

*Conscious sedation in
termination of pregnancy*

Report of the Department of
Health Expert Group

September 2002

Acknowledgements

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Executive summary

Conscious sedation (CS) is a technique to reduce the pain and anxiety associated with termination of pregnancy (TOP). Conscious sedation is generally considered to be safer than a general anaesthetic¹ (GA) because the patients can breathe without any assistance and recovery is faster. However, there is no clear dividing line between 'sedation' and 'anaesthesia', so the treatment must be administered by a trained sedationist.

This technique is not used widely for TOP in the UK, but it is being introduced by service providers so we have drawn up standards relevant to the use of CS for that purpose. The recommendations are:

- CS should only be undertaken in appropriately equipped premises. The drugs should only be administered by a sedationist trained in the technique. The training required is commensurate with the successful completion of two years of Senior House Officer (SHO) training in Anaesthesia in the UK. Appropriate assistance should be available.
- Written protocols for CS must be available in the units using it and systems in place to ensure that they are complied with.
- Women must be provided with clear and accurate information and advised of the available options for anxiety and pain relief management in order to ensure that informed consent is obtained.

Introduction

1. Conscious sedation is a technique to reduce the pain and anxiety associated with termination of pregnancy. The woman is drowsy during the procedure, but can respond to questions and is able to breathe on her own. Thus, it is an alternative for a woman who wishes to have neither a general anaesthetic and be asleep during the TOP or just a local anaesthetic where she will be "wide awake".
2. Conscious sedation is generally considered to be safer than a general anaesthetic¹ because the level of physiological depression is less, the patients can breathe without any assistance and recovery is faster. However, there is no clear dividing line between 'sedation' and 'anaesthesia' so the treatment must be administered in appropriately equipped premises by a trained sedationist with appropriate assistance.
3. Although conscious sedation is used during TOP in other countries it is not used widely in the UK. The technique may have advantages for patients and as it is being introduced by service providers, it is necessary to lay down standards. A number of drugs can be used to produce conscious sedation and one combination is propofol and fentanyl given by the intravenous route. These drugs are normally used for general anaesthesia, but careful use of appropriately smaller doses results in conscious sedation instead.

4. We are not aware currently of any adverse incidents associated with this technique for TOP, but this is a new application of the technique in the UK so the Chief Medical Officer (CMO) set up a small expert group (see Annex A for terms of reference).

Professional view of sedation

5. The general issue of sedation techniques has recently been considered by the UK Academy of Medical Royal Colleges and their Faculties². This Group concluded that sedation, as an adjunct to good pain relief and sympathetic patient management, can improve both patient tolerance and acceptance, and increase the technical success of the procedure, but safety must be ensured. The Group also concluded that many users of sedation have received no formal training and that they do not follow existing guidelines – often because they are not even aware of them. They recommended the development of protocols for particular specialties and thus the establishment of the Department of Health (DH) Expert Group is timely.

Requirements for the use of CS in terminations

6. Termination of pregnancy is a short procedure (typically 5–10 minutes) and it is carried out both in NHS hospitals and other places including non-hospital based centres (which have been approved by the Secretary of State for Health to perform termination of pregnancy). Thus, when protocols are developed, it is important to take account of factors such as the range of back-up facilities available.
7. This report only addresses issues directly related to conscious sedation and builds on the DH's "Procedures For The Approval Of Independent Sector Places For The Termination Of Pregnancy" document.

General requirements for CS in termination of pregnancy

8. The general requirements for CS in termination of pregnancy are:
 - 8.1 Formal written protocols must be available. Clinical governance should ensure adherence to these protocols and monitor the incidence of any complications.
 - 8.2 All equipment should be checked at the start of each session.
 - 8.3 All staff involved should receive formal training relevant to their individual roles in the sedation process. Staff who administer sedative drugs must be aware of the possible loss of consciousness and be able to deal with this. Required competencies are given in Annex B.
 - 8.4 Interactions between drugs of different types (especially opioids and sedatives) are often synergistic so that both the degree of effect and its rate of onset are increased significantly. Drug combinations must be used with particular care. For instance, fentanyl adds significantly to the depression of airway reflexes produced by propofol.
 - 8.5 Clinical and instrumental monitoring is required. A trained sedationist, present throughout the procedure, must be responsible for monitoring the patient and making a written record.
 - 8.6 Secure venous access is mandatory.
 - 8.7 A pulse oximeter should be attached to the patient until the end of the procedure unless abnormal readings are found when it will be required for longer. Blood pressure should be recorded before, and at intervals during, the operative procedure.

