

The Cardiac Society of Australia and New Zealand

Statement of the Cardiac Society of Australia and New Zealand regarding the Extraction of Implanted Cardiac Device Leads, in particular the provision of surgical support

The Cardiac Society of Australia and New Zealand (CSANZ) has adopted the Policy Statement of the Heart Rhythm Society (HRS, formerly NASPE) on Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads (PACE 2000; 23:544-551 available at <u>www.hrsonline.org/policy/clinicalguidelines</u>). The CSANZ established the Lead Extraction Advisory Committee to address the issue of certification of practitioners for extraction of chronically implanted pacemaker leads and the registration of such practitioners for recognition by the Health Insurance Commission. The Lead Extraction Advisory Committee has now been asked by CSANZ to amplify the HRS Guideline related to provision of surgical back-up services in the event of a serious complication of lead extraction. The Committee notes that this is dealt with at length in the HRS Guideline and this statement should be read in conjunction with that Guideline.

Percutaneous pacemaker and ICD lead extraction is a procedure which, in experienced hands, can be performed safely and effectively. However, even in the most experienced centres, there is a risk of major complications, particularly myocardial perforation, which occurs in 1 to 2 per cent of all cases. Myocardial perforation during lead extraction usually has catastrophic consequences by causing pericardial tamponade and immediate haemodynamic collapse. Although occasionally percutaneous pericardial drainage will relieve the tamponade, open chest drainage and repair of the perforation is nearly always required. If this is not performed immediately the patient will die or suffer irreversible brain damage from cerebral hypoperfusion.

The risk for myocardial perforation is primarily related to the length of time the leads have been implanted and to the number and nature of the leads. ICD leads have a higher risk than pacemaker leads and at a significantly less implant duration.

All procedures for lead extraction must have a back-up plan to deal with cardiac perforation. In some circumstances the risk is very low – such as for leads that have been implanted for only a short time and are to be removed without the use of extraction tools – and in these cases, the back-up requirements can be relaxed. Even in such cases the possibility of serious complications must be considered and a plan should be in place for dealing with them. If a procedure that is being performed without adequate surgical back-up proves to be more difficult, then it should be abandoned and re-scheduled with all the appropriate safeguards in place.

Doctors performing lead extraction should be properly trained and experienced in the procedure. The requirements for this are set down in a separate document of the Lead Extraction Committee. It is the responsibility of hospitals to only accredit appropriately trained doctors to perform this procedure.

The patient and their family should be informed of the indication for lead extraction, the nature of the procedure, the possible alternatives, the risk and nature of complications and the possibility of emergency surgery. The doctor performing the procedure should obtain consent for the operation, as junior staff usually have little experience.

Lead extraction must only be performed in hospital with a cardiac surgical unit. The proceduralist performing lead extraction must have a close working relationship with the cardiac surgical unit. The cardiac surgical team must be aware of all lead extraction procedures being performed in the hospital.

Transfer of a patient to a cardiac operating theatre in the event of a perforation is usually too slow to save the patients life and should not be relied upon. Lead extraction must be performed in an environment in which an immediate thoracotomy can be performed immediately. This requirement needs to be balanced against the need for high quality fluoroscopy. A hybrid cath lab/operating theatre is the ideal situation but is rarely found in Australian hospitals. For most procedures, portable fluoroscopy will be adequate and they should be performed in a cardiac surgical operating theatre. In other cases, a cardiac catheterisation laboratory is required to provide better imaging. Wherever lead extraction is performed, thoracotomy equipment including sternal saw and surgical instruments must be readily available and appropriately trained nursing and technical staff must be present. A cardiac surgeon should be in the room or able to come into the room immediately, at the time that lead traction and sheath delivery is being performed. The surgeon does not have to be available for the whole case, but must be available during the time of greatest risk of perforation.

High-quality fluoroscopy, whether by portable unit or in a catheterisation laboratory is essential.

An anaesthetist should be present. General anaesthesia is usually required for these procedures. Monitoring of the arterial blood pressure by intra-arterial catheter is essential to rapidly diagnose cardiovascular collapse. Good intravenous access is essential. Central venous access should be obtained in higher risk patients. All resuscitation equipment and medications must be available. At least 2 units of blood should be cross-matched and immediately available.

Temporary pacing and defibrillation equipment should be available. Percutaneous pericardiocentesis equipment should be available. All appropriate lead extraction equipment should be available including stylets, lead locking devices and passive and powered sheaths.

Echocardiography and trained staff must be available in the room. Transoesophageal echocardiography (TOE) throughout the procedure is recommended to allow early diagnosis of tamponade. However, if the patient suffers a haemodynamic collapse, it should be assumed that cardiac perforation has occurred, whatever is seen on the TOE.

The patient should be prepared as if for sternotomy with appropriate shaving, washing, antiseptic and draping. The femoral veins should usually be included in the operative field to allow for rapid access. A femoral venous sheath may be placed to allow both high quality venous access and insertion of a temporary pacing wire if required.

A percutaneous procedure should be abandoned if the risk of perforation or other cardiovascular damage becomes too great. Open removal by thoracotomy should be considered in these cases.

In summary, percutaneous lead removal, is generally safe but can lead to catastrophic haemodynamic consequences. It must be expected that these complications will occur at some time, so back-up cardiac surgery must be immediately available.