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Safe Sedation in Modern Cardiological Practice

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Safe Sedation in Modern Cardiological Practice

The Academy of Medical Royal Colleges has produced new Guidance on Safe Sedation in the UK¹. This document updates the 2001 document that has shaped UK sedation practice for some time. The document focuses particularly on issues that have arisen in dental and gastroenterological practice but has huge implications for cardiological practice.

The key Academy recommendations are:

- 1) Sedation should be based on competencies defined for each specialty
- 2) Continuing training and demonstration of relevant CPD should be performed and relate to revalidation
- 3) Sedation outcomes should be patient-centred and audited
- 4) Trusts should establish sedation committees to oversee training and monitor training in sedation
- 5) Sedation teams (akin to pain teams) should be established
- 6) The standards should apply in primary care and private healthcare as well as NHS trusts

The definition of competencies for sedation within cardiology will have big implications for medical and nursing training and will require the establishment of both local and national training programmes. The British Heart Rhythm Society will seek to lead on this crucial area which will not only align us more with Europe and the literature but most importantly improve the number of patients receiving high quality safe sedation in cardiology in the UK. Sedation is fundamental for many cardiological procedures particularly in the arena of arrhythmia management. This sedation environment is very different from many other situations such as dental and paediatric practice and a large number of procedures that involve sedation are performed annually in the UK.

Cardiological procedures involving sedation fall into 4 main areas:

- 1) Cardioversion of AF/atrial flutter/stable VT
- 2) Catheter ablation of AF and other complex arrhythmias
- 3) Transoesophageal echo
- 4) Complex device and other interventional procedures

General environment and facilities

All the above procedures are performed electively in areas in a hospital environment with full resuscitation facilities. Out-patient or community sedation is not appropriate for such procedures. Emergency procedures may be performed in facilities such as Emergency Departments or in theatres, particularly in the context of resuscitation for life-threatening arrhythmias.

These circumstances are dealt with elsewhere and normal resuscitation procedures and guidelines should be followed.

The Continuum of Sedation

There is a continuum of sedation from mild through to deep sedation to anaesthesia and cardiological procedures will usually performed under moderate sedation but occasionally deep sedation is required. This level of sedation has different implications for the patient and the staff may need to intervene particularly to maintain the airway. The table below, from the Academy of Medical Royal Colleges Document on Safe Sedation, describes the different levels of sedation.

	Minimal Sedation/ Anxiolysis	Moderate Sedation/ Analgesia ('Conscious Sedation')	Deep Sedation/ Analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained
Escalation of required competencies			
* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. Excerpted from Continuum of Depth of Sedation. Definition of General Anesthesia and Levels of Sedation/ Analgesia of the American Society of Anesthesiology. From the ASA, 520N, Northwest Highway, Park Ridge, Illinois, 60068-2573, USA.			

Many cardiological procedures require deep sedation and it is because of this grey area between sedation and anaesthesia that concern has arisen about safety.

For the patient it can be helpful to explain the different levels of sedation in a simpler form. An example from Sury to appropriately inform patients ⁵

	What will this feel like	What will I remember	What's the risk
NOT sedated	I am awake, possibly anxious There may be pain (depending on the what I am having done)	everything	Could be zero, or there may be risk related to my anxiety
Minimal sedation	I am awake and calm, There may be some pain	Probably everything	Very low risk with the sedation drugs
Moderate sedation	I am sleepy and calm. I will remain in control There may be some pain	I might remember things	Low risk with the sedation drugs
Deep sedation	I am asleep. I will not be in control	Probably very little	Sedation can temporarily stop the breathing when I am asleep – I may need help to breathe – a tube might need to be inserted into my mouth.
Anaesthesia	I will be asleep – more like a coma	Very unlikely to remember anything	My breathing may stop and my blood pressure and heart rate fall. I will need a specialist doctor to look after me.

Selection of sedation strategy for procedure and pre-assessment

The type of sedation should be assessed for each patient at outpatients or at pre-assessment rather than at the admission for the procedure. Patients are often pre-assessed for a cardiological procedure but should also be pre-assessed for the sedation technique that will be used to facilitate the cardiological procedure. An example of a sedation proforma is given in appendix A that could be adapted for electronic data collection to facilitate audit. Pre-assessment, procedural monitoring and post procedural monitoring in recovery are incorporated into a single record.

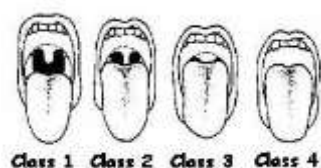
Features to be considered at pre-assessment include:

Factors that may make the sedation unpredictable:

- Age and frailty
- Previous procedures
- Alcohol and medication history

Factors that may airway maintenance difficult

- Weight
- Neck size (>17"for men ; >16"for women)
- Mallampati score (≥ 3 is associated with difficulty with intubation)

