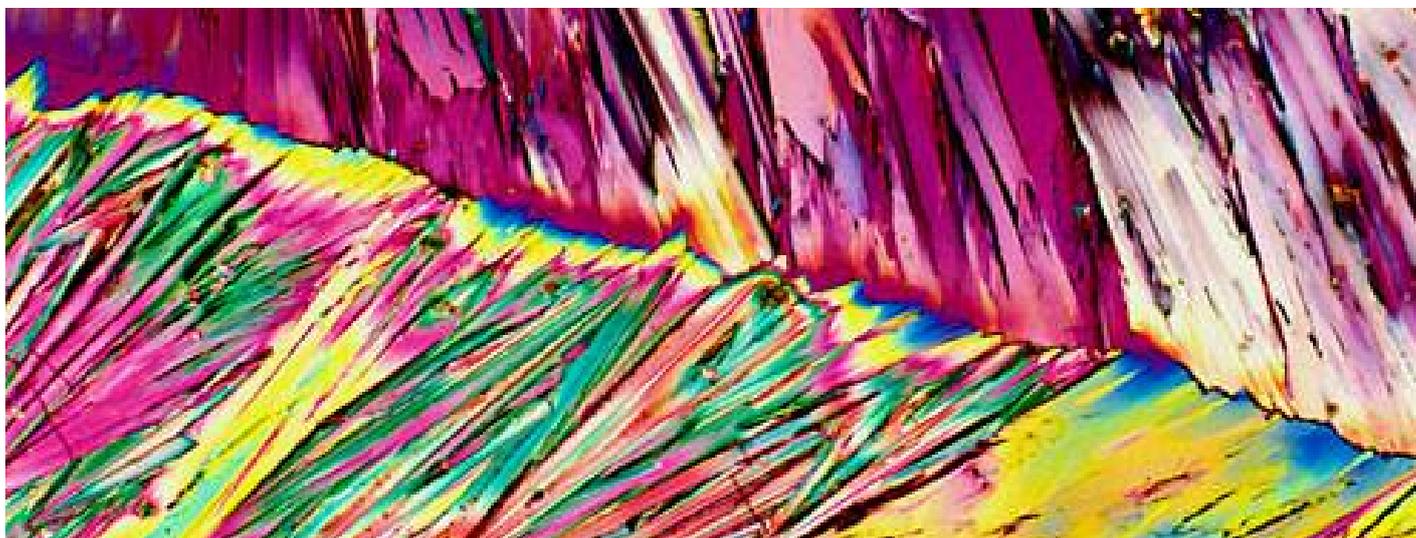
There were other nuisances. Being lipid soluble, Diazepam has a large volume of distribution and therefore a long half-life. Patients might therefore continue to feel "groggy" for hours afterwards. Sensible dose limits had to be followed and therefore a failure rate had to be accepted. A few patients became restless and less cooperative – so called "paradoxical excitement" and this was unpredictable and difficult to treat. In Laurence and Bennett's Clinical Pharmacology textbook, a disadvantage of Diazepam was "occasionally aggression, probably where the subject has hostile feelings, (the) outlet for which is frustrated" ~ which is somewhat thought provoking. A more serious issue was respiratory depression if diazepam was combined with an opioid. In an era before pulse oximetry, patients would be in danger once the pain had waned after the procedure had ended.

IV Diazepam, being dissolved in cremophor-EL, caused pain and thrombophlebitis. A lipid emulsion formulation (Diazemuls) was much better but the arrival of the water-soluble Midazolam in 1975 made IV Diazepam obsolete. Yet we still need a shorter acting drug because the problems of excessive sedation, paradoxical excitement and the danger of the combination with an IV opioid remain. Remimazolam (CNS-7056) is fast acting and is broken down easily by tissue esterases, not hepatic cytochrome oxidases. Recovery takes 10 minutes in comparison to 40 minutes with midazolam. Is this the future of benzodiazepines?

It might be in our hands next if it passes its phase 3 trials but it is so potent, it will need to be infused accurately by using a computerised syringe driver.

A patient has posted on the internet "I can't remember a thing, I was home the same day and things are a bit foggy, I can't remember getting home ... but after a couple of hours sleep, I woke up and felt fine!" Diazepam could do this and midazolam does it now. Can new drugs do any better? We, the clinicians, must test them in clinical trials.

Mike Sury





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The cover photograph is scanning electro-micrograph of diazepam. It is reproduced with the kind permission of the National High Magnetic Field Laboratory, Florida State University.

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I am delighted to welcome you to the *SAAD Digest* for 2016 as President of SAAD. It has been my honour to have held this post since the SAAD AGM last October.

I am acutely aware of the names of the many well known and eminent holders of this office in the past from reading my copy of 'A History of the Society for the Advancement of Anaesthesia in Dentistry'.

However, in a more contemporaneous vein, many of the more recent Presidents of the Society have been the very same people whose books and articles I read during my own sedation studies, as well as those who supervised my initial clinical cases as a postgraduate student at Guy's Hospital. My presidential activities will therefore, in the chronological sense, be viewed from both close at hand as well as afar.

The great strength of the Society is that the wide range of activities in which it is involved are carried out by a large multi-talented team of people who come from a variety of clinical backgrounds. You will be able to read the profiles of our two newest Board members who were elected last October, Dr Kellie Boles and Dr Yi Kwan Loo. I am delighted to introduce two such younger members to our team, and it is essential that more younger colleagues continue to present themselves for election to the Board, as well as involve themselves in the activities of the Society at all levels. In this regard I would wish to continue one of the stated themes of my immediate predecessor, Dr Carole Boyle, in making the Board more representative of the SAAD membership as a whole.

Another theme of my Presidency will be the continuing recognition of the importance of, and support for, sedation services in primary care environments, which I sincerely hope will remain the backbone of this element of service provision for the indefinite future. The publication of the IACSD 'Standards for Conscious Sedation in the Provision of Dental Care' in April 2015 will undoubtedly have, as it says, 'far reaching consequences' in some aspects of our sedation activities, particularly related to professional training, but contrary to much popular belief it certainly need not lead to the demise of conscious sedation in primary care locations. We were extremely fortunate to have three of our Board members, David Craig, Christopher Holden and Nigel Robb, as IACSD Committee members. They were very strong advocates for sedation in primary care and their contribution to the Standards Document, in no small way,

ensured that a more enlightened approach to the issues important for the continuity of primary care sedation prevailed over other possible and less palatable outcomes.

Another theme I would like to promote over the next three years is the important place of conscious sedation within our special care dentistry provision. I think it is extremely important that dental clinicians themselves within the speciality are encouraged to be able to provide an appropriate range of sedation techniques to manage their patients themselves, where possible in a primary care environment, for reasons of patient accessibility and reasonable economy.

Whilst longevity does not in itself confer any particular virtue on an organisation, our Society can justifiably claim to have evolved and developed successfully over the years, with the resultant high profile it enjoys both within and beyond our professional boundaries. I think we may allow ourselves a brief period of reflective celebration as SAAD reaches its Diamond Jubilee year in 2017, but such reflection should be accompanied by critical appraisal of where we are now, and constructive debate about our direction of travel into the future.

The *SAAD Digest* presents its usual informative and attractive format, thanks to the work of the Editor Nigel Robb and his Editorial Board. A welcome new member of the Editorial Board is the Consultant Anaesthetist, Dr Mike Sury, who many readers will recognise through his involvement in the 2010 NICE Guidelines 'Sedation in children and young people' as well as his past contributions both at SAAD Symposia and in the *SAAD Digest*.

There is a broad variety of topics covered in the content of the journal. The Society was able to award the Drummond-Jackson Prize for an essay on the use of intranasal midazolam, while a refereed paper discussed the use of oral midazolam, both techniques which have a place in managing patients whose co-operation is less than optimal. Outside of sedation techniques themselves, other issues pertinent to sedation practice such as an update on the consent process, patient escort awareness and patient safety, and the issue of defining over-sedation are all addressed. The teaching of local anaesthetic techniques to undergraduates is investigated, and the SAAD Essay Prize winner was a review of the pros and cons of articaine use for local anaesthesia.

Please enjoy reading this edition of *SAAD Digest*, and do remember the availability of associated verifiable CPD online through the SAAD website, which was reorganised last summer, and which allows access to a multitude of other items of interest such as regulatory documents, SAAD supplies and booking SAAD courses.

Francis Collier

What's new in... The Process of Consent

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Abstract

An understanding of mental capacity is fundamental to the process of obtaining valid consent. This article looks at the processes of both consent and capacity assessment, and highlights the importance of fully informed consent following recent changes in the law.

Dental patients often present with pain, severe anxiety and communication problems, and these factors together with age and mental ability may limit co-operation and capacity. The process of obtaining valid consent from such individuals is complex, yet this remains an essential part of any dental procedure. The General Dental Council (GDC) has identified this as a core ethical principle in its 'Standards for the Dental Team', and health professionals also receive guidance from the Department of Health². Recent changes in the law³ make this a good time for dentists to review the ethical and legal framework upon which consent is based.

Valid Consent

Consent may be implied by means of compliance or lack of objection, but this is not necessarily valid. Valid consent is based on three clearly defined principles:

1. A person must have the **capacity**, or **ability**, to make a decision
2. Consent must be **informed**, whereby the person has been given all of the information needed to make that decision
3. The decision made by the patient must be **voluntary** and the patient has the right to withdraw consent

Recent Changes In The Law

The finding in the case of Bolam v Friern Barnet Management Committee (1957) was for many years the legal test of medical negligence⁴. A clinician was not guilty of negligence if it could be shown that their actions were supported by a reasonable body of medical opinion and that they had shown 'reasonable' care. The 'Bolam' test has been subject to criticism for its reliance upon personal judgement, albeit that of fellow professionals. A new doctrine of fully informed consent follows a 2015 Supreme Court ruling in the obstetric case of Montgomery v Lanarkshire Health Board⁵. A clinician now has the responsibility to ensure that individuals genuinely *understand* material risks and benefits, as well as the reasonable alternatives to any given procedure.

Good Communication

Although a detailed discussion of communication skills is beyond the scope of this article, the following points are relevant. Informed consent relies upon effective communication. The process is a complex two-way delivery and receipt of information and there is a need for clarity without overload. The importance of

actively listening to what the patient has to say may sound obvious, yet be forgotten when delivering facts. It is equally important to assimilate body language, eye contact and facial expression, as non-verbal communication contributes significantly to the meaning of the spoken word. Because of this, it is more appropriate to discuss emotive subjects in person rather than by telephone.

There are many ways in which the process of communication can be interrupted or modified, and significant barriers include:

- Language
- Physical barriers such as poor hearing or eyesight
- Emotion
- Cultural barriers
- Information overload

Such problems are likely to be identified at the initial patient assessment when strategies can be explored to overcome them. It is inappropriate to ask family members, and especially children, to translate when discussing serious medical treatment such as the use of general anaesthetic (GA). Instead the use of an interpreter service should be considered.

Anxiety is the principal reason for patients seeking treatment with sedation and it has been identified as a significant barrier to dental care⁵. Given that emotion can disrupt good communication it may not be appropriate to ask a patient to consent to a procedure until the level of anxiety has been fully assessed.

The Ability To Consent²

Age 18 years and above

At the age of 18, it is assumed that a person is an adult who has the ability to consent to (or refuse) treatment. This ability relies upon an ability to understand, and to weigh the risks and benefits of any proposed treatment.

Gillick Competency and Fraser Guidelines

A child's ability to make decisions is often described in terms of their 'Gillick competence', or whether they meet the 'Fraser guidelines'. The terms are not interchangeable. Both arose from a legal case that considered whether doctors should be able to give contraceptive advice to children under the age of 16 without parental consent. In the case of Gillick v West Norfolk and Wisbech Area Health Authority (1985) the Law Lords, Scarman, Fraser and Bridge upheld that contraceptive advice and treatment could be provided without parental consent as long as the child was sufficiently mature and had the ability to understand the advantages and disadvantages of the treatment⁶.

The principles of this case are now widely applied and Lord Scarman's comments regarding understanding and maturity are

often referred to as the test of 'Gillick competency'. The 'Fraser guidelines' are more correctly applied to the use of contraception.

Age 16 or 17

It is generally presumed that young people of 16 and 17 years of age are Gillick competent and have the capacity to consent to investigation or treatment. If they have *given* consent this cannot be overruled by a person with parental responsibility, although it can be overruled by the courts. If treatment is *refused* it may be possible in some instances for a person with parental responsibility to overrule the refusal, but in the case of elective dental treatment with or without sedation it is very difficult to proceed rationally without the consent of the young person concerned. Sensitive behaviour management is far more likely to deliver a successful outcome than coercion.

Younger than 16

Children under the age of 16 are able to consent for their own treatment or investigations if they are Gillick competent. There is a presumption, however, that children under the age of 16 lack the maturity and understanding upon which capacity to consent depends. It is the responsibility of the clinician to assess a child's level of understanding not only of the procedure itself but also the risks, benefits and alternatives. Frank discussion of the risks of GA, for instance, may be inappropriate.

A person with parental responsibility (PR) will usually consent for young people under the age of 16 as well as very young children. Where the risks are measurable as in the case of general anaesthetic the person with PR must fully understand the alternatives available.

Who Has Parental Responsibility?

The person holding PR must themselves have the capacity to consent. Two or more people may hold PR for a child, and there may be disagreement as to what is in the best interests of the child. Family life is increasingly complex. It is essential to establish who has PR, and to diplomatically ask questions when there is doubt.

Regional variation exists across the UK and the following information is based upon the law in England and Wales. The Department of Health provides information regarding the situation in Scotland and Northern Ireland⁷.

Mothers

- The birth mother will always have PR, and only an adoption order can remove this from her.
- Law relating to surrogacy is complex. **A surrogate mother** is the birth mother and therefore automatically has PR until this is transferred by means of a Parental Order or adoption by the intended parents.

Fathers

- **The biological father** has PR if he was married to the mother at the time of the child's birth, or if he subsequently marries the mother. He will continue to have PR even if they divorce.
- If the birth father is not married to the mother, but if the child was born after December 1st 2003 and the father's name appears on the birth certificate he will have PR.
- If neither applies, the father does not automatically have PR, but application can be made through a court for a

Parental Responsibility Order. Alternatively, if the mother agrees, a Parental Responsibility agreement can be made which confers joint PR.

Other situations

- **Foster carers** are unlikely to have PR.
- **Adoptive parents** have PR. An adoption order gives the adopter PR and removes PR from all other persons including the birth parents and Local Authority.
- A person may gain PR by becoming a legally appointed **Guardian** following the death of persons with PR.
- **Special Guardians**. It is possible for one or more individuals to be appointed as a 'Special Guardian'. This arrangement is a private law order made under the Children's Act 1989⁸ for children who cannot live with their birth parents but who have been offered a legally secure placement, often with a relative such as a grandparent. Unlike adoption, this does not end the legal relationship between the child and birth parents who continue to hold PR with restrictions. In most situations the Special Guardian can consent on behalf of the child without consulting the parents.
- **Residence Orders** have now been replaced by **Child Arrangement Orders**. These confer PR on the holder. The child must live with the person making the application.
- Under the Children's Act 1989, a **Local Authority** may acquire PR under an Emergency Protection Order, Interim Care Order or Full Care Order. This will be shared with the parents although the extent to which parents can exercise their PR can be limited. If the treatment is associated with significant risk as in the case of GA, it is important to research the background. The responsible officer of the Local Authority will often be the appropriate signatory, but where PR is shared there is a moral obligation for the parents to be suitably informed.

Adults Who Lack The Capacity To Consent

The Mental Capacity Act (MCA) 2005 and associated Code of Practice provide legislative guidance for everyone working with, or caring for, someone over the age of 16 who is unable to make their own decisions⁹. Capacity is, however, *decision-specific* and many individuals have the ability to make some choices within the framework of a bigger and more complex decision with appropriate support.

The Mental Capacity Act 2005

The Mental Capacity Act has five fundamental principles as listed in Table 1.

Table 1: Fundamental Principles of the Mental Capacity Act 2005

1. Always assume that a person has capacity unless it has been proved otherwise
2. Appropriate support must be given to support individuals to make their own decisions
3. Individuals retain the right to make what might be seen as eccentric or unwise decisions
4. Everything done for, and on behalf of an individual must be done in their best interests
5. The least restrictive option must be used to achieve any outcome

Mental capacity is the ability to make a decision. In order to give valid consent a person must be able to understand relevant information for long enough to make the best choice, and then be able to communicate their wishes in some way.

Deprivation of Liberty Safeguards

The Deprivation of Liberty Safeguards (DoLS) were introduced to protect the liberty of people who are living in residential care or in hospital for an extended period of time¹⁰. They form part of the MCA 2005 but are under review by the Law Commission because of serious failings. The Safeguards were extended in 2014 and it is likely that the term 'DoLS' will be replaced by a scheme of 'Protective Care'. A report to the Lord Chancellor is in preparation and should be available by the end of 2016.

Sedation or general anaesthetics that are used to facilitate routine dental treatment are short-term interventions and application for a Deprivation of Liberty to provide this treatment is rarely necessary. The Scheme of Protective Care may be more relevant in such situations and it will be interesting to see the recommendations in due course.

Assessment Of Capacity

A person is always presumed to have capacity in the first instance. Their behaviour, medical condition, apparent inability to retain information or the concerns of others may, however, suggest that capacity is lacking. In this situation an independent, non-judgemental and unbiased assessment must be made and documented using the two-stage test of capacity shown in Table 2. Forms to record the process are available through Local Authorities and NHS Trusts, and all professionals working with adults in health and social care can carry out capacity assessments and arrive at best interest decisions.

Table 2: The Two Stage Test of Capacity (MCA 2005)

1. Does the person have an impairment or disturbance in the functioning of their mind at this time?

- What is the diagnosis and how does this affect the person?

2. If an impairment or disturbance of the mind can be documented, does this mean that the person is unable to make the decision in question at this time?

- Does the person understand the information relevant to the decision?
- Has the person been able to retain the information long enough in order to make the decision?
- Can the person use and weigh that information? Do they understand the risks and benefits of making or not making that decision?
- Can the person communicate the decision?
- Does this person lack the capacity to consent?

Many conditions have the potential to affect capacity including learning disability, dementia, head injury or the effect of drugs. If the mental state of the person is short term or fluctuating it may be possible for the decision to be delayed, and it should be remembered that a patient affected by short-term memory loss may still have capacity, although the decision made may be quickly forgotten. Extreme anxiety (such as needle phobia), may also compromise the ability to make a rational decision, but an unwise decision does not necessarily mean that there is a lack of capacity.

All practical steps must be taken to help the person make and communicate their own decision. If it is helpful, someone known and trusted should be present at the time of the assessment although it is important to address the individual rather than the escort.

The focus of the assessment, the decision to be made, must be clearly defined. If verbal communication is limited or impossible, other methods of communication should be explored, such as the use of pictures or sign language. The language used should be simple, and understanding checked and documented by asking appropriate questions or asking the person to repeat relevant information. If necessary the person should be allowed more time to explore treatment options, perhaps with a Key Worker or Social Worker, especially when there is measurable risk as with the use of GA.

A record of the decision and how this was communicated must be documented. If there is evidence that the person lacks capacity, they cannot consent and there is a legal obligation under the MCA to act in the individual's best interests.

Arriving At A Best Interest Decision

Best Interest decisions are achieved through a process and should include consultation with people close to the person especially where risk is significant. Families, carers including Key Workers, Named Nurses and Social Workers may all wish to contribute. An Independent Mental Capacity Advocate (IMCA) *must* be appointed if 'serious' medical treatment (such as treatment under GA) is planned and if the person is 'un-befriended' - they do not have close friends or family who can represent them. Paid carers are unable to act as advocates for service-users because of the potential for conflict of interests, and it must be remembered that no one can consent *for* the person: decisions are made in the individual's best interests.

The process that leads to a Best Interest Decision questions the support that has been given to the patient in the hope that they will be able to make their own decision, the past and present wishes of the patient and any beliefs and values that might influence them. It is essential to consider whether the outcome could be achieved in a less restrictive way - perhaps the use of sedation rather than GA - and the views of those close to the patient should be documented with the final decision.

Summary Of An Approach To Consent

Consent must be obtained before any investigation or procedure. The process must always be documented. Written consent offers greater protection to both clinician and patient at all times and is essential where general anaesthetic or any form of sedation is planned, using an appropriate consent form.

1. In the case of children and young people, identify the person with PR.
2. Ask yourself if there is any reason to doubt that the patient/person with PR lacks capacity. If there is doubt, carry out a formal Capacity Assessment. Where capacity is found to be lacking arrive at a Best Interests decision after appropriate consultation. An IMCA should be appointed if the person is 'un-befriended'.
3. Where sedation or general anaesthetic are under

consideration discussion of risks, benefits and alternatives should be carried out in person at a separate appointment in advance of the procedure.

4. Consider the procedure itself and make an assessment of the risks and benefits including those associated with not having the treatment. Ask yourself, 'what risks would a reasonable person undergoing this procedure want to know?' 'What risks might be specific to this individual's circumstances'? Inform the patient of these risks in an appropriate way. If written, explore any concerns verbally and record these.
5. Consider the alternatives, and ensure that these have been understood.
6. Consider if there are any justifiable reasons why you might withhold information from the patient.
7. Check the patient's comprehension of what you have told them using an appropriate method of communication – e.g. verbal, non-verbal, picture cards.
8. Fully document the consent process in writing. NHS forms available for this purpose are
Consent Form 1: Adults
Consent Form 2: Children and Young People
Consent Form 3: For procedures that do not impair consciousness
Consent Form 4: Adults who lack the capacity to consent (supported by Assessment of Capacity and Best Interest's documentation)

Conclusion

Consent is a process which, although complex and occasionally time-consuming, should strengthen the relationship between clinician and patient, and when capacity is lacking, those who care for them as well.

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Ed – this article describes the situation in England and Wales. It may be different in Scotland and Northern Ireland.

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An Investigation into Dental Local Anaesthesia Teaching in United Kingdom Dental Schools

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Abstract

Aim: To review the current teaching of the use and administration of local anaesthesia in United Kingdom dental schools, along with their local guidelines and protocols.

Methods: A qualitative and quantitative questionnaire was sent to sixteen UK dental schools to probe the methods of local anaesthetic teaching within each school.

Results: 14 of the 16 schools replied and the responses show a variety of practices being taught in the dental schools. 2% Lidocaine 1:80,000 Adrenaline is the first choice local anaesthetic solution for the majority of clinical situations.

Conclusion: 2% Lidocaine with 1:80,000 Adrenaline remains the gold standard dental local anaesthetic with teaching about its safety and uses in all but a few situations. Most are taught the use of additional aids such as safety syringes and topical anaesthesia. There is variation with regards to the use of alternative anaesthetic agents.

Introduction

The teaching of pain control at undergraduate level is fundamental to the practice of dentistry. Pain and anxiety control is required for the provision of dental treatment, and thus the effective use of local anaesthesia (LA) is required for the majority of dental procedures. There is also anecdotal evidence that good standards of pain control may enhance a dentist's reputation¹. It has been suggested that teaching of LA in United Kingdom (UK) Dental Schools is not given the priority that it deserves.^{2,3}

This project explores the teaching of LA to dental students across the UK, analysing and contrasting the methods involved and providing an overview.

Materials and Methods

A qualitative and quantitative questionnaire (available on request from the author) designed to reveal teachings of LA and delivery

methods was sent to members of staff responsible for teaching LA (identified by contacting each Dean) at all UK dental schools offering a Bachelor of Dental Surgery or Master of Dental Surgery degree applicable through the Universities and College Admissions Service (n=16).

The questionnaire was designed through a student brainstorming session highlighting areas of LA teaching. Following pilots on colleagues and subsequent changes and ethical approval from the University of Bristol, Faculty of Medicine and Dentistry Committee for Ethics, the questionnaire was distributed by post followed by postal reminder six weeks later. Responses were returned by post to an independent member of staff at the University of Bristol so that any identifying features were removed to ensure anonymity. The data was analysed using simple statistical calculations within Microsoft Excel.

Results

Ten of 16 questionnaires were returned. Following postal reminders, four more responses were received equaling an 88% response rate.

TEACHING

Which department is predominantly responsible for teaching local anaesthesia?

Seven (50%) schools teach through a multidisciplinary team. Four (29%) and three (21%) schools reported oral surgery and restorative departments were mainly responsible, respectively.

When are students first taught anatomy, pharmacology and administration techniques?

Ten (71%) schools teach pharmacology and techniques in second year, with remaining schools (29%) teaching it in first or third years. Nine (64%) teach anatomy in first year and five (36%) in second year.

How is local anaesthesia taught?

The number of hours spent on teaching ranged from 2 to 201 hours. On average, most time was spent on self-learning methods and the least in tutorials as shown in Table 1.

Table 1 The average number of hours spent on each teaching method.

Method of teaching	Mean time (to the nearest hour)
Lectures	8
Tutorials	3
Practical	5
Self Learning	47
E-learning	11
Clinical	7
Other	22

Can students practice on colleagues before patients?

Ten (72%) schools allow this practice. Four (29%) schools did not for ethical reasons as shown in Table 2.

Table 2 Reasons for not being able to practise on colleagues

'can't get ethical approval'
'difficulty due to consent and ethical reasons'
'unnecessary use of medicines'
'decision made by school not to allow practice, but simulation with covered needle or on models allowed'

Which textbooks are recommended?

Ten (71%) schools recommend 'Pain and Anxiety Control for the Conscious Dental Patient' by Meechan, Robb and Seymour. Other texts recommended were:

- Introduction to Dental Local Anaesthetics: Evers H, Haegerstam (1990)
- Practical Dental Local Anaesthesia: Meechan JG, Wilson NHF (2002).
- Handbook of Local Anaesthesia: Malamed S (2004).
- Local Anaesthesia in Dentistry: Robinson PD, Pitt Ford TR, McDonald F (2000).

Table 3 The range of assessment methods used.

Response	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Clinical competency test		X	X	X	X						X	X	X	
Objective Structured Clinical examination				X		X					X			
Multiple Choice Questions		X										X		
Multiple Short Answers	X	X	X			X					X	X		X
Structured Clinical Operative Test	X							X						X
Not Specified							X		X	X				

Do you have any plans to change the teaching of local anaesthesia?

Four (29%) schools planned no changes. Two (14%) gave no response. Two (14%) specified movement towards e-learning. One (7%) planned more interactive learning to replace lectures. Another (7%) school reported introducing more clinical sessions and earlier in the curriculum. One (7%) reported introducing more hands-on practice before clinics. One (7%) school reported recent change to the Septodont Safety Plus system.

ASSESSMENT

How do you assess knowledge and skills?

Five assessment methods are used. Seven (50%) schools use clinical competency tests, three (21%) use OSCEs (objective structured clinical examination), seven (50%) use MSAs (multiple short answers), two (14%) use MCQs (multiple choice questions), three (21%) use SCOTs (structured clinical operative test) and three (21%) did not disclose. Eight (57%) schools used multiple methods. The responses are illustrated in Table 3.

ARMAMENTARIUM

Is the use of topical anaesthesia taught and which patients are recommended for topical anaesthesia use?

All (100%) schools teach the use of topical anaesthesia. Eight (57%) teach students to use benzocaine and eight (57%) to use lidocaine based topical anaesthesia. Two (14%) taught the use of both. All (100%) schools taught use of topical anaesthesia for anxious patients, thirteen (93%) teach the use of topical anaesthesia for children, eleven (76%) for use with special care patients and nine (64%) for use with all patients.

Which syringe systems are students trained to use?

Eleven (78%) schools use the Septodont Safety Syringe system. Three (21%) do not use a safety syringe system and only teach the use of traditional re-usable syringes. Two (14%) teach the use of both.

ANAESTHETIC SOLUTIONS

Which anaesthetics are available in your school?

All (100%) stocked 2% Lidocaine, 1:80,000 Adrenaline (Lidocaine). Twelve (86%) stocked 4% Articaine, 1:100,000 Adrenaline (Articaine). Eleven (79%) stocked 3% Prilocaine, Felypressin 0.03 I.U. per ml (Prilocaine+). Seven (50%) stocked 3% Mepivacaine (Mepivacaine). Five (36%) stocked 3% Prilocaine (Prilocaine). Four (29%) stocked 2% Mepivacaine, 1:100,000 Adrenaline

(Mepivacaine+). One (7%) school stocked 4% Articaine, 1:200,000 Adrenaline (Articaine+). A plain solution without a vasoconstrictor was available in 11 (79%) schools.

Which do you teach as first choice LA for infiltrations and blocks in adults and children?

All (100%) replied that Lidocaine was their first choice LA for infiltration and block techniques in adults and block techniques in children. One (7%) school placed Articaine as first choice for infiltration techniques in children while the remainder (92%) schools would recommend Lidocaine as first choice.

Please comment on solutions available for students and their supervision levels

All (100%) schools allowed students to use Lidocaine, Prilocaine and Prilocaine+. Five (36%) schools identified Articaine and Mepivacaine+ as unavailable for student use in infiltrations. Eleven (76%) schools indicated that Articaine solutions not available for use with blocks techniques by students.

The staff felt most confident in students' use of Lidocaine with the least supervision in comparison to other solutions, closely followed by Prilocaine+.

Articaine was also widely available for student use with infiltration techniques during their final year. Plain solutions of Mepivacaine and Prilocaine were available for student use in nine schools (64%), requiring the same supervision level as with Lidocaine.

Supervision levels decreased as students progressed from early clinical work to final year. This is accompanied by students being allowed access to a greater number of anaesthetic agents.

What is the maximum amount of anaesthetic you teach should be used for a healthy adult?

Most schools agreed on the maximum recommended dose (MRD)

Table 4 MRDs recommended to students for each LA solution.

Anaesthetic Agent	MRD (number of schools)
2% Lidocaine 1:80,000 Adrenaline	4.4mg/kg (11) 1/10th cartridge per kg (1) 7mg/kg (1)
4% Articaine, 1:100,000 Adrenaline	7mg/kg (10) 1/10th cartridge per kg (1)
4% Articaine, 1:200,000 Adrenaline	7mg/kg (7) 1/10th cartridge per kg (1)
2% Mepivacaine, 1:100,000 Adrenaline	4.4mg/kg (3) 1/10th cartridge per kg (1)
3% Mepivacaine	4.4mg/kg (7) 1/10th cartridge per kg (1)
3% Prilocaine	6mg/kg (7) 1/10th cartridge per kg (1)
3% Prilocaine, Felypressin 0.03 I.U./ml	6mg/kg (8) 1/10th cartridge per kg (1) 8mg/kg (1)

for each agent although there was some slight variation. The results are shown in Table 4.

Which LAs do you teach to use during the following situations (Table 5):

Most schools rarely deviate from Lidocaine even in adverse situations. The solutions indicated and contra-indicated for each situation are shown in Table 5.

Table 5 The LA solutions indicated and contra-indicated for adverse situations.

Situation	Indicated Solutions	Contra-indicated Solutions
Latex Allergy	Prilocaine+ 57% (n=9) Lidocaine 43% (n=6)	
Pregnancy	Lidocaine 86% (n=12)	Prilocaine+ 50% (n=7)
Unstable Angina & recent Myocardial Infarction	Mepivacaine 43% (n=6) Lidocaine 29% (n=4)	Lidocaine 36% (n=5)
Unconfirmed allergy to Lidocaine	Prilocaine+ 29% (n=4)	Lidocaine 50% (n=7)
Past Radiotherapy to Mandible	Mepivacaine 43% (n=6) Lidocaine 36% (n=5)	Lidocaine 21% (n=3)
Bisphosphonate Therapy	Lidocaine 79% (n=11)	
Any Cardiac Medication	Lidocaine 71% (n=10)	
Uncontrolled Hyperthyroidism	Lidocaine 57% (n=8)	Lidocaine 14% (n=2)

Are there any side effects attributed to the following and are there any circumstances to preferentially pick one of the following?

There are a range of side effects and indications for each local anaesthetic solution as shown in Table 6.

Discussion

TEACHING

Students' learning styles and preferences vary and using a range of teaching methods contributes to a student-centered education process in which students are more likely to engage and take responsibility for their own learning⁴. Students on average received more lectures than any other direct teaching method, however, lectures are not considered the best method of teaching if applied alone⁵. The trend towards more personal and interactive teaching such as seminars in medical education can lead to more effective learning^{6,7}, however, no school used seminars to teach LA and little time was spent in tutorials. As dentistry requires both knowledge and skill, learning from more traditional methods is useful for theoretical concepts, but patient outcomes improve when direct supervision of the student clinician is combined with focused feedback⁸. The use of a multidisciplinary team to educate students can enhance understanding and knowledge⁹. Becoming competent at the administration of LA involves clinical application of basic science topics; anatomy, biochemistry, physiology and pharmacology. Results show the appreciation of these topics as a pre-requisite to clinical practice.

Table 6 Side effects and indications for use as taught to students

Anaesthetic Agent	Side effects (number of schools)	Indication (number of schools)
2% Lidocaine 1:80,000 Adrenaline	Cardiovascular effects (4) Safe, few side effects (3) Non-specific adrenaline related (3) Pregnancy (1) Convulsions (1)	Gold standard (6)
4% Articaine, 1:100,000 Adrenaline	Prolonged anaesthesia/paraesthesia (7) Precipitate acquired methaemoglobinaemia (1)	Failed I.D block, mandible infiltration (9)
4% Articaine, 1:200,000 Adrenaline	Prolonged anaesthesia/paraesthesia (4)	Failed I.D block, mandible infiltration (3)
2% Mepivacaine, 1:100,000 Adrenaline	Adrenaline effects (2)	Lidocaine allergy (1)
3% Mepivacaine	Amide allergy (1) Methaemoglobinaemia (1)	Cardiovascular disease (4) Radiotherapy (1) Short duration of action required (1)
3% Prilocaine	Methaemoglobinaemia (1)	Avoid adrenaline (2) Short duration of action (1) Methaemoglobinaemia (1)
3% Prilocaine, Felypressin 0.03 I.U./ml	Pregnancy, induce labour (4) Use with cardiovascular disease (2) Methaemoglobinaemia (1)	Adrenaline sensitivity (3) Methaemoglobinaemia (2) Latex sensitivity (1) Contraindicated in pregnancy (1)

Practical teaching

Practising injections on colleagues before patients has long been a tradition in dental curriculums, however, four schools have abandoned this practice for ethical and moral reasons as the procedure carries risks with only educational benefits¹⁰. Historically students who are unwilling to take part have felt forced against their will¹⁰. Under UK law a clinician giving medications that can have unwanted side-effects to a patient who does not consent could be charged with assault or battery. Common side effects reported whilst practising on students include syncope, haematoma and trismus; conditions that normally resolve without further issue, however, persistent paraesthesia and students being pre-medicated with anxiolytic medications have been reported¹⁰. Practising on colleagues now appears difficult for some school Ethics Committees to justify and the approval for the use of pre-medication may now appear unattainable. The use of pre-medications by students may influence the ability of the student to perform the procedure as well, potentially compromising the ability of the student to retain the learning experience. Learning how to administer LA and understanding the patient experience to foster empathy is used for procedural benefits, however, introduction of medical simulation models may eliminate the need for this. Although unable to mimic real life experience, medical simulation models improve dental skills in addition to traditional methods and are becoming a key part in students' education. Medical simulation models vary from purely synthetic models, virtual reality to human cadavers.^{2,11}

Many students benefit from practice on colleagues and if appropriately consented should students be denied the opportunity of this experience? Consent is valid when there is

voluntary and continuous permission from a competent patient to receive a particular treatment. Dental teachers and students ought to be best informed of the purpose, nature, likely risks and any alternatives in order to give valid consent to aid a student's education in empathy.^{12,13}

Textbooks

Only a small number of textbooks were recommended from the vast array available. Texts by John Meechan (UK) and Stanley Malamed (USA) are popular among the schools and are seen repeatedly throughout literature related to LA.

Changes

There has been much movement towards e-learning recently but there is no significant difference between technology-based and conventional methods of delivery in learning outcomes¹⁴. Dr Paul Redmond, a well respected head of careers and employability at the University of Liverpool, claims that Generation Y (born 1982-2001) currently studying at University do not want computer based learning but would rather learning that is through mentoring, fun, multi-sensory and most importantly face-face¹⁵. It is believed that *Boomers* and *Generation X* (born 1943-1981), the *Digital Immigrants*, are forcing electronic learning methods upon *Generation Y* the *Digital Natives*. However, there is evidence of the benefits of e-learning in current medical education.¹⁶

Assessment

A range of assessment methods are used in dental education. Classic open ended written assessments can be less reliable in assessing than SAQs. However, MCQs may only test factual knowledge compared to higher-order cognitive skills in open

ended questions. OSCEs have become popular across dental education. These can prove both valid and reliable methods of assessment providing the length of the stations is adequate for the task. OSCEs can also offer the opportunity to test technical/practical skills in an examination scenario with simple checklist assessments. However, communication stations may be better assessed with scales. OSCEs have been shown to have a good impact on student learning but can come at an increased financial cost relative to traditional methods.

