



The Cardiac Society of Australia and New Zealand

## Position Statement on Sedation for Cardiovascular Procedures

This Position Statement was developed by a Working Group comprising Stuart Thomas, Jay Thakkar, Pramesh Koor, Aravinda Thiagalingam, David Ross, Andrew MacIsaac and Richmond Jeremy. The authors have no Conflict of Interest to disclose.

The guidelines were reviewed by the Continuing Education and Recertification Committee and ratified at the CSANZ Board meeting held on Friday, 7<sup>th</sup> March 2014.

### BACKGROUND

Administration of intravenous sedation (IVS) has become an integral component of procedural cardiology. In Australia, sedation is employed as part of a wide range of cardiac procedures including electrophysiological studies, transoesophageal echocardiography and cardiac catheterisation. In the subspecialty field of clinical cardiac electrophysiology, IVS is widely employed in both diagnostic and ablation procedures for the treatment of cardiac arrhythmias, electrical cardioversion of arrhythmias and also the insertion of implantable electronic devices including pacemakers, defibrillators and loop recorders. The sedation is often administered by nursing staff, under the direct supervision of a procedural cardiologist. As the relevant procedures have evolved during the last twenty years, so procedural cardiologists have developed the skills and expertise required to administer the necessary sedation. Furthermore, cardiologists have also taken responsibility for teaching sedation skills as an essential component of procedural training for trainees in cardiology and, in conjunction with cardiovascular nurse specialists, of training of registered nurses participating in these procedures. This Position Statement describes the current standards of training, pre-procedural assessment, procedural conduct and post-procedure care, with reference to the available evidence base which is the foundation for these standards. This Statement also describes the environment in which sedation for electrophysiological and other cardiac procedures may be performed.

The Cardiac Society of Australia and New Zealand (CSANZ) has previously published a brief statement on IVS for cardiac procedures\*. There is also a separate CSANZ statement regarding the use of IVS for transoesophageal echocardiography\*\*. Several general guidelines and position statements dealing with the administration of sedative medications for medical procedures have been published (1-4). With the exception of the North American Society of Pacing and Electrophysiology (NASPE) guidelines of 1998, these published statements are designed for use in a very wide range of clinical environments and procedures and are not focussed upon cardiovascular procedures. This Statement is the first comprehensive document for Australian cardiovascular practice, developed by experts in the field of cardiac sedation, including interventional cardiologists, electrophysiologists and cardiac nurses.

Only the NASPE consensus document, (1) is specifically focused on cardiac electrophysiological procedures but it was produced prior to the publication of much of the current literature dealing with sedation for cardiac procedures. Cardiac procedures are distinct from many other procedures performed under sedation, as the patients frequently have serious cardiac disease and often multi-organ disease. For patients undergoing electrophysiological procedures the patient may have life threatening arrhythmias and inducing these arrhythmias may be a goal of the procedure. Patients

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\*CSANZ Position Statement Sedation in Association with Cardiological Procedures (2011)

\*\*CSANZ Position Statement on Sedation in Conjunction with Transoesophageal Echocardiography (2011)

may also undergo percutaneous coronary interventions while suffering a myocardial infarction, in order to emergently treat the causative lesion. The environment in which cardiac procedures are performed is highly specialised and such procedures are usually performed with continuous ECG, haemodynamic and pulse oximetry monitoring. Staff are experienced in the treatment of critically ill and unstable patients, and staff are dedicated to monitoring the patient throughout the procedure. Staff members are skilled in treatment of cardiac arrhythmias and cardiopulmonary resuscitation. Whilst there are some common elements with sedation in other environments, such as the similarity between sedation for endoscopy and transoesophageal echocardiography, many aspects of sedation for cardiac procedures are unique.

