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Developments in procedural sedation for adults

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Title page

Title: Developments in procedural sedation for adults

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37 References, 0 Tables, 2 Figures.

Abbreviated Title (running head): Procedural sedation in adults

Key words

Sedation, remimazolam, capnography

Key points (43 words, 436 characters including spaces)

- Capnography is now a core monitoring technique for procedural sedation
- Administration of propofol sedation by appropriately trained non-anaesthetists can be safe and effective
- Short acting agents (remifentanil, remimazolam) and innovative analgesics (oliceridine) may expand the boundaries of procedural sedation practice
- Dexmedetomidine lacks clear advantages over other agents
- Hypotension is common during propofol sedation

Clinical scenario (if appropriate) NONE PROPOSED

Learning objectives (46 words, 349 characters including spaces)

By reading this article, you should be able to:

- Describe developments in anaesthetic pharmacology impacting procedural sedation
- Discuss factors determining return to home, work and driving
- Recommend an appropriate starvation regimen for individual patients and their circumstances
- Explain the use of capnography for patients receiving sedation

Text of manuscript 2894 words, two Figures

Heading A

Heading B

Understanding the context of procedural sedation

Sedation is ubiquitous in clinical practice. A two day survey of six UK hospitals[1] found that outwith the operating theatres and Intensive Care Units, the most frequent sedation locations were endoscopy, radiology and cardiology facilities and Emergency Departments. However, sedation is also delivered infrequently in many other environments. Particularly on large hospitals sites, these minor locations may be a significant distance from the usual sources of help (emergency team, anaesthetists, intensive care). Off-site sedation is common in dental practice, typically in facilities very different from the hospital environment.

Defining procedural sedation

Procedural sedation supports the delivery of investigations and procedures that patients might be otherwise unable to tolerate. Whereas general anaesthesia is characterised by a lack of response to surgical stimulus, minor surgical procedures supported by procedural sedation still require effective loco-regional anaesthesia. Recently, an international consensus statement[2] defined procedural sedation's purpose as *"…to facilitate a diagnostic or therapeutic procedure"* with a target state in which *"…airway patency, spontaneous respiration, protective airway reflexes, and hemodynamic stability are preserved, while alleviating anxiety and pain"*. These carefully crafted phrases reflect a clear separation from anaesthesia and avoid territorial claims for particular professional groups.

Terminology and language also impact patient understanding. A clinician remarking 'You'll be asleep' or 'You won't remember' may set up expectations equivalent to general anaesthesia and by implication, anything less is equated to failure. Educational materials have been developed to assist pre-sedation discussions with patients.[3]

Trends in patients, procedures and service

Excepting fee-for-service systems (where insurers may capture charges for drugs or for an anaesthetist), procedural sedation may not be recorded separately from the underpinning procedure. Data capture also varies by circumstance. Thus, modern endoscopy suites operate bespoke software which includes some details of sedation. In contrast, a 'one-off' episode of sedation in the Emergency Department may be documented in the patient's notes but never become a hospital statistic. Nevertheless, the use of sedation appears to be increasing. An index procedure, colonoscopy is typically performed with sedation. UK colonoscopies increased by 13% in two years 2017-2019.[4] EU colonoscopies increased by 13% in the three years 2011-2015 (ec.europa.eu/Eurostat). Set-backs from COVID-19's impact on investigations[5] have increased pressure to conduct procedures and investigations swiftly and efficiently on an outpatient basis.

Developments in instruments, procedures and imaging, and a shift to outpatient provision have increased the volume and duration of procedural sedation whilst offering it to a broader range of patients who may be older and carrying co-morbidities.

Guidelines

Guidelines for procedural sedation have been developed by specialist and professional bodies. In the UK, baseline standards were established by the Academy of Medical Royal

Colleges in 2013[6] with a minor update in 2021.[7] These are accepted by all clinical groups except dentists who have acted independently.[8] Specialty groups are encouraged to develop supplementary guidance which builds on the Academy standards and interprets it into particular clinical contexts. Materials for specialty training curricula are provided. Similar initiatives have taken place in the USA[9] and in Europe.[10] British anaesthetists should ensure their familiarity with the Academy[6, 7] and AAGBI[11] documents.