ARMAMENTARIUM

Topical Anaesthesia

Modern needles are sharp, with bevelled tips designed to facilitate atraumatic entry, reducing pain.¹⁷ However, many patients still delay or avoid dental care due to needle phobia. Topical anaesthetics can be delivered using sprays, gels or ointments and used to eliminate the unpleasant sensation of a needle penetrating the mucosa. The most commonly used topical agents in the UK being either 20% benzocaine or 5% lidocaine based, with neither proving to be better than the other.^{18,19} These benefits are supported by all schools teaching use of topical anaesthesia.

Syringe systems

Disposable safety syringes reduce sharps injuries by 5.3 times during re-sheathing and disposal, when there is the largest chance of needle stick injury.^{20,21} Disposable syringes do, however, carry a high cost of disposal. When a disposable syringe is used, the whole needle, body, anaesthetic cartridge and in some cases the handle are disposed into the sharps bin compared to reusable syringes, which only require disposal of the needle and anaesthetic cartridge. Sharps bin disposal costs are high and disposable syringes will fill these quickly. When added to the purchase of replacement disposable syringes, it may prove uneconomical compared to decontamination. The European Biosafety Network guidance on the Prevention of Sharps Injuries in the Hospital and Healthcare Sector in 2013²² recommends the use of safety systems becomes common practice and is understood by some to be mandatory.

Local Anaesthetic Solutions

Lidocaine's availability in all dental schools clearly shows it remains the UK's gold standard LA.²³ Articaine's availability in all dental schools supports reports that it is as revolutionary compared to Lidocaine as Lidocaine was to Procaine in its ability to achieve deeper and quicker anaesthesia; nevertheless it has been associated with higher levels of nerve paraesthesia. Articaine is the gold standard LA in many countries across the world. For example, Articaine makes up 92% of the dental LA market in Germany²⁴ and is the most popular LA in Canada.²⁵ Prilocaine+ was widely available, supporting it as a common alternative to Lidocaine.

Articaine use in children may originate from the theory that Articaine can penetrate hard and soft tissue more easily than other LAs, which is believed provides palatal anaesthesia through a single buccal infiltration eliminating the need for an further infiltrations.²⁶ However, other studies have failed to prove this theory.^{27,28} The use of Articaine in children has also been supported by Wright, who recommended its use in children under the age of 4 due to the high potency, reduced toxicity and lower recommended dosage when compared to Lidocaine.²⁹ The results show the most commonly accepted practice is the use of Lidocaine for most situations, and the use of Articaine in children is known but less frequent.

Supervision Levels

Supervision decreases with progression through the

undergraduate course and is highlighted as an area of education difficult to get right for all students.³⁰ The dental undergraduate course is aimed at teaching students to be competent beginners to enable safe practice once qualified. During first clinical contact, close supervision will be required to aid student confidence, knowledge and skills. When a student is believed to be competent, less direct supervision occurs, allowing students the confidence of achievement and preparation for life in independent practice. Some dentists find achieving anaesthesia a stressful experience³¹ and have expressed a desire for further training,³² thus reduced levels of supervision in senior years of training may not be preferred for all students.

Maximum Recommended Doses (MRD)

The MRD is developed to prevent the administration of toxic levels of pharmaceuticals. There are guidelines on MRDs for each LA agent originating from evidence-based literature, textbooks, pharmaceutical information leaflets and local health authority recommendations. UK dental schools show a general consensus as to the MRD, though there is an array of views and best practices outside the UK. For example most schools replied that a MRD for Lidocaine is 4.4mg/kg of body weight, the summary of product characteristics (SPC) from Dentsply claims 7mg/kg of body weight, and manufacturers of LA available in North America recommend 6.6mg/kg of body weight. The MRD recommended by all dental schools is consistently lower and more conservative than MRDs from pharmaceutical information leaflets and shows a conservative, safe approach being taught.

It is important to remember these are 'recommended' doses and it is up to the discretion of the operator as to when the limit has been reached. However, in the overwhelming majority of healthy adults sufficient anaesthesia should be achievable before the lowest of MRDs is reached. Factors affecting the MRD for a patient can be; time course of injection (bolus or infusion), site of injection, presence of vasoconstrictor, patient age, kidney function, liver function, pregnancy or other medications.³³ There have been attempts to clear up the confusion and produce coherent guidelines, however, most of the evidence used derives from case series or poor quality cohort studies.^{33,34}

Clinical Scenarios

Lidocaine has already been shown to be many dentists' gold standard anaesthetic of choice; however, deviation from this is indicated in some situations.

Latex allergy

Latex can be found in the plunger and diaphragm of some LA cartridges which can be released into the solution, however, there are no documented allergic reactions to latex from a LA³⁵ despite the incidence of latex allergy reported between 0.2%³⁶ and 38%³⁷. Not all LAs contain latex parts, as since 2007 all Septodont LA products are latex-free and Dentsply advertise their Citanest 3% with Octapressin product as latex-free. However, Dentsply's Xylocaine (Lidocaine) is not advertised as latex-free, which may explain why some schools did not recommended Lidocaine as an option, instead recommending Prilocaine+. Not all Prilocaine+ solutions are latex-free either as those with a ten-number batch/lot are NOT latex-free. Dentists must be aware of the differences between LA solutions and brands which must be assessed individually to detect the presence of latex and its suitability for latex allergy patients.

Pregnancy

No LA solutions contain confirmed teratogens, but all medicines should be used with caution during pregnancy. Felypressin is used to induce birth and its inclusion in Prilocaine+ solutions is thought possibly to induce birth such that many will avoid Prilocaine+. This is only a theoretical risk as the volume available in Prilocaine+ is very low compared to a dose used to induce birth. It is interesting that avoiding the administration of Felypressin is the reason given for avoiding the use of Prilocaine and Felypressin in pregnant patients. A more justifiable reason for the avoidance of Prilocaine is that of all the commonly used LA solutions, it is the one which crosses the placenta most and thus has the potential to affect the unborn child more than any other agent.³⁸

Unstable Angina, recent Myocardial Infarction & Cardiac medications.

Cardiovascular disease is one of the most common presenting medical history factors that the dentist will be faced with, with over 16% of the 75+ population suffering from angina, and over 13% of the 75+ population have suffered from a previous heart failure.³⁹

LAs are one of the safest medications available, being associated with complications six times less than with general anaesthetics. However, severe life threatening complications occurred at similar levels with LA (0.07%) and general anaesthesia (0.05%).⁴⁰ Adrenaline is thought to induce acute heart conditions, yet as the medical risk to the patient increases, the importance of effective pain and anxiety control becomes more important.⁴¹

Historically 100mg of Lidocaine was given intravenously to patients following a myocardial infarction to stabilise the cardiac membrane and remains in use for some arrhythmias. In this circumstance, it is clear that Lidocaine itself is safe for use for cardiac disease patients and that the majority of contra-indications are due to the adrenaline, although the guidelines remain unclear on this.

LA agents are not contra-indicated in patients on cardiac medication. The issues appear from the cardiac diseases themselves rather than the medication.

Unconfirmed allergy to Lidocaine

A true allergy of Lidocaine is rare; however, many patients report an allergic reaction to Lidocaine.⁴²⁻⁴⁴ Many experts support this and it is important to take a full history regarding previous experiences to help determine what might have happened to lead the patient to believe they suffered an allergic reaction to Lidocaine.²⁵

Past Radiotherapy to Mandible or Bisphosphonate Therapy

Reports claim that adrenaline-containing solutions should be avoided in radiotherapy patients⁴⁵ and those on bisphosphonate therapy due its implication with reduced blood supply to healing areas and possible avascular necrosis. Exodontia on radiotherapy or bisphosphonate patients is discussed in the literature with emphasis on the use of antibiotics, oral hygiene and hyperbaric oxygen chambers⁴⁶ with no clear guidance of recommended LA. The associated risk of Bisphosphonate Induced Osteonecrosis of the Jaws is rare and is only associated with patients taking high oral doses or intravenous bisphosphonates.

Uncontrolled Hyperthyroidism

The risks of adrenaline containing solutions have been recognized

with hyperthyroid patients although appears more theoretical than real.⁴¹ Due to the effect of uncontrolled thyroid hormone, patients often present with hypertension, arrhythmias and cardiac insufficiency.⁴⁷ Adrenaline should not be used to avoid the possibility of it potentiating the vascular effect of thyroid hormone. It is of concern that some dental schools appear to not make their students aware of this.

Are there any side effects attributed to specific LAs and are there any circumstances to preferentially pick one of the following?

The most common side effects and indications for use of each LA were mentioned. However, areas of disparity were highlighted. Nerve damage associated with Articaine use as an inferior dental nerve block is well documented in the literature and reinforced. Prilocaine+ is associated with prolonged lingual and inferior dental nerve paraesthesia at a similar level to Articaine,⁴⁸⁻⁵⁰ however, no school highlighted this. Perhaps the more recent introduction of Articaine into an evidence based environment has highlighted this with greater publicity compared to the older Prilocaine+ circumventing this initial critical appraisal and publicity of a new product. Both Prilocaine and Prilocaine+ were also indicated for use in patients when avoiding adrenaline or to use with cardiovascular disease. This is supported in the literature but Felypressin is also linked with cardiovascular side effects and should not necessarily be used as a benign alternative to adrenaline.⁵¹ It is of concern that students may not be made aware of these potentially serious risks.

Conclusion

Students receive a variety of both practical and theoretical teaching methods to aid their education via both 'traditional' and more recently developed methods. Each school uses a variety of LA products, with most schools now teaching the use of safety syringes and topical anaesthesia.

Lidocaine with adrenaline remains the UK's gold standard LA for almost all patients and situations. Students are made aware of alternative solutions and when to use them.

There are a number of discrepancies in opinion between dental schools (especially in relation to Articaine and Prilocaine) and this study highlights areas that would benefit from further recommendations by groups such as the Scottish Dental Clinical Effectiveness Programme or National Institute for Health and Clinical Excellence. In addition there may be a need to achieve consensus for teaching dental LA in UK dental schools.

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Oral Midazolam Sedation For Uncooperative Children In Outpatient Paedodontics: Time For Reappraisal

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Abstract

Sedation is frequently desired to facilitate dental procedures in uncooperative paediatric patients. Oromucosal Midazolam sedation is a popular choice among paediatric dentists world wide due to its many advantages such as ease of administration, good efficacy, presence of reversal agents and a wide margin of safety. On the other hand, many investigators have reported that midazolam sedation may not be successful for carrying out all types of dental procedures. This may be attributed to diverse nature of various treatment plans coupled with the extent of behavioural changes in the child and operator's experience. Due to the heterogeneity involved in treatment of paediatric dental procedures, the specific indications for oral midazolam use that ensure its success rate, probably need to be defined. This may enable the clinicians to have a convenient and quicker option for managing the cases rather than facing sedation failure or at times, ending up giving general anaesthetics. This article therefore brings forth the possible causes of midazolam sedation failure and proposes a 'case selection criterion'.

Introduction

The incidence of early childhood caries (ECC) is very high affecting nearly 40-50% of children below the age of six years.¹ The majority of these children are in pre-co-operative stage and may require sedation for dental rehabilitation. Older children with behavioural problems are also candidates for sedation/anaesthesia for dental treatment. Over the last decade paediatric dentists have shown preference for use of sedation/anaesthesia over aversive techniques.² The reasons may be due to (i) an increase in the prevalence of early childhood caries (ii) increase in general awareness among parents (iii) increase in number of children with behaviour and emotional problems³ (iv) changing mindset of parents with majority of them not comfortable with the use of aversive technique^{4,5} (v) undesirable multiple visits by busy parents

with limited time at their disposal or those reporting from distant places. Although conscious sedation has been successfully administered outside the operating room, dental procedures pose unique challenges rendering a difficulty to complete treatment at times. The aim of this article is to highlight the probable causes of midazolam sedation failure and bring forth case selection criterion to improve sedation outcomes.

Oral Midazolam: Advantages/ Limitations in Paediatric Dental Sedations

Advantages: Midazolam is a favoured drug for conscious sedation procedures as it offers fast onset of action with quick recovery,⁶ has an excellent safety profile,^{7,8} a reliable dose dependent anxiolysis⁹ with a low-grade anterograde amnesic effect.^{10,11} In addition to relaxing the child and improving their disposition, the use of oral midazolam appears to have a synergistic effect with behaviour management techniques, contributing to a successful dental treatment.^{12,13}

The oral route is considered the most convenient and acceptable as it is rapidly absorbed with a reported bioavailability of 30-50%.¹⁴ Further oromucosal administration of midazolam improves its bioavailability to nearly 75%¹⁴ with very few reported side effects. Limitations: Certain adverse experiences have been reported such as hiccups, coughing, nausea and vomiting. Paradoxical reactions of midazolam have also been recorded in children, which include hallucinations, agitation, inconsolable crying, restlessness and disorientation.^{8,15}

The limitations of oral midazolam include a poor depth of sedation,¹⁶ poor analgesia¹⁷, respiratory depression^{17,18} and a short duration of action. The analgesic effect of intravenous midazolam

has, however, been documented in adult human volunteers.^{19,20} The major limitation is that it is associated with an unacceptably high failure rate during dental procedures in paediatric patients.^{21,22}

Based on dental records of 101 children aged 1-11 years, a retrospective study reported significant differences between Leeds and Westmead Hospitals with respect to success rates (65% vs 91% respectively) using oral midazolam. The authors concluded that oral midazolam sedation is not a general panacea for the dental treatment of young children and its use should be restricted to simple restorations and extractions.²¹ In another study, Erlandsson et al.²² evaluated a large sample (n=160) to study the effect of oral midazolam (0.2 mg/kg body weight) in paediatric patients aged 1 to 14 years. Local anesthesia followed by restorative treatment and/or extractions constituted more than 90% of the performed treatments. Of the 250 sessions, a failure was reported in 7% of sessions on children sedated with oral midazolam with only 63% cases having been performed with total acceptance and 30% with doubtful acceptance. A Cochrane database subsequently reported that current evidence supporting the use of oral midazolam in providing a cooperative child for completion of dental treatment was rather weak.²³

Since oral midazolam, as a sole sedative, is associated with variable success rate in children, we need to identify reasons for sedation failures, which add to the treatment cost, psychological trauma to the child and distress to the parents.

Possible Reasons For Failure Of Oral Midazolam in Paediatric Dental Sedations

As the child's active co-operation for adequate mouth opening is required throughout dental treatments differ from other out patient procedures under sedation. The sight of the operatory dental equipment, loud noise of the air turbine, fear of local anaesthetic injections, etc. also enhance a child's anxiety^{24,25} and may result in a paradoxical hyperactivity. The operator's behaviour management skills, pre-treatment anxiety levels of the child, as well as the nature of the dental procedure, become significant factors in determining successful outcome. We propose criteria for case selection of oral midazolam use in paediatric dental sedations (Table 1).

It has been based on four important factors that may influence the outcome of a conscious sedation procedure, which are (i) the anxiety levels of the child (ii) the age of the child (iii) the complexity of the treatment planned and (iv) operator's experience in behaviour management. The Modified Venham's Scale (Fig.1)²⁶ is used as it describes the behaviour displayed under each score very elaborately allowing the clinician to differentiate adequately between slightly, very nervous and extremely nervous behaviour and thus aids in better clinical judgment in giving a particular score to the described behaviour. Additionally it includes scores for mild to moderate anxiety (Scores 1,2,3) and hence can be applied to majority of the population.

Table No. 1: Case Selection For A Dental Sedation Procedure

Anxiety Score	Procedure	Oral Conscious sedation	General Anesthesia
Venham Score 0-2, Behaviour appropriate of 0-4 year age group	Minor procedure or restoration with no previous negative history	Yes (Depending on operator's skills*)	Failed conscious sedation
Venham score 0-2, Behaviour appropriate of 0-4 year age group	Complex procedure; extraction or RCT, no previous negative history	No	Yes
Venham score: 3 +, Behaviour appropriate of 0-4 year age group	Any procedure	No	Yes
Venham Score -0-2, Behaviour appropriate of 4-7 year age group	Complex procedure, no previous dental history	Yes (Depending on operator's skills**)	Failed conscious sedation
Venham Score: 3, Behaviour appropriate of 4-7 year age group	1. Previous dental history of co-operation but does not accept fear evoking procedures like LA. 2. Treatment requiring extraction	Yes	Failed conscious sedation
Venham Score: 4+, Behaviour appropriate of 4-7 year age group	Minor Procedure	Yes	Failed conscious sedation
Venham Score: 4+, Behaviour appropriate of 4-7 year age group	Multiple Complex Procedures	No	Failed conscious sedation
Venham Score: 3, Behaviour appropriate of 7+ year old	Any Procedure	Yes	Failed conscious sedation

*Can be taken straightaway for general anesthesia if operator not skillful in handling such a young child or referral to a more trained clinician.

**Can be managed without sedation depending on operator's skills

Therefore, in brief, a young child (aged up to 4 years) with no apparent anxiety or behaviour problem reporting for the first time for minor restorations would perhaps be a good candidate for mild sedation depending on the operator's skills whereas for a more painful procedure (extractions/root canal treatment), deep sedation would be a better choice. Slightly older children, between 4-7 years are usually more amenable to the routine behaviour management techniques, can communicate well and tend to settle down for a dental procedure after a few visits. Mild sedation may be considered if this child does not accept fear-evoking steps like administration of local anaesthesia or rubber dam. A few, however, may not show a good compliance and even show a progressive worsening of behaviour or complete refusal to accept treatment. Such cases can be better handled under deep sedation/general anaesthesia, especially when treatment is extensive and needs to be delivered without delay. The older children above seven years of age, may show mild apprehension towards dental treatment initially, but are mostly managed well without sedation. These case based criteria, provides us with a more objective evaluation for case selection under sedation and may be associated with higher success rates. However, this needs to be validated with the help of randomised trials.

It is very important with any procedural sedation to be ready with an alternate plan, in case of sedation failure. The other pharmacological agents used in paediatric dentistry, apart from midazolam, are ketamine,²⁷ propofol^{28,29} and sevoflurane.³⁰ These drugs provide moderate to deep levels of sedation depending upon the route and dose administered. Additionally, these drugs require administration by a trained health care professional in a fully equipped operator, who can vigilantly assess the depth of sedation and deftly manage complications should they arise.^{31,32} In an attempt to increase success of sedation, some authors are tempted to administer a mixture of various sedatives. This kind of polypharmacology should ideally be avoided as in case of an adverse event it may be difficult to identify the causative factor and thus its treatment. It is pertinent to mention here that the safety of the child is of paramount importance and standard guidelines should be adhered to before performing any kind of sedation.

Conclusion

Use of midazolam offers the paediatric dentist another option in their armamentarium where behaviour modification techniques prove deficient to render care. Despite the ease associated with its use, there are certain variables affecting the success of midazolam sedation such as age of the child, previous negative dental history, invasiveness of the procedure, length of the procedure, environment in the operator and the operator's experience. This is perhaps due to the fact that the child's active co-operation is required throughout for adequate mouth opening during the treatment. Therefore, if used with correct indications in place a successful treatment may be offered to a child in dental operator without resorting to deep sedation or general anaesthesia for all cases.

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A Clinical Audit of Escorts' Awareness And Patients' Safety Following Intravenous Sedation In Adult Oral Surgery

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Abstract

Aim: To evaluate current level of safety under the care of an escort following intravenous sedation, post-sedation arrangements and to identify potential risk levels.

Background: Information and post-sedation arrangements are important to patients' safety following surgery but although there is a general consensus over what is recommended for patients and their escorts, there is little, if any, literature on the escorts' awareness of sedation and accordance to post-sedation arrangement and recommendations.

Method: Escorts of 113 consecutive patients treated in oral surgery under sedation (midazolam) completed a questionnaire composed of 27 questions divided into seven sections including demographics, awareness of sedation, source of information and post-operative arrangement. From the data collected, two scores were calculated representative of the escorts' Safety and Reliability. Data were then analysed by ANOVA.

Results: Safety scores were statistically correlated with instruction source while Reliability correlated to a wider variety of parameters including gender, age as well as information source.

Conclusion: Provision of clear written information to escorts is recommended as likely to improve patients' safety. Assessment of escorts' Safety and Reliability could provide a means for improving quality and safety of sedation service.

Introduction

Single drug intravenous sedation with midazolam (IVS) delivered by an operator-sedationist is a technique used widely in the delivery of oral surgery services. It is useful to facilitate the treatment of highly anxious or phobic patients undergoing routine dental extractions, allowing general anaesthesia to be avoided and is also of benefit in facilitating the treatment of mildly-anxious patients undergoing a single episode of minor oral surgery.¹ Dental anxiety is recognised by the 2009 UK Adult Dental Health Survey² as a potential barrier for a patient to access dental care; its prevalence, assessed via the Modified Dental Anxiety Scale (MDAS)³ has been estimated at 49%

including moderate anxiety (36%) and severe anxiety / dental phobia (12%). The use of IVS for patients who are at risk of acute exacerbations of concomitant medical conditions (e.g. epilepsy and hypertension) during stressful oral surgery procedures is also recognised.^{1,4,5}

Regardless of the clinical setting in which IVS is delivered, guidelines require that following IVS a patient should be discharged in the care of a competent adult who assumes the role of the patient's escort.^{1,4,5} An "escort" is defined as a responsible adult and it can be paralleled by the Police and Criminal Evidence Act (PACE)⁶ definition of an appropriate adult. In the context of IVS, the escort is responsible for ensuring that the patient reaches their residence safely and that an appropriate level of support and care is available to them until recovery is complete;⁷ it is expected that escorts are informed about post-operative instructions.¹

Practice varies widely in terms of the nature and depth of information provided to escorts about the after effects of sedation in order to inform them of what their role entails. In most circumstances no formal assessment of the escort's ability or appropriateness to assume this role or care for the patient is made prior to the surgery appointment. Some centres request written acknowledgement of the receipt of written information, whilst others only ensure basic requirements are met (lack of physical impairment, adequate mobility, absence of accompanying children or others to care for etc.).⁸

The pharmacological effect of Midazolam usually extends beyond the time at which a patient is discharged from the clinical environment and it is therefore reasonable to assume that following sedation a patient might be at risk of harm if not adequately supported; hence the importance of having a suitable escort and post-operative arrangements to ensure the patient's safety during this time.⁹⁻¹⁰

We have been able to identify only anecdotal reports of adverse events involving patients who have undergone IVS and although likely to be rare, such episodes are likely under-reported.^{8,11,12}

Current protocols pertaining to consent and delivery of treatment under IVS at King's College Hospital Dental Institute require a two stage process where an assessment precedes the surgical treatment

under IVS.^{1,13,14} Assessment and consent for IVS follows discussion indications, risks and benefits alongside alternatives (LA and GA where appropriate) supported by an information leaflet on IVS¹⁵ for the patient to keep and review at home. Written instructions also include a checklist, released alongside the appointment letter, listing preparation and precautions required by both the patient and escort prior to treatment and afterwards. On booking their appointment patients are given further verbal instruction that they must be accompanied by an escort and the role of this second person in caring for and supporting them on the day of treatment.

On the day of treatment, patients are registered and clerked for treatment only if attending with an appropriate, autonomous adult escort and not accompanied by others who might need care (e.g. children). During the postoperative recovery period the escort (in the presence of the patient) receives verbal information on the persistent effects of sedation beyond discharge; advice on post sedation care arrangements and both written and verbal postoperative care instruction.

The primary aim of this audit was to identify potential risks to the patients following IVS at King's College's Oral Surgery unit as a result of being accompanied by an unsuitable or inadequately informed escort or as a consequence of inadequate post-sedation arrangements. We assessed the adherence to post-sedation care instructions as recommended in national and local guidelines to which the escorts accompanying patients treated in the department had been asked to conform.¹⁶ The escort's understanding of the effects of sedation, their knowledge of patients' general medical status and likely needs following sedation were assessed using a self-completed questionnaire. As a secondary outcome measure, data was collected and analysed to identify aspects of current practice which could be improved and any additional safeguards needed that could reduce the risk to patients following discharge.

Materials and Methods

Audit design

A prospective audit was conducted for a seven day period in November 2012 at King's College Hospital Oral Surgery department's outpatient clinic. 113 consecutive patients and

escorts attending for elective dental extraction under IVS with intravenous midazolam were invited to participate in a brief survey.

Patients were screened for relevant medical history and allocated according to the American Society of Anesthesiology (ASA) classification, ASA I-IV¹⁷, see Table 1.

All patients were presumed to have sufficient capacity to decide on their own dental treatment and in none of the patients there was any doubt over mental capacity;¹⁸ they all went through a two stage consent procedure according to King's protocols: A first stage consent was obtained in advance of the procedure and they were given informative leaflets on Intravenous Sedation for Dental treatment,¹⁵ whilst a second stage confirmation of consent was obtained prior to treatment.

Two patients were underage (14 and 17 years) and were accompanied by one of their parents for both assessment and treatment.

Escorts' participation in the survey was voluntary and their consent was sought after the surgical procedure was completed hence had no effect on clinical care.

After the recovery nurse had attended to the sedated patient in recovery room, the escort was asked to complete a brief questionnaire; assistance in understanding questions and tasks was offered to escorts by one of the auditors when required. The aim of the audit was to survey escorts' demographics, information level and source on IVS, post-sedation arrangements and to correlate data to an estimate of their reliability and patients' post sedation safety.

Questionnaire

The questionnaire consisted of 27 questions and was divided in to seven sections covering key survey areas, see Table 2, each introduced by a brief description to support escorts' understanding of the purpose of the questionnaire.

Data collected covered aspects of patient and escort demographics, information level and source, pre- and post-

Table 1 - American Society of Anesthesiologists (ASA) Physical Status classification system¹⁷

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient Healthy	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI)
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI,TIA,CVA or CAD/Stent ongoing cardiac ischemic or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis.

Table 2 - Questionnaire sections' titles and description.

1	Yourself	<i>This section will give some more insight on who our escorts are and what they do.</i>
2	Before the appointment	<i>We would like to know a bit more on how patients and escorts prepare for the appointment.</i>
3	Transport	<i>The journey home is particularly important to ensure the patient gets home smoothly.</i>
4	The patient	<i>Here we are looking at your relationship with the patient and your awareness of his/her health status.</i>
5	Sedation Awareness	<i>Being aware of what sedation is and how it affects patient abilities is considered helpful information for the escort to have. What about you?...</i>
6	Sedation Recovery time	<i>The effects of sedation are deep during the surgery and then gradually fade out. What would be your estimate of the recovery time for these effects?</i>
7	Post sedation arrangement	<i>We would like to know who will be with the patient at home following the sedation later the same day and overnight.</i>

operative arrangements and relevant medical information. To achieve the audit aims, we designed two empirical scores to assess escorts' responses and to rank their safety and reliability primarily based on the escort's awareness of the duration of the effects of IVS and their knowledge of co-morbidities of their accompanying patient.

The design of the questionnaire and the scoring algorithms was the result of a team discussion and aimed at collecting significant data to discriminate a "safe" from an "unsafe" escort within an allocated 5-10 minutes time to complete and using a single A4 sheet to minimise costs and impact on the normal running of the clinic.

Safety and Reliability scores

Sections 4, 6 and 7 of the questionnaire covered the escort's awareness of the patient's medical condition, an estimate of IVS effect and post-operative arrangements and were designed to include items of direct relevance for the patient's care. These sections were assigned two scores - referred to as safety and reliability- based on their impact on post sedation care. Scoring was weighted to reflect aspects relevant for the escort's safety and reliability taking into account the patient's ASA status as a positive modifier to account for the potentially more serious adverse events in medically compromised patients, see Table 3.

Safety Score

Safety score (0-3 / Safe 0 - Unsafe 3) was derived from escorts' estimate of sedation effects, patients medical history and circumstances.

In particular it focused on escorts' understanding of patients' medical conditions and recovery times or having ill-planned post-operative arrangements.

The total score was obtained by adding up all parameters; Overestimate of sedation effect was not considered to affect safety, while under-estimation was each given a score of 1 or 2 based on patient's ASA status.

Escorts' understatement of patients' medical status from III-IV to I-II was considered to affect safety while an overstatement (i.e. ASA I-II to ASA III-IV) was considered not to.

Being unaware of one or more of the patients' factors (smoking, Rx, etc.) or having poor post sedation arrangements was considered to affect safety and was scored in a non-cumulative way (i.e. max score 1).

Reliability score

Reliability score (0-20) was also calculated from escorts' knowledge of sedation and of the patient and takes into consideration the accuracy in estimating the effects of sedation and not just of the ability.

Each estimate outside the accepted range was considered indicative of lack of awareness and weighted differently according the seriousness of the corresponding risk.

The knowledge of patients' factors (smoking, Rx, etc.) is considered per item in a cumulatively way (i.e. max score 3).

Table 3 - Safety and Reliability scoresheet

Extracts from sections 4,6,7 of the escort questionnaire are presented (text explanations omitted) and in the two right columns the relative scores.

Section 4: Medical status						Safety score	Reliability score
Escort's knowledge of patient's medical status in an ASA-equivalent scale (I to IV)							
To your knowledge the patient's Medical conditions are:	Very good					For answer correspondent to patient's ASA status:	For answer correspondent to patient's ASA status:
	Minor issues (eczema, hayfever...)					0	0
	Some problems (Blood Pressure, Asthma, Diabetes, Depression)					For underestimate of ASA status	For answer different to ASA status
	Not very well (Serious conditions, hearth problems, stroke, cancer)					If pt ASA II-II	If pt ASA II-II
	Unwell (frequently in hospital)					+1	+1
					If pt ASA III-IV	If pt ASA III-IV	
					+2	+4	
Does he/she takes medications?		Y	N			If any answer incorrect +1	For each incorrect answer +1
Does he/she have any Allergies?		Y	N				
Is he/she a smoker?		Y	N				
Section 6: Risk Awareness						Safety score	Reliability score
Estimate the time in Hrs or minutes it will take before the patient:							
		Accepted range**				If any value under accepted range	For each value outside range (*) If pt ASA=III/IV
Can walk unassisted		60'	240'			If pt ASA=I-II	+2 (+4*)
Is not drowsy anymore		80'	300'			+1	+2 (+4*)
Can make tea		3Hr	12Hr				+3 (+5*)
Can drive		16Hr	48Hr			If pt ASA=III-IV	+4 (+6*)
Can be left alone at home		8Hr	24Hr			+2	+4 (+6*)
Section 7: Post sedation arrangement:						Safety score	Reliability score
Persons present at home daytime							
Suitable combinations**						Max for Section 7 +1	
A Me	B Family	C Friends	A, B, C	B, D, E	C, E	Suitable combination 0	
D Children	E Nobody	F Don't know	A+E	B+E		Unsuitable combination +1	
Persons present at home overnight							
Suitable combinations**							
A Me	B Family	C Friends	A, B, C	B, D, E	C, E	Suitable combination 0	
D Children	E Nobody	F Don't know	A+E	B+E		Unsuitable combination +1	
						Range 0-3 (if >3 =3)	Range 0-20 (if >20=20)
** not shown in original questionnaire						0 = Safe	0-5 = Reliable
						1 = No concerns	6-10 = Good
						2 = Minor concerns	11-15 = Sufficient
						3 = Unsafe	16-20 = Unreliable
Questionnaire template available from the authors on request							

Statistical analysis

Questionnaires collected were anonymised and input into a datasheet for analysis alongside the calculated Safety and Reliability scores.

Data obtained were analysed by Fisher's exact test, Pearson's correlation analysis and by analysis of variance (ANOVA). Significance was considered at p-value ≤ 0.05 . All analyses were performed using Minitab® 16.1.1 software.

Results

Of 113 escorts, 109 agreed to participate in this audit. In two cases, however, the recovery circumstances did not allow the questionnaire to be administered (one escort left before completing the questionnaire and another withdrew for undisclosed reasons), so these were excluded from the analysis.

Demographics

Patients

The cohort analysed consisted of 109 patients 70 were females covering an age range from 14 to 78 years (mean 38.5 ± 15.6 years). 94% of patients were either ASA I or II while six were ASA III; no patient in this cohort was ASA IV.

Table 4 - Demographics of patients and escorts

Patients' ages were recorded as exact values whilst escorts' ages were recorded by age-group; for comparison purposes patients' ages are presented in a matching age-group format

	Data n (%)								
	Age			Gender		Medical status (ASA equivalent)			
	18-29 yrs	30-55 yrs	56-75 yrs	Males	Females	1	2	3	4
Escort	36 (33%)	49 (45%)	24 (22%)	50 (45,9%)	59 (54,1%)	-	-	-	-
Patient	43 (39,4%)	50 (45,9%)	16 (14,7%)	39 (35,8%)	70 (64,2%)	83 (76,1)	20 (18,3%)	6 (5,5%)	0

Escorts

Of the 109 escorts 59 were females (M:F ratio 0.84:1; their age was acquired by age group rather than by exact value; when patients were grouped by age for comparison the escorts appeared slightly older than the patients although the difference was not significant.

Recovery period following IVS

We included 5 items to assess the escort's perception of the recovery period.

Between 27% and 39% of the 109 escorts underestimated the duration required for recovery among at least one of the effects of sedation. Time taken for the recovery of complete consciousness was the worst underestimate. Overestimates were less frequent ranging from 0% and 20%.

Table 5 - Escorts' performance in completing section 6 of the questionnaire^{Tab3}: In bold % of underestimate of recovery time

	Data n (%)								
	Age			Gender		Medical status (ASA equivalent)			
	18-29 yrs	30-55 yrs	56-75 yrs	Males	Females	1	2	3	4
Escort	36 (33%)	49 (45%)	24 (22%)	50 (45,9%)	59 (54,1%)	-	-	-	-
Patient	43 (39,4%)	50 (45,9%)	16 (14,7%)	39 (35,8%)	70 (64,2%)	83 (76,1)	20 (18,3%)	6 (5,5%)	0

Safety and Reliability scores

Safety and Reliability scores showed a bell shaped distribution, meaning that escorts' scores are not evenly distributed across the scale but tend to cluster around an average value, roughly in the middle, while fewer and fewer escorts return scores towards the edges of the scale; such a distribution of results is a prerequisite for statistical analysis based on variance as the predictive model assumes such a distribution of results (i.e. Normal distribution).

The most represented scores were 1 for safety (46%) and between 1-5 for reliability (41%).

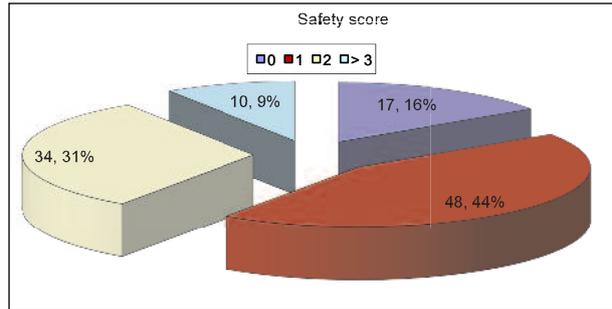


Figure 1 Safety score 0-3 : Distribution fractions presented (number, percentages)

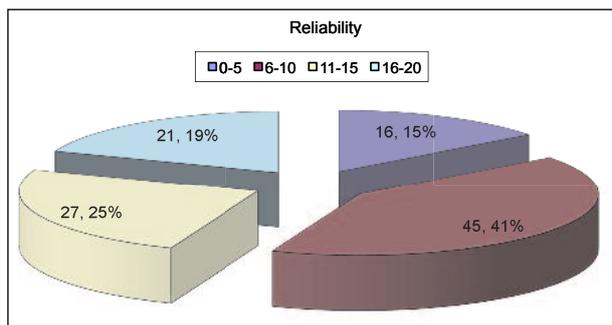


Figure 2 Reliability score 0-20: Distribution fractions presented by groups: 0-5 = Reliable, 6-10 = Good, 11-15 = Sufficient, 16-20 = Unreliable (number, percentages)

Statistical analysis

ANOVA of Safety and Reliability scores against demographics showed close but non-significant correlation between reliability score and Gender (p 0.053) while a significant correlation was seen between reliability and source of information (p 0.004).

Table 6a - ANOVA of Safety and Reliability scores against demographics and Information level and source

Parameters	ANOVA	
	Safety p-value	Reliability p-value
Patient Age	0.129	0.347
Escort Age	0.881	0.530
Patient Gender	0.888	0.053
Escort Gender	0.809	0.236
Transport	0.160	0.390
Relationship	0.557	0.907
Occupation	0.482	0.755
Information level (any source)	0.120	0.004
Information sources		
Verbal information	0.603	< 0.0005
Written information	0.022	0.002
Internet	0.032	0.008

Group analysis for Gender and source of information (by contrasting gender and means of information in correlation to safety and reliability) showed significant differences with females performing better than males (p values ranging from 0.02 to 0.011).