## **METHODS**

This Position Statement was constructed through a process of consultation within the CSANZ. The document has been reviewed by the CSANZ Councils representing staff responsible for administering IVS for cardiac procedures. These are the Interventional Council, the Electrophysiology and Pacing Council, the Interventional Nurses Council and the Cardiac Imaging Council. The draft Statement was reviewed by the Continuing Education and Recertification Committee of the CSANZ and finally by the Board of the CSANZ

Where possible, recommendations in this Statement are based on published data. The data was evaluated according to the NHMRC guidelines on evaluation of scientific evidence.(5). There are few randomised trials examining IVS for cardiac procedures so the level of evidence is generally low. However there is a body of published descriptive data addressing the safe practice of procedural sedation and the number of these studies, with a high level of consensus, results in the Grade of many basic recommendations being paradoxically high. Unless specified otherwise, the evidence should be considered Level IV, Grade A. This Statement is focused on the requirements related to procedural sedation. There will be additional requirements for environment, equipment personnel and training specific to each procedure type. For example, equipment and skills required to perform pericardiocentesis are necessary where interventional coronary and electrophysiological procedures are performed, but not for transoesophageal echocardiography or electrical cardioversion.

Attention was also given to recent studies of cardiac IVS practice by Conway et al (6). This group performed a comprehensive survey of sedation practice in Australia, concentrating on the nursing perspective.

## **PRE-PROCEDURAL ASSESSMENT AND PATIENT SELECTION**

Published descriptions of IVS techniques almost universally include a process of pre-procedural assessment and patient selection. Patients not meeting selection criteria either undergo their procedure with the supervision of a specialist anaesthetist or are considered unfit for the procedure.

Therefore a pre-procedural assessment and application of suitability criteria is considered an essential process prior to IVS.(7-9) Pre-procedural assessment should be performed on all patients where the need is not precluded by an urgent requirement for immediate intervention. The pre-procedural assessment should also include elements that may be important in the rare event of requiring airway intervention including paralysis and intubation.

Obstructive sleep apnoea is a relative contraindication and, in some units, may be an absolute contraindication. The use of CPAP to successfully facilitate sedation has been described in these patients.

### ***Recommendations***

1. Pre-procedural assessment and application of selection criteria should be performed in all non-emergency cases (Level IV, Grade A)
2. The nature of the procedure should be considered. This consideration should include duration of the procedure, likelihood of pain, the need for immobility and the need for different levels of alertness. These factors will dictate the aims of sedation in each case (Level IV, Grade A).

3. Past and present medical history noting abnormalities of major organ systems and how these may affect the patient's response to sedation should be taken into account. Particular note is required for cardiac and respiratory disease including obstructive sleep apnoea or a history of snoring. Note should also be made of any bleeding abnormalities or history of embolic events. The presence of hepatic and renal disease should be considered in relation to the metabolism of drugs. The presence of severe arthritis may cause difficulty in patient positioning and analgesia. The presence of active psychiatric illness or cognitive impairment also have an important effect on response to sedation. Patients with neurological or neuromuscular disease adversely affecting airway protection or respiratory function require special consideration. The presence of diabetes should be noted and a plan made for diabetes management during the procedure (Level IV, Grade A).
4. For patients undergoing transoesophageal echocardiography, additional history to elicit problems with swallowing and identify oesophageal pathology is required (Level IV, Grade A).
5. Previous adverse drug reactions and previous experience with sedation, analgesia and anaesthesia should be noted. (Level IV, Grade A)
6. Current medications, non-prescription drug use (including alcohol) and smoking should be documented, with reference to the possibility of interactions between these and sedative or analgesic agents (Level IV, Grade A)
7. Nature and time of last oral intake should be noted. Except in emergencies the patient should be fasted long enough to clear gastric contents. This is may be up to 6 hours for solid food but 2 hours for clear liquids. In practice most centres employ a minimum fasting interval of 4 hours (Level IV, Grade A).
8. Physical examination should be undertaken, including examination of the cardiac and respiratory systems, assessment of vasculature where it is required for procedural access and assessment of the airway. If there is a risk of emergency airway intervention, note should be made if the neck is short, if there is limited extension, hyoid-mental distance of <3cm, or deformities of the neck. Note should be made if the mouth opening is small (<3cm), macroglossia is present or there are other restrictions within the oral cavity. A Mallampati score may be used. The teeth should be examined and abnormalities noted. The patient's height and weight should be measured along with baseline blood pressure, oxygen saturation and heart rate (Level IV, Grade A).
9. Unstable medical conditions including angina, uncontrolled hypertension, cardiac failure, thyrotoxicosis or poorly controlled diabetes should be stabilised prior to an elective procedure. (Level IV, Grade A)
10. Patients with suspected limiting respiratory disease should undergo formal lung function testing pre-operatively.
11. For longer and more complex procedures and when there is suspected systemic disease, relevant pathology tests should be performed to quantify renal dysfunction, liver disease, electrolyte abnormalities, thyroid dysfunction, anaemia or coagulation abnormalities before IVS is undertaken. An electrocardiogram may also be required in these cases. (Level IV, Grade A)
12. The patient must be prepared for the procedure with information about their likely experience and expected degree of sedation. This should be incorporated into the procedural consent. (Level IV, Grade A)