The principal developments in sedation guidelines over the past decade reflect an emphasis on competencies rather than job descriptions qualifying an individual to give sedation. Thus, European[10], UK[6, 7, 11] and US[9] guidelines remind us that sedationists must achieve and sustain relevant competencies for the target state and for unplanned deeper states. This innocuous rescue provision is interpreted by some as grounds to prohibit use of propofol by non-anaesthetists. US guidance also distinguishes between "*Sedative or Analgesic Medications Not Intended for General Anesthesia"* and *"Sedative/Analgesic Medications Intended for General Anesthesia."* [9]

New drugs and updates on old ones

Remimazolam

Remimazolam is a water-soluble benzodiazepine with rapid onset of action. The sedated state produced by remimazolam appears broadly similar to that caused by midazolam with faster onset. Due to hydrolysis by tissue esterases, patients recover rapidly from remimazolam sedation with psychometric measures returning to baseline sooner than with midazolam.[12] Unlike midazolam, remimazolam metabolites have negligible sedative effect. Presented as a powder, remimazolam must be reconstituted prior to use. Licensed for

procedural sedation in the UK, Europe and the USA, remimazolam is also licensed for induction and maintenance of anaesthesia in China, Japan and Korea.

Oliceridine

Oliceridine is a new opioid analgesic which acts as an agonist of the μ-opioid receptor. When used intravenously for acute pain after surgery, oliceridine has been shown to be non-inferior to morphine.[13] Whether it is a partial agonist or a biased agonist is a matter of debate, and arguably unimportant. Oliceridine may have a superior side effect profile to that of morphine, i.e. possessing a reduced tendency to sedation and respiratory depression.[13] However, the extent and clinical relevance of these differences ~~is~~ are controversial. The drug has had a troubled path to regulatory approval and was initially refused a licence by the United States FDA. Oliceridine/remimazolam and oliceridine/propofol combinations have been proposed for procedural sedation during GI endoscopy although no trial data have been reported.[14]

Methoxyflurane

Methoxyflurane is an old inhaled anaesthetic agent that has been re-purposed as an inhaled analgesic. Now licensed in Europe for analgesia, it has also found use for procedural sedation of patients having colonoscopy or dental extractions.[15, 16] Limiting the single dose of methoxyflurane to 3mL (which supports up to 25-30 minutes of continuous use) appears to be an effective safeguard against renal injury. The manufacturers recommend no more than 6mL in a day, none the next day and maximally 15mL in a week.

Sevoflurane

Sevoflurane has been evaluated for procedural sedation during burns dressings and during painful procedures in non-burns patients.[17] When 0.8% sevoflurane was inhaled for analgesia for labour pain[18] it was more effective than nitrous oxide. However, metabolism of sevoflurane produces fluoride and hexafluoroisopropanolol (HFIP) which may accumulate in at least a proportion of patients.

Use of sevoflurane for either procedural sedation or for analgesia is off-label as the drug is only licensed for the induction and maintenance of general anaesthesia. The availability of CE marked apparatus to administer sevoflurane in these applications does not imply either safety or efficacy. Nevertheless, the use of low-dose sevoflurane to provide brief periods of analgesia or sedation is probably safe. In contrast, the use of sevoflurane for ICU sedation involves large doses of drug administered over extended periods. This type of use appears to be associated with a demonstrable incidence of renal injury,[19] so ICU sedation with sevoflurane cannot be recommended.