Table 6b - ANOVA of Safety and Reliability scores group analysis for gender and information source

ANOVA Group analysis		
Information source by gender	0.405	0.020
Verbal Information by gender	0.537	0.015
Written Information by gender	0.398	0.011
Male: No info vs Written / Verbal		0.038
Male Written vs Verbal		0.050
Male: No info vs Verbal		0.554
Male: No info vs Written		0.017
Female: No info vs Verbal		0.044
Female: No info vs Written		0.039
Internet excluded from ANOVA for statistical reasons (insufficient data)		

Considering each gender separately there were significant differences in the way they assimilated information depending on its source.

Among male escorts, there was no significant difference between no-information and verbal information (p 0.554) whilst written information resulted in increased reliability (p 0.017) and among female escorts verbal information was sufficient to achieve increased reliability (p 0.044).

Discussion

109/113 escorts returned the completed surveys (96.5%) indicating a very good compliance that eliminated any bias, and ensuring that the analysed sample was representative for patients/escorts reporting to the Department at the time.

The demographic distribution of patients by age and ASA status of this cohort reflects the referral base treated at King's Oral Surgery departments. Escorts' age seemed greater than that of patients' albeit not significantly, possibly due to the data collection method (exact age for patients / range for escort); this reflects how commonly parents attend as escorts for their adult daughters, sons.

A safety score of 3 (unsafe) was relatively rare in this group with an incidence of 9%. In our opinion this score was representative of escorts whose knowledge and/or arrangements were insufficient to guarantee a desirable level of post-operative care for a sedated patient.

The analysis and scoring of the questionnaire was done retrospectively after the completion of all the questionnaires and therefore no action could be taken for these "unsafe" instances; although in instances such as those we expect special recommendations to be made to an escort such as provision for private versus public transport or ensuring other family members being present at home. No formal record is kept of any variation from normal post-IVS recommendations.

Reassuringly, to our knowledge, no adverse incidents were reported in relation to the patients in this cohort.

However, it is difficult to quantify risk exposure due to poor post IVS care, nevertheless it appears logical that improvements in their awareness and information levels may reduce the frequency of an "unsafe" escort.

A reliability score over 15 was judged as indicative of an escort lacking awareness of IVS effects on their patient and, whilst this did not imply unsafe or inadequate arrangements, it renders post-IVS care as potentially unpredictable and potentially unsafe. In this sample 19% of escorts were found in this category, the majority showing over-estimate of IVS effect which can be described as being over-cautious rather than unsafe.

Nevertheless this indicates that about 1/5 of escorts had less than desirable knowledge and preparation to best look after their accompanied patient.

Since the ANOVA highlighted escorts' gender and information level as factors influencing safety and reliability, we tested these parameters further with group analysis, for differences between genders and sources of information.

The reliability score was significantly correlated with the level and type of information received by the escorts. It needs to be noted that both scores are independent from the information section in the questionnaire Tab3 and that therefore these two sets of data are suitable for comparison. The correlation (p 0.004) is a true reflection of the significance of information on the escorts' ability to correctly estimate IVS effect and to arrange appropriate post-IVS care. These results imply that a good level of information is a predictor for an escort's high reliability.

A correlation between information level and reliability was significant for both genders with between-gender differences in relation to information sources.

In the female group, the effect of receiving written or verbal information was similar (p 0.044, p. 0.039), i.e. either information source resulted in significantly greater reliability. Male escorts seem to respond to written information with increased reliability in a similar way to that of females (p 0.017) while the contrast between "no-information" and verbal information was not significant (p 0.554) meaning that receiving only verbal instruction does not seem to affect the reliability level in male escorts.

It is impossible to infer the reason behind such striking gender difference, although conjecture may be made about relevant factors; for instance most of the recovery nurses are females and there might be greater communication difficulties between genders in addition to a complex of social and cultural factors. Studies have shown both patient's and physician's gender having a relevant impact on communication.¹⁹

It seems that relying on verbal instruction only is not sufficient to increase escort reliability due to gender differences.

No significant correlation was found between the demographic and information source and the safety score; nevertheless, as the safety and reliability scores are derived from the same set of data in a similar manner it is logical to assume that they would be influenced by the same factors. Therefore it can be inferred that increasing the level of information of the escort would result in greater safety.

Limitations of the audit:

This audit has several limitations, some depending on the design and resources available and others unforeseen during the design phase.

The questionnaire was administered in an open recovery area, where four to five patients are attended to simultaneously; in the majority of cases no physical barrier is put between patients and it is normal for escorts to listen to instructions given to other patients.

Furthermore the questionnaire was administered only after post-operative instructions were verbally reinforced by the discharging nurse.

This makes it likely that the escort was exposed to relevant information shortly before completing the questionnaire, influencing their answers. Although this was, in theory, a less desirable setting than the escort completing the questionnaire in isolation without external influences, it was judged as impractical and, to an extent less representative of the true level of knowledge of escorts upon discharge as it was felt that a significant part of the escort's understanding of IVS is formed during the patient's recovery.

Ideally, this contribution to an escort's IVS knowledge could be estimated by contrasting an assessment before and after patient's recovery, however, this report is of a service audit and not a full research study. This could be considered in more rigorous research designs.

The scoring of safety and reliability was completed retrospectively and the audit end point was at patient discharge; this did not allow for immediate measure on suspect "unsafe" escorts and no post-operative survey was conducted to highlight unreported adverse episodes.

The outcome of this audit and the scoring algorithm used would allow in future for it to be used as real-time assessment tool of escort safety allowing for immediate action, it being a special arrangement and follow up, or even cancellation of IVS treatment.

Conclusions

Risk management is a key issue in the whole delivery of sedation service and as highlighted it does not end with discharge. Although upon discharge the responsibility for the patient falls on the escort, it is the duty of those discharging the patient to ensure that the escort and post sedation arrangements are adequate. Simple aspects of post sedation care could easily be overlooked such as will the patient take their medication? will he/she fall asleep smoking a cigarette and set the house on fire or was care for other family members arranged adequately?

For all these aspects, the attending surgeon often relies on the common sense of the escort, leaving some patients in potentially dangerous circumstances.

The data from this audit confirms guidelines on post sedation instructions recommending written instructions for escorts and suggesting this as an effective strategy to reduce the incidence of "unsafe" escorts and likely to reduce patients' exposure to danger.

Furthermore the mere handing over of an information leaflet should not be considered sufficient as it does not guarantee that this will be read; strategies to encourage active reading of relevant information such as, for instance, a "read together" of discharge instructions should be used to increase information level. Nevertheless a much greater attention to and recording of emergencies and complications related to escorts and post-operative arrangement is required to progress from simple inferences and common sense measures to an evidence based strategy.

Recommendations

In view of the results and their analysis the audit recommendations are:

- Provide written information for escorts, ideally before the sedation appointment to be reinforced by written post-sedation instructions upon discharge.
- Use a "read together" strategy for discharge instructions in recovery encouraging escorts not just to listen to the instructions but to read them for themselves from the leaflet provided.
- Consider audit of post sedation care beyond the point of discharge.

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Is Propofol Safe For Food Allergy Patients? A Review of the Evidence

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Abstract

Allergic cross-reactivity between propofol and food is frequently considered as a risk factor for perioperative allergic hypersensitivity reactions and anaphylaxis during dental anaesthesia and sedation. Better understanding of this cross-reactivity is important to providing safe care. There are, however, conflicting assumptions about anaphylactic reactions to propofol in patients reporting allergy to certain type of the food. Egg and/or soya allergy are often cited as contraindications to propofol administration but the evidence remains unclear. The main goal of this article is to review the available advice and evidence about the cross-reactivity between propofol and foods. A literature search was undertaken. The current published evidence does not elucidate that propofol allergy and food allergies are linked directly, but this drug should be used with caution in atopic patients with allergies to egg and/or soya bean oil. Clinical audit projects may gather data on anaphylactic events during anaesthesia and may aid the profession in this dilemma.

Introduction

Propofol, is an ultrashort-acting anaesthetic drug used for induction and maintenance of general anaesthesia in adults and children.¹ Of all the intravenous sedative or anaesthetic agents it causes fewest side effects and has the best characteristics for a fast recovery. Target controlled infusion of propofol is also used for conscious sedation in dental procedures.² This technique is particularly useful for patients who have developed a tolerance to benzodiazepines. Intravenous sedation, induced with a titrated dose of midazolam and then maintained with a continuous infusion of propofol,² is recommended for longer and more complex dental procedures for example, in patients with severe dental phobia in whom standard sedative measures have failed.

Propofol sedation can easily become too deep and the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland recommend that propofol used for deep sedation should only be administered by an anaesthetist³ in a safe environment. Therefore, the current propofol exposure in dental patients occurs mainly during the initiation and maintenance of monitored anaesthesia necessary for providing comprehensive dental care under general anaesthesia (GA) for patients with special needs or highly phobic individuals. Despite the current trend of gradually reducing the indications for general anaesthesia in dental patients, this method has still its well-established role in

dental care, particularly dedicated for patients with special and specific dental needs. The main clinical and social reasons for referring children for GA are multiple extractions of carious and unrestorable deciduous teeth followed by anxiety and fear in the paediatric patients. Many of the paediatric patients who require propofol sedation are phobic and are not able to co-operate with treatment.⁵

There are two main types of allergic related immediate drug hypersensitivity reactions: allergic (immune mediated) and non-immune mediated (pseudoallergic or anaphylactoid reactions).⁶ The agents most commonly associated with allergic reactions in anaesthesia are neuromuscular blocking drugs. Anaphylaxis associated with propofol is reported in approximately 2.3% of anaphylaxis cases during anaesthesia.^{7,8}

Propofol contains 2,6-di-isopropylphenol, in an oil-in-water emulsion containing soybean oil, glycerol, egg lecithin, and preservatives (metabisulfite, benzyl alcohol, disodium edetate).⁹ Propofol may therefore be dangerous in patients who have gastrointestinal allergy to the soybean oil or egg. Gastrointestinal allergy is defined as a history of allergic reaction to egg, soya or peanut and/or documentation of food sensitisation as evidenced by a positive skin prick test or elevated IgE.

Despite the very common use of propofol for almost all intravenous anaesthesia there are no clear guidelines regarding the administration of propofol in patients allergic to certain types of food, particularly egg, soya and nuts. This literature-based review aims to assess whether the evidence supports avoiding the use of propofol in patients with food allergies.

Search strategy

A literature review (publications within the last 60 years) of clinical reports, including retrospective studies was carried out, supported by published data available in medical databases: Medline/PubMed, PubMed Central, Embase and Cochrane Library. Articles were reviewed if they were relevant to case reports or reviews or guidelines involving propofol allergy. The databases were screened using various combinations of the search words: "propofol" and/or "food allergy" and/or "sedation" and/or "general anaesthesia".

Table 1. Food and Propofol allergen interactions.

FOOD	Potential food allergen (proteins)	Propofol protein component	Potential risk of allergic reactions
egg	egg white albumins	lecithin, a purified egg phosphatide (lipid vehicle)	contamination during processing
soy products	soybean protein fraction	refined soybean oil (lipid vehicle)	contamination during processing
peanuts	peanut proteins	n/a	cross-reactivity between soya and peanut (legume allergy)

Manufacturers' guidance

(Diprivan (Astra Zeneca, Macclesfield, UK) is contraindicated in patients with a known hypersensitivity to propofol or any emulsion components, ie. in patients with allergies to eggs, egg products, soybeans or soy products (Table 1). It should be noted that the soya ingredient of propofol is unlikely to contain highly reactive allergenic protein particles as it is substantially modified and refined during the production process.^{9,10}

Fresenius Propoven (propofol 1%, APP Pharmaceuticals, LLC) is also contraindicated in patients who are allergic to soy or peanut, but not in patients allergic to eggs.

Neither the British National Formulary (UK) or the Food and Drug Administration (US) provide statements about food allergy and the administration of propofol.

Literature review

The following is a discussion of the literature summarised in Table 2.

Table 2. Literature review of propofol use in food allergic patients and potential allergic reactions to propofol contents.

Data source	Study population	Potential and suspected allergen	Results and Conclusions
<i>References demonstrating a potential allergic reaction to propofol</i>			
Laxenaire et al., Lancet, 1988	Case report	Propofol	Propofol causative agent of anaphylactic shock
Laxenaire et al Anaesthesiology. 1992	Retrospective study, 14 patients	Active substance (?), intralipid solvent, isopropyl groups	Patients receiving propofol may experience anaphylactoid reactions
McHale S P, Konieczko K. Anaesthesia, 1992	Case report	Propofol	Propofol to be causative agent of severe allergic reactions
de Leon-Casasola O A et al. Anesthesiology. 1992	Case report	Propofol	Propofol to be causative agent of severe allergic reactions
Hofer K, et al Ann Pharmacother 2003	Case report 14 yr old with food allergies	Egg Peanut oil	Propofol should not to be administered in children with allergies to egg and soybean oil
Dueñas-Laita A N Engl J Med. 2009	Clinical cases report, 2 women	Soybean oil	Drug that contains soy may cause hypersensitivity reactions
Tashkandi J. Saudi J Anaesth. 2010;	Case report 4 yr old boy	Egg, soy Peanut	Patients with food allergies may be at risk of allergic reactions to propofol
You BC. Allergy Asthma Immunol Res. 2012	Case report 74 yr old woman	Soybean intralipid Propofol active substance	Anaphylactic reaction due to exposure to propofol
Ghatak T. Asian J Transfus Sci 2014	Case report Case report, 19 yr old male	Soybean oil	Anaphylactic shock with IV lipid emulsion

References confirming a safe use of propofol in food allergy patients

Harper N, et al Anaesthesia 2008	Consensus statement, children and adults	Egg Soy Peanut	No evidence data to avoid of propofol in food allergic patients
Dewachter P, et al, Curr Opin Anaesthesiol 2011	Review, children with egg allergies	Egg	No evidence data to avoid of propofol in food allergic patients
Murphy A, et al 2011, Anaesth Analg	Retrospective study, 28 children with egg allergies, 1-15 yr	Egg	Propolis is likely to be safe in children allergic to egg who do not have a history of egg anaphylaxis
Lambert R, et al, Critical Care Medicine 2011	Retrospective chart review, children 1-17 yr old	Egg Soy Peanut	No cases of allergic reaction to propofol in children with known food allergies
Molina-Infante J, et al, Allergy 2014	Retrospective study, 60 adult patients, 14-56 yr	Egg Soy Peanut	Propofol was safely administered in adults multisensitised to egg, soy and peanut
Wiskin AE, et al., Br J Anaesth 2015	Retrospective observational study, 131 children 1-17 y.o.	Egg Soy Nut	It is probably safe to use propofol in children with egg or soya allergy

Peanut and soya cross-reactivity

There is also potential concern for peanut allergic patients due to cross-reactivity, as peanut and soya have homologous proteins, and peanut allergic patients demonstrate increased IgE binding to soy proteins *in vitro*.^{10,11} Fontaine et al. described severe bronchospasm using Diprivan which was associated with a hypersensitivity reaction (asthma) in a child allergic to peanut and birch who underwent naevus surgery under general anesthesia.¹² This case raises the problem of cross allergy between birch, peanut, soya and Diprivan. *In vitro* assays and RAST (radioallergosorbent) tests confirmed a soya cross-reactivity with peanuts. However, clinical observations suggest low rate of co-reactivity to peanut in soy-allergic patients¹³ and clinical evidence does not support elimination of all legumes: peas, soya, from a patient's diet despite allergy to peanuts. Contrary to these statements Gangienieni¹⁴ concluded that the drug is likely to trigger a reaction in patients with peanut allergy. The updated product specification of propofol manufactured by Astra Zeneca (Diprivan, Macclesfield, UK) does not recommend its use in nut allergy sufferers.¹⁵ A standard pharmacology textbook revealed no definitive contra-indication to the use of propofol in this group of patients.¹⁶

Phenol or isopropyl component allergy

Similarly to the precautions taken when administering local anaesthetic agents, allergic reactions to propofol may be due to part of the phenol or isopropyl component, or the added preservatives¹⁰. Allergic reactions to propofol have been revealed to be triggered by the iso-propyl or phenol groups rather than the lipid vehicle¹⁷. Interestingly, a new formulation, Fresenius Propoven 1% (propofol 1%, APP Pharmaceuticals, LLC), does not contain an anti-microbial ingredient such as ethylenediaminetetraacetic acid

(EDTA), sodium meta-bisulfate, or benzyl alcohol/sodium benzoate.¹⁸ This anaesthetic drug contains a combination of lipid emulsions including long-chain triglycerides, which are also the component of generic drug Diprivan (Astra Zeneca, Macclesfield, UK) but additionally Fresenius Propoven 1% contains medium-chain triglycerides not found in the Diprivan formulation. According to the Manufacturer,¹⁹ special precautions need to be applied in patients with an impaired lipid metabolism condition, and medically compromised individuals receiving total parenteral nutrition.

Case reports of 'propofol allergy'

Single case reports of propofol-associated allergic reactions were found which can be related to cross-reactivity to foods. The first case reports describing life-threatening anaphylactoid reactions to propofol (Diprivan) appeared 25 years ago in 1992.^{20,21,22} Tashkandi presented a near-fatal cardiac arrest of 4-year-old boy admitted for elective adenotonsillectomy, with a past medical history of eczema and multiple allergies to food, who developed a severe allergic reaction to propofol, including rapid desaturation, as an effect of bronchospasm followed by bradycardia, and severe hypotension.¹⁷ You et al. reported a 74-year-old woman who had an anaphylactic reaction with severe oropharyngeal oedema and bronchospasm for a few minutes after receiving propofol during an endoscopic examination.²³ Hofer et al. described a possible anaphylaxis after propofol, in a child with food allergy.²⁴ Anaphylaxis following ingestion of a generic drug (omeprazole) containing soybean oil has also been reported.²⁵ Ghatak described an incident of anaphylactic shock with intravenous 20% lipid emulsion (Intralipid) in a young patient with a positive history of soybean allergy. Intralipid has a similar composition to propofol, containing soybean oil, egg lecithin and glycerol in an isotonic solution.²⁶ It needs to be stressed that although propofol is a respiratory depressant causing apnoea after an inductive dose,²⁷ it may also exhibit a positive influence on the respiratory system with a mild bronchodilation effect²⁸ in patients with asthma and chronic

obstructive pulmonary disease,²⁹ reducing the incidence of intra-operative wheezing. Moreover, it tends to slightly diminish the airways' reflexes and sensitivity, contributing to a lower risk of laryngospasm during suctioning of secretions,²⁹ it can, however induce bronchoconstriction in allergic patients.³⁰

No direct clear evidence found?

Direct evidence linking propofol exposure to 'true' anaphylactic reactions is rare and has not been reported clearly. According to a retrospective case review over an 11-year period (1999-2010), a cohort study performed in the Children's Hospital, Westmead, Sydney, propofol was found to be safe in egg-allergic children³¹. 43 propofol administrations in twenty-eight egg-allergic patients were investigated. The authors reported only one non-anaphylactic allergic reaction after propofol administration in a 7-year-old boy with a history of egg anaphylaxis and other IgE-mediated food allergies (cow's milk, nut, and sesame). Similarly, Dr Mehta, a pediatric allergist-immunologist at the Icahn School of Medicine at Mount Sinai, New York observed no allergic reactions in patients with known food allergies who had received propofol prior to undergoing endoscopy.³²

There were reports of children with confirmed egg, soya or peanut allergy who had propofol without any subsequent allergic reactions. According to Dewachter,³³ there is no obvious reason to avoid propofol in egg-allergic, soy-allergic or peanut-allergic patients.

The allergenic determinants have been characterised for soya, peanuts and remain unknown for other types of food. Patients who are allergic to eggs are specifically allergic to egg protein or albumin, but not may not be allergic to lecithin - the egg phosphatides present in the Diprivan emulsion.¹⁵ As mentioned above, a single cases of anaphylaxis following propofol administration has, however, been reported in the literature.

In cases of reaction to propofol, the cause and effect relationship has often been difficult to establish. Most of these cases lacked confirmatory testing for actual food allergy versus ordinary sensitisation.³⁴ Only a minority of patients were referred for allergy testing to confirm their hypersensitivity to propofol and the other anaesthetic drugs that could have also been responsible. There is no evidence to support the prophylactic use of antihistamines or corticosteroids in egg, soya, peanut allergic patients.³⁵

Molina-Infante et al. reported the safety of propofol for procedural sedation (endoscopies) in sixty patients with eosinophilic oesophagitis sensitised/allergic to egg, soya or peanut.³⁶ The authors carried out multiple tests including food-specific serum IgE and skin prick tests for egg, soya, peanut, and cross-reactant foods in all patients. About 28% of patients had a history of allergic reactions to egg, legumes, and nuts. No confirmed allergic adverse reactions were reported, apart from one episode of bronchospasm after intubation in an asthmatic individual receiving multiple anaesthetic drugs. They concluded that propofol can be safely administered for sedation in patients multisensitised to egg, soy or peanut, with clinical allergy to these foods.

The latest research carried out by Wiskin et al.³⁷ demonstrated that propofol anaesthesia does not increase allergic reactions in

children with food allergy undergoing endoscopy. Of the 131 children, 62% had a combination of egg and soy allergy and 38% had a single allergy, mainly to soy. Almost all children received intravenous anaesthesia with propofol.

Lambert et al. analysing retrospectively 94 children, 1-17 years of age with known food allergy who underwent procedural deep sedation, concluded that there were no reported cases of allergic or anaphylactic reaction during exposure to propofol in either the low-moderate risk or high risk groups.³⁸ They did not find any cases of allergic reaction to propofol in children with known food allergies, including those at high risk for anaphylaxis.

Discussion

A review of the literature found case reports of allergic reactions to propofol. Food allergy may have been a factor in some of these cases, however, in reports using numbers of children with food allergy, propofol has been used safely.

If propofol allergy is suspected, a close collaboration between dentist, allergologist and anaesthesiologist is desirable. It seems to be clinically justified to refer a dental patient with an increased risk of allergic reaction triggered by food to a specialist for additional tests, as an important step before subsequent anaesthetic exposure. The Sixth National Audit Project (NAP6) of the Royal College of Anaesthetists³⁹ will examine peri-operative anaphylaxis and collect comprehensive information concerning anaphylactic events, enabling the anaesthetic and allergy communities to collaborate and to make recommendations for future improvement in the quality and safety of patient care.

Conclusions

Food allergy to egg and soya has been suggested as a contra-indication to using propofol. The limited data available does not support avoiding propofol. Nevertheless, alternatives to propofol should be considered, and propofol should be used only after a cautious risk-benefit assessment.

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This article is dedicated to all dental teams providing comprehensive community and special dental care for children and patients with special needs

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Defining Over-Sedation: Literature Review and National Survey of Dental Hospitals Within the United Kingdom.

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Abstract

Aims: To review the literature, to investigate whether there was a consensus on what encompasses over-sedation, and to determine the guidance employed for the administration of flumazenil.

Methods: A literature search was performed following which a self-designed questionnaire was emailed to 14 sedation leads within UK Dental Hospitals.

Results: 10 documents in the literature review met the inclusion criteria. In their definitions of over-sedation, loss of consciousness and respiratory depression were the main terms used; but a variety of terms were also seen, indicating a lack of agreement. Fourteen dental institutes were contacted of which nine (64%) responded. Thirty-seven per cent of sedation leads who responded stated they were unaware of a definition for over-sedation. Seventy-seven per cent stated that when flumazenil was used this was recorded in a drugs book, with a broad range of justifications given.

Conclusion: This study shows that there is a lack of uniformity both from clinicians and the literature, in what encompasses over-sedation. This makes formulating an accepted definition of over-sedation difficult. In order to ensure accurate reporting, monitoring and auditing of such events, a clear definition for over-sedation is required and can be used to provide clarity when flumazenil is to be administered.

Introduction

In June 2015, the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD) published a Report for the provision of conscious sedation in dentistry in the United Kingdom (UK).¹ This Report described best practice and set national standards for conscious sedation in dentistry. For many patients, namely those with dental treatment anxiety or phobia, special care requirements or those with certain medical conditions, sedation forms an important adjunctive treatment modality to facilitate their dental needs, and is widely practised in the UK.

Conscious sedation is defined as:

"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".²

This definition is accepted by a number of committees including the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD),¹ the Scottish Dental Clinical Effectiveness Program (SDCEP),³ the Dental Sedation Teachers Group (DSTG),⁴ the Standing Dental Advisory Committee (SDAC)² and Department of Health.⁵ However, should the extent of sedation go beyond that defined earlier, then over-sedation may occur. The SDAC state that, "sedation beyond this level of consciousness [as stated in the definition] must be considered to be general anaesthesia and is then subject to different regulations".² The Academy of Medical Royal Colleges⁶ set their definition of sedation based on the American Society of Anaesthesiologists⁷ and describes deep sedation as "a state where the patient cannot easily be aroused but responds purposefully to repeated or painful stimulation; it may be accompanied by clinically significant ventilatory depression.⁷ The patient may require assistance maintaining a patent airway, and positive pressure ventilation."⁶ It can therefore be seen that although guidance agrees on what is deemed conscious sedation,^{1,6,7,8} there does not seem to be consensus on a definition of over-sedation.

In December 2008, the National Patient Safety Agency (NPSA) produced a report termed the Rapid Response Report (RRR).⁸ It stated that "flumazenil, is frequently used to treat inadvertent benzodiazepine overdose and, on occasion, no account is taken for the shorter half-life of flumazenil (compared to midazolam) leading to residual re-sedation." Additionally, the document reported that between November 2004 to November 2008, there were 498 midazolam patient safety incidents reported where three of these resulted in death. However, these incidents were across a range of specialties and there were only two within dentistry.⁸ Recommendations were made to all organisations in the National Health Service and independent sectors which included, but were not limited to, replacing high strength midazolam with a lower concentration (1mg/ml in 2ml or 5ml ampoules), and that the use of flumazenil be regularly audited as a marker of excessive dosing

of midazolam.⁸ If midazolam is given in excess then over-sedation will ensue so understanding over-sedation is imperative for several reasons. It would enable greater clarity for clinicians, providing confidence and guidance on when reversal may be required and justified. It would allow for clearer compliance to national recommendations, which include development of better reporting and categorising of critical or adverse events. Additionally, it would facilitate greater ability to compare research and audit, especially if conducted using a multi-centred approach, advancing high quality care and increasing safety for patients.

Aims

The main aims of this study were to review the literature and assess the opinions of sedation leads within UK based dental schools on what they considered defines over-sedation. A further aim was to compare the guidance used for the administration of flumazenil between the dental hospitals.

Methods

A literature search was performed to review over-sedation. This review aimed to search for any publications that mentioned over-

sedation and attempted to describe or define it. Studies were included if they met both of the following criteria:

- (i) Attempted to define over-sedation or provided characteristics of what over-sedation may encompass
- (ii) Were undertaken for dental surgery

Databases searched included Medline, Pubmed, Cochrane as well as a free text Google Scholar search. In addition, reference books were searched within Google Scholar.

The search strategy can be seen in table 1.

In addition, a self-designed questionnaire (Appendix 1) was emailed to 14 sedation leads within the UK Dental Hospitals. Identification of sedation leads was made by contacting each dental hospital or searching the Institute's website. Where identification could not be made, staff from the institutes were emailed to help identify who was the sedation lead. After 4 months, data supplied was collated and the results analysed.

Results

Outcome of the literature search

The literature search resulted in 410 documents which included journal articles and book chapters. Of these, 31 required full text review. Ten documents met the inclusion criteria of over-sedation

Table 1: Search strategies used for the differing databases

Embase (1974-July 30th 2015)	Pubmed	Cochrane	Google scholar
conscious conscious sedation dentist* (ti,ab) dentistry depression* (ti,ab) effect* (ti,ab) oversedation* (ti,ab) respiration depression respiratory sedation sedation* (ti,ab) side side effect	"Dentists"[Mesh] dentist*[tiab] "Drug-Related Side Effects and Adverse Reactions"[Mesh] side effect*[tiab] "Respiratory Insufficiency"[Mesh] respiratory depression*[tiab] oversedation oversedation*[tiab] Conscious Sedation* [tiab] "Conscious Sedation"[Mesh] "Deep Sedation"[Mesh] sedation*[tiab]	#1: "sedation":ti,ab,kw #2: MeSH descriptor: [Conscious Sedation] #3: "conscious sedation":ti,ab,kw #4: "oversedation":ti,ab,kw #5: "respiratory depression":ti,ab,kw #6: MeSH descriptor: [Respiratory Insufficiency] #7: "side effect":ti,ab,kw #8: MeSH descriptor: [Drug-Related Side Effects and Adverse Reactions] #9: "dentistry":ti,ab,kw #10: MeSH descriptor: [Dentists] #11: MeSH descriptor: [Dentistry] #12: #1 or #2 or #3 #13: #4 or #5 or #6 or #7 or #8 #14: #9 or #10 or #11 #15: #12 and #13 and #14	"oversedation" AND "conscious sedation" AND "dentistry"

Table 2: A summary of over-sedation features described in the included articles of the literature review

Author and Characteristics	Agitation	Eyes closed unarousable on mild physical stimulus	Eyes closed, rousable on mild physical stimulus	Hypoxia	Loss of communication	Loss of consciousness	Reduced co-operation	Respiratory depression	Other
Luhmann D et al. (2001) ⁹									Unresponsive
Nathan J.E et al (2002) ¹⁰									<ul style="list-style-type: none"> • Intense physical stimulation needed for arousal (deep sedation) • Partial or complete loss of protective reflexes (deep sedation/GA) • Somnolence which persists through visit requiring lengthy recovery
Wilson K.E et al (2002) ¹¹					✓	✓		✓	
Blayne M.R et al (2003) ¹²	✓	✓	✓				✓		Decreased SaO ₂ (<90%), Excitation, reduced co-operation from the patient, Reduced ventilator rate, Restlessness
Wilson K.E et al (2003) ¹³					✓	✓		✓	
Averley P.A et al (2004) ¹⁴		✓	✓						Slurred speech Partial ptosis Eyes closed and responds to speech
Kilborn A et al (2009) ¹⁵		✓	✓						
Island R (2010) ¹⁶				✓		✓	✓	✓	Respiratory arrest
Shaw I et al (2010) ¹⁷	E*					E*	S*	G*	G* Apnoea E* Disinhibition, dysphoria
IACSD (2015) ¹				✓					Loss of airway, hypoventilation

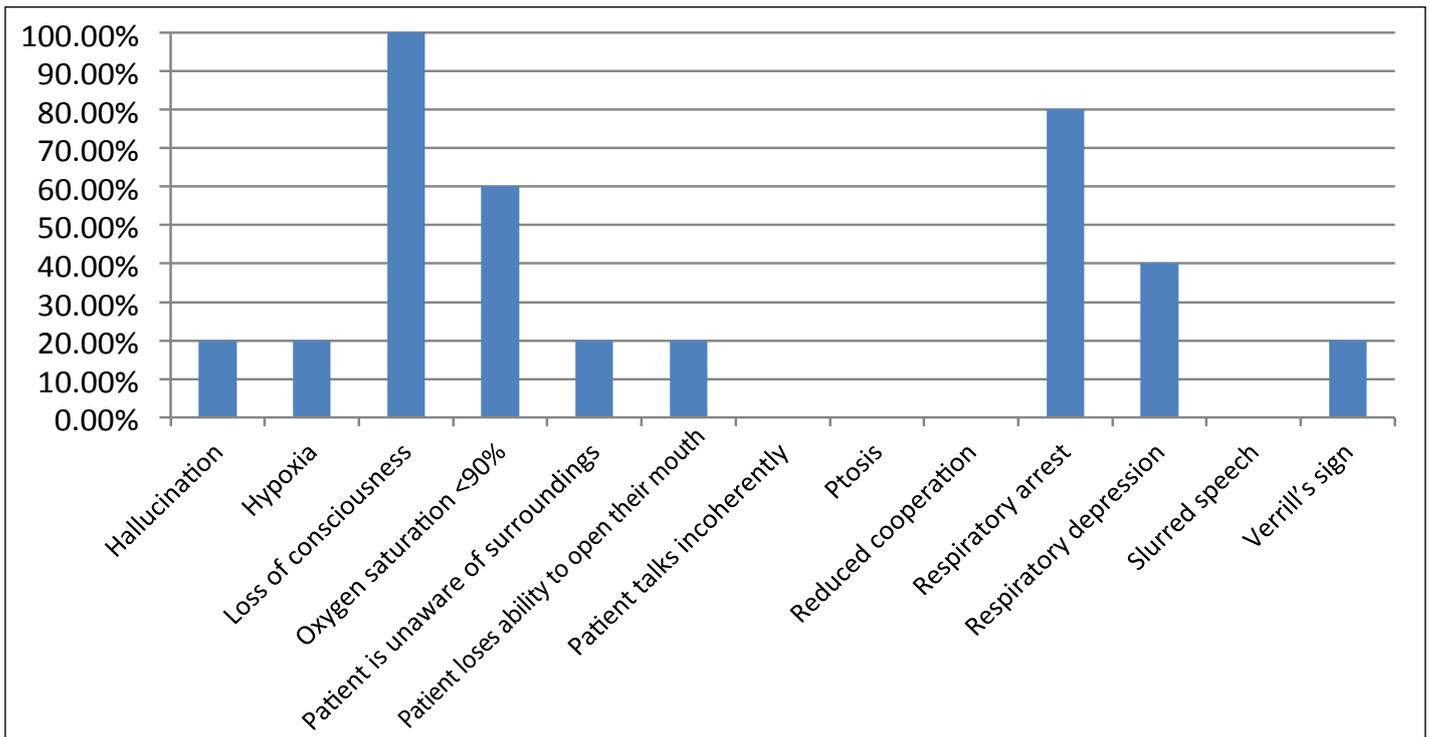
S* (small amount of over sedation), G* (gross oversedation), E* (Excessive oversedation)

within dentistry. There were no additional articles found following review of the reference lists of the included full text articles. Table 2 shows a summary of the characteristics of over-sedation mentioned in each document.

The majority of documents (n=4) included respiratory depression^{11,13,16,17} and loss of consciousness^{11,13,16,17} within their

description of over-sedation. Three documents stated that eyes closed, rousable on mild physical stimulus,^{12,14,15} eyes closed unarousable on mild physical stimulus^{12,14,15} and reduced co-operation^{12,16,17} described over-sedation. Loss of communication,^{11,13} hypoxia^{1,16} and agitation^{1,12} were only stated in 2 studies. The remainder of terms were only seen once within the 10 studies, indicating the variety of descriptors used.

Figure 1: Features of over-sedation selected by sedation leads. % = percentage of responding sedation leads (n=9)



Replies to questions

A total of 14 dental institutes were contacted of which 9 (64%) returned responses.

Over-sedation

Defining over-sedation

Of the nine leads who responded, three stated they were unaware of a definition for over-sedation. Six respondents were aware of a definition; of which two stated that over-sedation was the opposite of the standard conscious sedation definition, (i.e. the patient does not respond to verbal commands) as per the SDAC 2003² and SDCEP guidance³.

Features of over-sedation

When asked to select which features constitute over-sedation, a diverse range of answers were given with "loss of consciousness", "respiratory-arrest" and "oxygen saturations lower than 90%" being the most commonly selected responses. None of the respondents felt "reduced co-operation", "slurred or incoherent speech" or "ptosis" constituted over-sedation. A summary of results can be seen in Figure 1.

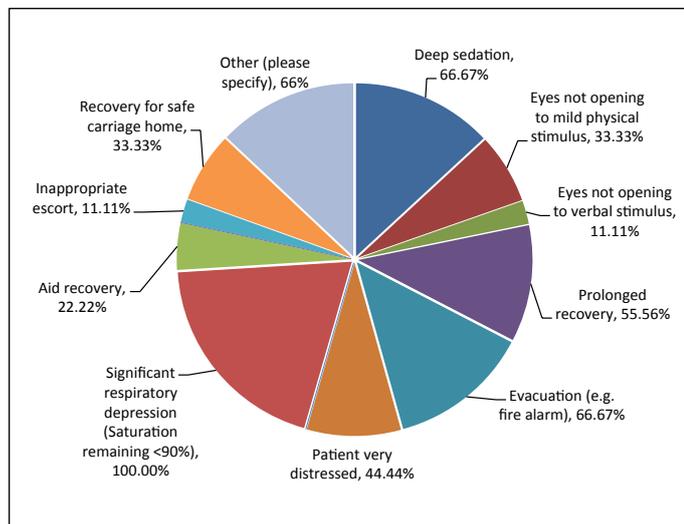
Recording the use of flumazenil

Seventy-seven per cent of sedation leads responded that when flumazenil was used it was recorded in a drugs book.