- 8.8 Monitoring of the ECG is not essential in young, healthy patients.
- 8.9 Oxygen, and devices for administering it by the nasal and facial routes, must be available.
- 8.10 All patient trolleys should be capable of being tipped head down, suction apparatus and appropriate resuscitation equipment must be immediately available, with all staff being familiar and trained in its use. Members of the team must practice resuscitation together at regular intervals. Records of servicing and training should be kept and a written protocol for emergencies should be available. The equipment listed in Annex C must be available for dedicated use during conscious sedation. Further guidance on equipment is available from the Resuscitation Council (UK) at www.resus.org.uk.
- 8.11 There needs to be further development of CS techniques, but such development must be carried out in formal, collaborative research projects, not by uncontrolled variations in day to day practice.

Information for women

- 9. In addition to the informed consent about the TOP itself, patients should be given clear, accurate and up to date information on the options for anxiety and pain relief management, including risks, to ensure that they can make an informed decision about treatment. Guidance^{3, 4, 5} on obtaining informed consent already exists, but vulnerable groups such as adolescents and those with learning difficulties may need additional verbal or written information on treatment options.
- 10. Patients selecting CS should be advised not to eat, drink or smoke before the procedure, should be escorted home, and should be advised not to drive for a minimum of 24 hours after the procedure. Local protocols should define detailed requirements. Information on aftercare should also be provided.

Patient suitability

- 11. Before deciding on CS women should be examined and asked for information on their general health and any current medication. Cases need to be assessed individually, but a local medical screening protocol should be available and the results of the discussion documented. The risk associated with obesity must be taken in to account. Only ASA (American Society of Anesthesiologists) I and ASA II grade patients⁶ should be treated in a non hospital setting.

Training of sedationists

- 12. The specifications for training, skills and knowledge are given at Annex B.

Recommendations

- 13. CS should only be undertaken in appropriately equipped premises, and the drugs should be administered by a sedationist trained in the technique.
- 14. For termination of pregnancy, two medical practitioners are required, one to perform the sedation and the other to perform the procedure.
- 15. Sufficient support staff should be available to allow any emergency to be dealt with during the procedure and to provide proper supervision of the patient during the recovery phase. The specific tasks that each

member of the team would perform in an emergency should be identified and practised regularly. The relevant telephone numbers for use in an emergency should be clearly visible by the telephone.

16. Written protocols for CS must be available and systems in place to ensure that they are complied with. General requirements for the use of this technique are listed above.
17. Women must be provided with clear and accurate information and advised of the available options for anxiety and pain relief management in order to obtain informed consent.

References

- 1 *"A Conscious Decision" A review of the use of general anaesthesia and conscious sedation in primary dental care" Report of a Group chaired by the Chief Medical Officer and Chief Dental Officer July 2000*
- 2 *"Implementing and ensuring safe sedation practice for healthcare procedures in adults" UK Academy of Medical Royal Colleges and their Faculties. Report of a Working Party established by the Royal College of Anaesthetists.*
- 3 *Department of Health "Good practice in consent initiative" see www.doh.gov.uk/consent*
- 4 *"Seeking Informed Consent: the ethical considerations" General Medical Council November 1998*
- 5 *"Best practice advice on the provision of effective contraception and advice services for young people" Department of Health 3rd November 2000.*
- 6 *American Society of Anesthesiologists. New classification of physical status. Anesthesiology 1963; 24: 111.*

Annex A

DH Expert Group on the use of Conscious Sedation in Termination of Pregnancy

Terms of Reference

The CMO has set up a short-term DH Expert Group to consider the use of conscious sedation in termination of pregnancy because this technique is not widely used in the UK and a professional view is required.

