

Guidance for the use of propofol sedation for adult patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) and other complex upper GI endoscopic procedures

Introduction

This guidance has been written because increasingly challenging diagnostic and therapeutic endoscopic procedures are being performed in adults and there is a need for more prolonged and satisfactory sedation to be administered; there is increasing evidence that this can be provided safely and appropriately by propofol when administered by those trained in its use. Sedation with propofol should be viewed as a completely separate entity from its use as a general anaesthetic.

These guidelines aim to cover UK practice in the use of propofol for sedation only in adult patients during endoscopic procedures, using ERCP as a specific example, as this group of patients can clearly benefit from the use of this drug administered by an appropriately trained anaesthetist or consultant anaesthetist supervised Physicians' Assistant (Anaesthesia) (see below), so allowing the endoscopist to concentrate fully on the procedure. It is recognised that there are certain circumstances where general anaesthesia may be more appropriate, but these guidelines will not consider this further.

This guidance is to be added as an appendix to the BSG guideline Safety and Sedation during Endoscopic Procedures.¹

The use of propofol for sedation

The use of propofol for sedation requires specific training and skills because it has:

- Potential to cause rapid and profound changes in sedative/anaesthetic depth.
- No specific antagonists.
- Marked synergy with other sedative drugs.

As a consequence its use for sedation results in significantly different challenges from the use of intravenous benzodiazepines and/or opioids; further, propofol's general anaesthetic properties reduce its margin of safety for sedation purposes. These challenges must not be underestimated, particularly in this group of patients who often present with significant co-morbidities.

Widespread experience indicates that propofol alone provides excellent sedation for the majority of patients; if opioids are also required, only small doses are needed and are best administered first, with sufficient time allowed for their peak effect to be reached. The synergistic effects of benzodiazepines in combination with propofol and opioids greatly increase the risk of the onset of general anaesthesia.

Previous BSG guidance¹ has indicated that there is 'No room for complacency' with regard to sedation and the American Society of Anesthesiologists (ASA) have stated that, 'the use of propofol for sedation requires special attention';² these views are supported by this Working Party.

Personnel responsible for administering propofol for sedation and training

In the USA and several European Union (EU) countries, the use of propofol by non-anaesthetists is described in the literature, although this practice still remains controversial. European guidelines on the non-anaesthetist administration of propofol (NAAP) for endoscopy were published in December 2010.³ They stipulated stringent regulations and demonstration of clearly defined competencies. A formal mentored training programme and achieving an appropriate qualification in the practice were strongly advised and self-training discouraged. Nevertheless, these guidelines have been rejected by many EU national societies of anaesthesia who remain clear that only anaesthetists should administer propofol. In the UK at present there is no provision for nationally recognized formal training programmes or qualification in NAAP.

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The opinion of the working party is that, at the present time in the UK, the administration and monitoring of propofol sedation for such potentially complex endoscopic procedures should be the responsibility of a dedicated and appropriately trained anaesthetist (with the minimum competencies identified as those for 'Intermediate Level' sedation training identified in the relevant section of the CCT in Anaesthetics, 2010 – attached as Appendix for information), or an appropriately trained Physicians' Assistant (Anaesthesia) working under the supervision of a consultant anaesthetist at all times;⁴ this will ensure that the potential complications of sedation and anaesthesia in such patients are appropriately managed. A review of this guidance and the use of NAAP may occur in the future when the wider topic of sedation practice has been revisited and reviewed by a Joint Working Party of the Academy of Medical Royal Colleges.

Patient selection

Patients with significant co-morbidities are likely to present greater challenges and risks for deeper sedation with propofol. The consultant anaesthetist with responsibility for sedation (see below) in the facility providing endoscopy must also ensure that appropriate assessment and selection of suitable patients is effectively carried out in their institution. Whilst they may not need to review all the patients personally, they should ensure an adequate pre-assessment procedure is followed for all potential patients. Patients with morbid obesity, a history of obstructive sleep apnoea, severe respiratory or cardiovascular disease, and also patients with known or predictably difficult airways would be examples (not an exhaustive list) of those who should be very carefully assessed prior to consideration for sedation techniques that include propofol in the endoscopy environment. It may be more appropriate to use general anaesthesia with controlled ventilation for ERCP for some of these patients.