Justification of flumazenil use

When asked why flumazenil was used a broad range of answers were given and these are summarised in Figure 2.

Figure 2: Showing sedation leads justifications for flumazenil usage. % = % of responding sedation leads



Additional reasons mentioned for flumazenil use included, to aid recovery of special needs patients, and clinician concerns or medical emergencies.

Four respondents indicated that they had completed an audit of flumazenil use since the release of the RRR. This indicated that the remainder of respondents have possibly not yet undertaken the audit recommended by guidelines produced in 2008. Likewise, four sedation leads responded that their unit had guidelines / protocols in place for flumazenil use.

Discussion

Over-sedation

Throughout the guidance for conscious sedation, over-sedation is an often mentioned key factor. However, there is little mention of what parameters actually constitute over-sedation. Our literature search had shown that although only a few documents attempted to describe the factors associated with over-sedation,^{1,9,10-17} and there were a variety of terms used, highlighting inconsistency and supporting the rationale for the study.

Guidance has also mentioned that over-sedation is a risk of intravenous midazolam sedation.¹ However, on the whole, over-sedation is treated as a separate entity with little explanation as to what this broad term encompasses. This was evident from the survey with approximately one third of respondents stating that they were not aware of a definition.

The study has shown that there is difficulty in recognising and formulating an accepted definition of over-sedation. This may be because of patients responding differently, and needing different levels of sedation, depending on their anxiety and/or the procedure. Miloro and Kolokythias¹⁸ suggested that over-sedation may occur once the procedure is complete since surgical stimulus can counteract the sedative effects. This supports the reason why the titration is advised^{2,18} allowing the clinician to achieve a suitable level of sedation as required by the individual patient, without going beyond the recognised safe therapeutic window.

According to the majority of respondents (n=5) loss of consciousness was a main feature that they would associate with over-sedation. This aligns with the literature search which also found loss of consciousness^{11,13,16,17} to be the most frequently mentioned term (n=4). Replies to the questionnaire felt that respiratory arrest was the second most common response (n=4), in contrast to the literature review where only one article¹⁶ included this term. The third most common term from respondents was oxygen saturation less than 90% (n=3). There was only one article¹² that used this term identified by the literature search. Terms such as ptosis,¹⁴ reduced cooperation¹² and slurred speech¹⁴ were not selected by any of the sedation leads in response to the questionnaire, but were associated with over-sedation within the literature search. The remaining responses from the questionnaire were only mentioned once.

The study has identified that sedation leads within the UK have associated terms to over-sedation that the literature did not. For example, hallucinations, unawareness of surroundings and Verril's sign. It would be expected that the opinions of experts would be aligned with that of the literature. However, what is seen is that a range of signs and symptoms of over-sedation described in the dental community.

It was interesting to note that Shaw et al¹⁷ sub-categorised over-sedation into "small amount of over-sedation", "gross over-sedation" and "excessive sedation". Given the difficulty in agreeing terms which define over-sedation and the lack of parity surrounding this broad-term, it is the belief of the authors that implementation of sub-categories would prove difficult, especially as there is no clear end-point between sedation and over-sedation as it stands. Pre-operative fasting is an area under consideration, with differing opinions. The risk associated being that if a patient becomes over-sedated then the protective airway reflexes are lost and the same

care as a general anaesthetic would be needed.¹ Therefore, the importance of understanding over-sedation is fundamental to prevent inadvertent general anaesthesia.

Fumazenil

Flumazenil is a benzodiazepine antagonist used for the reversal of the central sedative effects of benzodiazepines used in sedation such as midazolam¹⁹. When required it can be delivered via the intravenous route in titrated doses. Although it is effective in reversing the effects of sedation, anxiolysis, respiratory depression and muscle relaxation, by competitively binding to the benzodiazepine receptor.²⁰

Flumazenil has a shorter half-life than midazolam and therefore there is a theoretical risk that patients may become re-sedated and thus repeat doses of flumazenil may be necessary. It is this characteristic of the drug that the RRR was concerned with; stating patients were suffering from residual re-sedation.⁸

In 2008 it was estimated that 60,000 ampoules of flumazenil were used in the NHS in England annually, of which a proportion were used to reverse clinical overdose.⁸ As flumazenil is not a controlled drug it is not mandatory to record its use in a separate drugs book. However, to provide ease for recalling details when it has been used and for audit purposes the authors recommend that a recording system be implemented.

The majority of institutions had guidelines in place for the use of flumazenil. In greater than 70% of cases flumazenil use was recorded in a drugs book and the remaining institutes had their own protocol. Thus all were complying with suggested good-practice that use of flumazenil should be appropriately recorded. However, only half of respondents indicated they had audited their flumazenil use, implying that the remaining 50% possibly had not undertaken the audit required by the 2008 RRR.⁸ Furthermore, the results would suggest that within the dental community there is a lack of agreement as to the justification of flumazenil administration, with wide variance in responses, and more than 16 different reasons for administration of the drug given, including respiratory depression, deep-sedation, evacuation and long recovery time. Supporting this finding, an audit conducted by Henthorn and Dickinson²¹ concluded that a wide range of reasons existed for flumazenil use.

It is understandable that in certain situations where, given the nature of the patient base, there may be greater need for flumazenil administration, however, this should be made on a case by case basis, and not used as a regular process to reverse patients. After all, the drug has a side effect profile and if used without a clear justification such use could result in potential harm.

Conclusion

Over-sedation is an event of sedation that can develop into a complication of varying severity.¹⁸ The literature and our survey aimed to identify whether there was a consensus on the characteristics of over-sedation. The main term used in both was loss of consciousness. Other than this, there was a lack of agreement. The study demonstrated that this is an area which has a great deal of uncertainty, and amongst clinicians there are differing opinions, hence providing a general definition proves difficult. Although the April 2015 guidance document¹ clearly

states over-sedation with midazolam is a 'never-event', this is with the use of high strength midazolam (5mg/ml or 2mg/ml) for conscious sedation.¹ It is the authors' opinion that in order to ensure accurate reporting, monitoring and audit of such events, clear criteria of over-sedation must be determined. These can then be used to provide clarity when flumazenil may need to be administered.

Appendix 1

Questions asked within the Questionnaire to sedation Leads

1. If you are happy to do so, please state your institution.
2. Within your institute, is BMI recorded as part of the pre-sedation assessment process?
3. Within your department, is flumazenil use recorded in a drugs book?
4. From the list below, please mark the options that you feel justify the use of flumazenil administration:
 - Deep sedation
 - Eyes not opening to mild physical stimulus
 - Eyes not opening to verbal stimulus
 - Prolonged recovery
 - Evacuation (e.g. fire alarm)
 - Patient very distressed
 - Translation purposes
 - Significant respiratory depression (Saturation remaining <90%)
 - Aid recovery
 - Nausea
 - Inappropriate escort
 - Recovery for safe carriage home
5. Are you aware of a definition for over-sedation?
6. How would you define over-sedation?
7. From the list below, please select what features you believe constitute over-sedation?
 - Oxygen saturation <90
 - Patient loses ability to open their mouth
 - Reduced cooperation
 - Patient is unaware of surroundings
 - Hallucination
 - Patient talks incoherently
 - Respiratory depression
 - Respiratory arrest
 - Hypoxia
 - Loss of consciousness
 - Slurred speech
 - Ptosis
 - Verrill's sign

8. Does your hospital/department have policy/guidelines for the use of Flumazenil?
9. Has an audit of flumazenil use within your department / hospital been undertaken since the release of the rapid response report in 2008?

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SAAD Study Day in Sedation for Special Care Dentistry Saturday 12 March

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SAAD is hosting a Study Day for **Specialty Registrars, trainers in SCD and interested dentists.**

The day aims to:

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- To consider sedation for medically compromised patients
 - To provide a discussion forum for StRs
- To consider integration of sedation techniques into primary care dental services

The programme will include:

- Transmucosal sedation • Neuro-disability • Medically compromised • Dementia
• Propofol • Guidance, training and accreditation • Setting up a sedation service

The day will provide 4.5 hours CPD.

**The fee for the day is £40 with a discounted rate for StRs of £15
(StRs must contact fiona@saad.org.uk for their discount code)**

Further details at www.saad.org.uk

The State of UK Dental Anaesthesia: Results From The NAP5 Activity Survey

A national survey by the 5th National Audit Project of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland

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Abstract

The National Health Service anaesthesia annual activity (2013) was recently reported by the Fifth National Audit Program of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland. Within a large dataset were 620 dental cases. Here, we describe this data subset. The estimated annual dental caseload was 111,600: 60% were children (<16 y), 38.5% adults (16 - 65y) and 1.5% the elderly (>65y). Almost all were elective day procedures (97%) and ASA 1 or 2 patients (95%). The most senior anaesthetist present was a Consultant in 82% and a non-career grade doctor in 14%. Virtually all (98%) cases were conducted during GA. Propofol was used to induce anaesthesia in almost all adults compared with 60% of children. Propofol maintenance was used in 5% of both children and adults. Almost all adults received an opioid (including remifentanyl) compared with only 40% of children. Thirty one per cent of children had a GA for a dental procedure without either opioid or LA supplementation. Approximately 50% of adults and 16% of children received a tracheal tube: 20% of children needed only anaesthesia by face mask. These data show that anaesthetists almost always use general anaesthesia for dental procedures and this exposes difficulties in training of anaesthetists in sedation techniques. Dentists, however, are well known to use sedation when operating alone and our report provides encouragement for a comprehensive survey of dental sedation and anaesthesia practice in both NHS and non-NHS hospitals and clinics in the UK.

Background

The Anaesthesia Activity Survey (AAS) of the Fifth National Audit Project (NAP5) has the largest and most comprehensive dataset to date, of activity of anaesthetists within the National Health Service (NHS).¹ The estimated annual caseload in 2013 was 3,685,800 of which 2,766,600 (76.9%) were during general anaesthesia (GA), 308,800 (8.6%) during sedation and 523,100 (14.5%) managed awake. There were a substantial number of dental procedures within this dataset and the details of patient characteristics, airway and drug management should be of interest to both dentists and dental anaesthetists. The dental data have not been published before and are described here. We were especially interested in the rates of general anaesthesia versus sedation in which anaesthetists were involved, and in the age distribution of patients, since both features are important in helping to plan services.

Methods

Full details of the AAS methods have been published elsewhere.¹ Briefly, each surgical NHS hospital with the 4 countries of the UK was represented by a local coordinator (LC) who coordinated a survey within their own hospital group (n=265) on every patient who underwent a procedure under the care of an anaesthetist. "Care" was not restricted to GA, and included sedation² or with the patient awake. Only NHS patients were included.

Data collection over a whole week was not considered feasible or necessary,¹ and instead each LC was randomised to two consecutive days within the chosen week 9th to 16th September 2013. For each case anaesthetists were asked to complete a case record form indicating patient demographics and anaesthetic technique. Returned forms were processed by 'optical character recognition' technology (DRS Data & Research Services plc., Milton Keynes, Buckinghamshire, UK). All LCs responded and the median estimated return rate as a proportion of all cases from each LC was 0.98. A scaling factor 180.68 converted the number of returned forms into annual caseload¹. The data below are rounded to the nearest 100. For clarity, the number of forms (n) is stated whenever the number of forms within a specified category was less than 20. If a category size was ≤ 10 it was considered too small to describe in detail. There were 30 questions.¹ Where answers were uninterpretable (errors or marked unknown) these were discarded. Results relate only to interpretable forms.

All calculations were made using Microsoft Excel 2010 and the 'PivotTable' facility. Broad age groups were used: Children = <16 y, Adult = 16 - 65y, Elderly = >65y. Hospitals were divided into two groups; district general (DGH, n= 202) and specialist hospitals (n=65). Specialist hospitals included Childrens hospitals, Teaching and University hospitals and other specialist hospitals known to provide paediatric anaesthesia services.³

Results

There were 620 reports of dental procedures which results in an annual caseload estimate of 111,600; 3% of the total UK anaesthetic activity. Dental procedures were the 8th most common procedure overall. In school age children (6-15y), however, dental procedures

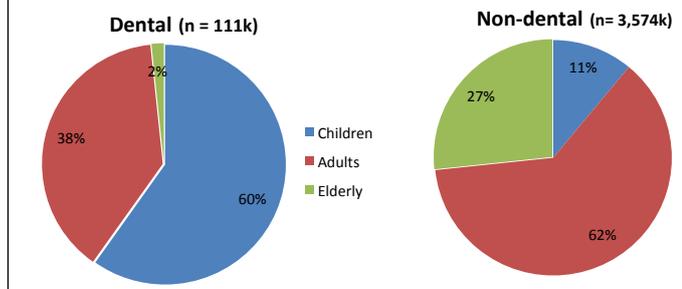
accounted for 17% of the caseload (3rd most common procedure). Unless stated otherwise, the following statistics refer to dental cases only.

Patient characteristics

Sixty per cent of procedures were in children and 38% were in adults (Figure 1) (compares with 11% and 62% in non-dental caseload in children and adults respectively). Only 10 cases were reported in the elderly (1.5% of the dental caseload, compared with 27% of the non-dental caseload). Across all age groups, the sex ratio was 47%/53% (male/female). Almost all were elective day procedures (97%) and in ASA4 1 or 2 patients (95%) (compared with 78% in non-dental patients). Fifteen per cent of the adults were obese or morbidly obese compared with 0.5% of children (22% in the whole dataset).

Figure 1: Proportion of children, adults and elderly patients undergoing dental and non-dental procedures

% = % of dental (n= 111,600) and non-dental procedures (n=3,574,200) within Anaesthesia Activity Survey of the Fifth National Audit Project. NB Dental caseload was 3% of the total UK anaesthetic activity.



General management

Approximately 2/3rds of the dental caseload took place in DGHs (60% of children and 70% of adults): the proportion in DGHs was similar for non-dental patients (67% overall but 40% of children and 70% of adults). Most activity took place during the week: approximately 10% of dental anaesthetics took place over the weekend (Figure 2). The site of induction of anaesthesia was either an operating theatre or other unspecified site in 42% of cases (i.e. not an anaesthetic room) (Figure 3); this proportion was higher in children compared with adults (52% v 28%). The most senior anaesthetist present was a Consultant in 82% and a non-career grade doctor in 14%.

Figure 2: Caseload across the week

% = % of caseload within age group. Elderly have been excluded from the Adult group.

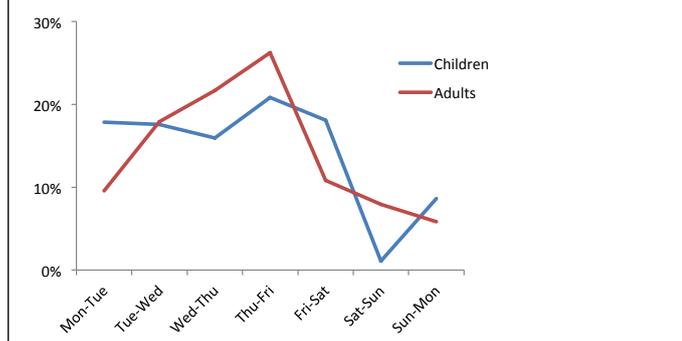
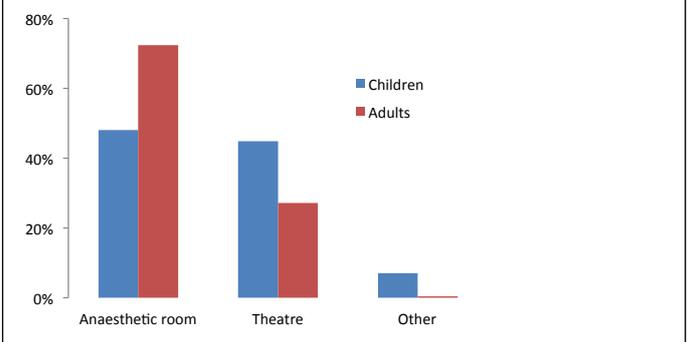


Figure 3: Location of induction of anaesthesia

% = % of caseload within age group. Elderly have been excluded from the Adult group. Other = unspecified site.



Anaesthesia management

Intended conscious level

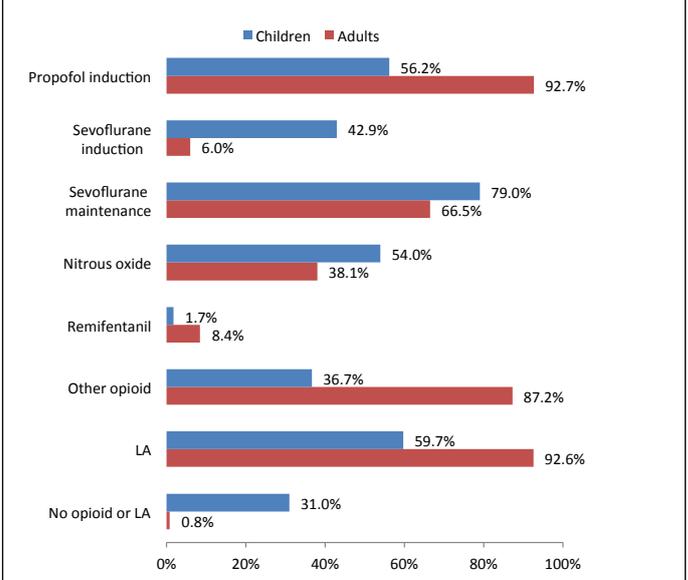
Virtually all (98%) cases were conducted with GA. The number of returned forms reporting sedation or awake was only 9 (1.4%) and 1 (0.2%) respectively. There were no deaths and no patient was returned to a high dependency or intensive care unit.

Anaesthesia and analgesia drugs

There were appreciable differences between adults and children (Figure 4). Propofol was used to induce anaesthesia in almost all adults compared with 56% of children (42% of children had sevoflurane) Sevoflurane was the most widely employed maintenance agent used in 67% of adults and 79% of children. Propofol maintenance was used in 5% of both children and adults; desflurane was used in 10% of adults; isoflurane was used otherwise.

Figure 4: Anaesthesia and analgesia drugs

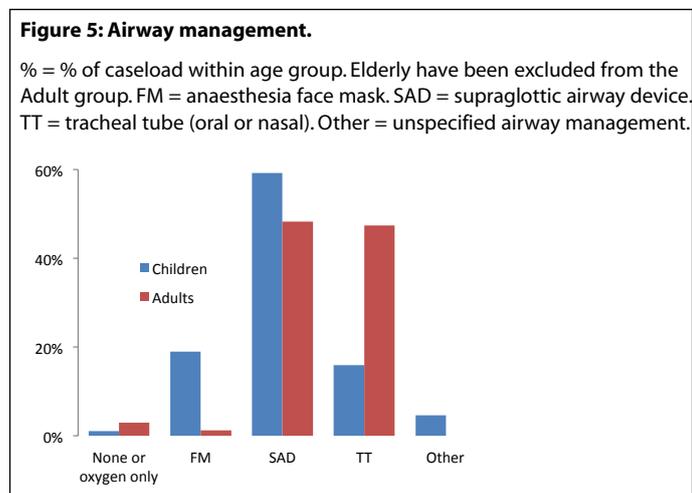
% = % of caseload within age group. Elderly have been excluded from the Adult group. LA = local anaesthesia.



Almost all adults received an opioid compared with only 40% of children. Similarly local anaesthesia (LA) was used more frequently in adults than children (90% v 60%). Thirty one per cent of children had a dental procedure during GA without either opioid or LA supplementation.

Airway

Figure 5 shows that few adults were managed without any airway device and approximately half received a tracheal tube (TT). Most children (59%), however, were managed with a supraglottic airway device (SAD) and almost 20% were anaesthetised by face mask alone.



Neuromuscular blocker (NMB) and depth of anaesthesia monitoring

Twenty-one per cent had a NMB (46% in the main dataset) and only 3 patients had suxamethonium: 33% of NMB cases were not reversed. Less than 1% (n=4) had any EEG based depth of anaesthesia monitoring (2.8% in main dataset).

Discussion

The two striking features of the data are that almost all NHS dental patients managed by anaesthetists received a GA and that very few of these were elderly patients. That there were so few reports of sedation was surprising. There are two interpretations: first that almost all patients referred for anaesthesia care either required or desired general anaesthesia rather than sedation, or alternatively that most anaesthetists default to use of GA without full consideration of the possibility of sedation-based techniques. The dental sedation caseload in the NHS is likely to be higher than that reported here but if a large sedation caseload does exist, it was not managed by anaesthetists. Whatever the cause, a consequence of the rarity of sedation techniques for dental surgery in the hands of anaesthetists is that few anaesthetists can be trained in these techniques unless they are trained by non-anaesthetists.

Claims are made that sedation is used widely in dental practice but recent estimates of sedation activity across the UK are limited. In 2013 266 members of SAAD and the Dental Sedation Teachers Group responded to an online survey and 82% stated that they sedated patients.⁵ In other regional surveys the use of sedation varied between 12 and 50% of primary care practices.^{6,7} Primary care practices were not included in the NAP5 AAS, but they are potentially important to gain a full description of dental sedation and anaesthesia practice.

Dental patients in this survey were usually healthy patients undergoing day case procedures and also, fewer adults were obese than found in the non-dental patients (obesity was reported in 22% of the AAS). Nevertheless almost all patients were managed by fully trained anaesthetists (as were virtually all patient groups in the NHS⁸). The majority of the dental activity took place midweek and

probably less than 10% at the weekend. However, because a two-day period was recorded and not the exact day, we are unable to be more definite about weekend activity.

There were clear differences between adults and children in terms of the airway management and drugs used. Many more children than adults, received a GA by face mask or SAD and did not receive any LA or opioid: almost all adults received opioid or LA. These differences were probably related to the type of dental procedure: simple dental extractions or conservation treatment may not require LA or opioid whereas treatment in adults is more painful. However, this assumption could usefully be examined further. It would be of concern if children were more likely to receive analgesia-free anaesthesia for potentially painful procedures. Anaesthesia in children was also less frequently induced in an anaesthetic room which suggests that they were more often managed in a dedicated dental facility, although we cannot be certain because the questionnaire lacked sufficient detail.

Our estimate of the annual dental caseload of 111,600 included 65,600 children, of whom two thirds (67%) were school age (age 6-15y). This caseload (45,000) was 17% of all school age children in the AAS, was similar in size to ENT (18%) and orthopaedics & trauma caseloads (20%) and larger than the general surgery caseload (12%). Our data are supported by estimates published by the Faculty of Dental Surgery:⁸ from 2013 hospital episode statistics (HES), approximately 67000 patients under 19y were admitted to hospital with dental caries in England Scotland and Wales. Our data were of children <16y old and will inevitably have included procedures for dental problems other than caries. According to HES⁹ dental caries is the most common reason why a child (5-9y old) is admitted to hospital and accounts for approximately 31% of GAs in this age group. Compared to non-dental procedures the proportion of dental cases involving the elderly (age >65) is low (1.5% dental v 27% non-dental).

The AAS gathered data only from NHS hospitals. Dental activity in hospitals and clinics outside the NHS, both anaesthesia and sedation, may be appreciable and its size is unknown. Understanding its activity would consolidate dental planning and training. Registration of private dental facilities within a central organisation could be an important step to enabling a comprehensive UK activity survey not only of size but also of quality of patient management, its difficulties and its safety.

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Short Report

Audit of Conscious Sedation Provision in a Salaried Dental Service

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Abstract

Clinical audit is a tool that may be used to improve the quality of care and outcomes for patients in a health care setting as well as a mechanism for clinicians to reflect on their performance.

The audit described in this short report involved the collection and analysis of data related to the administration of 1,756 conscious sedations, categorised as standard techniques, by clinicians employed by an NHS Trust-based dental service during the year 2014.

Data collected included gender, age and medical status of subject, the type of care delivered, the dose of drug administered and the quality of the achieved sedation and any sedation-related complications.

This was the first time that a service-wide clinical audit had been undertaken with the objective of determining the safety and effectiveness of this aspect of care provision.

Evaluation of the analysed data supported the perceived view that such care was being delivered satisfactorily.

This on-going audit will collect data during year 2016 on the abandonment of clinical sessions, in which successful sedation had been achieved, due to the failure to obtain adequate local anaesthesia.

Introduction

The recently published document, *'Standards for Conscious Sedation in the Provision of Dental Care, Report of the Intercollegiate Advisory Committee for Sedation in Dentistry'*¹ published in April 2015 created a national standard for conscious sedation in dentistry. In the foreword the document states, *'The foundation of this report is high quality training and robust assessment of outcomes. High quality care recognises the need for audit and reflection...'*

Clinical audit and clinical effectiveness are two components of clinical governance which may be used to assess quality of clinical outcomes. Data to assess these components was collected during year 2014 by the salaried dental service of Cumbria Partnership NHS Foundation Trust (CPFT) for all conscious sedations administered by dental staff who use such techniques to help those patients with problems related to excessive anxiety, cooperation, movement disorders and a sensitive 'gag reflex'.

The Trust's dental service is organised as an integrated network of three locality teams operating across the wide geographic area of

Cumbria. There are a total of seventeen dental officers involved in the delivery of all or some of the basic sedation techniques - intra-venous, inhalation and trans-mucosal (Intra-nasal) sedation and are supported by a team of sixteen dental nurses who hold the National Examining Board for Dental Nurses Certificate in Dental Sedation Nursing.

Rationale for the Clinical Audit

The rationale for the clinical audit was to answer the question, *'are we doing things right?'*, i.e. is safe and effective sedation being delivered? It was postulated that the results would indicate whether conscious sedation was being delivered within acceptable tolerance limits or else highlight significant variations that would require further investigation. Additionally, it is becoming increasingly necessary to demonstrate to Commissioners and referring colleagues the quality of care provided and that the service was focussing on those patients who exhibited 'complex needs' in contrast to those categorised as 'standard patients'.

The numbers of staff involved in the provision of sedation and the number of sedation administrations were considered a critical mass sufficient to render the resulting audit data meaningful.

Case Mix Model

The Case Mix Model² is an Index designed to measure patient complexity based on the individual's impairment or disability rather than the technical complexity of the clinical dentistry to be delivered; this tool was utilised in this audit. Six independent criteria are used to indicate a measurable level of patient complexity; ability to communicate, ability to co-operate, medical status, oral risk factors, access to oral care and legal and ethical barriers to care. Each criterion is independently measured on a four-point scale where zero represents an average fit and well child or adult with the other three points representing increasing levels of complexity. These points are assigned a weighting which is used to calculate the maximum score for each course of treatment and corresponds to one of five bands of patient complexity, (see Table 1).

Table 1. Case Mix Banded Scores

Total score	
0	Standard patient
1-9	Some complexity
10-19	Moderate complexity
20-29	Severe complexity
30+	Extreme complexity

CASE STUDY

Conscious Sedation Techniques used

The basic techniques used were inhalation sedation (IS) using nitrous oxide (N₂O) and oxygen, and intravenous sedation (IV) using Midazolam as a single drug. Trans-mucosal (Intra-nasal) sedation using Midazolam was utilised in a few cases to assist cannulation in learning difficulty patients and in some patients who exhibited a needle phobia.

Data Collection

Data was recorded on an electronic custom-designed spreadsheet by each sedationist using the proprietary software package, Microsoft Excel®; this data was collated and statistically analysed at the end of the calendar year and the results distributed to members of the sedation team and also to the Trust's Clinical Effectiveness and Audit Department.

Variables collected included the age of the patient, gender, the American Society of Anaesthesiologists (ASA) physical status classification system used to assess fitness for surgery³, was utilised to gauge medical fitness for sedation and was recorded at the assessment visit, the type of sedation administered, dose of Midazolam in milligrams (mg) and the maximum concentration of nitrous oxide used expressed as a percentage (N₂O%). Qualitative evaluation of the sedation was measured using criteria from the Dental Sedation Teachers Group (DSTG) Logbook of Clinical Experience in Conscious Sedation⁴ which consisted of three components: a categorical score to indicate the depth of sedation, the assessment of operating conditions and the recovery rate. An overall sedation rating was given by use of the Houpt Sedation Rating Scale⁵ using the categories: aborted, poor, fair, good, very good and excellent. Other information collected included the cannulation success rate for the first attempt, Case Mix Index, type of care delivered and complications of the sedation.

Results

The results presented in this report relate to the total number of sedation administrations rather than completed courses of treatment, (please see Table 2).

A total of 1,756 sedations were delivered of which 1,106 (63.0%) were inhalation sedation, 642 (36.6%) were intra-venous and 8 (0.5%) were intra-nasal administrations. The age range was from four to eighty-four years, with a median value of 19 years. The data revealed that, for all administrations, more sedations were administered to females than to males, 1,105 (63%) and 651 (37%) respectively and in adult patients, just over twice as many intra-venous sedations were administered to female patients 438 (68%) than to male patients 204 (32%). Of the total of inhalation sedations given 783 (70%) were to children aged sixteen years or less.

The majority of administrations, 1,656 (94%), were to patients graded as either ASA 1 or ASA 2. Case Mix Index analysis revealed that 1,003 (57.1%) administrations were to patients rated as Moderate Complexity, 696 (39.6%) were of the Severe Complexity category whilst 16 (0.9%) administrations were to patients categorised as Extreme Complexity.

The average dose of Midazolam used to achieve adequate sedation was 7.0 mg which was also the median value; 91 (14%)

administrations were of a dose equal to or greater than 10 mg and the range used was from 1 mg to 20 mg. The success rate for cannulation at the first attempt was 84.6%; a total of 7 (1.1%) appointments were abandoned due to failed cannulation attempts.

Both the mode and the median value for the concentration of nitrous oxide used to achieve satisfactory operating conditions for inhalation sedation was 40%; the minimum and maximum values ranged from 10%, three administrations, to 70% for one administration.

Unsurprisingly, the vast majority of care delivered was for basic restorative dentistry, routine exodontia or a combination where fillings and extractions were undertaken during the same appointment visit; these three types of care accounted for 1,587 (90%) of administrations. Inhalation sedation or intra-nasal sedation techniques were used on 23 (1.3%) occasions to facilitate cannulation.

Qualitative assessment using the Houpt Sedation Rating Scale revealed that 1,522 (86.6%) administrations were categorised as good, very good or excellent and 63 (3.5%) sedations were aborted. Use of the DSTG criteria for Assessment of Operating Conditions showed that these were 'good – patient fully cooperative with optimum degree of sedation' on 1,598 (91%) of occasions with only 54 (3.1%) sedations graded as 'Impossible – action taken, e.g. ref General Anaesthesia'. Recovery was found to be 'normal – Within timescale expected' on 1,732 (98.6%) of occasions.

The total number of reported complications for both types of sedation was 41 (2.3%) but in some cases the information was not detailed enough to meaningfully categorise. Examples for intra-venous sedation complications included short periods of desaturation where supplemental oxygen was given, 7 (17%) cases, 1 (2.4%) recorded paradoxical reaction in which the patient became more rather than less anxious, 1 (2.4%) report of tachycardia necessitating abandonment of the session and the patient being subsequently referred for a general anaesthetic and 1 (2.4%) instance of bradycardia. One case was abandoned after the administration of 20 mg of Midazolam; the patient had a previous history of substance abuse and no sedation effect was achieved after this amount had been given. Some of the reported incidents related to inhalation sedation included 2 (4.8%) incidents of crying with other reports of giggling, confusion, feeling nauseous during recovery periods and abandonment due to high levels of anxiety rendering the patient uncooperative. Using the National Patient Safety Agency definitions of degree of harm the complications were categorised as 'no harm' or 'low harm'.⁶

Flumazenil, a specific benzodiazepine antagonist drug that reverses the sedative, cardiovascular and respiratory depressant effects of Midazolam and is useful for both elective and emergency reversal of intra-venous sedation when benzodiazepines are used,⁷ was administered on 14 (2.2%) occasions; the reasons for this drug being used are described in the following section.

Discussion

A significant number of referrals related to child patients who were deemed to 'exhibit poor cooperation for invasive dental procedures in the dental practice' by their dental practitioner. Almost three-quarters of the inhalation sedation administrations were to subjects aged sixteen years or less which was reflected in the

Table 2

Clinical Audit of Conscious Sedation Administrations Year 2014

Total Number of Administrations

1,756

Age Range (years)

4 - 84

Median Age (years)

19

Gender	n	%
Males	651	37%
Females	1,105	63%

IV Dose information

Average amount of Midazolam (mg)	7.0
Range (mg)	1 - 20
Median value (mg)	7.0
Number of doses of 10.0 mg or more	91
Per cent of doses of 10 mg or more	14.2%

Use of Flumazenil	n	%
	14	2.2%

Haupt Sedation Rating Scale	n	%
Aborted	63	3.6%
Poor	33	1.9%
Fair	138	7.8%
Good	768	43.7%
Very Good	391	23.3%
Excellent	363	20.7%

Type of Care	n	%
Restorative	775	48.1%
Extractions	695	43.1%
Restorative & Extractions	117	7.3%
Cannulation facilitation	23	1.4%

Case Mix Index

Complexity and Score range	n	%
Standard (0)	0	0%
Some (1 - 9)	41	2.3%
Moderate (10 - 19)	1,003	57.1%
Severe (20 - 29)	696	39.6%
Extreme (30+)	16	0.9%
Total	1,756	100%

Cannulation Success Rate	n	%
First attempt	543	84.6%
Cases abandoned due to failed cannulation	7	1.1%

ASA	n	%
ASA 1	764	43.5%
ASA 2	892	50.8%
ASA 3	100	5.7%

Type of Sedation	n	%
Intra-Nasal	8	0.5%
RAs	1106	63.0%
IVs	642	36.5%

Concentration of nitrous oxide	n	%
N₂O		
30%	152	13.7%
35%	101	9.1%
40%	456	41.2%
45%	99	8.9%
50%	210	18.9%

CASE STUDY

median age of 19 years found in the audit; not unexpectedly, most of these patients were fit and healthy which accounted for significant numbers defined as ASA 1 and also for the high proportion of cases categorised by the Case Mix Model Index as being of 'Moderate Complexity'.

For all patients, conscious sedation was administered 1.7 times more frequently to females than males which was comparable to findings of a multi-centre audit in South and West Wales⁸ in which there were 1.4 times more female patients than male patients.

For adult patients in the CPFT audit, intra-venous sedation was administered more frequently to female patients than to males; however, unlike the Adult Dental Health Survey (ADHS) 2009,^{9,10} in which the Modified Dental Anxiety Scale (MDAS)¹¹ was used to measure anxiety levels, such information was not available in the CPFT audit. The ADHS found that 17% of women were categorised as being very or extremely anxious whereas the comparable figure for men was 8%; the dental service has included the MDAS variable in the ongoing audit for year 2015 which will enable anxiety levels to be determined by gender for comparison to the values reported in the ADHS.

The low number of reported incidents of complications suggested that the technique of 'titration to effect' was successfully utilised in patients who had been appropriately assessed prior to the sedation visit. In cases where a treatment session was abandoned due to 'impossible' operating conditions the facility to complete care on a subsequent occasion under a general anaesthetic was available.

Flumazenil was used on 14 (2.2%) occasions; a retrospective review of the case notes revealed that twelve administrations were to patients who exhibited significant mobility problems, severe learning disability or those patients who were diagnosed with autism and in some cases a combination of these conditions. Its prime use was to enable escorts to better able manage the return of such patients from the surgery to their place of residence; none of the administrations were for emergency reversal of complications. The dental service treats a significant number of patients who experience various impairments and disabilities who would benefit from the elective administration of Flumazenil; this is regarded as an appropriate and accepted practise in these circumstances and its use is safe and justified¹². Additionally, one administration was to reverse a situation in which a patient experienced bradycardia during the sedation process and one administration to electively reduce the recovery time in a 'routine case' which was deemed to be an inappropriate use of the drug. The low frequency of use of Flumazenil compares favourably with results from a study in a Hospital Sedation and Special Care Dentistry department where it was used in 7% of sedation treatment episodes;¹³ interestingly no sedations were reversed for emergency reasons in the above study.

The success rate for first time cannulation of 84% indicated a high level of operator skill for this invasive procedure which was a welcome finding; in only 7 incidences was cannulation not achieved for the sedation process to continue.

Records of the dental nurse team who had supported the sedationist in the dental surgery and undertaken recovery room duties was collected and subsequently given to each dental nurse. This information was readily extracted from the dataset and used by the dental nurse to evidence maintenance of skills to justify continued practise, a requirement clearly stated in the IACSD Report¹, and also to support Continuing Professional Development portfolios and the annual appraisal process.

The audit is on-going and for year 2016 it is intended to collect information relating to the abandonment of satisfactory sedations due to failed local anaesthesia.

Conclusion

Qualitative assessment using the Houpt and DSTG criteria indicate that the sedations were being carried out successfully and safely; analysis of dose administrations showed that the amounts of sedative agents were not excessive to achieve conditions at which operative care was delivered.