The remit is to advise DH on the safety and suitability of conscious sedation in termination of pregnancy. Conscious sedation is 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 should carry a margin of safety wide enough to render loss of consciousness unlikely.

To do this the Group will:

- Assess the available evidence on use, safety and acceptability of conscious sedation techniques and advise on the issue of using sedation techniques for terminations and suitable protocols.
- Consider how to ensure informed consent for choice of technique for anxiety and pain relief management.

Timetable

Evaluation to be completed by autumn 2001

Membership

Mr John Parker, DH, Chair

Members

Dr Jean Millar *

Dr Griselda Cooper *

Dr Tony Wilkey *

Dr Sarah Randall, Faculty of Family Planning

Dr Tim Black, Marie Stopes International

Ms Helen Axby, Marie Stopes International

Ms Liz Davies, Marie Stopes International

Professor JAW Wildsmith, Dundee*

Mrs M Kendell, Registration Inspection Officer, Avon Health Authority

Mrs Madeleine Wang, Royal College of Anaesthetists' patient liaison group

Mr Ian Jones, British Pregnancy Advisory Service

Ms Ann Furedi, British Pregnancy Advisory Service

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Mr Mike Bowen, Medical Secretary

Ms Sally Wellsted, Sexual Health Branch

Mrs Kay Ellis, Sexual Health Branch

Dr Mike McGovern, Health Services Directorate

Mrs Diana Vass, Nursing Adviser

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Annex B

Conscious Sedation for Termination of Pregnancy

1. The application of conscious sedation to procedures for the termination of pregnancy is a relatively new development. This Annex defines the requirements needed, particularly for training the sedationist. The recent report from the Sedation Working Party of the UK Academy of Medical Royal Colleges and their Faculties has drawn attention to the need for specialist organisations to define appropriate techniques as well as the resources required. Thus, the first stage must be defining the technique to be used.
2. First trimester termination of pregnancy, no matter how gently performed, may cause some discomfort or even pain which is not readily controlled by topical application or injection of local anaesthetic. Therefore some patients, particularly the nulliparous, will require systemic analgesia as well as sedation. When systemic analgesia is judged necessary, an opioid with an appropriate time course of effect, such as intravenous fentanyl, should be administered first. The dose will depend on assessment of the individual patient, but up to 0.75 mcg per kg of fentanyl should be sufficient. Adequate time should be allowed for it to become effective before any sedative drug is administered.
3. In most situations in the UK in which conscious sedation is used, the standard sedative drug is midazolam, injected at a rate of 1 mg per min until the appropriate state is produced. The patient should become calm, relaxed, 'sleepy' and dysarthric, but remain fully responsive to the spoken word and able to maintain a clear airway. Midazolam sedation is often administered by the individual who is to perform the procedure, and this is a common and acceptable practice for minor procedures (eg dentistry & upper gastro-intestinal endoscopy) during which the 'operator' is in close proximity to the airway.
4. However, the time course of action of midazolam (45-60 minutes) is excessive for first trimester termination of pregnancy, so that the recovery period is prolonged. Propofol, a drug normally used for the induction and maintenance of general anaesthesia, has some attractive properties for this purpose because its duration of action is much shorter. Unfortunately, its potency means that considerably greater skills and precautions are needed to ensure that the patient does not lose verbal contact with attendant staff and become, in essence, anaesthetised.
5. The safe use of propofol, especially in combination with fentanyl and in the context of termination of pregnancy where the procedure is performed at a distance from the airway, requires the presence of a **second medical practitioner** to ensure safety. Propofol should be administered as a slow intravenous injection, with 30 to 50mg being given over a period of 30 seconds. An additional dose (half of the initial one) should not be given until at least two minutes have elapsed after administration of the previous dose.
6. *Training Requirements*
The competencies expected of a person undertaking this procedure, which is often undertaken in an isolated setting, is commensurate with the successful completion of two years of SHO training in Anaesthesia in the UK. The specific knowledge, skills and attitudes required are itemised below.

