



Percutaneous (nonthoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia

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www.nice.org.uk/guidance/ipg295

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- The evidence on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia (VT) is limited to a small number of patients, but it shows that the procedure is efficacious in carefully selected individuals and raises no major safety issues, in the context of a condition which is potentially life-threatening. Therefore, the procedure may be used with normal arrangements for clinical governance, but with special arrangements for consent.
- During the consent process clinicians should ensure that patients understand the risks of potentially serious complications, including damage to the heart muscle.
- 1.3 Patient selection and treatment should be carried out only by a team specialising in the treatment of cardiac arrhythmias that includes experts in electrophysiology and ablation.
- 1.4 The procedure should only be carried out by interventional cardiologists with specific training in electrophysiology and in accessing the pericardial space and performing complex ablation procedures.
- 1.5 The procedure should only be carried out in units with arrangements for emergency cardiac surgical support in case of complications.
- 1.6 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD), and clinicians should enter details about all

patients undergoing percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for VT onto this database.

1.7 NICE encourages further research into and publication of the outcomes and potential serious complications of percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for VT in larger numbers of patients.

2 The procedure

2.1 Indications and current treatments

- Ventricular tachycardia (VT) is caused by abnormal electrical circuits originating from diseased areas of the ventricular myocardium. It usually results in a rapid heartbeat, preventing effective ventricular refill and adequate cardiac output. Untreated VT is usually life-threatening.
- 2.1.2 Depending on the type, VT may be managed by antiarrhythmic drugs. People who have recurrent VT episodes may need an implantable cardiac defibrillator (ICD) or endocardial catheter ablation to destroy diseased areas of the ventricular myocardium and interrupt the abnormal electrical circuits.

2.2 Outline of the procedure

- 2.2.1 The procedure is carried out with the patient under sedation or general anaesthesia. The pericardial space is accessed by a subxiphoid needle puncture under fluoroscopic guidance. A guidewire is introduced through the needle and a sheath is advanced over the guidewire so that the tip is placed inside the pericardial sac. The sheath is aspirated to check for bleeding. A radiofrequency catheter is inserted into the sheath. After electrophysiological mapping to determine target sites for ablation, radiofrequency energy pulses are applied to the epicardium.
- 2.2.2 During the procedure, catheter position is monitored with a three-dimensional

mapping system to avoid collateral damage. Saline is placed in the pericardial space to reduce the risk of oesophageal injury, and steroids are administered to reduce the risk of pericarditis.

2.2.3 Patients can have a combined procedure that includes electrophysiological mapping and ablation by both endocardial and epicardial approaches.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- In a case series of 48 patients with VT, of whom 18 had epicardial ablation, the procedure eliminated VT-inducing circuits in 94% (17 out of 18) of patients (mean follow-up 25 months). In a case series of 14 patients, an epicardial VT circuit was mapped in 7 patients and was successfully terminated with epicardial ablation in all patients (mean follow-up 14 months). In a case series of 10 patients, VT-inducing circuits were eliminated in 8 (there were no episodes of syncope at 18-month follow-up).
- The Specialist Advisers stated that key efficacy outcomes included termination of VT (acutely and making it non-inducible), lack of VT recurrence, and reduction in the need for ICDs.

2.4 Safety

2.4.1 No deaths directly attributable to the procedure have been reported in the literature. There were three deaths because of progression of severe heart failure. One patient in a case series of 48 patients died from decompensated congestive heart failure several weeks after successful epicardial ablation. Two patients in a case series of 20 patients died because of progressive heart failure during follow-up (mean 12 months).

Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia (IPG295)

- In a case series of 20 patients, one patient developed arteriovenous fistula formation needing surgical repair. In the same study, another patient developed an atrioventricular block.
- In a case series of 10 patients, one patient developed haemopericardium needing drainage. In the same study three patients developed pericardial friction rub without haemopericardium.
- In a case series of 48 patients, three patients developed transient pericarditis that resolved within 1 week. In a second case series of 10 patients, two patients reported acute thoracic pain needing analgesia.
- In a case series of 10 patients, five patients were in heart failure during the procedure, and one of these needed urgent heart transplantation after the procedure.
- The Specialist Advisers considered that potential safety concerns included myocardial puncture; pericarditis; coronary artery damage; perforation of the right ventricle; damage to the oesophagus, bronchi and phrenic nerve; gastric puncture and damage to abdominal vessels and organs when accessing the pericardial space.

3 Further information

- The National Patient Safety Agency runs the <u>National Reporting and Learning</u>

 <u>System</u> (NRLS), and clinicians should report any serious adverse events relating to the use of this procedure to the NRLS.
- 3.2 NICE has published interventional procedures guidance on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation and technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.