Minimum requirements for equipment and the environment

The Working Party agreed that the recommendations as laid down in the BSG document 'Endoscopy Related Services in District General Hospitals'⁵ adequately covered all requirements for equipment and the environment necessary for the use of propofol sedation.

In summary these are:

- A self-contained endoscopy unit including recovery area.
- Piped oxygen and suction in all areas.
- Appropriate equipment for supporting respiration.
- Appropriate 'tilting' trolleys.
- Monitoring as identified below.
- Full resuscitation facilities.

It is recommended that hospitals have identified sessions for the delivery of propofol sedation and that these are developed collaboratively between departments of gastroenterology and anaesthesia within individual hospitals. The Working Party considers that an anaesthetic machine is not essential when propofol is the sole agent used for sedation although it can automatically fulfil several of the requirements stipulated above.

The BSG document 'Endoscopy Related Services in District General Hospitals'⁴ identifies the need for pulse oximetry, ECG and automatic non-invasive blood pressure monitoring and the Working Party recommend that all these are used on all patients undergoing endoscopic procedures with propofol sedation. Oxygen should be administered from the commencement of sedation for the procedure through to readiness for discharge from recovery.⁶

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Monitoring of respiration with continuous waveform capnography is also recommended for all sedated patients and is essential for those whose ventilation cannot be directly observed. Such monitoring devices are now widely available and should be used for patients receiving propofol sedation for ERCP.⁷

Minimum staffing levels and generic training

In addition to the anaesthetist there should be a trained endoscopy assistant as directed by the BSG document, Staffing in the Endoscopy Room.¹ The Working Party does not consider that an ODP (or equivalent) is mandatory when sedation only is planned, however suitable equipment for providing airway support must be immediately available and the staff working in the area must be trained in their use to assist the sedationist in an emergency; this means competence in assembling airway adjunct devices (including supra-glottic airways, laryngoscopes and tracheal tubes) and assisting in their use. (Note: if general anaesthesia is likely to be required, or local practice dictates, dedicated trained assistance for the anaesthetist is mandatory).

If the endoscopy suite is in a 'remote' site, regular (at least annual), scenario training sessions should be undertaken by all staff to ensure they remain up to date with resuscitation guidelines and such sessions should be led by the consultant anaesthetist with specific responsibility for sedation (see below).

There should be a lead consultant anaesthetist and consultant endoscopist responsible for the development of audit and governance of safe sedation practice; this should include the development of an appropriate safety checklist.⁸ They should also be members of the Trust or Hospital Sedation Committee, the formation of which is a recommendation of the UK Academy of Medical Royal Colleges and their Faculties.⁹

References

- 1 Safety and sedation during endoscopic procedures. BSG, London 2003 (<http://bit.ly/1hvgid4>).
- 2 Statement on Safe use of Propofol. Ambulatory Surgical Care Committee. ASA, USA 2009 (<http://bit.ly/1hHYRV9>).
- 3 Dumonceau JM et al. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anaesthesiology Guideline: Non-anaesthesiologist administration of propofol for GI endoscopy. *Eur J Anaesthesiol* 2010;**27**(12):1016–1030.
- 4 PA(A) supervision and limitation of scope of practice (May 2011 revision). RCoA, London 2011 (<http://bit.ly/2s8RHHE>).
- 5 Provision of endoscopy related services in district general hospitals. BSG, London 2001 (<http://bit.ly/1hvjOUj>).
- 6 Safe sedation, analgesia and anaesthesia within the radiology department (para 3.4). RCR, London 2003 (<http://bit.ly/1jNbxP4>).
- 7 Capnography outside the operating theatre. AAGBI, London 2009 (<http://bit.ly/1hvkmtj>).
- 8 Implementing and ensuring safe sedation practice for healthcare procedures in adults. Report of an Intercollegiate Working Party chaired by the Royal College of Anaesthetists. RCoA, London 2001 (www.rcoa.ac.uk/node/2270).
- 9 Surgical safety checklist and implementation manual. WHO, 2008 (<http://bit.ly/1hvkMzZ>).