## CONTRAINDICATIONS TO INTRAVENOUS SEDATION

In most studies there are very few absolute contraindications to IVS.(7-12) As noted above, obstructive sleep apnoea is a potential contraindication. Because of the complexity of the procedure and the associated unpredictable need to convert to open thoracotomy, chronic device lead extraction procedures are usually performed under general anaesthesia.(7) and is usually considered a contraindication to IVS. Many of the relative contraindications for IVS are, however, also contraindications to general anaesthesia. The IVS contraindications depend on the depth and duration of the sedation.

The following are relative contraindications or barriers, which must be overcome prior to provision of IVS.

- i. Language barrier or other factors preventing effective communication with the patient;
- ii. Previous difficulty with sedation or difficulty with anaesthesia;
- iii. Allergy to sedative medications;
- iv. Uncontrolled medical conditions in elective cases where these conditions may be appropriately treated prior to cardiac IVS;
- v. Chronic device lead extractions.

Catheter ablation for atrial fibrillation is often performed under general anaesthesia. However the evidence supporting that approach is mixed. In one randomised comparison, performed in patients undergoing catheter ablation for atrial fibrillation, patients undergoing general anaesthesia had shorter procedure times and better procedural outcomes than those who had relatively light procedural sedation (conscious sedation).(13) However patients undergoing general anaesthesia also have a higher risk of oesophageal injury.(14) Another relatively small randomised trial, comparing deep sedation with propofol to lighter sedation with a combination of midazolam and fentanyl, demonstrated a higher incidence of complications in the deep sedation group.(15) It should be noted that ablation procedures for atrial fibrillation are now of shorter duration than previously and new techniques, such as cryoablation, are less sensitive to patient movement. Presently, no clear recommendation can be made about whether these procedures should be performed under general anaesthesia or intravenous sedation and both approaches are currently considered acceptable. Decisions about approach to sedation should be based upon individual patient circumstances, however it is noted that when sedation during catheter ablation for atrial fibrillation is very light, patient recall and distress may be high.(16)

## PHARMACOLOGICAL AGENTS

The most commonly used agents for cardiac sedation are midazolam and fentanyl. There is a large body of evidence documenting the safety of benzodiazepine-narcotic combinations for a variety of cardiac procedures.(7-10, 12, 17-21). The required dose of sedation varies widely. Adjustment should be made depending on the weight and age of the patient, other underlying medical conditions and the needs of the operator. In some cases such as transoesophageal echocardiography the maximum level of sedation is required early in the procedure. In other longer procedures the initial level of sedation may be low with increases for painful parts of the procedure such as electrical cardioversion or radiofrequency ablation. If doses described in the current literature are employed and correct airway monitoring is performed, cardiorespiratory depression resulting in disruption of the procedure is very rare. The most common problem with sedation is inadequate sedation resulting in patient discomfort or restlessness under sedation.(16)

### *Recommendations*

1. Combinations of benzodiazepines and narcotics (most commonly midazolam and fentanyl) may be administered safely for IVS during cardiac procedures.
2. For less painful procedures a benzodiazepine in isolation may be used.
3. IVS may be administered in the form of a bolus for short procedures, repeated boluses or as an infusion.
4. Reversal agents should be available when benzodiazepines and narcotics are administered.