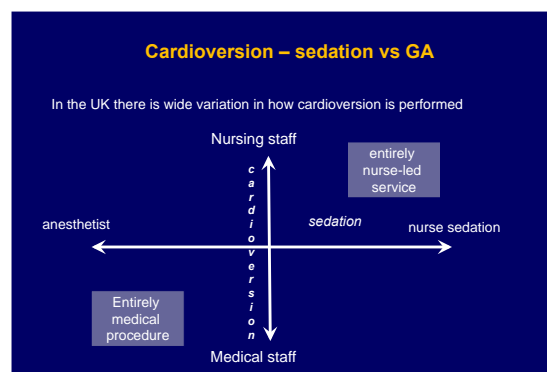


1) Electrical Cardioversion

Direct current cardioversion of AF or other arrhythmias is a well-established treatment modality. Brief sedation is required to allow the otherwise painful application of DC energy across the chest to depolarize the atria and allow restoration of normal sinus rhythm. It is occasionally useful as a destination therapy but with the advent of catheter ablation it is now more appropriately used as a “trial of sinus rhythm” to determine whether symptoms and/or LV function improve with restoration of sinus rhythm. This then allows an appropriate treatment option, particularly concerning whether rate or rhythm control is appropriate, to be selected.

Traditionally, anaesthetists have been involved in cardioversion often with the use of general anaesthesia. This however may not be desirable for such a short procedure and with the increasing numbers of procedures required³. If a cardioversion is difficult to arrange for a patient either urgently or as an elective procedure cardiologists will generally refer fewer patients. Scheduling difficulties together with cancellations because of poor INR control are common reported difficulties with cardioversion services.

Nurse-led cardioversion services are already operational in the UK with good safety and efficacy rates but there is considerable geographical variation in their use. Some cardioversion services operate within an entirely medical model (anaesthetists sedate and doctors cardiovert) running through to the entirely nurse-led model where nurses perform sedation and also cardioversion.



Nurse-led Cardioversion Services

A high quality cardioversion service can be delivered by appropriately trained nurses. In some UK hospitals patients referred for cardioversion are pre-assessed and consent is obtained by a nurse, are admitted by a nurse and are sedated by a trained nurse-sedationist whilst another nurse performs the cardioversion procedure. The patient's monitoring post cardioversion, discharge, GP reporting and procedure audit is also all performed by nurses³⁻⁵. Excellent outcomes with positive patient experiences have been reported. Although many Trusts deliver very effective medical models of cardioversion (anaesthetist-delivered anaesthesia or sedation and doctor administered cardioversion) this model may not be appropriate for every hospital and may not be the most cost-effective or easiest to run.

Requirements for sedation for cardioversion

All procedures should be performed in high dependency facilities with full resuscitation facilities immediately available (CCU, ITU, cath lab, theatre anaesthetic room).

Sedation delivered by an operator-sedationist is not appropriate. There should always be one trained individual who performs the sedation and another who applies the electrodes and performs the DC version.

Benzodiazepines (midazolam or diazepam) are traditionally used in the UK by non-anaesthetists and this has been shown to be safe and effective. Although pharmacokinetic studies would suggest that midazolam would seem preferable to diazepam, in one randomized study comparing sedation for cardioversion with either diazepam or midazolam efficacy of sedation and amnesia were the same but normalization of mental test score was much quicker with the use of diazepam. This earlier waking may have advantages for the monitoring of patients in the recovery phase post procedure (5)

Oxygen administration via mask or nasal cannulae with pulse oximetry and ECG monitoring is required. All procedures should be performed by staff who are trained in airway management and are ILS/ALS trained. Flumazenil administration is not normally required but it should be available and its usage should be monitored and reviewed. Facilities and staff for monitoring should be available for all patients and a bed should be available in the facility if it is deemed that the patient following sedation is not fit to be discharged home.

As with all sedation services the pre-assessment, recovery and discharge planning are also important and a designated recovery area is essential.

2) Catheter ablation

Catheter ablation of AF is now the commonest form of ablation in the UK and together with atrial flutter ablation makes up more than 50% of all ablations. AF ablation involves delivery of radiofrequency energy to the left atrium which usually produces pain. The procedure is performed in the UK either under general anaesthesia or, more commonly, with benzodiazepine / opiate sedation. Relatively large doses of benzodiazepines may be required but procedures are becoming shorter and can be performed as day cases.

In Europe the commonest approach for sedation is using propofol delivered by nurse-sedationists. There are large registries and also randomized trials to show that this strategy is effective and safe ⁶⁻⁹. There is also a suspicion that with propofol there is less patient movement than with the combination of benzodiazepines and opiates and hence the

ablation procedure (which often depends on anatomical mapping systems that are disturbed by patient movement) is more straightforward and effective. One of the most feared but extremely rare complication after AF ablation is atrio-oesophageal fistula and there is concern that this may be commoner when the procedure is performed under general anaesthetic¹⁰.