Remifentanil

During the clinical development programme for remifentanil, it was evaluated for procedural sedation.[20] Patients having hip or hand surgery under regional block received remifentanil at 0.1, 0.07 or 0.04 mcg kg min^{-1} in a double -blind, placebo controlled study. The ED_{50} to achieve an Observer's Assessment of Alertness/Sedation Scale (OAA/S) derived measure of moderate sedation was estimated as 0.043 mcg kg^{-1} min^{-1}. Haemodynamic changes associated with remifentanil were modest. Nausea, vomiting, respiratory depression and pruritus were frequent and dose related. Licensing for procedural sedation was not pursued and remifentanil is only approved for sedation in patients undergoing mechanical ventilation.

A special instance of procedural sedation with remifentanil is to facilitate awake tracheal intubation. In this circumstance, the powerful anti-tussive effect of remifentanil enhances patient tolerance of airway manipulation. Further, there is typically a sustained dialogue between the proceduralist and the patient allowing early identification of apnoea and if necessary, encouragement of the patient to breathe.

Dexmedetomidine

This α_2 adrenoreceptor agonist is restricted to *"..health care professionals skilled in the anaesthetic management of patients in the operating room or during diagnostic procedures"* (medicines.org.uk). Onset of sedation is slow and bradycardia and hypotension are frequent, especially in the elderly. Dexmedetomidine appears to diminish perioperative inflammatory responses in surgical patients although this may not be relevant to procedural sedation. Dexmedetomidine has been evaluated in colonoscopy. When used as sole agent, bradycardia and hypotension were problematic and recovery was slow. When dexmedetomidine or midazolam were combined with fentanyl $1mcg.kg^{-1}$, performance was broadly equivalent. However, the dexmedetomidine regimen was markedly slower in achieving the desired degree of sedation since it required pre-treatment with a ten-minute loading infusion. When compared with propofol for gastrointestinal endoscopy, dexmedetomidine was less acceptable to patients. Adding low-dose dexmedetomidine to BIS guided propofol sedation decreases propofol requirements but reduces heart rate and blood pressure whilst delaying recovery and discharge.

Ketamine

Minimal cardio-respiratory depression and a profound analgesic effect make ketamine a candidate for procedural sedation, however, unpleasant psychiatric side effects prevent its use as mono-therapy. Propofol-ketamine combinations have been explored and appear to offer a reduction in adverse respiratory events when compared with propofol.[21]

Nitrous oxide

Although standard anaesthesia machines with the ability to deliver up to 70% N_2O are widely available, Entonox® (a 50:50 mixture of O_2 with N_2O) is preferred for procedural sedation with nitrous oxide. Well established as a labour analgesic, Entonox® is probably under-utilised in other applications. Outwith dentistry, where it is typically used in combination with local anaesthesia, Entonox® is commonly used as a sole agent. When compared with midazolam/fentanyl for sedation during colonoscopy, Entonox® gave lower pain scores, faster recovery times and was preferred by patients without compromising the quality of the procedure.[22] A similar study reported Entonox® and propofol/fentanyl to be equally effective. Nitrous oxide is recognized as a greenhouse gas and environmental concerns have impacted its use.[23]

Commented [AHM1]: Please add a reference for the "similar study" and move reference 23 to the supplementary reading material

Propofol

Propofol remains the drug of choice for anaesthetist delivered procedural sedation although concerns have been raised about its tendency to cause hypotension, especially in the elderly.[24] Concurrent administration of lidocaine during propofol sedation for endoscopy reduced propofol dose, shortened recovery time and improved endoscopist satisfaction. [25]

Propofol delivery options now include Target Controlled Infusion and Patient Controlled Sedation. The use of propofol by non-anaesthetists remains controversial although it is demonstrably safe and procedural outcomes are similar.

In the USA, where propofol use is limited to anaesthetists, propofol sedation underpins increased participation by anaesthesia services in outpatient colonoscopy (from 16.7% to 58.1% in the USA during the decade 2006-15) whilst achieving minimal impact on procedural quality indicators at considerable expense.