## ENVIRONMENT

Complications of cardiac procedures include respiratory arrest, prolonged cardiac arrest, stroke, dissection or perforation of great vessels, myocardial infarction and shock due to haemorrhage, drug or contrast reaction and cardiac tamponade. The facility in which procedures are performed must have the capacity to deal with these complications.

The infrastructure required to perform complex electrophysiological and interventional procedures generally dictates that it is performed in larger hospital settings.(7-10, 17, 18, 20-23) This provides the advantages of multidisciplinary care in the case of adverse events. It is particularly desirable, though not considered essential, to have cardiothoracic surgical services on site. This allows management of cardiac tamponade that cannot be provided percutaneously. The alternative is rapid transfer of patients to a centre that can provide this service.

Other disciplines which are synergistic with cardiac intervention include interventional neuroradiology which may assist with intervention in cases of embolic stroke and vascular surgery which may assist in cases of vascular injury. At present the onsite representation of these disciplines is considered desirable but not essential.

The room in which a procedure is performed should be large enough to allow cardiopulmonary resuscitation if required. There should be appropriate lighting. There should be a means of summoning emergency assistance.

### **Recommendations**

1. Where moderate and deep levels of sedation are administered procedures should be performed in an environment where an Advanced Life Support Team is available emergently.
2. The response time of this team must be less than five minutes. The team must include a medical practitioner with anaesthetic skills, capable of intubating the patient and establishing mechanical ventilation. This person should be skilled in endotracheal intubation, the use of muscle relaxant drugs and airway management. They should also understand the use of medications required in resuscitation and sedation, and understand the use of a defibrillator.

The following equipment or its equivalent is required in the procedure room where deeper levels of sedation are administered or complex procedures are performed, for lesser procedures they should be readily available but not necessarily within the room:

- i. Venous or arterial access: gloves, tourniquets, alcohol wipes, sterile gauze pads, intravenous catheters, intravenous fluids, needles for drug aspiration and injection, syringes and tape.
- ii. Airway management: oxygen, suction, suction tubing and catheters (including Yankauer), face masks for oxygen delivery and non-rebreathing valve to provide higher concentrations as required and equipment for manual ventilation, oral and nasal airways, lubricant, laryngeal mask airways, laryngoscope, endotracheal tubes, stylet.
- iii. Pharmacological agents: midazolam, fentanyl, adrenaline, atropine, lignocaine, 50% dextrose for injection, naloxone, flumazenil, ephedrine, metaraminol, muscle relaxants.

## PERSONNEL AND TRAINING

Sedation should be performed under the supervision of a cardiologist experienced in sedation techniques.(7, 9, 21) This experience should be obtained consistent with training guidelines for those procedures as specified on the CSANZ website. It is expected that proceduralists learn the skills required for cardiac IVS in parallel with the appropriate cardiology subspecialty training. Sedation should be administered by a person trained in the necessary skills who is not the proceduralist.(7, 8, 11, 12, 17, 21).

### **Recommendations**

1. Subspecialty training for procedural skills should include the skills necessary to supervise the administration of cardiac IVS. This should include an understanding of the requirements for sedation, pre-procedural assessment, an understanding of the drugs used, their actions,

pharmacology and adverse effects, recognition of the need for intervention and when to call assistance.

2. The prime responsibility of the person administering sedation is to the sedation and monitoring of the patient. This person can only participate in other tasks if they do not detract from their primary role.
3. Where procedures are performed under sterile conditions at least one additional person is required to assist the operator (scout). This role cannot be performed by the person administering sedation.
4. The person administering IVS should have airway management skills including the ability to ventilate a patient using a bag and mask system. These skills are usually acquired through an Advanced Life Support (ALS) course.
5. The person administering IVS should be a registered nurse or medical practitioner.
6. The person administering IVS should have additional training to:
  - a. Identify respiratory effort, rate and depth;
  - b. Understand the actions, pharmacology and adverse effects of the drugs they are administering;
  - c. Understand the triggers for airway intervention;
  - d. Understand the triggers for calling an ALS team for assistance;
  - e. Manage adverse events including agitation;
  - f. Use reversal agents.

