



Safe Sedation in Modern Cardiological Practice

- **Focus on Arrhythmia Care Procedures**

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On behalf of The British Heart Rhythm Society

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Abstract

Safe sedation is fundamental to many modern cardiological procedures and following the publication of the Academy of Medical Royal Colleges Report on Safe Sedation¹ this report discusses sedation specifically in cardiological practice. The major areas within cardiology that use sedation are cardioversion, catheter ablation particularly of AF, TOE, implantable device (CIED) procedures and other procedures such as TAVR. There is increasing demand for cardiological sedation but there is wide geographical variation in its use and there are also growing data to support non-anaesthetists giving sedation. The use of benzodiazepines, particularly for short procedures is common but even here good record-keeping and audit together with an understanding of the continuum of sedation and having appropriately trained staff and the necessary facilities are vital. Nurse administration of propofol may be appropriate for some procedures in cardiology that require at least moderate sedation. Appropriate training is essential and the use of capnography and TCI pumps for propofol administration is recommended.

Background to Safe Sedation in Modern Cardiological Practice

The Academy of Medical Royal Colleges has produced new Guidance on Safe Sedation in the UK¹. This document updated the 2001 document that has shaped UK sedation practice for some time and focused 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

Sedation is fundamental for many cardiological procedures particularly in the arena of arrhythmia management. The environment for cardiological sedation varies internationally^{2,3} and is very different from many other situations such as dental and GI practice and a large number of cardiac procedures that involve sedation are performed annually.

This report is produced by consensus mainly by the Academy Committee member (SSF) who represented the British Cardiovascular Society (BCS) and the

British Heart Rhythm Society (BHRS), with support from the Academy Committee chair (JRS) after consultation with BCS and BHRS members.

Cardiological procedures involving sedation fall into 5 main areas:

- 1) Cardioversion of AF/atrial flutter/stable VT
- 2) Catheter ablation of AF and other arrhythmias
- 3) Transoesophageal echo
- 4) Cardiovascular implantable electronic devices (CIEDs)
- 5) Other diagnostic or interventional procedures eg TAVR

General environment and facilities

All the above procedures are normally performed electively in a hospital environment with full resuscitation facilities immediately available. 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 be 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. Table 1 below, from the Academy of Medical Royal Colleges Document on Safe Sedation, describes the different levels of sedation.

Table 1

	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			

The "ideal" level of sedation is traditionally viewed as moderate but for some procedures periods of deep sedation may be required. The transition from

moderate to deep sedation may be rapid and hence there is a need for both continuous monitoring and appropriate training.

For the patient it can be helpful to explain the different levels of sedation in a simpler form and an example ⁴ to aid appropriately informing patients is given in table 2 below.

Table 2

	What will this feel like?	What will I remember?	What's the risk of the sedation ?
NOT sedated	I am awake, possibly anxious There may be pain (depending on 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 may 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)⁵

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 required. 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 some centres 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 hospitals patients referred for cardioversion are pre-assessed and consented 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 and procedure audit is also all performed by nurses⁶⁻⁸. Excellent outcomes with positive patient experiences have been reported. Although many units 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 be the easiest to establish.

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 ⁶.

Oxygen administration via mask or nasal cannulae with pulse oximetry and ECG monitoring is required. All procedures should be performed by staff 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 including AF ablation

Catheter ablation of AF is now the commonest form of ablation 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 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 many countries the commonest approach for sedation utilises propofol delivered by nurse-sedationists. There are large registries and also randomized trials to show that this strategy is both effective and safe ⁹⁻¹². There is also a suspicion that there is less patient movement with propofol 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 with improved outcomes. 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 anaesthetic¹³.

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

Although many units 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 in the UK for example, only approximately 0.3% of the new cases of AF each year are ablated and AF ablation is now NICE endorsed¹⁴. For many units 1 hour, day-case AF ablation procedures are now common and quick procedures and rapid changeovers are going to be essential for effective service delivery. Establishing a medical anaesthetist model for sedation may be logistically difficult for some centres and not necessarily cost effective. Limited access to anaesthetists has been reported as a major limitation to delivery of an effective cardiological sedation practice .³

2) Cardiac Cath lab Environment.

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 Report occurred¹. 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 (as performed in GI practice) is not relevant or appropriate
- c) nurses are at least ILS trained and for deep sedation ALS training is required

3) International experience and clinical data .⁶⁻¹³

In parts of Europe experience of propofol given by cath lab nurses in the context of catheter ablation is very positive. Despite this positive experience in some countries, in other countries, which may have similar nurse training models, propofol is restricted to anaesthetist-use only.

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 widely¹⁵. 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 ILS trained.

4) Cardiovascular implantable electronic devices (CIEDs)

CIED procedures include:

- i) Permanent pacemaker implantation (PPM)
- ii) Pulse generator change
- iii) Implantable cardioverter-defibrillator (ICD) insertion (+/- defibrillation threshold (DFT) testing)
- iv) Cardiac resynchronisation therapy (CRT-P, CRT-D with integrated ICD)
- v) Pocket and/or lead revision
- vi) Chronic device and lead extraction

Typically CIED procedures are performed in a cath lab environment using local anaesthetic agents, injected by an operator, and IV sedation/analgesia administered by a nurse.