In the Executive summary of the IACSD Report¹ paragraph 7 states, "Sedation services must demonstrate a high level of safety and a continuing improvement in quality. The use of appropriate audit tools to review clinical outcomes is an essential component of good clinical practice. Careful and reflective use of such data will enhance patient safety and improve quality of care"; this audit begins to address this requirement.

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A Synopsis of articles of interest from the last twelve months to inspire further reading



Fareed Ahmad

The Impact of Dental Phobia on Patient Consent

Muschik S, Kallow
J. Br Dent J 2015; 219: 183-185

Aim: This paper discusses the impact of dental phobia on the informed consent process, with the aim of identifying shortcomings in the standard procedure for obtaining informed consent with particular reference to patients who are dentophobic. The authors explore practical steps that can be taken to help such patients to achieve valid informed consent.

Discussion: The authors examine the steps normally followed for obtaining informed consent from patients and suggest a re-evaluation of this process when dealing with anxious patients. The standard procedure should include the giving of written information; taking into account the extent of the patient's understanding of the treatment; assessment of the patient's capacity; the need for informed consent to be given voluntarily; the recognition that the patient has the right to refuse.

Written information is useful but a survey of dental sedation leaflets in four regions showed they lacked important points. Although studies repeatedly report that patients struggle to comprehend medical information, the authors found that dentophobic patients seemed to feel *more* secure about their understanding of their treatment than their non-phobic counterparts because *'threatening information is prioritised (...) with prioritised attention.'*

Capacity may be impaired because 'phobias cause irrationality in perception.' Informed consent should be given voluntarily but the decision to give consent may be perceived to have been thrust on the patient in an emergency situation. Research suggests that patients are unaware that, even after initial consent is given, they are still able to change their minds or refuse the procedure. The ongoing nature of informed consent does not end with a signature.

Conclusion: Informed consent is an ethical and legal principle that protects patients' rights to make autonomous decisions about their treatment. Patients who are dentophobic may struggle to weigh

information fairly to come to a balanced decision, but can be aided in doing so by improving the quality of information they are given and establishing a trusting rapport with their dentist. It is important to ensure that patients with dental anxiety can make decisions under circumstances with as little pressure as possible, and to raise their awareness that they may refuse treatment at any point. This will also return a sense of control, which in turn reduces anxiety. Other barriers to valid informed consent are institutional in nature, and it is both an ethical and legal duty to overcome these to ensure patients can achieve a truly informed consent.

Reviewer's comments: This is an important contribution on the subject of informed consent and highlights the need to take extra care with patients who are dentophobic. It suggests that dental phobia may affect patient understanding as information may be perceived as threatening or being offered in a threatening environment. Therefore, there is need to consider an 'enhanced' consent process for nervous patients. The authors have been focussed and precise in offering several common sense recommendations to improving the informed consent process for dentophobic patients which sedation practitioners should find useful.

FA



Mike Sury

Personal view. "This may hurt": predictions in procedural disclosure may do harm.

Baruch S Krauss
BMJ 2015;350:h649

Krauss begins "'procedural disclosure" involves clinicians providing a description of the sensations that they assume patients are likely to experience during a procedure. The presumed rationale is threefold: as a corollary of the principle of informed consent; as part of truth telling in the clinician-patient relationship that fosters trust; and to help patients cope with procedures. But this seemingly intuitive rationale has not been critically assessed."

It is common for clinicians to use the generic script of "I am going to do X, and you will feel Y" because it is believed that most patients will respond similarly to a noxious stimulus. Moreover such disclosure is considered to be ethically the right thing to do because it is accurate, does no harm, and benefits patients.

However, this does not account for the wide range of individual responses (based on temperament, experience, coping style, and cultural tradition). Indeed Krauss argues that studies on nocebo effects have shown that "Negative expectations may produce symptoms or worsen existing symptoms." For example, in one study "Videos of patients undergoing interventional radiological procedures show that warning them of impending pain or an undesirable experience results in significantly greater pain and anxiety than informing them with a neutral statement (for example, "What does it feel like?") or a statement focusing on competing sensations (such as "cooling, tingling, or numb")."

In a study of women receiving epidural or spinal anesthesia who were randomised to "reassuring" words ("We're going to give you a local anaesthetic that will numb the area, and you'll be comfortable during the procedure") had lower pain ratings than those who heard "harsh" words ("You're going to feel a sting; this is the worst part of the procedure"). A recent study involving neuroimaging found that, compared with no expectation, positive and negative expectations doubled and abolished (respectively) the analgesic effect of remifentanyl. Positive expectation was associated with activation of pain inhibitory regions in the brain; negative expectation was correlated with increased hippocampal and prefrontal cortex activity. "Therefore, calibrated and nuanced language is required to communicate truthful information that positively influences the patient's affective state while minimising negative responses.

Because it may not always be possible to match disclosure language to the patient's subjective experience, open ended statements, can be more helpful than firm predictions. For example "I am going to give you an injection now," instead of "This may hurt a little"; or "You may feel something now," instead of "This will sting for a moment"; or "You may be feeling some of the changes from the medication," instead of "This medication may make you dizzy."

"Although there is a method for, and training in, communicating a terminal diagnosis or poor prognosis (that is, compassionate delivery of information that tells the truth but does not destroy hope), no analogous training or method exists for delivering procedural disclosure information. Nocebo research highlights the need for such training and provides a framework for developing an evidence based method through the specific phrasing of information—one that avoids negative expectations without compromising the ethical standards of informed consent.

He concludes "Open ended statements such as "You may feel something now" allow for patients' widely varying responses to stimuli and are less likely to invoke a nocebo reaction." Reviewer's comments: This paper is a personal view of the problem of "procedural disclosure" or "what to say"; or indeed "what not to say" to patients before a painful procedure. A nocebo, unknown to many clinicians, could be as important as the more well-known placebo. A placebo is the beneficial effect of therapy based on an expectation of benefit and a nocebo is the harmful effect related to the expectation of harm. Krauss explains that clinicians need to

be mindful that patients have widely different expectations and some patients will suffer unnecessarily if they expect to suffer. Probably, many dentists and anaesthetists will already know this yet I could find no internet reference to the concept related to dental practice. I found a short podcast from by the The Royal College of Emergency Medicine highlighting some common nocebos and also a course run by the British Society of Clinical and Academic Hypnosis.

The correspondence following this article was interesting. The points raised were that some patients will be shocked by the pain if they are not warned; some prefer to prepare for it. Not warning them could lose their valuable confidence, and this might be regarded as "Paternalism". A cancer sufferer responded and thought that minimising information to reduce fear was a form of "lying by default" or "dumbing down" and was not wanted – by this individual! Kraus's main point is that we need to be mindful of what we say and help patients through a procedure without causing unnecessary distress. It's the "words" that could be tailored to individuals. The choice of non-verbal behaviour will also be important.

MS

Enhancing a sedation score to include truly noxious stimulation: the Extended Observer's Assessment of Alertness and Sedation (EOAA/S).

Kim TK, Niklewski PJ, Martin JF, Obara S, Egan TD. *Br J Anaesth.* 2015;115 :569-77.

Background: The depth of anaesthesia can be described by the noxiousness of a stimulus used to test responsiveness. The Modified Observer's Assessment of Alertness Sedation (MOAA/S) scale already has trapezius squeeze and the authors sought to expand the scale with a more painful stimulus.

Methods: Volunteers (n=20) were given a fentanyl and propofol anaesthetic. Doses were adjusted to achieve target blood levels. Propofol doses were gradually increased, in stages, from 0.5µg ml⁻¹ to 5µg ml⁻¹. At each stage the response (using the MOAA/S scale) to tetanic electrical stimulation was tested. The electrical current was then slowly increased to a maximum of 50mA or until the volunteer responded. A pharmacodynamic relationship between propofol concentration and MOAA/S scores was developed.

Results: Volunteers required higher propofol concentrations to prevent responsiveness to tetanic electrical stimulation than trapezius squeeze. The pharmacodynamic relationship, or model, was adequate.

Conclusions: Tetanic electrical cutaneous stimulation may be equivalent, in terms of noxiousness, to surgery. The Extended OAA/S (or EOAA/S) incorporates two noxious stimulations, (trapezius squeeze and tetanic electrical stimulation) and may have utility to assess depth of anaesthesia.

Reviewer's comments: It used to be said that anaesthesia was a "black and white phenomenon" but anaesthetists have come to accept that there are depths of anaesthesia and that we need descriptors to help to compare patients at similar depths. This

paper develops the idea by applying two painful stimuli to patients and shows that one stimulus (trapezius squeeze) can be suppressed by lower doses of anaesthesia than the other (electrical skin stimulation). These, therefore, are clinical markers of depth of anaesthesia and the authors suggested that failure to arouse or respond to tetanic stimulation could be used as a marker of surgical anaesthesia.

They have, therefore, created a combined scale of conscious level with anaesthetic depth – the Extended Observer's Assessment of Alertness and Sedation (EOAA/S) score (Table 1). I think this could be tested in the dental setting. Is a specified type of dental extraction equivalent to tetanic stimulation?

The type of anaesthetic is likely to be important. In this paper a combination of propofol with fentanyl was tested. The fentanyl dose was fixed, but the propofol target controlled infusion was gradually increased. The observers waited at least 5 minutes between each dose increment before they tested responsiveness. Responses were defined but the paper is somewhat vague about the definition of a positive response because it could have been purposeful or reflex movement. Nevertheless, if it was movement, movement is mainly a spinal response and as such will be suppressed by anaesthetics acting at both the spinal cord and the brain. Propofol is a poor immobiliser and it needs therefore to be combined with an analgesic to prevent pain related responses. The paper is also helpful because it shows that the doses required to cause deep sedation in 50% of subjects is very near that capable of anaesthetising 50% of subjects: the margin of safety is indeed narrow when considered in terms of a population. Moreover, for individual subjects it was not possible accurately to predict the effect of any increase in propofol blood level: in other words some patients are more sensitive than others and each must be taken, therefore, as an individual. It should also be appreciated that the blood levels were predicted, not measured, and predicted from uncertain pharmacokinetic models.

Table 1 (adapted from Kim et al, Br J Anaesth. 2015)

Score	Description	Level of sedation or anaesthesia
5	Responds readily to name spoken	Minimal
4	Lethargic response to name spoken	Moderate
3	Responds after name called loudly/repeatedly	Moderate
2	Purposeful response to mild-to-moderate shaking	Moderate
1	Responds to trapezius squeeze	Deep
0 _r	No response to trapezius squeeze*	Light general anaesthesia
0 _e	No response to electrical stimulation†	Deeper general anaesthesia

*10 pounds per square inch (~0.7kg cm⁻²) for 5s. †50 mA tetanus for 5s

MS

Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years.

Ashley PF, Williams CE, Moles DR, Parry J.
Cochrane Database Syst Rev. 2015 Sep 28;9

Background: Large numbers of children need sedation or anaesthesia for restorations or extractions of carious teeth. This paper is a literature review attempting to compare the efficiency of

sedation with general anaesthesia: it is an update of similar reviews conducted in 2009 and 2012.

Objectives: To compare sedation and GA, in terms of the morbidity and effectiveness, in children aged less than 18y having dental treatment.

Search methods: The following were searched: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, System for Information on Grey Literature in Europe, Latin American & Caribbean Health Sciences Literature, and Institute for Scientific Information Web of Science. Journals of all languages were included.

Selection criteria: Only randomized controlled clinical trials were included.

Data collection and analysis: Two reviewers applied a defined process of evaluation.

Main results: Sixteen studies were originally identified but none were eligible. Two new studies were identified but were not eligible.

Conclusions: No randomized controlled studies have been published exist comparing dental GA with sedation in children: these studies are needed.

Reviewer's comments: The authors should be credited for a careful literature search that had a negative result. It shows that there were no trials in which patients were randomised to receive sedation or anaesthesia. This statement is important but not surprising. Randomised Controlled Trials (RCTs) are expensive, time consuming and have major ethical problems. Indeed RCTs should only be considered when there is equipoise ie the investigators truly are unsure whether sedation or anaesthesia is best. Such thoughts would have to be expressed in the consenting process of participants. The type of sedation or anaesthesia would also need to be "thought-through" for example: Is a short propofol anaesthetic comparable to a midazolam technique? Would a patient (or parent) wish to be sedated (conscious) or unconscious? Would sufficient children be ambivalent about this? What are the benefits of one method over another? Is cost relevant to patients in the NHS? Would the cost be important to fee paying patients? Given that sedation has a less certain outcome, how would sedation failure or accidental anaesthesia be considered? In respect of morbidity, is this not dependent on the technique and the skill of the clinician? Is it not self-evident that parent and clinicians choose the best and most appropriate technique for children? With all these questions in mind, could a RCT be designed?

I think that it could, but I suggest that the authors' questions are more readily answered by large service evaluations. These are cheap, and have few ethical considerations. The profession could gather information about important outcomes of safety and time of recovery from the thousands of children who undergo an agreed standard of care. Randomisation of children to one method or another has been too difficult, so far. Will Ashley and colleagues prove that it can be done?

MS

An audit of the use of intravenous ketamine for paediatric dental conscious sedation.

Wood MN, Manley MC, Bezzina N, Hassan R.
Br Dent J. 2015; 218:573-7.

Aim: To determine the safety and effectiveness of conscious sedation with intravenous ketamine in children in a local dental practice.

Audit design: Over 3y, 3,751 children were treated (all were ASA I and II, mean age 7.5 years). The children were anxious (4 or 5 on the Venham scale). The initial dose of ketamine was 0.25 mg/kg (additional increments were 0.25 mg/kg). The mean dose 0.41 mg/kg.

Results: Seventy six per cent accepted the treatment without any problems: 19% experiencing gave minor resistance. Treatment was mainly extractions of carious primary teeth. There were no adverse reactions. Post-operative nausea was common.

Conclusion: Ketamine was safe. Training and service delivery were discussed.

Reviewer's comments: Michael Wood, who died unexpectedly this year, was a pioneer of paediatric sedation. His ideas have been honoured by Manley and colleagues who have gathered his data and created this report. It shows that one dedicated clinician can develop a method and, with careful record keeping, explain to his colleagues its success or otherwise. Michael used ketamine only (mean dose 0.41mg/kg (\pm SD 0.17, range 0.1–2.06mg/kg) in 3,751 anxious children: to achieve 76% acceptance (no crying) in a series of this size is impressive. Was the tiny 26g venflon influential in this? Some children cried but all had their treatment completed. The average treatment and recovery times were 6.7 and 26.6 minutes respectively. None desaturated. However, nausea and vomiting were nuisances and perhaps Ondansetron would have helped.

These data, albeit from an audit of one clinician, show what can be done. Other clinicians can now move forward to develop this technique. Ketamine is surprising safe at low doses, but all should know that unpredictable unconsciousness or laryngospasm can occur. The public and the profession will expect the necessary rescue skills and equipment to be present.

MS

A prospective, randomized controlled trial of conscious sedation using propofol combined with inhaled nitrous oxide for dental treatment.

Yokoe C1, Hanamoto H2, Sugimura M3, Morimoto Y4, Kudo C3, Niwa H5.
J Oral Maxillofac Surg. 2015; 73:402-9.

Purpose: Propofol can cause hypotension, injection pain, and airway obstruction. This study aimed to determine if combining inhaled nitrous oxide with propofol could decrease these problems.

Patients and methods: Eighty-eight patients undergoing dental procedures were randomised to receive either propofol alone (Group P) or propofol with 40% nitrous oxide (Group N+P). Using a target controlled propofol infusion, sedation was adjusted to

achieve Observer's Assessment of Alertness/Sedation scale score of 4.

Results: The mean (SD) dose (mg) of Propofol was significantly less ($p = .022$) in Group N+P (249.8 (121.7) v 310.3 (122.4)). The mean target concentration (μ g/mL) was significantly less ($p = 0.006$) in group N+P (1.81 (0.34) v 2.05 (0.44)). The mean (SD) fall in systolic blood pressure (mm Hg) was less ($p = 0.034$). in group N+P (11.0 (8.0) v 15.8 (10.2)). Injection pain was also significantly reduced with nitrous oxide ($p = 0.048$).

Conclusions: Nitrous oxide reduces the dose of propofol required for dental procedures. It also reduces the fall in blood pressure and the pain of propofol injection.

Reviewer's comments: In almost 90 anxious adults (20-68 years old) Propofol target controlled infusion was used to create conscious sedation. The target blood level was set at 3mcg/ml and then reduced according to clinical judgement. Sedation lasted close to one hour. In addition patients were randomised to either 40% nitrous oxide or air via nasal cannulae. Those who had nitrous oxide had a better experience in terms of venous access and reduced memory of dental pain; they also required less Propofol. The authors focus on hypotension yet hypotension was not defined and lowest blood pressure was not reported. Both groups had similar blood pressures, heart rates and bispectral index values. The main defect in this study was that the observer clinician knew whether nitrous oxide or air was being used and was therefore open to bias. The authors do not explain why this was not concealed but it was probably because they did not use a conventional relative analgesia machine with nasal mask. The authors did not describe the type of nasal cannulae but they admit there was much dilution with ambient air; they did not use inspired gas monitoring and they estimated that the true inspired nitrous oxide levels may have been near to 20%.

MS

Considerations during intravenous sedation in geriatric dental patients with dementia.

Sugimura M1, Kudo C, Hanamoto H, Oyamaguchi A, Morimoto Y, Boku A, Niwa H.
Clin Oral Investig. 2015;19:1107-14.

Objectives: To report on the complications and problems of intravenous sedation (IVS) in demented geriatric patients undergoing dental treatment.

Materials and methods: Complications are described in 25 geriatric dental patients. Records included local anesthesia dose, mouth water irrigation and type of dental treatment.

Results: There were 65 treatment episodes. Cardiovascular complications occurred in 46.2 % (13.8 % bradycardia 12.3% hypotension). Respiratory complications occurred in 52.3 % (41.5% coughing spells and 16.9% snoring). Many cases did not require water irrigation; but those who did needed longer sedation and more propofol and suffered many problematic coughing spells.

Conclusions: Specific care should be applied to prevent the aspiration of fluids in the mouth and pharynx. Dentists should

receive training to better manage these vulnerable group of patients.

Reviewer's comments: Old, frail uncooperative patients, with dementia, will be a challenge to dentists. Should they be managed under sedation or anaesthesia? Sugimura and colleagues managed 65 procedures (in a cohort of 25 patients) with sedation. The patients, classed as ASA 1 or 2, had a mean age of almost 80 years. The ASA grades were, however, not perhaps representative of the patients because 50% of them had either cerebral infarcts or hypertension (although, in fairness these diseases may not have affected their general health). The age range was not quoted ~ only the SD of 7.6 years. All were given intravenous sedation with midazolam and propofol. Approximate mean doses were 2.8mg/kg/h for propofol and 1.5mg of midazolam. The authors used Bispectral Index (BIS) (in 30 procedures only) and this they attempted to keep between 70 and 80. They expected some of the patients to have airway obstruction and respiratory depression. Instead of capnography, they used a stethoscope on the patients' necks to monitor breathing. All patients had nasal oxygen and so it is surprising that capnography was not used. There were plenty of potentially dangerous complications but no patient was harmed. Almost 90% of the complications occurred when the BIS was <70 and in some cases the BIS remained low long after the procedure was completed. This shows that BIS is difficult to target and its utility is doubtful. We cannot know from these data whether or not formal anaesthesia (involving a tracheal tube or supraglottic airway) would be safer than sedation. Anaesthesia would have used higher doses of propofol and would probably have caused more hypotension and bradycardia. Perhaps this is a scenario for equipoise and the place for a randomised comparison of GA versus sedation in this difficult patient group.

MS



Jennifer Hare

Computerized Tool to Manage Dental Anxiety: A Randomized Clinical Trial

Tellez M et al.
J Dent Res 2015; 94: suppl 1745-1805

Abstract: Anxiety regarding dental and physical health is a common and potentially distressing problem, for both patients and health care providers. Anxiety has been identified as a barrier to regular dental visits and as an important target for enhancement of oral health-related quality of life. The study aimed to develop and

evaluate a computerized cognitive-behavioral therapy dental anxiety intervention that could be easily implemented in dental health care settings. A cognitive-behavioral protocol based on psycho-education, exposure to feared dental procedures, and cognitive restructuring was developed. A randomized controlled trial was conducted (N = 151) to test its efficacy. Consenting adult dental patients who met inclusion criteria (e.g., high dental anxiety) were randomized to 1 of 2 groups: immediate treatment (n = 74) or a wait-list control (n = 77). Analyses of covariance based on intention-to-treat analyses were used to compare the 2 groups on dental anxiety, fear, avoidance, and overall severity of dental phobia. Baseline scores on these outcomes were entered into the analyses as covariates. Groups were equivalent at baseline but differed at 1-mo follow-up. Both groups showed improvement in outcomes, but analyses of covariance demonstrated significant differences in dental anxiety, fear, avoidance, and overall severity of dental phobia in favor of immediate treatment at the follow-up assessment. Of the patients who met diagnostic criteria for phobia at baseline, fewer patients in the immediate treatment group continued to meet criteria for dental phobia at follow-up as compared with the wait-list group. A new computer-based tool seems to be efficacious in reducing dental anxiety and fear/avoidance of dental procedures. Examination of its effectiveness when administered in dental offices under less controlled conditions is warranted.

Reviewer's evaluation, opinion and points of interest: This is an interesting paper in which the authors explore the benefits of a brief computerised intervention for dental anxiety management, based on Cognitive Behavioural Therapy (CBT) principles. The essential concept of the intervention is to provide a 1-hour computerised CBT (CCBT) intervention, immediately before attendance at a scheduled dental appointment. The CCBT programme consists of psycho-education on dental anxiety; some motivational interviewing (MI)-based techniques on the pros/cons of tackling their anxiety in order to foster engagement; following which patients are guided through their chosen 3 (from 6) dental procedure videos, in line with the concept of graded exposure (i.e. systematically working with the least to the most feared aspect of the specified dental treatment). The videos are graded in respect of the following levels; firstly individuals are provided with an explanation and animations of the chosen dental procedure, including close-ups of the tools involved; secondly they view videos focussed on a patient's use of cognitive coping skills (though these are not specified in the paper); and thirdly, a video is shown from the "patient perspective" providing more intensive exposure to demonstrate how the patient manages their anxious thoughts. The six dental procedures included in the graded exposure are restorations, cleaning, local anaesthetic injection, root canal treatment, X-rays and extractions.

The results of this randomized controlled trial demonstrate an encouraging reduction in anxiety levels at one-month follow-up, reported by the Modified Dental Anxiety Scale (MDAS) and other specific phobia scales. However, baseline measures indicate anxiety levels just at the cut-off point of the MDAS. Nonetheless a significant reduction was seen compared to wait-list controls. While there are limitations with the research that the authors recognise, the use of a brief CCBT approach for dental anxiety management certainly warrants further investigation. Its consideration within a stepped-care approach to the management of dental anxiety would be of interest in the context of other primary and secondary care services in the UK in the future.

JH

The use of Midazolam as an Intranasal Sedative in Dentistry

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Abstract

Intranasal delivery of midazolam is emerging as a significant tool in our dental armamentarium for the treatment of anxious children, phobic adult patients and patients with learning disabilities.

The administration of midazolam intranasally exploits the unique structure of the nasopharynx thus ensuring rapid delivery to the systemic circulation (The Nose – Brain Pathway). The absorption of midazolam nasally is influenced by the volume and concentration of midazolam, its physicochemical properties and the characteristics of the nasal mucosa. Delivering midazolam intranasally is non-titratable. The level of conscious sedation may be equivalent to that achieved by intravenous routes but is approached in a less controlled manner. Randomised Control trials using intranasal sedation in children have shown the technique to be safe and effective in secondary care for dental procedures at concentrations varying from 0.2mg/kg to 0.5mg/kg. A combined technique of intranasal midazolam (to facilitate cannulation) and intravenous midazolam is used for adults with moderate to severe learning disabilities. This has revolutionised dental treatment for this group of patients as treatment under General Anaesthesia (GA) may be avoided.

This paper explores the current use of midazolam as an intranasal sedative in dentistry and highlights the advantages of intranasal midazolam for adults and children requiring anxiety management and patients with moderate/severe learning disabilities.

Introduction

Intranasal drug delivery is emerging as an inexpensive and non-invasive method of delivering medications directly to the bloodstream.^{1,2} There are numerous routes of administration to consider when delivering therapeutic medications to a patient such as intravenous, intramuscular, or rectal. The delivery method will be influenced by the patient's individual requirements, patient selection, the specific medication chosen, the environment worked in and the relevant experience or training of the clinician.³ Intranasal sedation may be considered for a dental patient when the titratable techniques (inhalation and intravenous sedation) are deemed to be inappropriate.⁴

The management of an anxious or phobic dental patient has evolved substantially in the last fifteen years. The widespread availability of non-invasive monitoring, short acting sedatives and specific benzodiazepine antagonists have enabled clinicians to administer sedation safely in dental surgeries.^{5,6} Pain and anxiety management of patients is paramount in dentistry. All patients need and deserve to expect appropriate and individually considered pain and anxiety control for any dental procedure. The

desired outcome of procedural intranasal sedation is the safe and effective control of anxiety and motion that allows a necessary procedure to be performed and to provide an appropriate degree of memory loss or decreased awareness.⁵

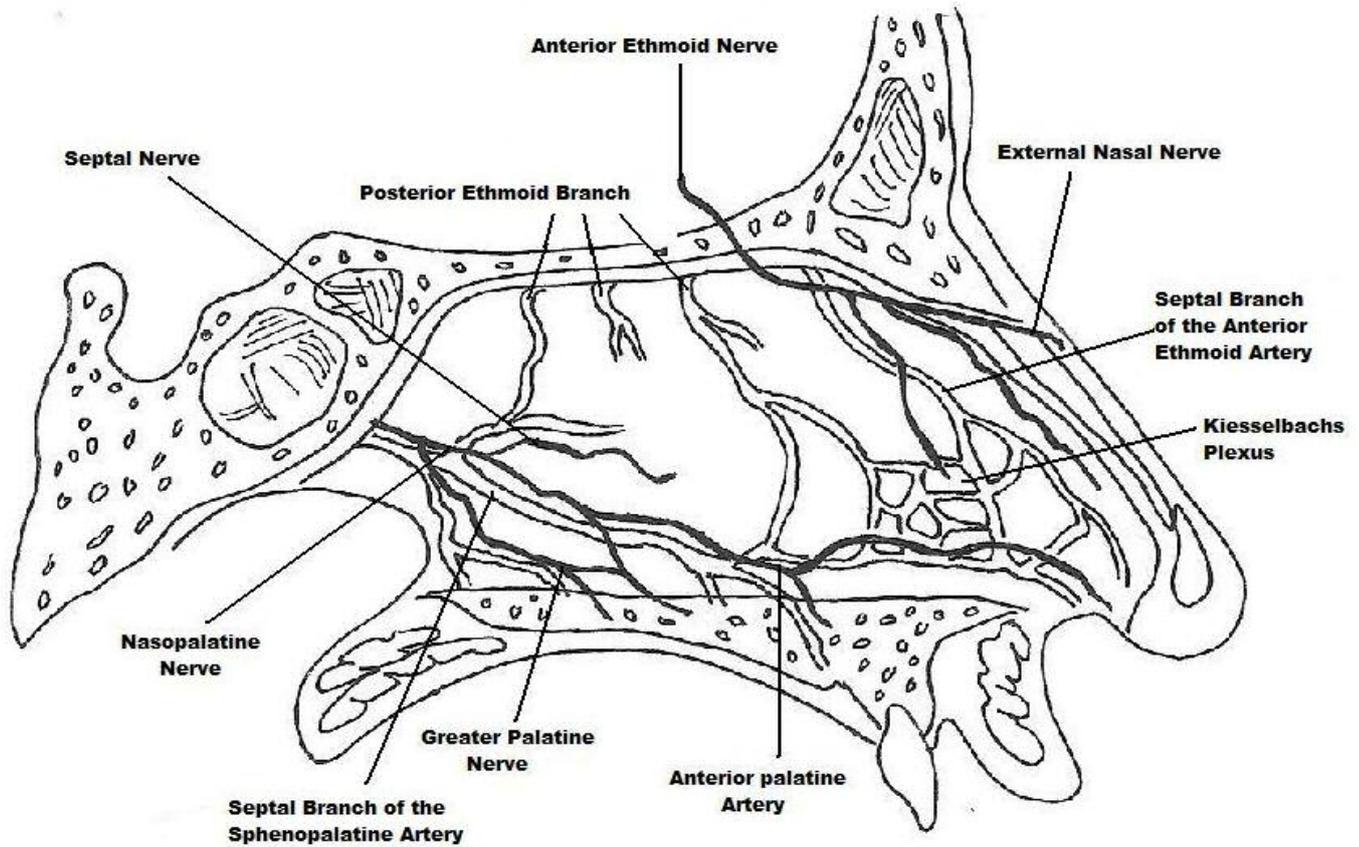
The majority of medications administered via the intranasal route are used "off-label".³ This is defined as 'the prescription of a registered medicine for a use that is not included in the product information'. This practice is common, with rates of 40% in adults and up to 90% in paediatric patients.⁷ Intranasal midazolam is used "off-label" when treating status epilepticus in adults and children.⁸ It also has a role in the premedication of anaesthesia in paediatric patients.⁶ In selected cases, intranasal delivery has many advantages over other administration routes, particularly when considering conscious sedation in the dental surgery. A widespread interest in the intranasal route for therapeutic purposes arises from the particular anatomical, physiological and histological features of the nasal cavity, which provides potential for rapid systemic drug absorption and quick onset of action.

Intranasal sedation is emerging as a significant tool in our dental armamentarium for the treatment of anxious children, phobic adult patients and patients with learning disabilities.

Anatomy of the Nasopharynx – A Unique Structure Enabling Drug Absorption

The primary function of the nose is olfaction but the secondary functions are filtration, heating and humidification of air,⁹ and to aid the movement of drugs into the bloodstream. The nose is divided into two nasal cavities by the midline septum. Each cavity opens at the face through the nostrils and extends posteriorly to the nasopharynx.² The volume of each cavity is approximately 7.5ml which provides a total surface area of approximately 150cm².^{2,10} Each nasal cavity contains a convoluted set of passageways called turbinates (superior, middle and inferior) on its lateral wall. The turbinates interrupt the flow of air as it travels into the nostril and divert the air through small passages that are covered with moist respiratory mucosa.¹¹ The turbinates maximise effective intranasal surface area and rapidly humidify and warm the inspired air.^{1,9} The respiratory epithelium lining the nasal cavity consists of basal mucosa containing goblet, ciliated columnar and non-columnar cell types.² Microvilli aid absorption into the lamina propria which supports a rich, vascular capillary bed. Branches of the nasal septal artery, nasopalatine and the external nasal artery branch to form this dense and concentrated capillary network.^{10,12} (Fig.1). When medications of suitable concentration and molecular character are delivered to the nasal mucosa, they are rapidly transported to the capillary bed and delivered to the patient's systemic circulation.

Fig. 1: Schematic Diagram of a Sagittal section of the Nasopharynx. Depiction of the blood and neural supply. (Author's drawing).



The Nose - Brain Pathway

Drugs delivered intranasally are transported directly to the cerebrospinal fluid via the olfactory mucosa. This concept of transfer of molecules from the nose to the brain is referred to as the 'Nose-Brain pathway'.^{1,10} The olfactory mucosa is located in the upper aspect of the nasal cavity and extends a short way down the septum and lateral wall. It lies just inferior to the cribriform plate of the ethmoid bone.^{9,10} The cribriform plate is perforated with tiny foramina that are transversed by olfactory nerve filaments that descend directly from the olfactory bulb. The neuroepithelium of the olfactory region is the only part of the CNS that is directly exposed to the external environment.¹³ Direct drug transfer to the CNS after nasal administration, via olfactory pathways that bypass the blood brain barrier, has been demonstrated in both animals and humans.^{14,15} This provides a unique pathway for the non-invasive delivery of therapeutic agents to the central nervous system (CNS).

Nasal drug delivery ensures that 'First Pass Metabolism' is avoided. Intranasal absorption avoids gastrointestinal and hepatic metabolism which greatly enhances drug bioavailability.^{1,8} There is no breakdown of the drug by liver enzymes as it does not enter the portal circulation.^{1,6,11} Levels of 80%-90% bioavailability can be reached with certain drugs e.g. intranasal Fentanyl (Sublimaze®) – a synthetic opiate used to treat pain.¹ An approximate bioavailability of 70% is accepted for intranasal Midazolam¹⁶ which is greater than that achieved with orally administered medications.

Guidelines for the Practice of Intranasal Sedation in Dentistry

A Report from the Standing Committee on Sedation for Dentistry (2007) describes oral/transmucosal benzodiazepine delivery as a 'Standard Technique'. Adequate competence in intravenous techniques must be demonstrated by the practitioner in conjunction with documented experience and relevant continuing professional development (CPD)/training.³

The use of intranasal midazolam combined with intravenous midazolam (non-sequential) routes is deemed an 'Alternative Technique'. This requires the practitioner to have documented experience of relevant standard techniques – at least 100 cases over last 2 years and not less than 4 years post-registration experience.³ Any form of conscious sedation for patients under the age of 12 years (other than nitrous oxide/oxygen inhalation technique) is deemed an 'Alternative Technique'. Patients under 12 years of age should only have sedation in a secondary care facility carried out by a trained and experienced sedationist.^{3,17}

Drug Administration : The Mucosal Atomisation Device

The most common method of intranasal drug delivery is via a Mucosal Atomisation Device. These devices deliver an atomised mist of medication to the mucosa of the nasal cavity (Fig 2). A

preferred technique is the use of a 1ml syringe with a Mucosal Atomisation Device attached. A small volume of Midazolam (0.25ml) at a concentration of 40mg/ml may be delivered to sedate adult patients with a learning disability prior to dental treatment.¹⁸ A smaller syringe enables the operator to control the dose with more specificity. It is debateable if intranasal solutions can be titrated; a bolus is usually required to achieve sufficient serum levels to produce an adequate clinical effect. Lazol et al¹⁹ describe their technique of second dose 'titration' of intranasal midazolam in children prior to echocardiography. A description of a titrated approach to intranasal midazolam delivery in dentistry has not currently been published.