7. *Knowledge*

- The psychological and physiological effects of early pregnancy.
- The impact of early pregnancy on cardiovascular and respiratory status and the disposition of drugs.
- The pharmacology of fentanyl, propofol, drugs for resuscitation and oxytocics.
- The physiological effects of conscious sedation with these drugs.
- Impact of conscious sedation on patients with intercurrent disease and/or obesity.
- Complications of termination of pregnancy.
- After-effects of conscious sedation and the requirements for after-care of patients who have received this technique.

8. *Skills*

- Venepuncture.
- Assessment of medical status.
- Assessment of anxiety level.
- Assessment of cardiovascular and respiratory status before and during drug administration.
- Airway maintenance and basic resuscitation techniques.
- Advanced life support techniques.

9. *Attitude*

- Sympathetic approach to patients undergoing conscious sedation for termination of pregnancy.
- Recognise the need for a chaperone.
- Good team working.
- Importance of working within the definition of conscious sedation.
- Recognition of the dangers of excessive drug administration.

10. *Qualifications*

There is as yet no defined qualification for this type of work, and the development of formal training courses, based on the above recommendations is encouraged. Because these procedures may be performed outside the hospital setting, individuals must hold a current advanced life support provider certificate.

11. *Annual Revalidation*

Definitive proposals on revalidation have yet to be put forward by the General Medical Council, but the recommendation from the Group is that individuals undertaking this work should maintain continuing medical educational activity in core knowledge (see RCA's Continuing Education and Professional Development documentation) and attend at least one operating session per month with a consultant to maintain the clinical skills that might be required in an emergency situation.

Annex C

Equipment for the Treatment of Emergency Situations

Drugs

Immediately available in prefilled syringes:

Adrenaline/epinephrine	1mg (10 ml, 1 in 10,000) x 8
Amiodarone	300mg x 2
Atropine	3mg x1

Other readily available drugs:

Adrenaline/epinephrine	1mg (1 ml, 1 in 1,000) x2
Atropine sulphate	1mg x2
Sodium Bicarbonate 8.4%	50ml x1
Calcium Chloride 13.24%	10ml x2
Lignocaine/lidocaine 1% or 2%	100mg x2
Sodium Chloride 0.9%	10ml ampoules x10
Naloxone	400 mcg x2
Midazolam	10mg x 1
Hydrocortisone	200mg x 1
Chlorpheniramine	10mg x 1
Flumazenil	100 mcg /ml (5ml) x 1
Oxytocin (Syntocinon)	5 units/ml x 5
Salbutamol	100 mcg metered inhalation & spacer

Emergency Equipment

Monitoring:

Cardiac defibrillator with cardiac monitor and appropriate connection devices
Defibrillation gel pads
Pulse oximeter
Non-invasive automatic BP
Sphygmomanometer
Stethoscope

Airway equipment:

Size F oxygen cylinder with flowmeter

Cylinder key (if oxygen cylinder does not have screw valve)

Oxygen tubing with mask

Pocket face mask with an oxygen connector

Guedel oropharyngeal airways: sizes 2 & 3

Self-inflating (Ambu) resuscitation bag with oxygen reservoir and tubing

Clear face masks size 3, 4 and 5

Laryngeal mask airways: sizes 3 and 4

Two laryngoscopes with long and short blades/spare bulb and battery

Cuffed oral endotracheal tubes: sizes 6, 7, 7.5, 8

20 ml and 50 ml syringes for inflating endotracheal tubes and laryngeal mask airways

Gum elastic bougie

Lubricating jelly

Anaesthetic suction machine with tubing

Suction catheters

Yankauer suckers

1" ribbon gauze

Scissors

IV administration equipment

IV Administration set

Blood administration set

IV fluids as required by the Department of Health document "Procedures For The Approval Of Independent Sector Places For The Termination of Pregnancy"

Venous cannulae: sizes 14, 16, 18 and 20g

Cannula fixing dressings

IV Needles, green and white

Syringes: 20ml, 10ml, 2ml

Sterets or similar antiseptic skin wipes

Adhesive tape

Tourniquet

Pen torch



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