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Appendix 1

Basic and Intermediate Section competencies from the CCT in Anaesthetics

Sedation [Basic]

The use of sedation in clinical practice, particularly in non-theatre areas, is increasing and anaesthetists are frequently asked to provide/oversee its administration. It is essential that CT 1/2 anaesthetic trainees understand what is meant by conscious sedation [‘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’] and how it is administered safely.

Learning outcomes:

- To gain a fundamental understanding of what is meant by conscious sedation and the risks associated with deeper levels of sedation
- To be able to describe the differences between conscious sedation and deeper levels of sedation, with its attendant risks to patient safety
- Understands the particular dangers associated with the use of multiple sedative drugs especially in the elderly
- To be able to manage the side effects in a timely manner, ensuring patient safety is of paramount consideration at all times
- To be able to safely deliver pharmacological sedation to appropriate patients and recognise their own limitations

Minimum clinical learning outcome:

- Provision of safe and effective sedation to ASA 1 and 2 adult patients, aged less than 80 years of age using a maximum of two short acting agents.

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Knowledge			
Competence	Description	Assessment Methods	GMP
CS_BK_01	<p>Can explain:</p> <ul style="list-style-type: none"> ■ What is meant by conscious sedation and why understanding the definition is crucial to patient safety. ■ The differences between conscious sedation, deep sedation and general anaesthesia. ■ The fundamental differences in techniques/drugs used/patient safety. ■ That the significant risks to patient safety associated with sedation technique requires meticulous attention to detail, the continuous presence of a suitably trained individual with responsibility for patient safety, safe monitoring and contemporaneous record keeping. 	A,D,E	1,2,3
CS_BK_02	Describes the pharmacology of drugs commonly used to produce sedation.	A,C,E	1

Knowledge			
Competence	Description	Assessment Method	GMP
CS_BK_03	Explains the need for and means of monitoring the sedated patient including the use of commonly used sedation scoring systems.	A,C,E	1,2
CS_BK_04	Describes how drugs should be titrated to effect and how the use of multiple drugs with synergistic actions can reduce the therapeutic index and hence the margin of safety.	A,C,E	1,2
CS_BK_05	<p>Describes the importance of recognising the following when multiple drug techniques are employed:</p> <ul style="list-style-type: none"> ■ Increased potential for adverse outcomes when two or more sedating/analgesic drugs are administered and the importance of titrating to effect. ■ Knowledge of each drugs time of onset, peak effect, duration of action and potential for synergism leading to unpredictable responses. 	A,C,E	1,2,3
CS_BK_06	Can list which sedative drugs should not be given to the elderly [over 80 years of age], with reasons.	A,C,E	1,2,3,4

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CS_BK_07	Can explain the minimal monitoring required during pharmacological sedation.	A,C,E	1
CS_BK_08	Describes the indications for the use of conscious sedation.	A,C,E	1,2
CS_BK_09	Describes the risks associated with conscious sedation including [but not exclusively] those affecting the respiratory and cardiovascular systems.	A,C,E	1,2
CS_BK_10	Can explain the use of single drug, multiple drug and inhalation techniques.	A,C,E	1,2
CS_BK_11	Describes the particular risks of multiple drug sedation techniques.	A,C,E	1,2,3
CS_BK_12	Outlines the unpredictable nature of sedation techniques in children [Cross ref paediatrics].	A,C,E	1,2,3
CS_BK_13	Explains the need for robust recovery and discharge criteria when conscious sedation is used for out-patient procedures and the importance of ensuring appropriate escort arrangements are in place [cross ref day surgery].	A,C,E	1,2,3