## **PROCEDURE CONDUCT AND MONITORING**

The method of sedation and monitoring varies depending on the nature of the procedure, patient characteristics and proceduralist requirements.(7-12, 17, 18, 20-22), however there are common general principles. Supplemental oxygen reduces the risk of hypoxia for endoscopic procedures.(24). Monitoring of expired CO<sub>2</sub>, is desirable for longer procedures during which deeper levels of sedation are employed, however it is not considered essential for shorter procedures, including electrical cardioversion, transoesophageal echocardiography, or in longer procedures when low levels of sedation are used.

### ***Recommendations***

1. Supplemental oxygen was used in almost all studies of sedation during electrophysiological procedures and is routinely used for transoesophageal echocardiography. Therefore it is recommended in all electrophysiological and transoesophageal echocardiography procedures.
2. Where the intended sedation level is below that of general anaesthesia local anaesthesia should be used at sites of skin incision or in the pharynx prior to transoesophageal echocardiography.
3. The dose of sedation should be calculated prior to the procedure and adjusted according to pre-specified criteria. After an initial bolus dose further boluses or infusions may be required for longer procedures.
4. The level of sedation should be monitored using an appropriate scale.
5. Monitoring of respiratory function should include direct observation of breathing, auscultation and/or by monitoring of expired CO<sub>2</sub>.
6. Pulse oximetry should be used to monitor oxygen saturation in all cases.
7. Continuous electrocardiography is required in all cases.
8. Regular recording of the arterial blood pressure is required in all cases (most studies describe 5 minute intervals). Continuous arterial pressure monitoring is desirable for complex electrophysiological and interventional procedures where haemodynamic collapse is likely.

9. Excessively light sedation (conscious sedation) for complex procedures such as catheter ablation for atrial fibrillation with radiofrequency energy may extend the procedure duration, result in patient distress and compromise outcomes. (Level of Evidence IIa, Grade B).
10. Restraints may be used where necessary to prevent patient movement. Care must be taken not to compromise patient comfort or cause injury.

### ***Triggers for intervention***

Oxygen desaturation is a common event during sedation for cardiac procedures. It occurs in 2.4-4.6% cases when narcotic and benzodiazepine combinations are employed(8, 9, 12, 18,21). The most common cause is hypoventilation due to airway obstruction followed by central respiratory depression. Airway intervention is required if there is hypoventilation. The initial steps include chin lifting and transient reduction or cessation of sedative medications. Further intervention may require the use of an oropharyngeal airway or manual ventilation. Opioid and benzodiazepine antagonist drugs may also be rarely required.

Hypotension is another common event during sedation for cardiac procedures. It is expected in 2-2.6% of cases when narcotic and benzodiazepine combinations are employed(8, 18, 21). When hypotension occurs during electrophysiology studies, pacing or cardiac biopsy, cardiac tamponade should be excluded by clinical signs, fluoroscopy of the heart border or transthoracic echocardiography. Depending on the cause of hypotension, intervention may require intravenous fluid replacement, and/or administration of adrenaline or metaraminol.

Patient movement may put the patient at risk of injury or impede the progress of the procedure. This is particularly the case when electro-anatomical mapping devices are used to facilitate electrophysiological procedures. Patient movement is a complex problem because it may have several causes. Pain should be minimised where possible and airway obstruction prevented. Additional sedation may be required but in cases where the response to benzodiazepines has been disorientation without sedation, a reduction in dose may be more effective.