Pocket formation or manipulation is the most painful part of the procedure and local anaesthetic as a sole agent is frequently insufficient. This is particularly relevant to devices that have a larger footprint, such as ICDs, or if a pocket is sub-pectoral and more extensive tissue dissection is necessary. Anaesthetic agents, including propofol, can be used safely for such procedures although in the reported literature these are most frequently administered by anaesthetists.¹⁶⁻¹⁸ However, as outlined below, in a cath lab environment, nurse-led sedation could include propofol as required for these procedures. This may be a preferred approach for other device interventions with longer procedure times, such as device upgrades from pacemakers to ICD or CRT systems or implantation of entirely subcutaneous ICDs that do not have a transvenous intracardiac lead. With subcutaneous ICDs a lead is tunnelled from the parasternal region to a generator usually sited in a lateral chest position.

Chronic device and lead extraction

Extraction of chronic devices and leads can be complex and associated with an unpredictable requirement for open thoracotomy. As such, a significant proportion of these procedures will be performed under general anaesthesia. Some centres may perform selected procedures using IV sedation and analgesia but immediate support from anaesthetic personnel should be available.

5) Other interventions

Many cardiac interventional procedures require sedation or general anaesthesia and are best discussed on a case-by-case basis. The numbers of procedures are generally small compared to the electrical procedures described above. In the US TAVR is increasingly being performed under sedation although GA remains commoner in Europe ¹⁹. The issue of timing of TOE guidance during structural interventions tends to influence the choice between GA and sedation but there may be advantages of sedation in terms of post-op recovery ²⁰. Whether nurse-led sedation for such high-risk patients is appropriate will no doubt be debated in the future as TAVR technology and results improve ²¹.

General Recommendations on Cardiological Sedation

- 1) All UK Hospitals 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 will be required for specialists who will use this technique
- 3) Hospitals should establish a sedation committee, perhaps 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 centres after appropriate training and supervision
- 7) Nurse-led sedation services may be particularly relevant in areas of high clinical demand such as cardioversion, AF ablation and complex device intervention. Extension of sedation into areas such as TAVR may become relevant soon.
- 8) Propofol administered by appropriately trained nurses may be appropriate for some patients during cardiological procedures

Recommendations for the use of propofol in nurse-led cardiological sedation

Although the use of propofol for sedation in other fields remains controversial ²², for the above reasons it is appropriate, with restrictions, for use in cardiological sedation. The issue of training and the need for new guidelines have been highlighted elsewhere^{23,24}. The following are recommended :

- 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. This is a key recommendation also of American and Australasian guidance^{23,24}.

2) A dedicated nurse-sedationist is essential. The cardiologist performing the procedure is scrubbed and it is inappropriate for that individual to also deliver the sedation and monitor the patient.

3) Cath lab nurse-sedationists performing propofol-based sedation should be ALS trained and be competent at resuscitation, defibrillation and airway protection.

4) The nurse team involved in sedation should attend formal sedation training sessions and also annual practical refresher sessions including airway management.

5) If propofol is to be used it should be delivered via a Target Controlled Infusion (TCI) pump²⁵. Staff using TCI pumps should receive appropriate training in their use.

6) 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 hospital sedation team particularly for continuing training, CPD, audit and record keeping.

7) Sedation procedures should be fully recorded and audited.

8) Although propofol will be considered for long procedures such as complex device implantations or AF ablations it may also be appropriate in some short procedures such as cardioversion on the basis of prior intolerance or excess dosage of benzodiazepines.

9) Patients with markers of possible difficult airway maintenance (eg Mallampati score ≥ 3 , collar size ≥ 17 ", history of OSA) should be excluded or discussed with anaesthetic colleagues.

Conclusion

This report arises from the Academy of Medical Royal Colleges Report on sedation¹ which recommended that each specialty produce its own guidance on sedation. There is increasing demand for effective and safe sedation for a growing variety of cardiological procedures and availability of anaesthetists is a major issue.²³ There is now data to support the safety and effectiveness of nurse-led sedation services but there are important issues of training and credentialing that must be addressed. The continuum of sedation is highlighted and guidance that covers pre-assessment, procedural issues such as nurse administration of propofol, training and audit are discussed.

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Appendix A

Below is a proforma designed to facilitate cardiological safe sedation. It may be possible to incorporate this into an EPR in the future. It is designed to aid record-keeping for audit purposes and to encourage pre-assessment for sedation as well as for a cardiological procedure and also to link pre-assessment, procedure and recovery records.

Sedation for Cardiological Procedures

Patient Label

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

Pre-assessment

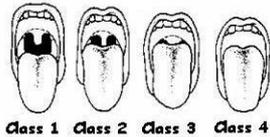
Procedure Cardioversion/AF ablation/device/other

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

Morphine dose:

Age Weight (Kg)
 Mallampati score

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 e.g. micrognathia, scoliosis, excess fear