Skills			
Competence	Description	Assessment Method	GMP
CS_BS_01	Demonstrates the ability to select patients for whom sedation is an appropriate part of clinical management.	A,C,D	1,2,3
CS_BS_02	Demonstrates the ability to explain sedation to patients and to obtain consent.	A,D	1,2,3
CS_BS_03	Demonstrates the ability to administer and monitor inhalational sedation to patients for clinical procedures [cross ref obstetrics].	A,D	1,2,3
CS_BS_04	Demonstrates the ability to administer and monitor intravenous sedation to patients for clinical procedures.	A,D	1,2,3
CS_BS_05	Demonstrates the ability to recognise and manage the complications of sedation techniques appropriately, including recognition and correct management of loss of verbal responsiveness.	A,D	1,2,3

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Sedation [Intermediate] Learning outcomes:

- Builds on the knowledge, understanding and clinical skills in sedation developed in basic level training.
- To be able to discuss where and when deeper levels of sedation may be indicated.
- To be able to deliver pharmacological sedation to patients of all ages, safely and effectively, whilst recognising their own limitations.

Minimum clinical learning outcome:

- To recognise the important principal of minimum intervention, where the simplest and safest technique which is likely to be effective is used to achieve the clinical goal.
- Provision of safe and effective sedation to any adult patient using multiple drugs if required.

Knowledge			
Competence	Description	Assessment Methods	GMP
CS_IK_01	Explains what is meant by 'deep sedation' and when its use may be justifiable, identifies the associated risks and how these may be minimised to ensure patient safety is not compromised [see also CK_IK_07].	A,C,E	1,2
CS_IK_02	Discusses how multiple drug use may enhance sedation techniques, whilst detailing how this increases risks.	A,C,E	1,2,3
CS_IK_03	Explains why it is essential to titrate multiple drugs [sedatives, analgesics and anaesthetic agents] to effect whilst recognising that the possibility of differing times of onset, peak effect and duration, can result in unpredictable responses.	A,C,E	1,2,3
CS_IK_04	Discusses the place of infusions compared to bolus doses as well as target-controlled infusions [TCI], and the pharmacological models and pump technology relevant to their use.	A,C,E	1,2
CS_IK_05	Discusses options for 'alternative' route of delivery of drugs used for conscious sedation including intra-nasal and rectal.	A,C,E	1,2
CS_IK_06	Discusses the unpredictable nature of sedation techniques in the 'extremes of life' and strategies for safe delivery [cross ref pæds].	A,C,E	1,2,3
CK_IK_07	Discusses the use of sedation in the high risk patient and the advantages/disadvantages of using general anaesthesia as opposed to sedation to cover necessary investigations/procedures in such patients.	A,C,D	1,2,3,4

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Skills			
Competence	Description	Assessment Method	GMP
CS_IS_01	Demonstrates the ability to select sedation techniques appropriate to management in patients of all ages [above 5 years [cross ref paed] to the elderly].	A,C,D	1,2,3
CS_IS_02	Demonstrates the ability to administer and monitor sedation techniques to all patients [identified in CB_IS_01 above] for appropriate clinical procedures, safely and effectively.	A,D	1,2,3
CS_IS_03	Demonstrate the ability to consider the following when considering the choice of sedation technique: <ul style="list-style-type: none"> ■ That no one technique is suitable for all patients and that the most appropriate technique is that based on minimum intervention, using the simplest and safest effective technique based on patient assessment and clinical need. ■ That techniques using multiple drugs/anaesthetic drugs should only be considered where there is a clear clinical justification, having excluded simpler techniques. 	A,D	1,2,3

These guidelines have been published on behalf of the Joint Royal College of Anaesthetists (RCoA) and British Society of Gastroenterology (BSG) Working Party

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