Fig.2 A Mucosal Atomisation Device attached to a 1ml syringe (LMA[®]MAD NasalTM)



Advantages and Disadvantages of Intranasal Drug Delivery

Intranasal drug delivery is essentially painless. It does not require a sterile technique or the use of invasive delivery systems. It is a method that can be accessed quickly and readily in adults and children, even those with poor compliance. It achieves rapid, effective blood levels of the medication administered with a greater predictability than drugs administered orally. An improved bioavailability ensures a more cost-effective outcome. There is a no risk of needle stick injury with this method and at the present time no formal training is needed to deliver drugs intranasally.^{1,2,5,6} Patients with a needle phobia or learning disability can be sedated in the dental surgery initially with intranasal midazolam prior to achieving intravenous access for further increments of midazolam.¹⁸

A disadvantage is that very few drugs can be administered with this method. The drug must be of an adequate concentration at a low volume for successful absorption.^{1,2} The clinician may have limited working time with intranasal midazolam due to the small volumes of drug delivered which may result in 'top ups' of the drug being required,¹⁹ particularly in children. Well-documented side effects of benzodiazepine sedation may be observed e.g paradoxical effects in children of non-compliance and hysteria²⁰ and in some cases respiratory depression. The incidence of respiratory depression in healthy adult male patients with midazolam intranasal sedation has been reported as very low in a 0.2mg/kg study group.²¹ This double blind, randomised control study showed greater individual variations in midazolam plasma concentrations within the 0.3mg/kg group with one episode of severe respiratory depression. This study showed no benefit in using a dose of 0.3mg/kg of intranasal midazolam in adult patients.²¹

Factors Influencing Nasal Absorption of Midazolam

(i) Physicochemical Properties of Midazolam

The nasal membrane is predominantly lipophilic. This characteristic results in lipophilic drugs being well absorbed.^{1,2} Benzodiazepines e.g. midazolam are highly lipophilic and permeate the nasal mucosa well. It is important to clarify that this is true for lipophilic compounds presenting with a molecular weight lower than 1kDa. Midazolam has a molecular weight of 325.77 Da in its free base form and permeates well.²

The solubility of midazolam is less than 0.1mg/ml at neutral pH but increases considerably in acidic media. Intranasal midazolam has a pH of approximately 3. Patients report a burning, stinging sensation of the nasal mucosa following administration, due to its acidity.^{6,22} To prevent this pain and irritation, which may result in poor absorption, lignocaine 2% (0.5ml) can be delivered as a spray before administration of midazolam to anaesthetise the mucosa.^{1,22}

(ii) Midazolam Volume and Concentration

The use of the Mucosal Atomisation Device is not dependent on patient compliance and head position, which is advantageous for use with unco-operative children and adults in the dental surgery.²³ The use of a 'syringe dropper' to deliver drugs intranasally is not effective in patients with poor co-operation, as the technique requires the patient to be in a semi-recumbent position. If the patient is unable to comply with this then the drug is either lost to the external environment or swallowed by the patient.²³ The Mucosal Atomisation Device delivers a concentrated particle mist of midazolam to the large surface area of the nasal mucosa. The volume of midazolam should be low but at a high concentration. A volume of 0.25ml to 0.33ml per nostril is preferred as there is less 'run off' with smaller volumes. It is important to utilise both nostrils as it doubles the surface area for absorption and halves the volume delivered per nostril.¹

Historically, intranasal sedation of an adult patient was achieved with 10mg of midazolam, using a 10mg/2ml concentration.²² This concentration had many limitations as an excessive volume of 1ml was delivered per nostril. The development of a highly concentrated midazolam solution for intranasal use only was pioneered by Manley and Ransford in 2008.¹⁸ A vial containing a total volume of 0.5ml at a concentration of Midazolam hydrochloride 40mg/ml and Lignocaine hydrochloride 20mg/ml was developed with Guy's and St. Thomas' Hospital Pharmacy. Manley and Ransford researched the safety and efficacy of a combined IN/IV technique to sedate adults with a learning disability prior to dental treatment. Their research revolutionised the use of intranasal sedation in primary care; many adults with learning disabilities were able to have an oral examination and diagnosis made without an immediate referral for a general anaesthetic. This concentration is now used for intranasal sedation in primary care facilities and dental teaching hospitals in adults and children. Adult patients (needle phobic or those with a learning disability) are provided with a standard 10mg dose (0.25ml) usually as a combined method with IV midazolam.¹⁸

The Eastman Dental Institute advocate an intranasal midazolam dose of 0.2mg/kg in anxious children prior to dental treatment at a concentration of 40mg/ml with 20mg/ml lidocaine.¹⁷ Abrams

(1993) researched the safety and effectiveness of intranasal midazolam for urgent brief paediatric dental procedures in a secondary care facility. Midazolam dosage was calculated by weight at 0.4mg/kg. He reported that intranasal midazolam when compared to Sufentanil and Ketamine was 'ideal' for short procedures of approximately ten minutes duration.²⁵

(iii) Nasal Mucosa Characteristics

The condition of the nasal mucosa will determine the quality of drug absorption and drug bioavailability. A detailed preoperative medical history is imperative to highlight any previous nasal pathology or recreational drug abuse early in the consultation.

Nasal mucosa characteristics that may reduce drug absorption are:

- Previous nasal pathology e.g. Nasal polyps, Deviated/fractured nasal septum
- Blockage of nasal passages e.g. blood, mucus, foreign body
- Previous nasal surgery or drug abuse e.g. cocaine usage
- Medical conditions affecting nasal development e.g. Binders Syndrome^{1,3,9}

Conclusion

The anatomy of the nasopharynx is of a unique structure enabling drug absorption.^{2,9,12} It has a complex vascular supply and is lined with respiratory epithelium.² The nose – brain pathway is a route of direct access for therapeutic medications to the CNS.^{1,10}

The pharmacokinetic characteristics of midazolam make this drug a preferred choice as an intranasal sedative.² A high bioavailability of 70% is advantageous.¹⁶

An intranasal technique should be used only when titratable techniques are deemed to be inappropriate. The state of conscious sedation might be as deep as that produced by the intravenous administration of drugs, but approached in a less controlled manner.⁴

The randomised control trials using intranasal sedation in children have shown the technique to be safe and effective.^{24,25} Sedation in children under the age of 12 years must be carried out in a secondary care facility with an appropriately trained sedationist.^{3,17} The literature has revealed that various dosages of intranasal midazolam are being used in secondary care for dental procedures in children.^{24,25,26} The use of 0.5mg/kg intranasal midazolam provides a longer duration of sedation enabling the dentist sufficient time to perform a more complex dental procedure e.g. restorative work. The use of 0.2mg/kg is a preferred dose used at UCL Eastman Dental Institute for 'rapid' procedures lasting approximately 10 minutes e.g. extraction of a deciduous tooth.¹⁷

There is a limited literature base for the use of intranasal midazolam in adult dental patients. Manley and Ransford (2008) demonstrated a technique of using intranasal midazolam at a concentration of 40mg/ml and lignocaine hydrochloride 20mg/ml to sedate adult patients with a learning disability.¹⁸ The technique was shown to be safe and effective in primary care.

The use of intranasal Flumazenil has been shown to be effective in reversing the effects of midazolam over-sedation in children.²⁶ This technique shows promise but further substantiated research is required in this area.

In summary, intranasal midazolam is easy to use and is an effective mild sedative prior to dental procedures. Patient selection is critical in its overall 'success' and provides an alternative choice for sedating non-compliant children, needle phobic adults and patients with a learning disability.

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Articaine – to use or not to use?

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Introduction

A recent survey¹ showed that the majority of dentists in Australia use articaine for local anaesthesia, which is also favoured in North America and continental Europe; whilst in the UK, lidocaine is viewed as the gold standard local anaesthetic agent.² This may be linked to concerns over articaine's potential to cause post-operative paraesthesia.^{3,4} However, there is evidence refuting these claims. Lidocaine is often used as the benchmark local anaesthetic agent in articaine research and the results of these studies are conflicting. The objective of this essay is to review the literature both for and against the use of articaine and to explore the scientific rationale behind these findings. However, it is important to note that studies do not always account for confounding factors, which can contribute to failure to achieve adequate anaesthesia in the dental chair.

It is essential to consider what the local anaesthesia is needed for when making a clinical decision on local anaesthetic agent. Placement of a rubber dam for a composite restoration may only require soft tissue anaesthesia and incomplete pulpal anaesthesia may well suffice. Exodontia will require complete soft tissue anaesthesia for a relatively longer period of time although complete pulpal anaesthesia may not be absolutely necessary. Pulpotomy is perhaps the procedure in dentistry which requires the highest level of anaesthesia possible; removal of inflamed pulp tissue involves direct manipulation of A- δ and C-fibres, which convey pain and may already be sensitised by inflammatory products, for an extended period of time.

Advantages and Disadvantages of using articaine

Neurotoxicity and nerve damage are commonly cited reasons for not using articaine. Renton⁵ and Meechan⁶ have suggested that suspected adverse effects of articaine may have been over-reported, a commonplace practice when drugs are newly introduced. In the *US Food and Drug Administration's* (FDA) clinical caveat⁷ accompanying their Adverse Event Reporting System data; they state, "For any given report, there is no certainty that a suspected drug caused the reaction ... Accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate drug risk. Comparisons between drugs cannot be made from these data."

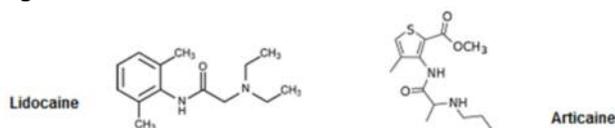
Drug Analysis Prints (recording reported suspected adverse drug reactions) from the UK's *Medicines and Healthcare products Regulatory Agency* (MHRA),⁸ has only documented three cases of suspected nerve injury linked to articaine use from its approval in 1998 up to February 2015. A retrospective review by Gaffen et al.⁹ found the incidence of nonsurgical paraesthesia from articaine use to be 1:410,000.

It has been proposed that local anaesthetics can cause nerve damage by post-operative inflammation. A study¹⁰ has shown that lidocaine produces an inflammatory response of a lower intensity than articaine. Lidocaine formulations are commonly used for local anaesthesia in dentistry and are not linked to reports of increased neurotoxicity and nerve damage. However, another study¹¹ found that nerve damage prevalence from lidocaine was greater than articaine, concluding that reports of nerve injury from articaine administration are proportional to their usage.

Although data comparing the incidence of pulpal anaesthesia of articaine against lidocaine formulations have been conflicting, a recurrent finding is that articaine formulations have a quicker onset than lidocaine.¹² Meta-analysis by Brandt et al.¹³ concluded that articaine's potency is 1.6 – 3.5 times that of lidocaine. Another study¹⁴ has found articaine to be 3.8 times superior in infiltration anaesthesia and 2.4 times more potent overall. Meta-analyses^{13,15-18} investigating articaine have all recommended articaine over lidocaine. These findings may be explained by its chemical structure.

Lidocaine is a derivative of a benzene ring structure (C₆H₆) whilst articaine derives from thiophene (C₄H₄S). Thiophene's structure is more lipid-soluble than benzene. Consequently, articaine diffuses through the lipophilic membrane of the epineurium more easily than lidocaine^{12,19} and increases the likelihood of local anaesthesia.²⁰

Figure 1 Chemical structures of lidocaine and articaine



Allergic reactions to articaine are caused by its amide group, which can also be found in lidocaine. This can account for the similar frequency of allergic reactions to both drugs.²¹ Articaine also contains an ester group which allows metabolism by plasma esterase enzymes (as well as in the liver, similar to amide-containing anaesthetics)²⁰ reducing its risk of systemic toxicity. Although articaine in tissue fluid is broken down faster than lidocaine, articaine provides a longer period of anaesthesia.¹² This may be explained by its greater potency.

Articaine's enhanced duration of soft tissue anaesthesia²² may be advantageous in oral surgery. Patients are routinely advised to take analgesics before local anaesthesia subsides; the underlying rationale is to ensure that the analgesics reach their effective dose before local anaesthesia diminishes. The time period from administration of local anaesthetic to post-operative analgesics reaching effective levels can be affected by numerous factors; such as the length of the procedure, how long it takes for the patient to obtain analgesic medication and the absorption time from the

gastro-intestinal tract). Hintze et al.²³ reported a mean duration of almost three hours of soft tissue anaesthesia when using 4% articaine solution. Taneja et al.²⁴ suggested 4% articaine use would provide more effective post-operative pain management. Hillerup et al.²⁵ reported a disproportionate number of cases of neurosensory disturbance when articaine was administered as a mandibular nerve block. Similar to Meehan,⁶ they found higher involvement of the lingual nerve compared to the inferior alveolar nerve (IAN) and have previously suggested increased neurotoxicity of articaine.³ However, no disproportionality was found in another study²⁶ when administering articaine as an IAN block (IANB) with nerve damage. Pogrel et al.¹¹ concluded that the incidence of permanent nerve damage was independent of the local anaesthetic agent. Malamed²⁷ comments that articaine administered using Akinosi and Gow-Gates techniques and in general surgery have not been linked to increased incidence of nerve damage. He suggests that the conventional IAN block technique itself is traumatic; with the wide mouth opening causing the needle to shear, rather than deflect, the lingual nerve and/or IAN upon contact.

It has been suggested that bone contact deforms the tip of the needle and shears the nerve whilst being withdrawn. Nerve damage when administering an IAN block may be attributed to mechanical perineural, epi-neural or intra-neural trauma, causing haemorrhage, inflammation and scarring² and ultimately resulting in demyelination.²⁸ However, there is no reported method of preventing IAN damage when administering an IANB.²⁹ Cadaveric studies by Pogrel et al.²⁸ have found that the lingual nerve may have as few as a single fascicle at the level of the lingula whereas the IAN has at least three. Such neuroanatomy explains why the lingual nerve and its entire distribution³⁰ is more susceptible to neurosensory disturbance than the IAN, which may have more fascicles to compensate for those which are damaged.^{26, 28}

It is important to remember that the majority of the local anaesthetic cartridge is deposited at the IAN and not the lingual nerve, however, lingual nerve damage is much more prevalent.^{3, 28} This would support the idea that nerve damage is independent of local anaesthetic agent and more likely to be technique related.³¹ Haematoma formation has also been proposed as a mechanism of nerve damage after an IAN block^{26, 28, 30, 31} due to epineural vasculature product release within the epineurium during formation of a haematoma, resulting in fibrosis and scarring which will consequently pressurise and inhibit nerve regeneration.

Increased occurrence of paraesthesia has been reported following administration of 4% local anaesthetic solutions,⁴ which substantiates claims of increased anaesthetic concentration causing nerve damage. Hoffmeister³² found intra-neural injections of 4% articaine formulation did not cause toxic lesions and concluded neurosensory disturbances after injections are attributed to haematoma and scarring. It is currently unclear why articaine solutions are manufactured in 4% formulations,³³ it may be related to articaine's reduced systemic toxicity.³⁴ However, Malamed³⁵ concluded that associating 4% local anaesthetics with increased risk of neurotoxicity is unjustified given the level of evidence available at the time of writing.

Studies^{33, 36-40} comparing articaine against lidocaine often administer the same dosage, intending for the local anaesthetic agent to be the only experimental variable. Although the volume of local anaesthetic solution deposited is the same, the effective dose of an

articaine cartridge is double that of a lidocaine cartridge. A 2.2ml cartridge of 2% lidocaine formulation contains 44mg of lidocaine, whereas the same volume cartridge of 4% articaine solution contains 88mg of articaine. This point is often overlooked when comparing the efficacy of the two agents. Furthermore, the amount of adrenaline administered in both formulations is different, creating another variable; the effect of adrenaline on local anaesthesia success is currently contentious.⁴¹⁻⁴⁴

A suggestion could be for studies to use half of a 4% articaine cartridge in comparison to a full lidocaine cartridge. Although depositing precisely 50% is impractical, the effective doses of both drugs would be similar, though not identical. Alternatively, the efficacy of two 2% lidocaine cartridges could be compared against a 4% articaine cartridge but administering two lidocaine IANBs at precisely the same site is just as impractical as the previous suggestion. However, these two approaches would amplify any effect adrenaline dosage may have on efficacy.

It is the opinion of the author that use of equimolar solutions containing identical vasoconstrictor content, or none at all, would be required for a conclusion to be made over the drugs' relative efficacies. However, it may be more rational to consider the efficacy of articaine and lidocaine in their supplied formulations.

Maxillary Anaesthesia

Anaesthesia of maxillary teeth is commonly achieved by infiltrating the buccal vestibule fold adjacent to the appropriate tooth. It is often reliable enough to obviate the need for nerve blocks of maxillary nerve branches.⁴⁵

Studies often use the maxillary first molar as the test subject tooth but, in some patients, the thick zygomatic buttress can lie superficial to the tooth's root apices⁴⁶ and impede anaesthetic infiltration. Cranial anatomy can be highly variable between individuals but is not mentioned in studies^{38-40, 47, 48} investigating infiltration anaesthesia in maxillary molars. This may explain articaine and lidocaine producing similar results when used to anaesthetise maxillary molars with irreversible pulpitis.⁴⁹ However, meta-analyses^{13, 15, 17, 18} endorse the use of articaine over lidocaine. Articaine demonstrated a higher efficacy anaesthetising lateral incisors,⁴⁸ where there is no obvious anatomical factor of influence.

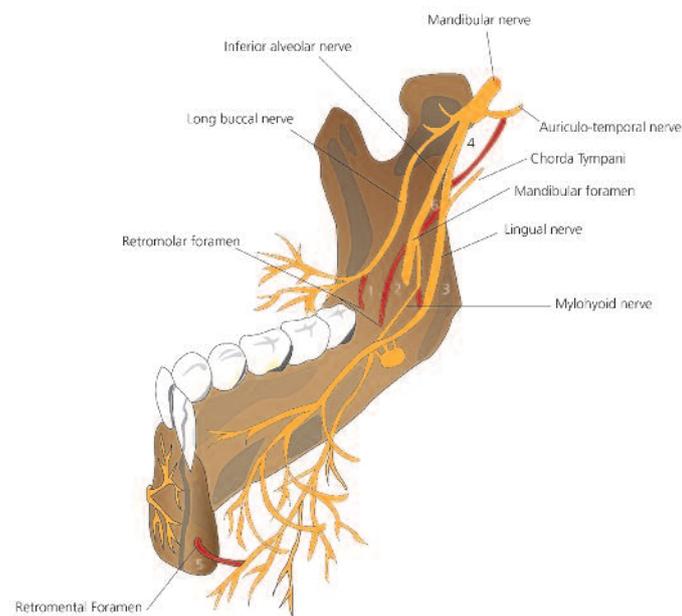
Maxillary infiltration using articaine provides a longer duration of anaesthesia than lidocaine.¹² The significance of this finding is variable and depends on the purpose of the local anaesthetic, as discussed previously. Using articaine for maxillary teeth may obviate the need for the palatal injection,⁵⁰⁻⁵³ which is unpopular with patients.

Mandibular Anaesthesia

The IANB is commonly used for mandibular dental anaesthesia. Using this technique, investigators^{13, 16, 53-56} found no significant differences in efficacy between lidocaine and articaine.^{13, 16, 54-57} Meehan concluded that there is no benefit in choosing articaine over lidocaine for an IANB.⁶ A recent literature review³³ yielded no evidence to contradict this conclusion.

Accessory nerve supply to the mandibular molars from other branches of the mandibular nerve (long buccal, lingual, mylohyoid, auriculotemporal, see Figure 2) may contribute to failure of an IANB to anaesthetise mandibular molars^{46,58}. Most significantly, Meechan^{46,58} lists cervical spinal nerves as accessory sensory supply of mandibular molars; cervical spinal nerves convey sensory signals to the brain via the spinal cord and would not be affected by an IANB. This suggestion could explain why IANBs can have significantly lower success in anaesthetising lower molars than infiltration techniques.^{56,57,59}

Figure 2 Diagram of mandibular nerve and its branches. Nerve communications (shown in red):



1. Additional branches of long buccal nerve
2. Additional Branches of inferior alveolar nerve
3. Mylohyoid-lingual
4. IAN – Auriculo-temporal
5. Mylohyoid innervation of lower incisors
6. IAN-Lingual Nerve

Supplementing IANBs with a long buccal block or buccal infiltration would be prudent in anaesthetising lower molars. Articaine reports greater success than lidocaine when used as a supplement to an IANB.⁶⁰⁻⁶² Consistent with Haase et al.,⁶⁰ Kanaa et al.⁵⁷ reported 92% success rate in pulpal anaesthesia when complementing an IANB (2% lidocaine with 1:80,000 adrenaline) with 4% articaine with 1:100,000 adrenaline formulation by buccal infiltration. The work of Kanaa et al.⁵⁷ and Haase et al.⁶⁰ supports Meechan's^{46,58} idea of accessory innervation to mandibular molars undermining the efficacy of an IANB. However, one would expect lidocaine supplemental buccal infiltrations to have a similar efficacy to articaine if accessory innervation came predominantly from the buccal nerve situated within soft tissue.⁶³ This suggests that accessory innervation may come from other branches of the mandibular nerve, or even cervical spinal nerves. Lower incisors may receive accessory nerve supply from the contra-lateral IAN due their proximity to the midline and the IAN crossing over the midline of the mandible.

The IANB may be now obsolete.⁶⁴ Reports^{56,57,59} show that, when comparing the incidence of mandibular molar pulpal anaesthesia,

articaine infiltration alone can match or better lidocaine given as an IANB. Corbett et al.⁵⁶ carried out a randomised controlled trial which found buccal infiltration of articaine to have a 70% success rate in lower molar anaesthesia compared to a 55% success rate of administering lidocaine as an IANB. Leith et al.⁵⁰ concluded that articaine administered as a buccal infiltration could obviate the need for an IANB. Furthermore, Miller⁶⁵ described an alternative technique which could replace an IANB. Studies^{36,37} comparing the efficacy of lidocaine and articaine in mandibular molar infiltrations have found articaine to produce better clinical data. The British Committee for Standards in Haematology recommends avoiding IANBs in patients taking oral anti-coagulants due to anecdotally reported associated risks of haematoma formation and airway compromise.⁶⁶

Articaine usage in children

Meta-analysis¹⁷ has shown articaine to be safe for use in children but there was no conclusive evidence regarding its use in children under the age of four. It may be unnecessary to reduce the maximum dosage of 7mg/kg bodyweight in children,⁶⁷ although some recommend reducing to 5mg/kg when used in conjunction with sedatives.⁶⁸ A retrospective audit⁶⁸ found no adverse systemic reactions to articaine in children under four, even when the recommended dosages were exceeded, which can easily be done. Consider that a 2.2ml cartridge of 4% articaine formulation contains 88mg of articaine and in a five year old paediatric patient typically weighing 20kg, the maximum dosage will be 140mg; which translates to just 1.59 cartridges. In this case, lidocaine may be preferable as the same patient could be administered over three cartridges of 2% lidocaine with 1:80,000 adrenaline anaesthetic solution.

No adverse systemic effects were reported in children aged between four and thirteen but one case of lip damage was documented.⁶⁹ Although previously discussed as an advantage in oral surgery, prolonged soft tissue anaesthesia²⁹ may be a contra-indication of administering articaine in children. However, Dudkiewicz et al.⁷⁰ had a 100% success rate in achieving primary mandibular molar anaesthesia by administering articaine using an infiltration technique, bypassing the need for an IANB. This avoids anaesthetising the lingual nerve which reduces the field of soft tissue anaesthesia in young children, therefore preventing traumatic biting of the tongue.⁵⁰ Avoiding an IANB or palatal injection (discussed under Maxillary Anaesthesia) could perhaps improve the child's attitude towards visiting the dentist.

Other factors affecting the efficacy of local anaesthesia

The patient

Although the local anaesthetic may have been shown to be active by electronic pulp testing or thermal testing, patient fear and anxiety may cause patients to experience pain; the dental setting is a common citation for patient anxiety.⁷¹ The dentist's explicit efforts towards preventing pain are deemed paramount for the patient.⁷² This point is relevant in studies where test subjects' teeth had irreversible pulpitis as subjects may be experiencing a degree of anxiety or fear, introducing a new variable. Teeth in irreversible

pulpitis contain higher levels of Prostaglandin E-2,⁷³ which causes pain hypersensitivity⁷⁴ by upregulation of pain receptors,⁷⁵ thereby reducing the effect of local anaesthesia. It is important to note that conscious sedation with triazolam, a benzodiazepine, will not decrease the need for profound local anaesthesia.⁷⁶

Patients with irreversible pulpitis may have taken analgesics before presenting. Ibuprofen is a common choice and can increase the chance of local anaesthetic success,⁷⁷ creating another possible variable in research. Some studies^{55,78,79} investigating teeth with irreversible pulpitis did not mention standardisation of pre-operative analgesia.

Adrenaline (Epinephrine)

Lidocaine and articaine formulations contain different adrenaline levels (1:80,000 and 1:100,000 or 1:200,000 respectively). Adrenaline levels may not affect the efficacy of anaesthesia in IANBs^{41,43,44} and mandibular infiltration.⁸⁰ Dagher et al.⁴¹ found no difference in efficacy between 2% lidocaine formulations containing 1:80,000 and 1:100,000 adrenaline. However, one must consider the causes of IANB failure, which were mentioned earlier under Mandibular Anaesthesia. When maxillary incisors were infiltrated, anaesthetic success correlated with adrenaline concentration.⁴² There is insufficient evidence to decide whether the adrenaline content of the two formulations contributes to their efficacy. However, lidocaine's increased adrenaline content may be preferable for surgical procedures by causing vasoconstriction, which can reduce bleeding and aid vision in a surgical field.⁸¹

Considering cardiovascular disease in patients, some may choose to avoid adrenaline-containing formulations, despite lidocaine-adrenaline solutions producing insignificant effects on blood pressure and pulse differences, compared with lidocaine alone.⁸² Adrenaline solutions ensure appropriate anaesthesia intensity, avoiding distress and excessive endogenous catecholamine release in high risk cardiac patients,⁸³ Malamed⁸⁴ recommends a maximum of 0.04mg, just 1.4 cartridges of 2% lidocaine with 1:80,000 adrenaline formulation. In such cases, 4% articaine with 1:200,000 adrenaline may be prudent, as the patient could then be administered up to 3.6 cartridges to obtain local anaesthesia. In a higher risk cardiac patient, it would be practical to first control the cardiac risk, in conjunction with their physician, and use 4% articaine with 1:200,000 adrenaline solution combined with local haemostatic measures to aid surgical field vision.

Conclusion

When deciding whether to use articaine, one should first consider the level of anaesthesia required. Following this, one should consider whether the lower adrenaline content of an articaine cartridge would be beneficial to the patient and the procedure to be performed. There are reports of lingual nerve damage associated with articaine usage in an IANB; investigations on nerve damage and lack of similar reports from other surgical specialties undermine such claims, but insufficient data exists to promote the use of articaine over lidocaine in an IANB. Studies comparing the two drugs' efficacies do not use the same effective dose and have confounding factors super-imposed. Meta-analyses have found the use of articaine to be advantageous in infiltration techniques. The successful use of articaine for mandibular infiltration has perhaps

signalled the beginning of the end of the IANB, especially in children, in whom articaine usage is safe.

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The Nocebo Effect

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Abstract

A growing body of evidence is emerging for a phenomenon known as the nocebo effect. This is when a person is conditioned to expect a negative response, or to anticipate negative effects from an experience.

The placebo effect has been widely researched, but new studies have shown that nocebo can have a greater effect than placebo.

The nocebo effect is prevalent in interactions between patients and healthcare workers. Research has demonstrated that if a patient deems a healthcare professional not to understand or believe them, this can cause distress, and the physiological effect can reduce the prognosis of treatment. It has also been demonstrated that patients who are anxious or expect pain during a procedure, feel more pain because of this negative expectation.

These findings highlight the importance of effective communication with patients and the influence that good anxiety and pain management control can have in improving treatment outcomes.

Introduction

There has been much contemporary research focusing on the "placebo effect" – the ability of the mind to create a beneficiary effect from an ineffective stimulus. However, far less studied is the concept of nocebo – when a person is conditioned to have negative expectations, or to anticipate negative effects from an experience or substance.¹ The nocebo-effect is, in essence, the mind's ability to harm. Nocebo derives from the latin root 'noceo', to harm.² While nocebo research is still in its infancy, the phenomenon could have a profound impact on the way patients are treated. This essay looks to explore the research on the nocebo and explain how the effects are relevant to dentistry.

Background

Many research/clinical trials use a placebo as a control and report its positive impact on patients. For instance, studies have shown how a placebo can stimulate changes in blood pressure, reduce pain and fatigue and even some signs of Parkinson's disease³. However, reports have shown that up to 25 per cent of patients taking placebos as part of a trial, report negative side effects⁴, in other words, a nocebo effect. These side effects are often subjective – such as pain, dizziness, fatigue and nausea. Some effects wrongly attributed to taking a placebo treatment can often be explained as mild ailments or normal physiological functions, such as postural hypertension. However, others have included dermatological episodes such as rashes and real physiological responses.^{4,5}

How Your Perception Influences Your Response

Kapchuk et al. completed a randomised trial, comparing two placebos. They divided 270 subjects, all of whom experienced severe arm pain, into two groups. One half was given a placebo pill made from cornstarch, and the other half were treated with sham acupuncture needles that never pierced the skin. After just two weeks, almost a third of the patients were experiencing side effects including 'feeling sluggish'. Subjects receiving the sham acupuncture needles reported that they felt the needles were causing 'swelling and redness'. The patients were experiencing the exact side effects that they had been warned of prior to treatment.⁶

Such nocebo effects, however, have been shown not just to be subjective. In one trial, patients were exposed to thermal pain and given opioid analgesia. The trial population was randomly divided into three groups, with all participants exposed to the same pain stimulus and given the same opioid pill. Group one was exposed to positive treatment expectancy as they were given the pill, group two had no expectation of analgesia, and group three were told that the pill would exacerbate the pain experienced. The results showed that positive treatment expectancy enhanced the effectiveness of opioid analgesia for pain, compared to the control group who were just given analgesia. Patients who experienced negative treatment expectancy did not feel the analgesic effect of the opioid. As such, the negative expectation had eliminated the pharmacological effect of the analgesic drug.⁷

The Nocebo Effect at the Neurological Level

In addition to subjective reporting by the patients in this trial, MRI scans were also carried out. The scans highlighted significant changes in the brain regions where pain is felt.⁷ This showed that the patients' endogenous brain pathways had been affected by their expectations. Physiological trials have also shown that the nerve pathways which govern these nocebo effects begin responding before conscious reflection can set in.⁸ This reposes the belief that patients are pretending to feel an effect. Benedetti et al. completed a blinded randomised control trial to assess the nocebo affect. Pain was induced in subjects by making their arm ischaemic and placing pressure on the arm with a tourniquet for ten minutes. The nocebo group were given a sham pill and verbal suggestion that it was a vasoconstrictor that would increase the ischemia and produce a quicker and more intense pain. These patients experienced increased pain compared to the control.⁹

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The Physiology

What is happening in the brain to create such an extraordinary effect? Endogenous pain mechanisms can be modulated by a wide-range of regions within the brain including the hypothalamus, anterior cingulate cortex and the prefrontal cortex (in the limbic system).^{3,10} Specific areas affected by the nocebo have been highlighted with MRI scans of patients' brains during trials, specifically the hypothalamus, pituitary and adrenal glands (the HPA axis).^{8,10}

While feelings of both pain and analgesia are generated in the brain it is how these are modified – across different brain areas – that creates the placebo and nocebo effects.

The pain pathway is complex and is multi-factorial. The placebo effect induces analgesia by activating opioid pathways in the brain which inhibit the pain pathway.¹¹ Nocebo however, has an entirely different mode of action. It stimulates Cholecystokinin (CCK) release by affecting those regions of the brain associated with stress, anxiety, memory and conditioning.³ If patients anticipate pain, they become anxious which increases brain activity in these areas and therefore increases the pain experienced by the patient. CCK antagonists could therefore potentially be used to suppress the nocebo response. Benedetti et al⁹ in their research also looked at this therapeutic effect in the nocebo group. They gave participants diazepam and proglumide, a cholecystokinin antagonist, in response to pain. These should be ineffective as analgesics but could alter the hyperalgesic affect induced due to anxiety in the nocebo group. Both of these drugs reduced the pain patients experienced, to the point that patients felt the same pain as the control groups, where no negative verbal cues were used. This same response was shown by Andre et al.¹² Exactly how negative expectation causes CCK release is not yet known and requires further research.⁹

Medical Ethics

One of the reasons that the nocebo effect has not been more closely researched is due to conflicts with medical ethics. Medical professionals have an ethical obligation to do no harm which is contrary to the very idea of the nocebo. To respect a patient's autonomy, one must carry out a valid consenting process, which includes full disclosure of the risks and benefits of treatment, which would defeat the purpose of the research.

The Media

The media can have a huge impact in influencing public perception and causing a nocebo effect. In 2007 the pharmaceutical company GSK changed the manufacturer of their levothyroxine medication for supply in New Zealand. The pills changed in shape and size due to being made in a different factory, but remained the same basic formula. There was an immediate increase in reported side effects to the Centre for Adverse Reactions Monitoring (CARM) who had only previously received 14 reports. 462 reports were made, 419 of them in just over a month following media attention about the change in the medication. Forty per cent of the reports were direct from the public.¹³ This highlights the complex interaction between the nocebo effect, patient's expectations and the media. Responsible and accountable reporting by the media would help

to defuse health scares; however, scandal is much easier to sell than reason. This is of particular interest in dentistry as it already has a widely perceived negative image,¹⁴ not helped by how the profession is represented in the media. It is difficult to counterbalance such a long-held belief. Dental professionals need to be mindful of this when dealing with patients whose perceptions of treatment may be influenced by what they have heard in the media.

Nocebo and Dental Anxiety

Patients present with anxieties and phobias which are frequently grounded in prior bad experiences. It is this conditioning that causes the negative associations and can affect the patient's response to treatment. This anxiety and negative expectation has now been proven to increase pain perception. Dental anxiety can be associated with fear of dental pain, dental treatment, injections and clinical surroundings.¹⁵ Wijk et al.¹⁵ found that anxious patients felt an increased and longer period of pain when given a dental aesthetic than non anxious patients.¹⁵ Elevated levels of pain can create negative expectations which can influence how future treatment is perceived.¹⁶ Knowing this we should seek to use alternative methods to help those patients who are anxious about dental treatment. Meta analysis of relaxation, CBT and hypnosis have been shown to reduce pain.^{17,18,19} Repeated exposure to the dental environment also reduces dental anxiety.¹⁸ Relative analgesia (RA) and intravenous sedation can be used to reduce anxiety and facilitate the acceptance of treatment by patients. Clinicians should also look at evaluating dental treatment with patients post operatively, to help patients to discuss the positive aspects of treatment, and reinterpret their experience.

Nocebo and the Analgesic Response

Clinicians should too be aware when advising the use of analgesic medications. Patients associate branded medications with reduced side effects and an increased therapeutic effect. Generic drugs are reported by patients to have more side effects and be less effective.^{5,20} Patients also often undervalue the positive analgesic effects of over the counter medications because they are so readily available.²¹ However, clinicians can reassure patients by appropriately explaining how non-prescription analgesia such as paracetamol and ibuprofen, is proven to be the best, and to help them understand and self limit symptoms.²²

Informed Consent and the Nocebo Effect

Another interesting note is that of informed consent. In modern dentistry consent is a key issue and part of the GDC's core CPD. However, the aforementioned studies show that 'truly' informed consent can actually increase the expectation of side effects and in turn, increase the incidence rate.⁶ The Afshar vs Chester²³ test case legally defined that practitioners have a duty to divulge all serious risks associated with a treatment. However, this must be balanced against the need to not scare the patient and prevent them from accepting treatment. It is therefore a clinician's personal choice on how to warn patients and what information to include. Gender, depression and cultural background are some key factors to consider.²⁴ However, with 'Dr Google' at everyone's finger tips, it is likely that the nocebo effect will worsen.

Conclusion

Knowing the potential for harm caused by negative expectations serves to highlight the importance of good communication with patients. The nocebo effect has been shown to occur in consultations between healthcare professionals and patients, due to poor communication. For example, telling patients that there is no cause for their pain or symptoms may be intended to reassure, but in reality the patient can feel patronised and angry. Greville-Harris demonstrated that if a patient deems a healthcare professional not to understand or believe them, this can cause distress, and the physiological effect can cause the patient to deteriorate.²⁰ The key is to identify the patient's concerns before treatment commences. This is of particular importance in anxious and depressed patients and those suffering chronic pain symptoms.⁴ A patient who expects pain and adverse symptoms is more likely to experience them. It is important to recognise that everything we say and do counts, from explanations to non-verbal cues. It all affects the relationship we have with our patients. We need to understand that we are a part of the treatment, and be aware how our choice of words can affect treatment outcomes. For some patients it may be necessary to explain the strong connection between anxiety and perception to help maximise treatment outcomes.²³ Despite all the progress in pharmaceuticals, surgical techniques, and use of technology, it may be something as basic as a good doctor – patient relationship that helps to eliminate patient's pain.²³

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SAAD ESSAY PRIZES

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Details on page 76

Prospective study on dental extractions carried out for paediatric patients under general anaesthetic in a district general hospital

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Abstract

Background: The first line approach to managing healthy anxious children requiring dental extractions should include behavioural management and treatment under local anaesthetic.¹ This can be coupled with conscious sedation.

Aim: To evaluate alternative methods attempted prior to treatment under general anaesthesia (GA), to establish the incidence of repeat GA procedures.

Method: Paediatric cases requiring dental extractions under GA were audited from October 2014 – December 2014 in the Oral and Maxillofacial Department, Great Western Hospital, Swindon.

Results: 78 paediatric cases requiring dental extractions were carried out during the study period. 91% of referrals came from local general dental practitioners (GDPs). The indication for the GA was included in 59% of the referral letters. The number of teeth extracted per case ranged from 1 – 14. In 18% of cases treatment under local anaesthetic had been attempted previously. Conscious sedation had not been attempted in any of the cases. There were 5 cases (6.4%) of repeat general anaesthetic procedures.

Conclusion: Local guidance regarding appropriate paediatric referrals should be distributed to primary care referrers. Treatment under conscious sedation should be considered for paediatric cases and an improved referral pathway to the community dental service should be developed. Preventative advice should be reinforced to the referrer and to the patient.

Introduction

Providing comprehensive dental treatment for paediatric patients can prove challenging due to higher levels of anxiety and poor co-operation.² Based on the 'UK National Clinical Guidelines in Paediatric Dentistry',³ the first line approach to managing healthy anxious children should include behavioural management, prevention and treatment under local anaesthetic. This can subsequently be coupled with conscious sedation for selected cases. Guidance on established behavioural management techniques can be found in *The American Academy of Paediatric Dentistry*.⁴

The Department of Health's report *A Conscious Decision*⁵ discourages the use of general anaesthesia for management of

pain and anxiety associated with dental treatment and emphasises that it should be considered as a last resort.