Equipment for sedation

Infusion pumps

Except in the USA (where it is not approved) Target Controlled Infusion is the preferred means of propofol administration, and increasingly for remifentanil. Patient Controlled Sedation (PCS), with repeated propofol boluses or through titration of a TCI system is associated with fewer adverse events than clinician administered propofol whilst using similar median doses.[26] PCS is feasible and appears to be safe but the onset of sedation may be slow with implications for patient throughput. Current commercially available infusion systems are not licensed for Patient Controlled Sedation and their use should therefore be considered experimental. Recently, a simulation study showed that TCI models for remifentanil deliver doses that lie within the envelope of the product licence.[27] Given the lack of commercial incentive to develop drug licenses and equipment for generic drugs, this imaginative approach might be more broadly applicable.

Methoxyflurane inhaler

Penthrox® is a single use device through which patients may inhale up to 3mL of methoxyflurane. Primarily intended for analgesia, the system produces a degree of sedation in a proportion of patients.[28]

Patient monitoring

In addition to regularly assessing and recording the patient's sedation status, current guidelines[6, 7, 9-11] require monitoring of blood pressure, ECG and oxygen saturation. Recently, capnography has been upgraded to mandatory, albeit with some caveats.

Capnography

In sedated patients the principal use of capnography is to confirm (on a continual basis) the presence of spontaneous respiration without apnoea, bradypnoea or obstruction. In sedation applications, exhaled breath is collected around the lips and nose and transported through a fine tube to an analyser which may be several metres away. The exhaled breath of the patient may be diluted by entrained air which distorts the capnogram waveform and presents an apparent End-Tidal CO_2 which is lower than the true value. However, provided that a clear (albeit distorted) respiratory waveform is visible, ~~then~~ derived values of respiratory rate are likely to be accurate.

Whilst a useful capnogram may be achieved by tucking a sampling tube inside a standard facemask, the resulting waveform may be positional and therefore confusing. Recently, the development of soft plastics allows the manufacture of patient-friendly equipment with administration of supplementary oxygen to the front of the nose whilst sampling within the nares and in front of the mouth. When appropriate, the incorporation of a bite guard facilitates upper GI endoscopy.

Figure 1 near here

Like the pulse-oximeter, the capnogram waveform is intuitive and easy to understand. In contrast, interpretation of the ECG and the EEG require significant specialist training. Because the application of capnography is simple, this monitoring can easily be incorporated into routine clinical practice. Importantly, capnography has no capacity for causing patient harm. Capnograpy during procedural sedation has been evaluated in Randomised Controlled Trials, however their design and analysis ~~is~~ are heterogenous. Metanalysis suggests that capnography reduces the number of airway incidents and interventions, with decreased hypoxaemia.[29] The evidence base is far from comprehensive, especially in procedures around the airway. Acceptance of capnography as a core monitor for sedated patients is general amongst anaesthetists with slower uptake by other professional groups, notably dentists.[8]

Neither parachutes nor pulse-oximeters were evaluated by clinical trials before their introduction, however their use is widespread. Further, consideration of utility only in terms of critical incidents and major outcomes may miss the point. Situational awareness errors contribute to or underpin as many as 75% of catastrophic outcomes and anaesthesia malpractice claims. A common world view is an integral element of Crisis Resource Management and a clear understanding of patient status forms a priority component of this information. The combination of capnography with pulse oximetry provides the entire team with a continuous reassurance that the patient is breathing, is oxygenated and has a circulation. The availability of compact reliable monitors and well-designed apparatus to ensure effective gas sampling make capnography a logical addition to the practice of

procedural sedation. Whilst the evidence base for sedation capnography is moderate rather than overwhelming, its value is enhanced by supporting safety culture in busy clinical teams.

