Non-anaesthetist administration of propofol for sedation: caught 'NAAP'ing?

Propofol (2,6 diisopropyl phenol) is the most popular anaesthetic agent in use in the UK, largely because of its rapid onset and offset and relative lack of any 'hangover' effects. There is increasing worldwide interest in the use of propofol for procedural sedation, typically for gastrointestinal endoscopy but also for a wide variety of other interventional procedures. The evidence base for non-anaesthetist use of propofol in sedation, in terms of efficacy, safety and cost effectiveness, has expanded rapidly in the last few years with over half a million reported cases showing a low incidence of problems. The term 'NAAP' (non-anaesthetist administration of propofol) is in widespread global use but remains highly controversial, with conflicting guidelines from different professional bodies.

Concurrently, in the UK, the systems-based approach to patient safety has led to concerns about the safety of existing drugs for procedural sedation. Over a 4-year period to November 2008, 498 incidents involving midazolam were reported to the National Reporting and Learning System, including three deaths. 'Overdose of midazolam during conscious sedation' is now listed as a 'never event' by the National Patient Safety Agency, implying an adverse patient outcome that is both serious and largely preventable; hence there is national focus on improving the conduct and the clinical governance of procedural sedation.

National Institute for Health and Clinical Excellence (NICE, 2010) guidance on the sedation of children and young people encompasses many key concepts that are equally applicable to adult patients. In considering better patient care, NICE look at each step in the patient journey:

1. Pre-sedation: patient assessment, preparation and involvement in choosing a suitable technique
2. During sedation: clinical environment and monitoring
3. Post-sedation care and discharge.

Overarching all of this is the key consideration of personnel and training.

What do we mean by 'sedation'?

In the UK, we have conventionally aimed for a state of 'conscious sedation' where verbal contact with the patient is retained throughout the procedure, rendering loss of consciousness unlikely. NICE guidance, in contrast, chooses to use the American Society of Anesthesiologists definition of sedation as a continuum where deeper levels of sedation ultimately lead to general anaesthesia (*Table 1*). In this paradigm, the safety margin is maintained by being prepared for the problems that will be encountered in going one level deeper of sedation than was originally intended.

This definition brings the concept of 'deep sedation' into mainstream UK practice. Deep sedation can perhaps be useful in complex cases, such as endoscopic retrograde cholangiopancreatography, but by definition it is only a short step from the potentially dangerous state of general anaesthesia without proper control of the airway. Propofol has a narrow therapeutic range and thereby facilitates this accidental administration of general anaesthesia.

Non-anaesthetist administration of propofol

Controversy over NAAP is exemplified by the debate on this in the United States, where the opinion of anaesthesiologists and gastroenterologists has become almost diametrically opposed. The American Society of Anesthesiologists' opinion is that propofol sedation requires specific training and skills for the following reasons:

1. Propofol has the potential to cause rapid and profound changes in sedative or anaesthetic depth
2. Propofol has no specific antagonists
3. Propofol can have marked synergy with other drugs.

The propofol product insert leaflet contains the advice that propofol 'should be administered only by persons trained in the administration of general anesthesia'. Anaesthesiologists are caricatured as using this leaflet as their benchmark of practice, whereas the American College of Gastroenterology petitioned the Food and Drugs Administration, ultimately unsuccessfully, to have this advice removed.

The American College of Gastroenterology subsequently published a landmark review of 460 651 NAAP cases, along with a position statement on NAAP (Vargo et al, 2009). In almost half a million cases there were three deaths, all of whom had significant comorbidities and would be considered 'high risk'. The authors conclude that the safety profile of NAAP is equivalent to standard sedation; moreover, using anaesthesiologists for sedation results in higher costs with no proven benefit with respect to patient safety or procedural efficacy. They estimate that using anaesthesiologists to sedate every gastrointestinal endoscopy would cost $5 million per life-year saved, or a staggering $5 billion annually in the United States.