Based on the Royal College of Surgeons guidance⁶ there are specific factors influencing the decision to conduct dental treatment for paediatric patients under general anaesthesia:

- The co-operative ability of the child
- The perceived anxiety of the child and how the child has responded to similar procedures
- The degree of surgical trauma anticipated
- The complexity of the operative procedure
- The medical status of the child

According to the guidance the following conditions rarely justify a general anaesthetic: carious, asymptomatic teeth with no clinical or radiographic signs of sepsis or orthodontic extractions in a healthy child.

Comprehensive treatment planning for dental paediatric patients may include the general dental service, community dental service and hospital dental service. It is essential that all services co-ordinate effectively in order to plan the most appropriate treatment for paediatric patients.

Repeat general anaesthetics (GAs) are undesirable in terms of repeated risk of morbidity, potential mortality and the emotional impact on the child. They reflect a potential failure in the overall treatment planning and management of the patient.

From September 2013 – September 2014, 461 dental extractions were performed on children under general anaesthetic in the Oral and Maxillofacial Department, Great Western Hospital, Swindon. Of these, 10 had previously had extractions under general anaesthetic, a repeat GA rate of 2.14%.

Aims

The aims of this audit were to prospectively evaluate the incidence of repeat GAs and assess the extent to which:

- the justification for treatment under GA had been documented
- alternative treatment options had been attempted and discussed
- preventative advice was communicated to the primary referrer and patient.

Criteria and standards

Criteria and standards were based on guidance from the Association of Paediatric Anaesthetists of Great Britain and Ireland (APA)¹:

Table 1. Criteria and standards

Criteria	Standard
1. The referral letter should clearly justify the use of general anaesthesia	100%
2. Options for dental extractions, including whether they are performed under local anaesthesia, local anaesthesia supplemented with conscious sedation or general anaesthesia should be discussed with the parent / carer and child	100%
3. The incidence of repeat Gas should be within the range quoted in contemporary studies ^{7,8,9}	3.1% - 11.9%

Method

Paediatric cases requiring dental extractions under general anaesthetic were audited during the period from October 2014 – December 2014 in the Oral and Maxillofacial Department, Great Western Hospital, Swindon. Data was collected using a pro-forma and descriptive analysis carried out using Microsoft Excel 2007©.

Table 2. Data capture form

Patient demographics	
- Gender	
- Age	
- ASA grade	
Referral	
- Source of referral	
- Number of teeth requested for extraction	
- Alternative methods attempted (LA, SED)	
- Indication for general anaesthetic	
Consent	
- Written consent obtained	
- Alternative methods discussed (LA, SED)	
Procedure	
- Number of teeth removed under GA	
- Repeat GA	
- Number of teeth extracted during original GA	
Correspondence with primary referrer	
- Preventative advice (Y/N)	
- Additional diagnoses and treatment required	

Results

78 paediatric cases were carried out during the study period, ages ranged from 4 - 15 years, with a mean age of 7 ½. 50% of cases were male, 50% female. In 96% of cases the patient was an ASA grade 1.

Referrals

91% of cases were referred from their general dental practitioner (GDP), 1% from the community dental service (CDS) and 8% from their orthodontist.

Chart 1 presents the alternative treatment methods attempted by the referrer. It can be seen that in 82% of cases, alternative treatments attempted had not been stated in the referral letter.

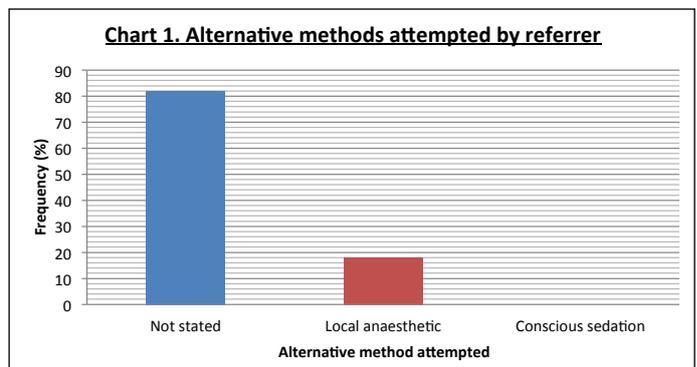
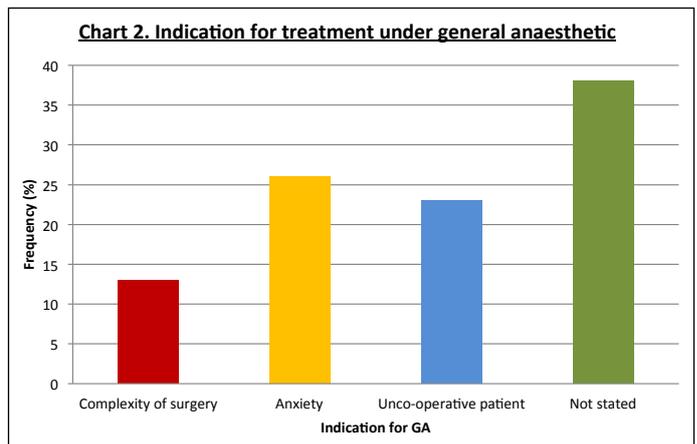


Chart 2 presents the indications for treatment under general anaesthetic recorded in the referral letter. In 38% of referral letters no justification for general anaesthetic had been documented.

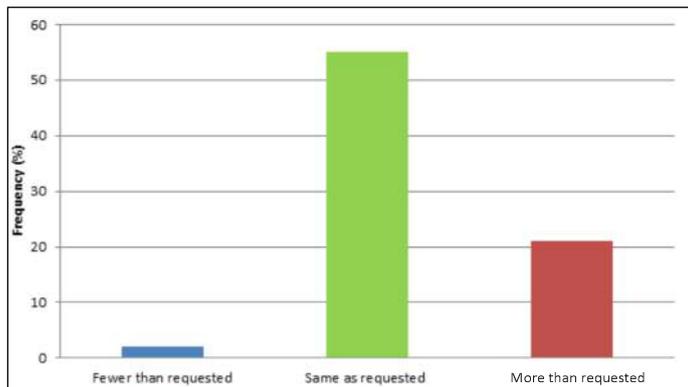


Treatment carried out under general anaesthetic

In 100% of cases a pre-assessment had been carried out and a treatment plan formulated. From chart 3 it can be seen that in 71% of cases the treatment plan included the same number of teeth to be extracted as in the referral letter. In 2% of cases fewer teeth were planned to be extracted than the referrer's request and in 27% of cases more teeth were planned to be extracted than the referrer's request.

SAAD ESSAY PRIZE RUNNER UP

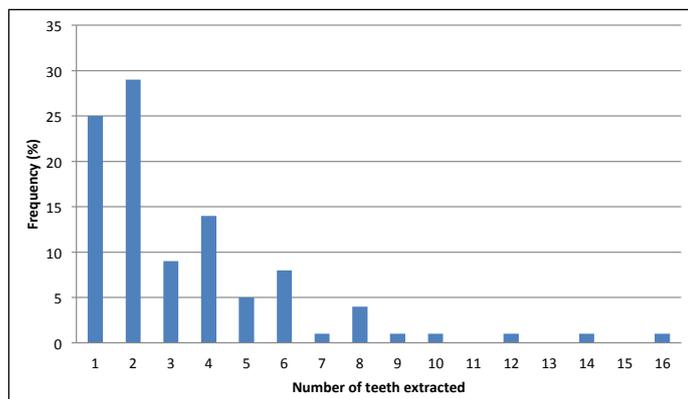
Chart 3. Number of teeth extracted compared to referrer's request



In 100% of cases written consent had been recorded prior to the operation. However, alternative treatment options such as local anaesthetic or conscious sedation were not discussed or documented on the consent form.

The number of teeth extracted under general anaesthetic ranged from 1-16 with a mean of 3.5 (Chart 4). In 54% of cases two or fewer teeth were extracted under general anaesthetic.

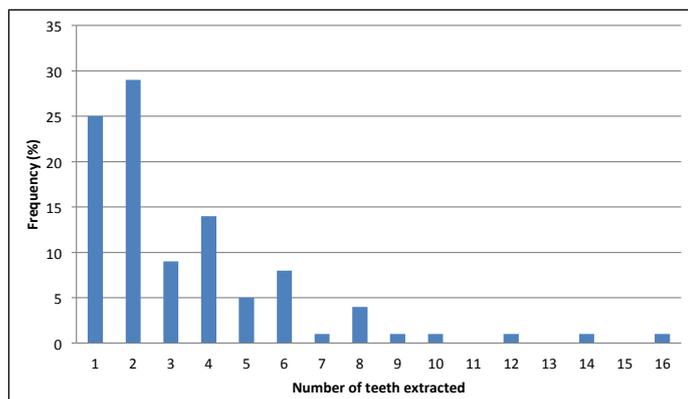
Chart 4. Number of teeth extracted under general anaesthetic



Single tooth extractions

In total, 19 cases (25%) had single tooth extractions under general anaesthesia. Chart 5 presents the range of ages of the patients undergoing a general anaesthesia for a single tooth extraction.

Chart 5. Single tooth extractions - Ages of patients



Repeat general anaesthetic procedures

Out of the 78 cases, 5 cases (6.4%) had previously had dental extractions under general anaesthetic within the last 24 months.

Table 3. Repeat general anaesthetic cases

Total number of repeat GA cases	5
Average ASA grade	1
Average number of teeth removed in first general anaesthetic	4
Average number of teeth removed in repeat general anaesthetic	3
Preventative advice included in correspondence to referrer and patient	0

Preventative advice given to referrer and patient

Written correspondence was sent in all cases to both the referrer and patient, outlining the proposed treatment plan. Preventative advice was not included in any of the 78 cases.

Discussion

In accordance with current APA guidelines¹ the referrer should provide clinical information regarding diagnoses made, previous treatment attempted and indication for general anaesthetic. However, it is ultimately the responsibility of the service provider to justify the treatment under general anaesthesia.

It is advised that service providers should develop a local referral pro-forma and relevant guidance. In this study 41% of referrals did not state the indication for treatment under general anaesthetic and 82% did not state any alternative treatment methods attempted. This is non-compliant with APA guidance¹. This indicates the need to distribute local guidance to GDPs, who are the main source of referrals (91%). It must be emphasised that treatment under local anaesthetic combined with behavioural management techniques should be considered in many cases. There should be improved communication between the referral centre and primary referrer to address any shortfalls in referrals received.

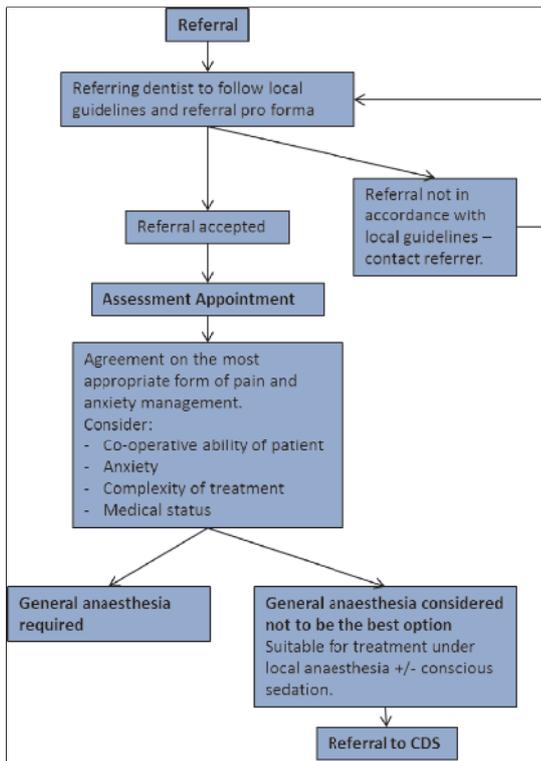
Treatment under conscious sedation was not attempted or discussed in any cases in this audit. Single tooth extractions accounted for 25% of procedures in this audit and in 54% of cases two or fewer teeth were extracted under general anaesthetic. From chart 5 it can be seen that the ages of patients undergoing general anaesthesia for a single tooth extraction ranged from 4 – 12 with a mean age of 7 ½ years. In many of these cases local anaesthesia combined with conscious sedation would enable the procedure to be carried out³.

At present the Great Western Hospital does not have the facility for dental extractions under conscious sedation for paediatric cases. The Community Dental Service provides inhalation sedation from two other centres in Wiltshire. This highlights the need for improved communication between the Community and Hospital Dental Services and an improved referral pathway for appropriate paediatric patients requiring a minimal number of dental extractions.

Based on the APA proposed care pathway for paediatric patients,¹ the primary referrer should refer a paediatric patient, who is not manageable within general dental settings, to a dentist with

experience in paediatric dentistry, whether this is to the hospital or community dental service. At the pre-assessment stage the co-operative ability, anxiety, complexity of procedure and medical status of the child should be considered and the appropriate form of pain and anxiety management selected. It is essential that all options are discussed with the patient as part of the informed consent process. Figure 1 presents a proposed referral pathway that should be adopted based on current guidance.

Figure 1. Proposed local referral pathway for paediatric cases



A study by Albadri et al⁹ found an incidence of 11.9% repeat GAs from 278 cases. In this study there was a 6.4% incidence of repeat GAs. Poor treatment planning and inadequate preventative education have been indicated in the incidence of repeat GA.¹⁰ It has been suggested that a more radical approach towards treatment planning, with an emphasis on extracting rather than restoring carious teeth in these high risk patients may reduce the incidence of repeat GA procedures.¹⁰ In 27% of the cases in this study more teeth were extracted than the referrer's request, reflecting the more radical approach to treatment planning adopted in the department.

It should be acknowledged that the majority of these paediatric patients requiring treatment under GA are high risk for dental caries.¹⁰ Clinicians working in secondary care should take the opportunity in the pre-assessment stage to reinforce preventative messages to these high risk patients. As standard, all patients requiring dental extractions under general anaesthetic receive a letter outlining the proposed treatment plan and a copy is forwarded to the referring dentist. Preventative advice was not included in any correspondence to the patient or primary referrer. It would be advisable to include a copy of preventative information including dietary advice and oral hygiene instruction as standard in all correspondence to the patient. Figure 2 outlines the key preventative messages based on guidance from Public Health England.¹¹

Figure 2. Preventative messages to be included in written correspondence to patients

Preventing tooth decay

The following information is aimed to help reduce the likelihood of your child developing further tooth decay.

Oral hygiene	Diet
Brush twice daily for at least 2 minutes.	Reduce the amount and frequency of sugary foods in your diet.
Use a fluoridated toothpaste (1350 – 1500 ppm fluoride).	Avoid sugary foods or drinks at bedtime.
Spit out after brushing and do not rinse.	Added sugars should provide less than 10% of total energy in a healthy diet.

(More information can be found from www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention)

Conclusion

The majority of referral letters received by the hospital failed to comply with local guidance for paediatric dental cases. There was a failure to document the indication for treatment under general anaesthetic and any alternative methods attempted. Local guidance and education needs to be delivered to GPs in the area.

Treatment under conscious sedation was not utilised in any cases of this audit. An improved referral pathway needs to be developed between the Hospital Dental Service and Community Dental Service in order to offer appropriate paediatric patients the option to have dental extractions under conscious sedation.

The incidence of repeat GA procedures in this audit was 6.4%, which was consistent with the incidence found in other studies. Clinicians involved in any stage of the care pathway for these paediatric cases should reinforce preventative advice, including diet advice and oral hygiene instruction. It would be beneficial to include such advice in written correspondence to the patient.

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SAAD Symposium 2015

Dental Sedation: Staying Ahead of the Curve

Saturday 3 October

Royal Society of Medicine, London, UK

The annual SAAD symposium is always a popular event on the sedation CPD calendar, and this year's entitled "Dental Sedation: Staying Ahead of the Curve" was no exception. With the biggest delegation yet of any SAAD symposium, the stage was set for an informative and stimulating day.

Carole Boyle, on her last day as President of SAAD, welcomed the participants, introduced the day's programme and later presented awards to the SAAD prizewinners: Anwen Greaves, winner of the Drummond Jackson Essay Prize of £500 for her essay... 'The use of Midazolam as an Intranasal Sedative in Dentistry' as well as Vinson Yeung winner of the Dental Student Essay Prize of £300 for his essay 'Articaine – to use or not to use? Amy Pitcher-Sage, the winner of the SAAD Prize for the Highest Score in the NEBDN Sedation Exam 2014/15 was unfortunately unable to attend.

The first speaker of the day was Prof. Richard Ibbetson, Chair of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD) which produced the report Standards for Conscious Sedation in the Provision of Dental Care 2015. He delivered a very informative and entertaining lecture providing insights into the way the new sedation guidelines for dentistry were produced and also highlighting some of the more controversial changes from earlier guidelines. Following his lecture, delegates had the opportunity to comment and direct questions directly to Prof. Ibbetson, which provided more food for thought.

The next speaker, Colette Bridgeman provided a much needed overview of commissioning sedation services in England, her session received very favourable comments from the delegate feedback.

The next two speakers, Graham Manley and Will Botha both spoke from the position of active practising sedationists, sharing their knowledge and experience. Graham Manley paid particular attention to the use of nasal Midazolam as a useful tool for facilitating dental treatment in anxious adults and children. Dr. Will Botha's presentation described a pilot study conducted into the safety of multidrug sedation in a paediatric population.

Before breaking for lunch, Honorary Life Member of SAAD Jim Grainger made a very heartfelt speech thanking SAAD and particularly the SAAD trustees for their tireless work in supporting and advancing sedation in dentistry.

Whilst enjoying lunch, delegates had the opportunity to visit the trade stands of our sponsors Cestrudent McKesson, DPS and RA Medical.

SAAD trustee Dave Pearson introduced the afternoon session where the first speaker was Mike Clarke, a qualified dentist and also a medico-legal expert. He delivered a very lively and entertaining presentation demonstrating, through various case studies, how safe is sedation in the U.K when current guidelines are followed.

Kellie Boles then gave an excellent overview of her experiences setting up a sedation practice through the SAAD RA loan scheme.

The penultimate speaker of the day, Aditi Desai, gave a very thorough overview of the issues surrounding patients with obstructive sleep apnoea and the difficulties faced when sedating these patients.

David Craig from SAAD, our last speaker of the day gave a concise talk on the changes to the current SAAD courses which now include airway management skills to comply with the new IACSD guidelines.

The symposium was then concluded with a 'thank you' from Carole Boyle and an invitation to all SAAD members to attend the AGM.

We look forward to 24th September 2016 at the same venue, The Royal Society of Medicine, London, where we are sure our next Symposium will be as successful as this one certainly was.

SAAD Annual Symposium Abstracts

IACSD: Emerging Guidelines and Regulation

*Professor Richard Ibbetson BDS MSc FDS RCS(Eng) FDS
RCS(Edin) FFGDP(UK) FFD RCSI
Chair, Intercollegiate Committee for Sedation in Dentistry &
Director of Dentistry
University of Aberdeen*



Richard Ibbetson is Director of Dentistry at the University of Aberdeen and Professor of Restorative Dentistry. In 2011 whilst Dean of the Faculty of Dental Surgery at the Royal College of Surgeons of Edinburgh, he was asked to chair the Inter-Collegiate Advisory Committee for Sedation in Dentistry with the aims of reviewing existing guidance and producing a new report to be made available to patients, clinicians and those who fund healthcare services.

"The effective management of anxiety and pain is an essential part of the delivery of dental care. Behavioural management, the use of local analgesia and methods of conscious sedation are all central components of care for patients...." This is taken from the Introduction to the recent report "Standards for Conscious Sedation in the Provision of Dental Care". The presentation outlined the rationale for the report and discussed its implications for healthcare professionals and their patients.

SAAD Symposium & AGM

**SEDATION IS ALIVE AND WELL IN
GENERAL DENTAL PRACTICE**

Saturday 24 September 2016

**Details and registration at
www.saad.org.uk**

Guides for Commissioning Dental Specialities - implications and opportunities for commissioning sedation

*Dr Colette Bridgman MBE
Consultant in Dental Public Health
NHS Greater Manchester*



Colette Bridgman is a PHE Consultant in Dental Public Health located in Greater Manchester. She is a member of NHS England National Commissioning Group for dentistry and is supporting the CDO office develop national commissioning guides for dental specialties. She led DPH advice in the development of 'Securing Excellence in Commissioning NHS Dental Services' published Feb 2013 having been associate specialist clinical adviser with primary care commissioning PCC National Dental Team since 2003. Following 20 years of clinical practice in hospital (including 6 months in anaesthetics/sedation post) and primary care she was appointed Consultant in DPH 2003. She served as President of BASCD in 2009/10 and was awarded MBE in 2013 for services to Oral Health and Dentistry.

The presentation explained the context of the commissioning guide in England by outlining the direction of the 5 Year Forward View. An update on the development of the Specialty Commissioning Guides was included, together with a discussion of the implications of the Commissioning Guides for sedation services.

The objectives of producing the guides were confirmed: to improve access, equity of access and to identify need, unmet need and demand, ensure consistency and parity of outcome regardless of the area in England where the service is delivered, utilise resources to maximise patient care, have sight of the whole pathway in order to commission coherent services and to support development of intermediate care and capacity in primary care. It was also suggested that if

sedation is needed, patients should be able to access this adjunct to dental care safely with quality standards assured. The guides do make reference to current inefficiencies in the dental delivery system but it was confirmed that the guides are not about reducing costs but rather about releasing resources from one part of the dental system and using it more efficiently in another to meet need. This is possible because NHS England is the single commissioner for the entirety of dental services and there exists a unique opportunity to define services required at national and local levels, to really transform the way we deliver services locally.

The five year forward view was a recommended read for clinicians wanting to get involved in managed clinical networks. It heralds services integrating around the need of patients not organisations or training programmes. It states that NHS England (the commissioner of all dental services in England) will take decisive steps to break down barriers between primary care and hospitals in how care is provided..

The intended pathways will expand and strengthen primary and 'out of hospital care', they will improve health not just treat ill health, and provide isolated episodes of care.

A conclusion was drawn that suggests a more consistent approach to commissioning dental specialist services will be adopted, using the current investment and work force more effectively and efficiently.

It is advised that the overarching guide is read first, and all the guides, regardless of specialty have the same structure. They each contain, a description of the specialty, an outline of the current national workforce and training capacity, a description of population need and delivery at a national and regional level (where data exist) giving commissioners a methodology to collate and understand local need and the impact of current services. They also include an illustrative patient journey, quality standards and metrics for competency of clinicians, environment and equipment together with generic and specialty specific PROMs and PREMs to assist commissioners write specifications.

The guides have been produced to communicate what good looks like and to address deep-rooted inequalities, inequity, and variable quality of care and they are intended to promote consistent value and quality of specialist (including sedation) dental care provided to patients. As responsible clinical stewards, SAAD and providers of sedation services can assist in leading change and provide a more effective use of resources by broadening their influence with primary care clinicians and commissioners in dentistry.

It was suggested that some time would be better spent (by some clinical sedation leaders) to benefit more patients by supporting implementation rather than just continuing to

respond to referrals received at a local level. Leadership from SAAD and sedation providers could make integrating sedation in care pathways a reality locally and perhaps nationally?

Finally a commissioning sedation 'to do list' was shared. Apart from describing standards for service specifications, there are gaps such as identifying need, using the IOSN, describing the service offer, workforce and current spend, impact of services and highlight impact of gaps in service. Getting involved in Managed Clinical Networks, when they develop, was encouraged.

Safe Sedation Practice: The Literature

*Graham Manley BDS DDPH(RCS-Eng) MSc PhD FDS (RCS-Eng)
Consultant in Special Care Dentistry at the Royal Hospital for
Neuro-disability, Putney.*



Graham Manley is a consultant in Special Care Dentistry working at the Royal Hospital for Neuro-disability at Putney. He has had experience in providing intravenous sedation for adults and children within Primary Care and Dental Teaching Hospital. He developed a trans mucosal (intranasal) sedation technique for the treatment of adults with challenging behaviour.

A personal account was presented outlining various aspects of sedation for people with disability including those adults with profound complex Neuro-disability. Supporting evidence was provided to illustrate the experiences described. This included transmucosal (Intranasal) and intravenous midazolam also intravenous propofol. Intravenous sedation for children was described using midazolam and also ketamine as single drug techniques.

Producing Evidence for Safe Paediatric Sedation - A Pilot Study

*Dr. Will Botha MBChB(Pret), PDD(Sedation)
Medical Sedationist
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Will Botha is a medical practitioner and has been working as a full time sedationist since 2005, treating both adult and paediatric patients in NHS and private dental practices. He completed a post graduate diploma in sedation and pain control at the University of the Western Cape under Prof James Roelofse. With a special interest in paediatric sedation, Will joined the sedation team at the Toothbeary Dental Practice in Richmond at the start of 2011, treating children from age 2yrs and older, using advanced, multidrug sedation techniques for patients requiring complex treatment or with complex needs.

The demand for adequate paediatric dental care in the U.K is substantial and on the increase. A recent report from the British Society of Paediatric Dentistry said that the current provision of adequate dental care for children in the U.K is poor, and that access to the appropriate services seems to be the main cause.

This emphasises the need for some form of sedation service, which can be minimal to moderate sedation requiring regional and local anaesthesia (LA), sedation with Midazolam and LA only, advanced multidrug sedation or general anaesthesia. It is, however, clear that many children, especially the very young or those requiring complex treatment, will often require more advanced forms of sedation. The controversy surrounding advanced sedation for dentistry in children is mainly due to concerns over safety, even in the absence of any significant evidence.

In order to try and address these concerns, we embarked on a pilot study with two main objectives: testing whether our practice falls within the definition of conscious sedation, and

secondly to assess safety during sedation. We used a modified version of the Dartmouth Operating Conditions Scale to assess 127 children undergoing complex dental treatment facilitated by the use of advanced intravenous sedation. Our findings were that more than 85% of children (most of whom were under 5yrs of old) were sedated within the definition of conscious sedation and that more than 90% were not at any increased risk. A small percentage (6%) who did display an increased risk during their sedation, were immediately rescued from a potential unsafe state and all treatment was successfully completed with full uncomplicated recovery.

We concluded that to ensure safe advanced paediatric sedation, three important conditions needed to be fulfilled: Adequate training and experience of the whole sedation team, using a properly equipped facility to enable appropriate patient monitoring and rescue if needed, and following of established sedation guidelines. The SAAD RA machine Loan Scheme and its advantages to General Practice

SAAD RA Loan Scheme and Building an RA Practice

*Miss Kellie Boles BDS MFDS DIPCONSED
Principal Dentist
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Kellie Boles is the principle dentist in her own practice in Crawley West Sussex which provides a local referral service for dental treatment with inhalation sedation or intravenous sedation. She also works for Kingston hospital restorative department providing care under general anaesthesia and sedation. She has a keen interest in providing dental care for anxious and phobic patients. Following successful completion of the sedation diploma with Newcastle University in 2012, she has also been involved with the inhalation sedation SAAD loan scheme.

SYMPOSIUM 2015

Recent guidance further supports the importance of the implementation of safe sedation practices. Inhalation sedation plays a vital role in this. Access to dental care utilising inhalation sedation varies across the United Kingdom. It is still the first port of call for anxious children and a useful tool for adults with mild levels of anxiety or with sensitive gag reflex.

The SAAD loan scheme invites general practitioners to submit a business plan for the introduction of inhalation sedation to their practice, if successful this leads to a loan of inhalation sedation equipment for 12 months (including scavenging equipment).

Inhalation sedation is seen as a practice builder and particularly ensures that children are not over prescribed other sedation methods, or general anaesthesia for their dental treatment. The benefits for the practitioner include a pride in their ability to provide the best level of care for their patients.

Following a successful loan year, the practitioner can present their results to the SAAD board and if successful purchase the loaned equipment at a reduced price to continue to develop their practice.

Medico-legal Aspects of Sedation – so just how 'safe' are we?

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Mike Clarke qualified from Cardiff in 1979 and practised in North Yorkshire until 2005. He joined DPL in 1995 and having worked as an advisor for many years is now the Head of Dental Underwriting Policy. He has been active in dental politics for many years and is a regular contributor to the dental press. He is a past chairman of the Dental Practitioners'

Association, a former member of the Department of Health's Standing Dental Advisory Committee and a past vice-chairman of the BDA's Private Practice Committee. He is currently a senior member of the Research Ethic Committee.

Sleep Apnoea and Sedation: The Role of the Dental Practitioner

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Aditi Desai graduated as a dentist from University of Wales, Cardiff in 1977. President Elect of the British Society of Dental Sleep Medicine, Aditi is founder of Global Sleep Solutions, a company set up to bring about a multidisciplinary approach to the management of sleep disorders. She serves on the Council of the Odontological and Sleep Section of the RSM. Aditi is a restorative dentist and part of a multidisciplinary dental specialty team in Harley Street where she predominantly manages patients with sleep-disordered breathing. She maintains a multidisciplinary approach in Harley Street and London Bridge Hospital, working with a team of medical professionals with an interest in Sleep Medicine.

Sedation in dentistry is a valuable tool in the management of anxiety in patients. Sedative agents depress the central nervous system and can have an adverse effect on the patient. These adverse events are further compounded in the medically compromised patient. One of the most common diseases amongst the general population is sleep disordered breathing (obstructive sleep

apnoea). These patients are at particular risk of airway obstruction during sedation and identification, assessment, and perioperative management minimizes the risk of any such adverse event during sedation and during the recovery phase.

Deployable airway skills training on SAAD courses

*David Craig BA BDS MMedSci FDSRCS(Ed)
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David Craig is Consultant / Honorary Senior Lecturer / Head of Sedation and Special Care Dentistry, Guy's & St Thomas' NHS Foundation Trust. Immediate Past-Chairman, Dental Sedation Teachers Group. Member, Intercollegiate Advisory Committee for Sedation in Dentistry. Member, Independent

Expert Group on Training and Standards for Sedation in Dentistry. Past Chairman & Emeritus Examiner, National Examining Board for Dental Nurses.

Standards for Conscious Sedation in the Provision of Dental Care (IACSD, 2015) states that 'anyone providing conscious sedation must be able to manage any event which might reasonably arise. The syllabuses published by IACSD state that practitioners must be able to have life support skills appropriate to the patient's age and the sedation technique employed and be able to recognise and manage sedation-related complications, including: over-sedation, respiratory depression/apnoea, the unconscious patient, airway obstruction, vomiting, idiosyncratic responses, delayed recovery failure of conscious sedation. "Deployable" airway competencies, including basic airway manoeuvres, the use of airway adjuncts and the ability to administer positive pressure ventilation are mandatory.'

In response to the new Standards, SAAD has introduced an additional practical session on all our courses to cover the above skills. All participants will be required to demonstrate competency and confidence in the principles of establishing and maintaining a patent airway and providing adequate ventilation on an airway training manikin.

The following techniques will be demonstrated and taught:

- Basic airway opening manoeuvres – head tilt/chin lift and jaw thrust
- Insertion of airway adjuncts – oropharyngeal and nasopharyngeal airways
- Use of suction
- Ventilation using a bag valve mask device – 2 person technique
- Insertion of and ventilation with a supraglottic device (I-gel)

A certificate of satisfactory completion of this session will be issued.

RA LOAN

Inhalational Sedation and Scavenging System

Available for a six-month loan to SAAD members who have recently attended a SAAD course

Opportunity to purchase the system after the loan period

**Details of the scheme at
www.saad.org.uk or email fiona@saad.org.uk**

Interview With Francis Collier President of SAAD

Sadie Hughes (Honorary Secretary)



Sadie Hughes: Congratulations upon your appointment as SAAD President.

Francis Collier: Thank you, Sadie. I am both delighted and honoured to accept this appointment. Thank you for inviting me to this interview.

SH: For how long have you been connected with SAAD?

FC: I joined and attended my first SAAD Conference in 2001, after I had been accepted to join the Diploma in Sedation course at Guy's which started the following January. I joined the Board in 2009, as Assistant Honorary Secretary, taking the Honorary Secretary post from 2011, which had been held for a long period by our late colleague, Dr Derek Debus.

SH: I know you live in the North of Scotland now, but I think you come from London originally. Why did you move away?

FC: My mother came from Tarves in Aberdeenshire, and after many happy holidays and ongoing family connections, I was pleased to relocate there in 2007, to a primary care service sedation post. As you can tell from my diction, my origins are more 'East Enders' or 'Only Fools and Horses' than 'Take the High Road' or 'Taggart', as I grew up at Eltham in south east London.

SH: Had you always wanted to be a dentist?

FC: No, I was initially intending to study medicine, but prior to that had intended to teach history, a subject which has given me much pleasure over the years. I also had a great desire to go into politics in my younger years, but ultimately found my current profession more interesting and rewarding.

SH: Why the change of career choice?

FC: I became aware of, and subsequently interested in, a career in dentistry after my older sister Hazel studied dentistry. Consequently, I followed in her footsteps, entering Guy's Hospital Medical School, School of Dental Surgery (as it was then called) in September 1974. This was a decision I have never regretted.

SH: How much sedation was taught on your undergraduate course at that time?

FC: I graduated in 1978, and there was very little exposure to sedation at that time. I recall a demonstration of inhalation sedation, but my main impression of intravenous sedation was of a technique that should be avoided as it was potentially dangerous. However, I did have the opportunity to carry out some episodes of general anaesthesia, which was still taught to undergraduates at that time, and I received more anaesthetic training in the Royal Air Force, where the provision of anaesthetics was part of my war role during the period upon graduation in which I served as a Dental Officer.

SH: Who or what were the main influences which led you towards an interest in sedation?

FC: I had always had an interest in managing anxious patients, but beyond the use of what we now describe as behavioural management techniques and oral premedication, I had no sedation skills to offer patients.

When I left the Royal Air Force at the end of my Short Service Commission, I worked as a Dental Officer in the Community Dental Service in Bedfordshire. I was introduced to the use of Inhalation Sedation by a talented young colleague, Dr Mark Elvins, who used it regularly, demonstrating very effectively the necessary combination of excellent patient management skills to supplement the pharmacological effects of the nitrous oxide.

After the withdrawal of GA from primary care locations in 1998, when I worked as Assistant Clinical Director in the CDS in Hertfordshire, our visiting anaesthetist, Dr Satish Saxena started to provide intravenous sedation in these clinical sessions. The team which developed around this service provided dental care to an impressive range of patient groups, including those with learning disabilities, mental health problems, dementia and movement disorders as well as those with pure anxiety.

Finally, my Clinical Director in Hertfordshire at that time, Gillian Lowey, gave me the opportunity to attend the Diploma course in the Sedation & Special Care Dentistry Department at Guy's Hospital. The rest, as they say, is history.

SH: In what way did your sedation training change your clinical practice?

FC: In every positive way imaginable. It has made my work more

interesting, sometimes more challenging, but I am able to provide dental care for a whole range of patient groups for whom general anaesthesia might be the only other option. If I have any regret at all about my involvement in sedation, it is just that I didn't become engaged at an earlier stage in my career. For this reason it has always been a great delight to provide encouragement and training to younger colleagues, both dentists and nurses, who show an interest in conscious sedation.

To paraphrase a well known boxer when interviewed on the BBC Radio 4 programme 'Desert Island Discs', I will answer you by saying: Sedation's been good to me, Sadie!

SH: What changes do you intend to make in SAAD over the next 3 years?

FC: In a mature and essentially functional organisation such as ours, change needs to be evolutionary, rather than revolutionary, or you run the risk of 'throwing the proverbial baby out with the bath water'.

I believe the far reaching effects of some of the IACSD Standards document will require our attention well into the future, particularly elements relating to training in sedation. I also believe that we need to give our wholehearted support to the large number of our members, including me, whose sedation provision is in the primary care arena, as well as to provide a lead to ensure that conscious sedation techniques are fully and appropriately utilised in the context of special care dentistry. I think we may allow ourselves a short period of reflective satisfaction as the Society reaches its Diamond Jubilee in 2017. Unexpected matters which arise between our thrice yearly Board meetings will continue to be discussed and acted upon promptly with the aid of email and the telephone.

So in terms of radical change, Sadie, I am no Jeremy Corbyn in any sense that you might understand that statement. I haven't even got a beard, despite the current fashion for that particular addition to many men's faces!!

SH: You seem to have had a varied and interesting career in dentistry. Can you tell me which has been your favourite job or role?

FC: The factors that have sustained my interest over the years have been the diversity and variety of roles in which I have been involved. I enjoyed my time as an RAF Dental Officer, my 3 years in a Saudi Arabian military hospital, all my CDS posts with varying duties and my part time teaching post at Guy's. My move to Scotland in 2007 presented new challenges that have been interesting and enjoyable as well.

I want to pay tribute to my many friends and colleagues with whom I have worked in the Community Dental Service over the years in Bedfordshire, Hertfordshire and most recently in Aberdeenshire. I have the greatest respect for the way in which they have striven to provide dental care for some of the most challenging patient groups we serve, and it has been a great privilege to work with them over the years.

SH: How do you see the future of the NHS in general?

FC: I still think that the concept of a universally accessible

healthcare system is both laudable, and with imagination, still affordable despite the demographics of the population.