Bispectral Index (BIS)

Whilst it is not specified by European[10], UK[6, 7, 11] or US[9] guidelines, BIS monitoring may be used to confirm the degree of sedation achieved and to avoid un-necessarily deep sedation. Post-operative delirium is common and associated with adverse patient outcomes. Development of anaesthetic strategies to minimize delirium and other forms of perioperative neurocognitive disorder is an emerging research priority. Recently, BIS guided titration of anaesthesia to target values of 50 rather than 35 for high risk patients undergoing elective major surgery was demonstrated to decrease the incidence of new delirium from 28% to 19%.[30] Median average BIS scores were 51 and 38 in the two groups respectively. In contrast, when patients having lumbar spine fusions were randomized to BIS guided sedation and un-guided general anaesthesia with median average BIS values of 62 and 45 respectively, incident delirium was not different.[31] However, a pre-planned sub-group analysis did demonstrate benefit in patients with pre-operative cognitive impairment. Since many surgeries can be achieved with loco-regional and procedural sedation rather than general anaesthesia, there is continued effort to clarify whether these techniques can impact the incidence and severity of perioperative neurocognitive disorders. Whilst clinicians may find BIS monitoring useful, its use remains controversial. Certainly it remains un-proven whether BIS monitoring can decrease the incidence of perioperative neurocognitive disorders.

Haemodynamic monitoring

Improvements in engineering and signal processing allow non-invasive extraction and display of arterial pressure waveforms. Further analysis yields a predictive index which forecasts hypotension. Currently deployed for major cases, we may expect to see this and similar technologies progressively deployed in standard monitors.

Hypotension

Recognition that perioperative hypotension is associated with adverse outcomes has made its identification and avoidance a clinical priority. In contrast, changes in blood pressure during procedural sedation have received little attention. Propofol sedation is particularly problematic, and hypotension is frequent when propofol is used for sedation of patients having colonoscopy.[24] Further, its hypotensive effects are amplified by haemorrhage. Barends[32] reported 2973 episodes of sedation provided by specialist nurses using target controlled infusions of propofol and remifentanil. ~~8.8% experienced~~ "Significant Hypotension" (mean arterial pressure below 65 mm Hg, longer than 10 minutes requiring treatment) occurred in 8.8% of patients. For the 286 undergoing "Lower Endoscopy", the incidence was 12.9%. The occurrence of material hypotension during procedural sedation is thus established. Further work is required to establish its determinants and significance. Gregory[33] makes the case for intra-operative hypotension as a crucial target "*…we believe hypotension in the operating room is a serious public health issue, and should not be ignored in any age group." We suggest there is an urgent and currently unmet need for prospective interventional studies focused on its prevention.*"[33] Arguably it's time that hypotension during procedural sedation receive~~d~~ the same attention as its equivalent in the operating room.

Fasting

A recent international consensus statement on fasting before procedural sedation concluded that *"The probability of clinically important aspiration during procedural sedation is negligible."* And *"Current concerns about aspiration are out of proportion to the actual risk."*[34] An algorithm based approach to decision making is recommended, Figure 2. The algorithm attempts to pragmatically recognise that needless fasting inconveniences patients and staff whilst acknowledging the fine line between sedation and anaesthesia. In addition, a small minority of procedures where sedation is planned may evolve into needing anaesthesia.

Figure 2 near here

Recovery from sedation and driving

Patients undergoing procedural sedation require clear guidance on the timing of their discharge from a clinical facility, the need for an escort, and the appropriate intervals before driving, operating machinery, or making important decisions. Whilst surgical considerations or the persistence of regional blocks may determine some of these recommendations, the principal consideration is residual psychometric effect from hypnotics and opioids. In the UK, colonoscopy patients self-sedated with 50% nitrous oxide (Entonox®) are considered safe to drive home 30 minutes later. The application of 'soft' pharmacology to procedural sedation through the tissue esterase hydrolysed agents remifentanil and remimazolam offers the prospect of swift recovery to baseline cognitive capability but is not yet validated to a degree sufficient to justify changed clinical practise.

Current guidance derives from pharmaceutical companies (drug data sheets), national bodies, specialty associations and local practice. Whilst research using driving simulators and psychometric testing can suggest where there may be scope for relaxation of guidance, there is little evidence of its implementation. The difficulty of proving a negative – i.e. that

an individual is unimpaired – and an abundance of caution[35] represent substantial obstacles to progress in this area.