Allergic reactions, problems with venous access and bleeding may also occur during sedation and staff members need to be able to recognise the signs of these problems and deal with them appropriately. Laryngospasm or bronchospasm are extremely rare during electrophysiological procedures. These complications may require manipulation of the sedative medications, bronchodilators or paralysis. If the airway is threatened a practitioner with the skills to manage these problems should be called emergently.

### ***Recommendations***

1. The nature of the intervention should be agreed between the supervising interventionalist and the doctor or nurse administering sedation. The following are recommended triggers for intervention (modified from Geiger et al.)
  - a) 5% drop in oxygen saturation
  - b) Oxygen saturation below 92%
  - c) Expired CO<sub>2</sub> above 50mmHg
  - d) Loss of spontaneous respiration
  - e) Cyanosis
  - f) Blood pressure below 90 mmHg systolic or mean below 70 mmHg
  - g) Evidence of peripheral hypoperfusion
  - h) Excessive patient movement
  - i) Allergic reaction
2. Triggers for calling an Advanced Life Support team include:
  - a) Failure to correct the above leading to patient compromise
  - b) Laryngospasm or bronchospasm causing respiratory distress
  - c) Cardiac or respiratory arrest

## DOCUMENTATION

The following should be documented when sedation is administered.

- a) Pre procedural assessment results;
- b) Doses of medications and their time of administration;
- c) Observed parameters including oxygen saturation, heart rate, blood pressure;
- d) Details of any intervention including jaw support, oropharyngeal airway placement;
- e) The occurrence of complications.

## POST PROCEDURAL CARE

The site of post procedural care depends on the capability of the recovery areas. Transition in level of care occurs when a patient moves from the operating room to a recovery area, from the recovery area to a ward or home and from a ward to home. The principles and guides below represent an adaptation of the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists.(2)

### **Recommendations**

1. At the conclusion of the procedure patients should be monitored in a specialised environment until alert.
2. Heart rate, level of consciousness, blood pressure and oxygen saturation should be monitored until there is no risk of respiratory depression or haemodynamic compromise has normalised.
3. Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner until the patient leaves the operating room environment or immediate recovery area.
4. A nurse or doctor trained to monitor patients and recognise and perform immediate management of complications should be in attendance during the initial intensive monitoring period until transition or discharge criteria are fulfilled.
5. The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
6. Criteria should be established for transition from recovery to general ward and for discharge to home. The duration and frequency of monitoring should be individualised depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.

## DISCHARGE

### **Recommendations:**

1. Patients should be alert and oriented or should have returned to their baseline status. In most cases this means the patient should be able to stand and walk unaided.
2. Vital signs should be stable (for at least 30minutes) and within acceptable or baseline limits.
3. Sufficient time (up to 2 hrs) should have elapsed after the last administration of reversal agents (naloxone, flumazenil).
4. Pain, discomfort and nausea should be adequately controlled.
5. Outpatients should, where possible, be discharged in the presence of responsible adult who will accompany them home and be able to report any post procedure complications.
6. Outpatients and their escorts should be provided with instructions regarding post procedure diet, medications, pain relief, driving, operating machinery and resumption of normal activities and a phone number to be called in case of emergency.

## AUDIT

Procedures performed under sedation should be subject to regular morbidity and mortality auditing.

## CONCLUSION

The recommendations above provide consensus based guidance for procedural sedation in the context of cardiac procedures. They represent the common requirements for safe sedation, whether it is administered by a nurse with appropriate training or a medical practitioner. We have emphasised the importance of safe sedation practices, the importance of cardiologists supervising sedation practice and the importance of training for administration of sedation as an essential element of procedural training.

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## APPENDIX

The following CSANZ Councils, the Continuing Education and Recertification Committee (CERC) and the Board were consulted in the drafting and review of this Position Statement.

The names of the Chairs of the Councils, CERC and members of the CSANZ Board may be found on the CSANZ website, [www.csanz.edu.au](http://www.csanz.edu.au).

- CSANZ Board
- Continuing Education and Recertification Committee (CERC)
- Cardiac Imaging Council
- Electrophysiology and Pacing Council
- Interventional Council

- **Interventional Nurses Council**