Options for sedation for catheter ablation & the differences from GI or dental sedation

Although many Trusts deliver very effective anaesthetist led sedation for catheter ablation there are several drivers of a change of strategy:

- 1) AF is common and there is a growing demand for AF ablation. Although AF ablation is the commonest form of ablation it is estimated that only 0.3% of the new cases of AF each year are ablated. For many units day case, 1 hour AF ablation procedures are now common and rapid procedures and changeovers are going to be essential for effective service delivery. A medical anaesthetist model may be logistically difficult and not cost effective.
- 2) Cath labs are very different environments from community dental surgeries or endoscopy suites, where most of the issues addressed in the Academy of Medical Royal Colleges Report¹ arose, and a different model of sedation is appropriate. Some of these differences include:
 - a) cath labs have full resuscitation facilities. ECG monitoring, oximetry, intubation, piped oxygen and defibrillators are all standard in cath labs and these facilities are essential for safe sedation.
 - b) an operator-sedationist model is not appropriate
 - c) nurses are at least ILS trained and for deep sedation ALS training is required
- 3) European experience of propofol given by cath lab nurses in the context of catheter ablation is very positive. The staff model employed for example in Germany, which has the highest AF ablation rate in Europe and where procedures are mainly done using nurse led propofol-based sedation, is very similar to the UK model with cardiologist supervision of benzodiazepines administered by cardiological nurses.

Recommendations for use of propofol in nurse-led sedation

- 1) Capnography (monitoring of end-tidal CO₂ and ventilation) although not currently routine is strongly recommended. Training in correct use of capnography monitoring is required.
- 2) The cardiologist performing the procedure is scrubbed and it is inappropriate for that individual to also deliver the sedation and monitor the patient. A dedicated nurse-sedationist is thus essential.

- 3) Cath lab nurse-sedationists performing propofol based sedation should be ALS trained and be familiar with resuscitation, defibrillation and airway protection.
- 4) The nurse team involved in sedation should attend formal sedation training sessions and also 6 monthly practical refresher sessions including airway management.
- 5) If propofol is to be used it should be delivered via Target Controlled Infusion (TCI). Staff using TCI pumps should receive appropriate training in their use.
- 5) The nurse responsible for sedation in the cath lab environment should be responsible for patient monitoring and drug delivery during the procedure and be answerable to the consultant performing the ablation procedure. They should ideally also be responsible to the Trust sedation team particularly for continuing training, CPD, audit and record keeping.
- 6) Sedation procedures should be fully recorded and audited.
- 7) Initially approximately 20% of patients will be considered for propofol sedation and should be on the basis of prior intolerance or excess dosage (>30mg diazepam) of benzodiazepines. Patients with markers of possible difficult airway maintenance (Mallampati score ≥ 3 , collar size ≥ 17 " , history of OSA) should be excluded.

3) Transoesophageal echo

Preparation of the patient and delivery of sedation for TOE will be similar to sedation for endoscopy.

The British Society for Echocardiography (BSE) has produced sedation guidelines which have been accepted and adopted widely¹⁴. Procedures are generally much shorter than for other interventions and are well covered elsewhere.

An operator-sedationist approach is feasible but sedation should be performed with another staff member available and with full resuscitation facilities at hand and with staff who are ALS trained.

4) Other interventions

Many cardiac interventional procedures require sedation or general anesthesia and are best discussed on a case-by-case basis. The numbers of procedures are generally small compared to the electrical procedures described above. Many of the structural interventions performed require TOE guidance and because the patient is supine rather than in the normal left lateral position a GA is generally preferred for the TOE anyway. Device implantation however is becoming increasingly complex and there is a growing demand for conscious sedation to be available for such procedures.

Recommendations

- 1) All Trusts should adhere to the recommendations of the Academy of Medical Royal Colleges for Safe Sedation
- 2) Training in sedation should become part of the core curriculum for cardiologists and be required for specialists who will use this technique
- 3) Trusts should establish a sedation committee, under the chairmanship of a consultant anaesthetist, in which cardiologists should be actively involved
- 4) Cardiological sedation should be established in conjunction with the sedation committee
- 5) Cardiological sedation should be appropriately documented and audited
- 6) Nurse-sedationist models for sedation are appropriate for some Trusts with appropriate training and supervision

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NHS Trust

Sedation for Cardiological Procedures

Patient Label

Consultant:
Planned Procedure Date:
Pre-assessment Date
Nurse
Time:

Preassessment

Procedure Cardioversion/AF ablation/device/other

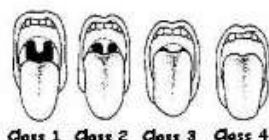
Previous sedation procedure Y/N
Date of last Tolerated Y/N
Total dose of benzodiazepine:
Recollection (0-3)

Morphine dose:

Age
Mallampati score

Weight (Kg)

Collar size



Blood Pressure __/____
INR stable for 3 weeks?
LV function good/mod/poor

Rhythm
NOAC? Y/N

Medication

Lung disease Y/N

FEV1/VC

Other issues eg micrognathia, scoliosis, excess fear

Procedure:

Operator 1

Location

Other Staff

Sedation plan

Sedation Nurse

Benzo alone Benzo+opiate

Date

Operator 2

Propofol TCI

Premed:

Time

Time	BP	HR	Saturation	Ventilation	Medication	Comments

Total doses:

Heparin

Diazepam

Morphine

Reversal agent used?

Flumazenil dose

Naloxone dose

Haemostasis

Recovery:

Time arrived

Time left:

Discharged to

Time	BP	HR	Saturation	Ventilation	Medication

Date

Time

Signature