Audit and adverse event reporting

An initiative to support the capture of coherent and comparable data describing episodes of procedural sedation has developed tools for quality improvement and research.[36] These have been deployed by ED physicians to demonstrate their safe practice in sedation of adults, children and the elderly.

Current and future practice and staffing

The predominant current sedation strategies are hypnotic/opioid combinations. Anaesthetists typically provide deep sedation or general anaesthesia using propofol as a~~n~~ hypnotic supplemented by an opioid, usually remifentanil or fentanyl. Non-anaesthetist operator-sedationists most frequently use midazolam/fentanyl.[1]

In the USA, anaesthetist provision of propofol sedation for colonoscopy has grown rapidly but its cost and necessity are being challenged. Non-Anaesthetist Administration of Propofol, NAAP is restricted by drug labels reserving propofol for certain professional groups (USA), reluctance of non-anaesthetists to use an anaesthetic agent or by law (some European countries). In addition, traditional inter-professional boundaries and custom and practice have restrained uptake of NAAP. Overall efficiency may be greater with NAAP. Non-anaesthetist (nurse-sedationist) use of propofol may even be preferable to administration by anaesthetists, when nurses sedate with propofol they use less drug and cause less hypotension than do anaesthetists in the same institution.[37]

The future

Looking ahead, the demand for sedation will probably continue to exceed the capacity of anaesthetists to provide it. Where non-anaesthetist colleagues are providing sedation, anaesthetists are well positioned to support them through standards, training, simulation and audit. Anaesthetists should be at the centre of hospital sedation practice with key roles at institutional levels including Sedation Committees, Formulary Committees and general support for pharmacovigilance and patient safety. Anaesthesia department provided hospital-wide sedation services using non-medical providers have been established in the Netherlands and elsewhere and appear to be safe.

Conclusion

New drugs and equipment, as well as developments in policy and procedure ~~all~~ offer opportunities to improve our practice in procedural sedation.

Reading list

A reading list of additional references is provided in Supplementary Materials.

Biography

Robert Sneyd MD FRCA SFHEA is Emeritus Professor at the University of Plymouth (formerly Executive Dean for Medicine and Dentistry). His academic interests are in clinical pharmacology.

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Legends to Tables - none

Legends to Figures

Figure 1. Combined bite block airway, oxygen delivery and capnography for patients undergoing upper gastrointestinal endoscopy. Separate small-bore tubes deliver oxygen and sample airway gasses.

Figure 2. Algorithm linking risk stratification and fasting guidance. Notes: (1) Suggested definitions for moderate obesity are a body mass index (BMI) of 30–39 kg.m−2 in adults or from the 85th up to the 95th BMI percentile based on age/sex in a child, and for severe obesity a BMI of 40 kg.m−2 or higher in an adult or at the 95th percentile or greater in a child. (2) Includes micrognathia, macroglossia and laryngomalacia; (3) Includes gastroparesis, achalasia, atresia, stricture and tracheoesophageal fistula; (4) Includes ileus, pseudo-obstruction, pyloric stenosis and intussusception. (5) Clear liquids are generally considered to include water, fruit juices without pulp, clear tea, black coffee and specially prepared carbohydrate-containing fluids. (6) Fasting intervals are not absolute, with exceptions permissible when the volumes of oral intake are minor, or the fasting time reasonably close. Reproduced with permission from,[34]

Podcast – none provided

Social media – tweets @robsneyd

- Capnography during procedural sedation is safe and decreases the number of critical incidents
- Hypotension is common when patients receive propofol sedation for colonoscopy
- Remimazolam provides raid onset procedural sedation with swift recovery of psychomotor function
- Guidelines for procedural sedation emphasize competencies rather than specialty or clinical role

Declaration of interest

JRS acts as Consultant and Advisory Board member for Paion and as Consultant for Medtronic

Authorship

This work was conceived and written by JRS