I have already alluded to my enthusiasm for sedation for dentistry being provided in primary care settings, where appropriate, for the advantages of both access and economy, and this ethos should be extended wherever it is possible in all medical and surgical specialities.

One of the things that concerns me about the current system is the amount of time many experienced clinicians are engaged in managerial or administrative roles, and not in clinical, teaching or research duties.

I have worked extremely constructively and productively with some non- clinical managers over the years, where their positive and visionary contribution to our teams can allow clinicians to spend more time with their patients.

However, I do not see the resolution of all our NHS ills in the construction of ever increasing administrative empires. The focus needs to remain firmly on resources being spent on the provision of healthcare, rather than an ever expanding job creation scheme for otherwise unemployable managers and administrators who have been rejected from other sectors of the economy, and whose understanding of the clinical services to which they are allocated is poor or non- existent. I am sure that we have all seen examples of this!

SH: So what is an average week like for you at the moment?

FC: An average week would be difficult to pin down! I spend 4 days in two primary care locations- one in Aberdeen City and one at Fraserburgh in Aberdeenshire. I have teaching roles with NHS Education Scotland and NEBDN, and dental students from Aberdeen Dental School and a Dundee Dental School Outreach Clinic visit my clinics to see the sedation cases. I work 4 days in my NHS post, and am engaged in teaching sedation with NES and some peripatetic sedation in private practices on my other day. I also work at the emergency out of hours dental service in Aberdeen some evenings and weekends. Again, I enjoy good variety in my work.

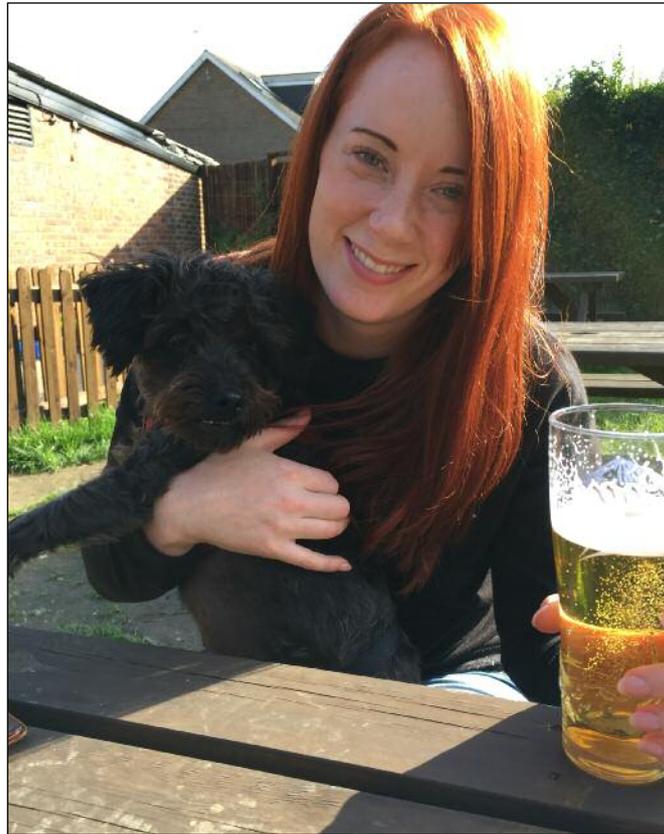
SH: What about interests outside dentistry?

FC: I am a great devotee of Sherlock Holmes, so my many trips to London remind me of the many locations mentioned in the original Conan Doyle stories. I am an enthusiastic member of the Royal Air Force Club in Piccadilly, which affords me accommodation on my London visits. I love to get out walking in the great countryside in Aberdeenshire. I have great interest in politics and political history as well as military and transport history. I have a life long love of railways (and yes, I own several anoraks!). Hopes for the future? Maybe a model railway in the garden when time permits?

SH: Thank you for sharing your thoughts with me, and very good wishes for your forthcoming period in office.

FC: Thank you Sadie. I wish you well in your new role as Honorary Secretary

Kellie Boles *New SAAD Trustee*



Growing up with a love of all animals and as an avid horse rider, I decided from an early age I would be a vet. However, following my work experience in a veterinary practice and assisting a vet to put a dog to sleep, I was too sad to continue! Our family dentist was really encouraging and offered me work experience in his practice. He was a positive role model and set me on the path to my future career - something I'm very grateful for.

I was accepted by Glasgow University and completed general professional training, with awards in prosthodontics and conservative dentistry. Following this, I decided to enter into the longitudinal training scheme. This involved a one year oral surgery rotational post in Glasgow Dental Hospital followed by a one year vocational training post in general practice. Having visited the maxillofacial department at Queen Victoria Hospital in East Grinstead during my elective study period, I had been inspired to continue my study and become a maxillofacial surgeon. My year in the dental hospital, post qualification, helped to shape me as a practitioner. I got to grips with evidence-based practice and reflective study and also achieved the MFDS qualification. My general practice placement allowed me to continue to develop my interest in sedation and the treatment of anxious patients in a different setting. Following this placement, I decided I was a general practitioner at heart. I loved the continuity, and the opportunity to follow up patients, getting to know them, watching families grow and develop and having people really trust and care about me and what I did to help others.

I decided to formalise my sedation training and completed the Newcastle Diploma in Conscious Sedation and joined SAAD to stay up to date with the advancement of conscious sedation techniques in general practice.

In 2012, I made the move down South to take over the running of Crabtree dental practice in Crawley, West Sussex. This has been a new challenge for me in many ways, however, 3 years on, we are now an established sedation referral clinic offering inhalation and intravenous sedation for local practices.

This year I commenced my role as an educational supervisor for foundation training. I hope to provide the right environment for a new dentist to learn about and experience the many career opportunities available to a general practitioner, as well as to allow new dentists to consolidate their knowledge and refine their skills.

I have continued my hospital career part time with Kingston Hospital, mainly in a restorative capacity, performing treatment for anxious patients with the aid of sedation or general anaesthesia.

Being a member of SAAD has benefitted me in many ways including my successful involvement with the inhalation sedation equipment loan scheme. I hope as a Trustee to assist in the development of safe sedation practice in the dental field.

When I am not providing dental care or assisting in the management of our clinic, I can be found horse riding or walking my two dogs.

Yi Kwan Loo

New SAAD Trustee



Following five amazing years at Newcastle University, there was one experience from the BDS course that stuck with me. I had never seen a grown man so anxious, unable to compose himself and physically shaking and sweating. Yet, 10 minutes later, and with some seemingly magical sedation, he became transformed into a happy relaxed man. There, my desire to find out about this magic was born.

In 2007, I embarked on General Professional Training at Newcastle Dental Hospital, completing Vocational Practice at a practice providing intravenous sedation. Following this Senior House Officer post, I took on a Clinical Tutor role, delivering chairside and seminar based sedation teaching in Paediatric Dentistry for dental undergraduates at Newcastle Dental Hospital.

After becoming a Member of the Faculty of Dental Surgery in 2009, I sought to gain more experience in being able to help anxious patients. I was very fortunate to become an Associate at Queensway Dental Clinic in Teesside. There, I worked as part of a multidisciplinary team providing general dental care but also, care for adults and children referred from throughout the North East of England for sedation. My skills in basic intravenous and inhalation sedation techniques were strengthened as I picked up tips and techniques from the experienced team under the guidance of Paul Averley. I enjoyed working closely with the Consultant anaesthetic team to provide alternative technique sedation for children and obtained the Diploma in Conscious Sedation from Newcastle University in 2010. This experience of exemplary teamwork and

sedation technique to benefit children with dental problems, was inspiring.

After a decade in the North-East, I decided to move back to my home town of London. I currently work part time in general dental practice and also as a Specialty Dentist at King's College Dental Institute Paediatric Department, providing paediatric oral, intravenous and inhalation sedation. I teach on the BDS undergraduate programme and undertook the Certificate in Academic Practice to become a Fellow of the Higher Education Academy in 2014. My role as the Paediatric Department Deputy Sedation Lead, involves provision of teaching, organising governance activity and developing local protocols.

2016 will be the start of my next challenge as I embark on Paediatric Specialty Training at Kent Community Health Foundation Trust and King's College Dental Institute. I look forward to the new challenge and the added experiences that this will bring.

Away from work, my husband and I enjoy exploring London and sampling its gastronomic delights, country walks with a good Sunday lunch and planning more cycling adventures on our tandem and Bromptons.

Miss Margaret Hughes 1925 - 2015

A tribute from Ian Brett and Christopher Holden



*Miss Margaret Hughes
and Dr Peter Sykes*

Margaret Hughes died in November 2015 at the age of ninety. Miss Hughes devoted the majority of her working life to the management of the West End dental practice of Stanley Drummond-Jackson (DJ), and as the general secretary of the Society for the Advancement of Anaesthesia in Dentistry, (SAAD) as it was known at its inception.

Margaret Hughes was born in 1925, the middle child of three girls. The family lived by Russell Square, in central London. Her secondary education was interrupted when she was admitted to University College Hospital with life threatening pleurisy, a situation made doubly worrying for her parents by the fact that UCH was at that moment on fire having been struck by a German bomb. After many months of recuperation (pre-antibiotics days), Margot, as she was always addressed by her family and personal friends, was discharged but did not continue schooling, but rather took a course at Pitman College to train as a secretary. Having reached the required age of entry, seventeen and a half, she became a Red Cross Nurse based at Ashridge House, a branch of Charing Cross Hospital.

After the war Margaret worked as a secretary for a theatrical agent before joining DJ's practice in June 1951.

At that time DJ was establishing his practice, confined to giving general anaesthetics for dental procedures, firstly in Harley Street and finally at 53 Wimpole Street. Miss Hughes – DJ always referred to Margaret in public as Miss Hughes - was his secretary and ran the practice, allowing DJ to spend an increasing amount of time establishing SAAD. The group was formed in 1957 with forty members, and Miss Hughes became its first secretary. She arranged the early meetings, held at the Royal Society of Medicine, and using a Gestetner cyclographic copying machine in DJ's office, produced the first Digest Reports. These Reports consisted primarily of transcripts of papers given at the meetings, compiled by Miss Hughes from tape recordings she made at the time.

In 1959 the first SAAD Course was held at 53 Wimpole Street in the basement, where DJ had constructed a lecture theatre with a projection room – he held the lease on the whole building. While DJ ran the teaching and clinical side of the courses, Miss Hughes took care of the administration and logistics.

SAAD grew rapidly and by the mid sixties was the largest dental group in the UK after the British Dental Association, with over 4000 members. This needed some management in an era without e-mail, computers or even fax machines. Carbon copied letters were produced in vast quantities to maintain communications, and for much of the time there was just Margaret Hughes to deliver all the paperwork.

Throughout this time DJ had a very successful practice to run as well as devoting a great deal of time to the advancement of SAAD. He could not possibly have achieved this without Miss Hughes. It was not just the time involved, it was Miss Hughes's management skills and quiet application which carried it through. "The important thing is to keep calm at all times" she would say.

In 1966 the first "Jumbo" course took place, by now held at University College, Gower Street, with a hundred and twenty participants and lead by a Course Organiser (the first being the late very gifted Peter Sykes). To go with the new course went a new textbook, *Intravenous Anaesthesia- SAAD*, edited firstly by DJ and then by Peter Sykes. Between 1967 and 1979 there were six editions. It is hard to imagine the work involved, - and all managed by Miss Hughes.

By the nineteen-seventies Miss Hughes was managing what could only be described as a small company. DJ's fame was now worldwide, with international awards and demanding lecturing engagements. He was elected to the General Dental Council with the highest number of votes of any candidate. His practice had patients beating a path to his door. And SAAD's activities

continued to expand with increasing uptake of courses and an increasing and significant political influence. While DJ may have been Chairman of the company, Miss Hughes was the Operations Manager.

Then quite suddenly in November 1975, Drummond Jackson died. To Margaret this was an enormous loss. She then had to deal with two problems; firstly the practice and then the management of SAAD. The practice continued with the help of friends and locums and was finally sold in August 1977. And out of the wings came another giant of SAAD, Peter Hunter. If Margaret thought that things would quieten down after the heady days of DJ she was mistaken. Peter was the most extraordinarily imaginative person. He and Margaret – she was now Margaret to all her SAAD colleagues – knew each other well and made a very efficient team. A new era in SAAD had begun.



Peter was the long term Honorary Secretary of SAAD at the time of DJ's death and thereafter became the driving force of its activities. He foresaw a place for SAAD in the teaching of Basic Life Support and Advanced Life Support to dentists and dental nurses and so were born SAAD Lifesaver one day courses touring the country; and then the world. Margaret found herself now running a course "factory". By the time Lifesaver was discontinued, more than half the dentists in the UK had attended a course and it had been staged all over the UK, the Gulf States and in Australia.

Throughout her association with SAAD Margaret guided new council members and course lecturers to ensure a seamless transition from one generation to the next giving the society a continuity and understanding of its past. She drew together divergent personalities with a polite diplomacy that was the cement

of a stable and active SAAD council. This diplomacy enabled the necessary multidisciplinary co-operation for SAAD council to produce its first guidance document on standards for monitoring during general anaesthesia and sedation for dentistry. From there followed a tradition of SAAD providing standards guidance.

Margaret was one of the prime instigators of The Drummond Jackson Memorial Prize. She created a large prize fund by garnering donations from universities all over the UK and the world. Such was her quiet influence that donations came not just from the dental profession but from famed names in medicine and specifically anaesthesia. Even those who had been professional adversaries in life contributed to this prize fund in recognition of DJ's contribution to pain and anxiety control in dentistry. It is this legacy that still funds SAAD's prizes today.

In 1988 Margaret retired from SAAD. At the party given in her honour she was made an Honorary Life Member of SAAD. She was also a Life Member of the American Society for the Advancement of Anaesthesia in Dentistry, and of AINOS, the Italian society.

In retirement Margaret maintained an interest in dentistry, forming a company, Blackwell, together with Peter Hunter and David Phillips, that retailed anaesthetic and sedation supplies including their own product, an emergency drug kit – ZetaPack.

She remained very close to Ruth Drummond-Jackson, DJ's widow and did much to support Ruth in her latter years. Travel was a keen interest and she travelled widely with DJ on his many lecturing tours abroad. In 1975, in recognition of her twenty five years of service with DJ, she, DJ and Ruth undertook a world tour. Margaret loved dancing as a youth and in later life was an avid balletomane, being a regular at the Royal Ballet, Covent Garden, Sadler's Wells and the Coliseum. She travelled to Russia to attend the Bolshoi in Moscow, and to the Kiev. She never married.

SAAD owes a huge debt of gratitude to Margot, Miss Hughes, Margaret; without her we would not be what we are today.

Dedication Loyalty Dignity

PRACTICE EVALUATIONS

Have your Practice evaluated in accordance with the SAAD Safe Sedation Practice Scheme: A Quality Assurance Programme for Implementing National Standards in Conscious Sedation for Dentistry in the UK.

**The Evaluation document may be downloaded from the Documents section of the SAAD website
www.saad.org.uk**

**For further details or to arrange an evaluation
Please contact fiona@saad.org.uk**

Secretary's Correspondence

Sadie Hughes BDS MFDSRCPS(Glas) MSc,
SAAD Honorary Secretary

Q. I have been advised that the two day SAAD course for nurses is not enough to be a sedation nurse (as per the new sedation standards April 2015). What are the minimum qualifications that dental nurses should have, to be able to assist with sedation?

A. The IACSD Standards state that dental nurses who want to assist with conscious sedation need theoretical knowledge, skills training and supervised clinical experience. The first two elements are provided on a SAAD course (Part I) but dental nurses then need to access supervised clinical experience, with someone suitable supervising, so that a log book of cases demonstrating experience can be completed. Following this, a dental nurse should be competent to assist during sedation sessions and act as the second appropriate person. Note that experienced dental nurses are covered by the 'Transitional Arrangements' on page 87 of the IACSD Standards. The IACSD Standards state that the NEBDN Certificate in Dental Sedation Nursing (CDSN) should be considered the gold standard and nurses should be encouraged to work toward this qualification. The SAAD Part II course for dental nurses may be of assistance but it is not mandatory. This information is summarised in the IACSD FAQs page at RCS Eng which is linked from the SAAD website.

Q. Hello, I understand the method for ordering Midazolam has changed. Please can you provide further information?

A. Yes, new regulations were introduced from 30th Nov 2015. Please see the link below for further information.
<https://www.gov.uk/government/publications/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording>
Midazolam must now be ordered on a specific form that has been signed. The link to the form is below.
http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf

Q. Does a dentist have to be on the premises when hygienists and therapists undertake inhalation sedation with nitrous oxide/oxygen for dental patients?

A. As long as the Dental Therapist or Hygienist is supported by an appropriately trained and experienced Dental Nurse ('second appropriate person'). The GDC, in their code of practice, say that hygienists and therapists can practise IS on patients without a dentist on the premises. Further information can be found on the IACSD FAQs page at RCS Eng which is linked from the SAAD website.

Q. I have never received any training in sedation and a patient who has had oral premedication prior to dental treatment at their last dental practice is asking for this again. Do I need to ask their General Medical Practitioner to prescribe it?

A. Even without any sedation training, it is within your scope of practice to prescribe small doses of anxiolytics such as

Francis Collier MSc BDS DipDSed (Lond)
President of SAAD

diazepam or temazepam to aid an anxious patient's sleep the night before, journey to the surgery and acceptance of the dental care you are providing. For example, 10mg temazepam may be prescribed the night before and an hour before dental appointments for this purpose. However, it is extremely important that the patient receives written instructions to ensure that they are accompanied both to and from your surgery, and that they do not drive for the rest of the day. When the provision of such oral premedication is carried out by the patient's GMP such instructions are rarely if ever given, and this could leave you, as the dentist, in a vulnerable situation should the patient unfortunately have an accident because appropriate instructions were not given.

Q. Do sedation nurses have to complete 12 hours of CPD in a five year cycle?

A. Yes, the IACSD Standards state that all members of the sedation team should complete 12 hours of verifiable CPD over a 5 year cycle. Examples of CPD include attendance at a SAAD symposium, SAAD website CPD questions linked to the annual Digest publication, sedation update courses or in-house refresher courses, as long as the criteria that mean it is verifiable are met. For further information please refer to page 21 of the IACSD Standards for Conscious Sedation in the Provision of Dental Care – 2015 Report

Q. I would like to run a sedation update course in my area for verifiable CPD. How do I get my course accredited in line with the IACSD guidance?

A. As you are going to be running an update course for experienced practitioners as opposed to a course training beginners who want to provide sedation/assist with sedation, no accreditation is necessary. Please refer to question 4 of the IACSD FAQs at RCS Eng which is linked from the SAAD website.

Q. Which members of the sedation team are required to hold an Immediate Life Support (ILS) certificate?

A. All members of the sedation team, irrespective of the type of sedation provided, require ILS +/- Paediatric Immediate Life Support (PILS), or equivalent, appropriate to the age group you provide sedation for. Courses accessed must include defibrillator training and deployable airway skills. Further information can be found in the IACSD FAQs page on the RCS Eng website.

Useful Links

Standards for Conscious Sedation in the Provision of Dental Care

Report of the Intercollegiate Advisory Committee for Sedation in Dentistry (IACSD)

<http://www.saad.org.uk/images/Linked-IACSD-2015.pdf>

IACSD FAQs

<https://www.rcseng.ac.uk/fds/Documents/faqs-4-dec-2015.pdf/view?searchterm=IACSD>



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Online registration is now open at www.saad.org.uk

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DENTAL ANAESTHESIA**

- Write an essay on one topic in **ENGLISH** in A4 format with double spacing, as a Microsoft word document. Drummond-Jackson not exceeding **5,000** words, Dental Nurses not exceeding **2,500** words, Dental Students not exceeding **3,000** words.
- Entries must be received and acknowledged by **31st March 2016**.
- Essays must be written in accordance to SAAD's Guidelines for Authors available from the SAAD website and on page 80 of this Digest.
- The decision of the panel of assessors appointed by SAAD will be final.
- Entries, accompanied by name, address and telephone number, should be emailed to fiona@saad.org.uk



NATIONAL COURSE IN CONSCIOUS SEDATION FOR DENTISTS AND DENTAL NURSES DENTAL HYGIENISTS AND THERAPISTS

Patients appreciate being offered sedation for their dental treatment, whether they are fearful, phobic or simply have a long and tedious procedure in prospect.

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ENQUIRIES:

Fiona Trimingham (Executive Secretary)

Course payments, cancellations and deferrals, hygienist & therapist course logbooks
01302 846 149 fiona@saad.org.uk

Toni Richman (Course Administrator) Course content and course weekend logistics
07583 039 309 (text) toni@saad.org.uk

Dental Nurse Part 2 Courses

Emma Lee (Dental Nurse Examination Co-ordinator) emma@saad.org.uk

FORTHCOMING COURSES:

5/6 March 2016	4/5 March 2017
18/19 June 2016	17/18 June 2017
5/6 Nov 2016	4/5 Nov 2017

DETAILS AND ONLINE REGISTRATION

www.saad.org.uk

SAAD Supplies

	Members	Non members	Postage & Packaging
Intravenous Sedation Pre-sedation instructions (per 200)	£24.75	£33.00	£8.50*
Dental Treatment for Anxious Patients Information brochures (per 200)	£24.75	£33.00	£8.50*
Inhalation Sedation Information leaflet (per 200)	£24.75	£33.00	£8.50*
Medical History Forms (per 200)	£16.50	£22.00	£7.00*
Sedation Record Forms (per 200)	£16.50	£22.00	£7.00*
CBT Toolkit	£22.50	£30.00	£3.00
A History of SAAD by Peter Sykes	£5.00	£5.00	£3.00

*If four or more items are ordered together, the postage and packing will not be more than £15.60.

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It is now possible to place orders on-line at www.saad.org.uk. Be sure to log-on if you want to claim member's reduced prices.

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WEBSITE

www.saad.org.uk

- **Online CPD**

Log-on the membership area and follow the link 'Online CPD'
Answer multiple choice questions related to the refereed papers in this issue of the Digest.
Download your CPD certificate

- **Latest news relating to conscious sedation**

- **SAAD courses**

details, dates and application forms – *online registration*

- **Online shop for SAAD literature**

- **Sedation related documents for downloading**

- **Membership details and subscribe online facility**

- **Download back issues of the Digest and Newsletter**

- **Details of RA machine loan scheme, research grants and essay prizes**

- **Online registration for the symposium**

- **SAAD contact numbers and email addresses**

IN THE MEMBERSHIP AREA

- **Media page – members of SAAD may use the SAAD logo on their literature.**

The logo is available in PDF or JPEG format to download from the website.

- **Documents – course handbook**

- **Pay subscriptions online**

- **Forum for adverts**

(equipment, positions vacant, positions sought etc)

- **Online shop for SAAD literature at reduced rates**

Guidelines for Authors

SAAD Digest: Guidelines for Authors

SAAD Digest is the Journal of the Society for the Advancement of Anaesthesia in Dentistry and has been published regularly in London UK, since 1970. It has been produced in its current format since 2006. One edition is published each year in January. Copies of all editions produced since then are available online at <http://www.saad.org.uk/saad-digest/>

The Digest has become a unique and invaluable international forum for all interested in advancement of knowledge in pain and anxiety control for dentistry. The Editorial Board invites contributions from all active in the field. Since only one edition is produced each year, potential Authors should be aware of the following details and schedule to avoid excessive publication delay and disappointment.

Contribution formats

The Board welcomes Research articles, Reports of Randomised controlled trials, articles derived from Diploma Dissertations, Practice-related articles, Education, Professional Opinion, Case Reports and General articles. If in any doubt about the format or content of a proposed article please contact the Secretary before submission. It should be noted that articles are now only accepted in digital format and via email. It is a condition of acceptance of manuscripts that they are the work solely of the author or authors stated and that they have not been previously published elsewhere (either in print or electronic format) nor are they under consideration by any other periodical. Manuscripts should meet the following criteria: they should be original, clearly written, relevant to dentistry, reader-orientated (in other words written to appeal to the readership of any interested in pain and anxiety control in Dentistry) and designed to inform, add to discussion or debate, or entertain. Research papers should also have appropriate study methods, valid data and conclusions that are supported by the data.

Publication Schedule

The following annual publication schedule is provided for guidance only and assumes a Digest publication date of January Year 01.

August Year -1 > July 31st Year 00: Articles may be submitted for Jan 01 Edition

August 1st 00: Submission for Jan 01 edition closed. (Articles submitted after 31st July will be considered for Year 02 Edition)

Submission and review

Manuscripts may only be submitted by email to the Secretary at fiona@saad.org.uk. Manuscripts will generally be processed as they are received and it is expected that submission will be acknowledged by the Secretary soon after they are received, with a reference number allotted for future correspondence.

Authors should note that submitted papers not fully conforming to these 'Authors Guidelines', **especially in terms of length and manuscript format**, will be returned for correction without consideration or peer review, and in such cases publication might well be delayed or subsequently declined.

Peer review is carried out by at least two anonymous referees, and the Chairman of the Editorial Board. Additional statistical advice may be sought if required.

Authors will be advised as soon as possible, that either their Paper....

1. is suitable for publication without amendment,
2. is suitable for publication with some amendments,
3. may be suitable but requires major rewriting,
4. is rejected.

In any case, Authors will receive the anonymous structured feedback of the reviewers from the Secretary advising them of the decision level as above, and the action (if any) to be taken before resubmission. Delays in action on such advice may cause publication delay or even rejection if the publication deadlines are missed.

Once a manuscript is accepted for publication, authors will be advised whether their paper is to be published in the next issue or is, at the discretion of the Board, to be held for the following issue in order to obtain the appropriate balance for each edition. For similar reasons, in some cases the final decision on acceptance may be delayed. All decisions to publish are at the discretion of the Board alone whose decision is final.

The principal author of a manuscript accepted for publication will later be e-mailed a pdf version of their article for proofing. Any errors identified and requiring correction must be notified by email without delay, and at the latest within 1 week. No revision of the wording or other change, other than correction of proofing errors, will be allowed at this stage.

Manuscript Format

Manuscripts should be word-processed in Microsoft Word format and double-spaced with a margin of at least 4 cm on the left-hand side. The pages should be numbered consecutively with the numbers centred at the bottom of each page. The first page of the manuscript should give only the title of the article, and the author's/authors' name(s), qualifications and address(es) including email address(es).

Length of contributions

Contributions should be of no more than 3,000 words, to include tables and figures. Each table and figure will count as 100 words. Case reports are welcomed, but should be of no more than 750 words in length.

Titles must be descriptive of the contents of the article, but yet concise. Papers should be introduced with a short abstract which should be able to stand alone. The abstract should not contain references or abbreviations, and should be no longer than 200 words. The abstract will not contribute to the 3000 word limit.

Data or tables may be submitted in Microsoft Excel format or embedded in the text of the Word document.

Figures or images should be submitted as separately attached and clearly labelled files in JPEG format at a high resolution of 300 dpi. Colour illustrations are preferred where possible. If the illustration is of a subject's face, written consent for its publication must be obtained from the subject and attached with the article. Illustrations obtained from other sources such as books, or from colleagues, must again be accompanied by appropriate documentation indicating approval for their publication as part of the article from the copyright holder, or individual concerned.

Units used in the manuscript must conform to the *Système Internationale d'Unités* (SI).

References must be in the Vancouver style. They should be numbered in the order in which they appear in the text. The numbers should be inserted as superscripts each time the author is cited (Robb^{3,5} reported similar findings). Other references to the paper should be given in the same way after punctuation (Other studies have shown this to be true.^{4,5} Drummond-Jackson et al.⁶ demonstrated...). At the end of the article the full list of references should give the names and initials of all authors unless there are more than six, in which case only the first three should be given followed by et al. The authors' names must be followed by the title of the article; the title of the journal abbreviated according to *Index Medicus* and *Index to Dental Literature* style; year of publication; volume number; and the first and last page numbers in full. Titles of **books** should be followed by the place of publication, publisher, and the year. If this reference citation style is not followed exactly, **especially in relation to punctuation and spacing**, the manuscript will be returned without review.

Examples of reference styles

Reference to an article

1. Molar L R, Fang-Jones Q, Jaw U. Are Teeth biting back?. *Br Dent J* 2006; 200: 144-146.

Reference to a book

2. Craig D C, Skelly A M. *Practical Conscious Sedation*. 1st ed. London: Quintessence, 2004.

Reference to a book chapter

3. Robb N D. Conscious sedation in Dentistry. In Heasman PA (ed) *Master Dentistry*. Vol. 2; Restorative Dentistry, Paediatric Dentistry and Orthodontics. pp 149-168. Edinburgh: Churchill Livingstone, 2003.

Reference to a report

4. Re-accreditation and re-certification for the dental profession. London: General Dental Council, 1997.

Reference to a webpage

3. General Dental Council. Scope of practice. 2009. Online information available at [www.gdc-uk.org/Newsandpublications/Publications/Publications/ScopeofpracticeApril2009\[1\].pdf](http://www.gdc-uk.org/Newsandpublications/Publications/Publications/ScopeofpracticeApril2009[1].pdf) (accessed April 2012).

The author/principal author is responsible for the accuracy of the reference list.

Acknowledgements should be grouped in a paragraph at the end of the text before the references. Permission and approval of the wording must be obtained from the person(s) thanked. Where any research project was supported by industry, this should be acknowledged in a covering letter to the Editor on submission of the manuscript.

Declaration of interests: Author(s) must ensure that they declare any possible conflicts of interest in their paper. This includes matters such as: direct funding from an organisation or company for the research; funding received (or payment in kind) for any related work carried out from an organisation or company that could be linked to the research; consultation or advisory positions held in an organisation or company involved in the research or an organisation involved in similar research; any other situation that could be construed as a conflict of interest.

Ethics

Articles reporting clinical research must include a statement indicating that appropriate Ethical Committee approval has been granted.

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Upon acceptance for publication in SAAD Digest, it is assumed that the author(s) assign(s) copyright of the article to the Society for the Advancement of Anaesthesia in Dentistry. Single copies of the published article for personal study may be made free of charge but multiple copies will require permission of the Editor prior to production.

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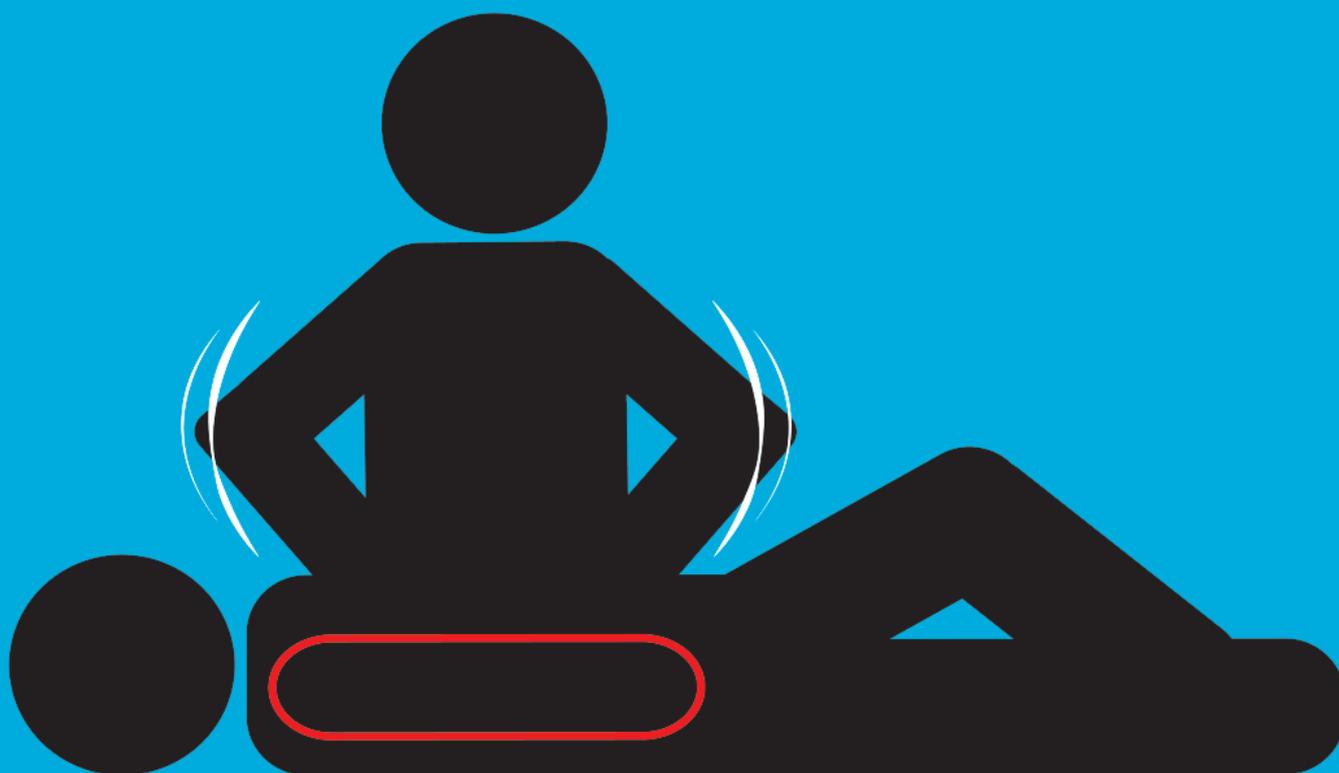
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DIARY SCAN

Compiled by Dr C E Mercer

2016	DATE	ORGANISATION	THEME/TITLE	VENUE	CONTACT
FEBRUARY					
	20-21	SAAD	Dental Nurse Part II Course	London	www.saad.org.uk
MARCH					
	4-5	ADSA	Las Vegas Meetings	Aria Hotel and Casino	www.adsahome.org/vegas.html
	5-6	SAAD	National Course in Conscious Sedation for Dentistry (inc nurses)	London	www.saad.org.uk/index.php/coursesbyrole/view-all-courses
	12	SAAD	Study Day in Conscious Sedation for Special Care Dentistry	London	www.saad.org.uk/index.php/str-study-day-in-sedation-for-special-care-dentistry
APRIL					
	23-25	ADSA	Annual Session	JW Marriott Austin, Texas	www.adsahome.org/annual1.html
	29-2 May	NWAC	World Anaesthesia Convention VI	Vancouver, Canada	www.nwac.org
MAY					
	10-12	British Pain Society	Annual Scientific Meeting	Harrogate International, Centre	www.britishpainsociety.org/mediacentre/events/future-asms/
	17	DSTG	Annual Symposium 'Should I Sedate or Should I Not?'	Royal College of Physicians & Surgeons, Glasgow, Scotland	www.dstgsymposium.co.uk
	20-23	World Institute of Pain	8th World Congress	Hilton NYC, New York, USA	http://wip2016.kenes.com/
	28-30	ESA	Euroanaesthesia 2016	ExCel, London	www.esahg.org/congresses/euroanaesthesia-2016
JUNE					
	15-17	GAT	Annual Scientific Meeting	Nottingham	www.aagbi.org/education/events/conferences
	18-19	SAAD	National Course in Conscious Sedation for Dentistry (inc nurses)	London	www.saad.org.uk/index.php/coursesbyrole/view-all-courses
SEPTEMBER					
	3-4	SAAD	Dental Nurse Part II Course	London	www.saad.org.uk
	7-10	ESRA	35th ESRA Conference	Maastricht, Netherlands	www.esraeurope.org/meetings/esra-annual-congress/
	13-16	AAGBI	Annual Congress	Birmingham, England	www.aagbi.org/education/event/1896
	24	SAAD	Annual Symposium & AGM	Royal Society of Medicine 1 Wimpole St, London W1	www.saad.org.uk
	24-25	European Resuscitation Council	Resuscitation 2016	Reykjavik, Iceland	www.erc.edu/index.php/events/en/09/2016/12/eid=118/
	29-1 Oct	ESPA	8th European Congress on Paediatric Anaesthesia	Crowne Plaza Hotel Belgrade, Serbia	www.euroespa.com/congress/2016-belgrade
OCTOBER					
	20-25	ADA 2016	Annual Conference	Colorado Convention Center, Denver, CO	www.ada.org/en/meeting/attendee-information/future-meetings/
NOVEMBER					
	5-6	SAAD	National Course in Conscious Sedation for Dentistry (inc nurses)	London	www.saad.org.uk/index.php/coursesbyrole/view-all-courses
	25-26	SIVA	Annual Scientific Meeting	Holiday Inn, Stratford-upon-Avon	www.siva.ac.uk
DECEMBER					
	4-5	ADSA	General Anesthesia and Deep Sedation	Swissotel, Chicago, USA	www.adsahome.org/chicago.ga
2017					
JANUARY					
	11-13	AAGBI	Winter Scientific Meeting	QEII Centre, Westminster, London	www.wsmlondon.org