In Europe, the consensus statement of professional bodies is similar (Dumonceau et al, 2010): propofol sedation has similar rates of adverse events to traditional

Table 1. American Society of Anesthesiologists levels of sedation

Level	Minimal sedation	Moderate sedation (conscious sedation)	Deep sedation	General anaesthesia
Response to stimulus	Normal response	Voice or light touch	Repeated or painful stimuli	Unresponsive
Example drugs	Midazolam, nitrous oxide	Midazolam, propofol	Propofol, ketamine	Propofol
Life support qualification	Basic	Intermediate	Advanced	

From National Institute for Health and Clinical Excellence (2010)

agents; furthermore, propofol gives higher patient satisfaction, decreases time to sedation, decreases recovery time and may improve the quality of endoscopic examination. In the UK, there is some consensus: the Royal College of Anaesthetists and British Society of Gastroenterologists agree that propofol is useful for complex cases such as endoscopic retrograde cholangiopancreatography, but state that propofol sedation should be the responsibility of a dedicated and appropriately trained anaesthetist (Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland, 2011).

Personnel and training

Traditionally, competence in medicine has been assessed by a combination of 'time served' and formal written examination. We have now moved to a system where specific workplace-based assessment tools are used to assess clinical skills and knowledge, and progression is made on the grounds of clinical competence, based on the results of these tools. The Royal College of Anaesthetists has devised a curriculum for procedural sedation, for anaesthetists, with competencies laid out in knowledge and a skills matrix. The question is to the general application of such an approach. If we honestly believe in the validity of these tools then should they be equally applicable to any clinical group, whether anaesthetist, physician or nurse practitioner?

It is universally recognized that the practitioner giving sedation should have this as his/her sole task; a dual seditionist/operator is not defensible. Most bodies also agree that training in sedation should be competence based, with knowledge and skills components. Key skills should include airway rescue and advanced life support skills; there is likely to be a role for an airway workshop and simulation in acquiring some of these abilities. In the Royal College of Anaesthetists' model, these competencies are assessed using workplace-based assessment tools and can form part of the formal anaesthetic fellowship examinations (Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland, 2011).

There is also consensus on the need for a period of 'preceptorship', where sedation techniques are practiced under expert supervision, as complications are more likely during this preliminary period. How many cases this preceptorship should involve and who should constitute the 'expert' supervisor are important questions that have not yet been fully answered. It is also important that, once qualified, practitioners keep up-to-date by continuing education and practical experience.

Table 2. Principles of local sedation governance

Local guideline development	Nominated lead (senior clinician)
	Multidisciplinary governance group
Education and training	
Pharmacovigilance	Midazolam and flumazenil use and storage
Local incident reporting and analysis	
Annual audit with board level reporting	

Sedation governance

The National Patient Safety Agency and intercollegiate guidelines have made several recommendations on the governance of sedation (*Table 2*) (UK Academy of Medical Royal Colleges and their Faculties, 2001; National Patient Safety Authority, 2008). Each hospital trust should have a multidisciplinary team, headed by a senior clinician, to ensure this governance on a local level. There is continued debate on the role of the sedation team: should this be limited to governance and education or should this be a practical body, more akin to an acute pain team, providing 'on the ground' advice and practical help with sedation throughout the hospital trust?

Conclusions

There is mounting evidence that propofol is an effective drug for use in sedation, with similar rates of complications to traditional sedative agents, even when used by non-anaesthetists. However, the complications of over-sedation can be fatal and are as a cause for concern at national level; there is no room for complacency in this field.

The key principle in safe sedation practice is the competence of those involved. The tools and systems for building and assessing this competence are not yet fully developed but should include a curriculum of knowledge and practical skills, and a period of preceptorship before moving to autonomous practice, as part of a multidisciplinary team. BJHM

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KEY POINTS

- Propofol causes rapid and profound changes in sedative and anaesthetic depth and has no specific antagonists. It is increasingly used, worldwide, for procedural sedation but its use by non-anaesthetists remains highly controversial and contrary to the advice of many professional bodies.
- Evidence from large trials shows that propofol provides rapidly acting sedation, with good patient and endoscopist satisfaction and a quick recovery time. Rates of adverse incidents are similar to those of traditional sedation agents.
- The key to the safety of any procedural sedation is the involvement of a multidisciplinary team, all of whom have proven competence in their respective roles.