

# **NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

## **INTERVENTIONAL PROCEDURES PROGRAMME**

### **Interventional procedure overview of percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia**

Ventricular tachycardia is a life-threatening heart condition. It occurs when the electrical impulses controlling the heartbeat become erratic, causing the heart to beat too quickly. When this happens, the heart cannot efficiently pump blood around the body. Ventricular tachycardia, if left untreated, may cause sudden cardiac death. In percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation, selected areas on the outside of the heart are destroyed using heat, with the aim of preventing abnormal electrical impulses responsible for ventricular tachycardia from occurring. The procedure is carried out by inserting a special catheter into the sac around the heart and using it to deliver heat to selected areas of heart muscle where abnormal electrical impulses responsible for the ventricular tachycardia are detected.

## **Introduction**

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## **Date prepared**

This overview was prepared in July 2008.

## **Procedure name**

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

## **Specialty societies**

- Society of Cardiothoracic Surgeons of Great Britain and Ireland
- British Cardiovascular Intervention Society

- Heart Rhythm UK

## **Description**

### ***Indications and current treatment***

Ventricular tachycardia (VT) is characterised by a very rapid heartbeat (often over 200 beats per minute) resulting in insufficient time for effective ventricular refill and ejection of blood to the systemic circulation. Episodes of VT are usually life-threatening medical emergencies and if left untreated may rapidly lead to ventricular fibrillation, pump failure and death.

Ventricular tachycardia usually originates from the development of abnormal electrical circuits within diseased areas of the ventricular myocardium (endocardial, epicardial or transmural ectopic ventricular foci). Most commonly, the diseased areas relate to scarred myocardial tissue, resulting from infarction, inflammation or infiltration. Abnormal electrical activity is sustained through a circuit re-entry mechanism, giving rise to VT. Less commonly, VT may be associated with congenital cardiac abnormalities of the conduction system.

Management of patients with recurrent VT may include the prescription of anti-arrhythmic drugs to prevent attacks occurring. Risk stratification is undertaken to identify individuals at an increased risk of recurrent VT and sudden cardiac death in whom treatment with an implantable cardiac defibrillator (ICD) is considered.

When an ICD is implanted, recurrent VT may still occur despite arrhythmic therapy necessitating multiple therapeutic shocks. This is uncomfortable for the patient and psychologically unsettling. Recurrent VT may also lead to pump failure and death despite the presence of an ICD. An alternative approach to treatment, therefore, is to undertake electrophysiological mapping followed by ablation (using an energy source such as radiofrequency waves) to identify and interrupt the electrical re-entrant circuits that have caused VT. This procedure is usually undertaken from an intravascular approach via the endocardium of the heart but may be ineffective if the arrhythmic substrate is predominately located on the epicardial surface. Under these circumstances, an epicardial approach has been considered in selected patients.

### ***What the procedure involves***

The procedure is carried out with the patient under sedation or general anaesthesia. Under fluoroscopic guidance, a needle is inserted through the skin (usually via a subxiphoid approach) and advanced towards the pericardium to access the pericardial space. Access into the pericardial space may be identified by a loss of resistance against the needle and confirmed with the injection of a small amount of contrast medium. Visualisation of the contrast medium around the cardiac silhouette indicates that the needle has

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accessed the pericardial space. 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 ablation sites radiofrequency energy pulses are applied to the epicardium.

In practice patients will often have a combined procedure that includes electrophysiological mapping and ablation from both endocardial and epicardial approaches.

## ***Efficacy***

This overview is based on about 110 patients from seven case series.

In a case series of 48 patients (18 of whom had epicardial ablation), epicardial ablation successfully terminated VT in 94% (17/18). There was no recurrence of VT demonstrated by repeated ambulatory Holter monitoring at follow-up (mean: 25 months). In the remaining patient, RF ablation could not be carried out epicardially because of high impedance<sup>1</sup>.

In a case series of 14 patients, epicardial ablation successfully terminated VT in all 7 patients in whom it was judged that an epicardial substrate was responsible. All patients were asymptomatic during follow-up (mean: 14 months); one patient continued to take beta-blocker medication and another continued to take antiarrhythmic medication<sup>2</sup>.

In a case series of 10 patients, VT was terminated and was no longer inducible 30 minutes after epicardial ablation in 8 patients. Epicardial ablation was not successful in 2 patients. In the first of these patients, VT was finally ablated through an endocardial approach (that had failed previously). The second patient required urgent heart transplantation for haemodynamic instability and refractory heart failure. During 18 months of follow-up, no patients had any episodes of syncope after discharge. Three patients continued to require antiarrhythmic medication after ablation. In one patient, VT recurred 2 years after the procedure; however, the morphology and rate of VT were different and it was successfully ablated endocardially<sup>3</sup>.

A case series of three patients reported that two patients were in sinus rhythm and that it was not possible to induce VT immediately after the procedure. All patients were taking a single antiarrhythmic drug and there were no symptomatic recurrences of VT reported during follow-up (mean: 24 months)<sup>4</sup>.

## ***Safety***

Three case series of 14, 3 and 5 patients reported that no serious intraprocedural complications occurred (serious intraprocedural complications were not defined)<sup>2,4,5</sup>.

No deaths directly attributable to the procedure have been reported in the literature. There were three deaths due to progression of severe heart failure. One patient in a case series (1/48) died from decompensated congestive heart failure several weeks after successful epicardial ablation<sup>1</sup>. Two patients in another case series (2/20) died due to progressive heart failure during follow-up (mean: 12 months)<sup>6</sup>.

Complications reported in the literature included: transient pericarditis that resolved within 1 week (3/48); acute thoracic pain requiring analgesia (2/10); atrioventricular block (1/20; no details about additional treatment were reported); arteriovenous fistula requiring surgical repair (1/20; no details about the anatomical location of the fistula were reported); haemopericardium requiring drainage (1/10); and pericardial friction rub without haemopericardium (3/10)<sup>1,3,6,7</sup>.

In addition, 5 out of 10 patients in one case series were in heart failure during the procedure. One patient required urgent heart transplantation and in the other four patients, the haemodynamic state compensated immediately after ablation<sup>3</sup>.

## **Literature review**

### ***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation. Searches were conducted of the following databases, covering the period from their commencement to 9 July 2008: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of the search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

<b>Characteristic</b>	<b>Criteria</b>
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with ventricular tachycardia.
Intervention/test	Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### ***Existing assessments of this procedure***

There were no published assessments from other organisations identified at the time of the literature search.

### ***Related NICE guidance***

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed below.

### **Technology appraisals**

- Implantable cardioverter defibrillators for the treatment of arrhythmias (review of TA11). NICE technology appraisals guidance 95 (2006). Available from [www.nice.org.uk/TA095](http://www.nice.org.uk/TA095)

**Table 2 Summary of key efficacy and safety findings on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia**

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Schweikert et al. (2003)<sup>1</sup></p> <p>Study type: <b>case series</b> Country: USA Study period: July 2002–June 2004 Study population: consecutive patients referred after unsuccessful endocardial ablation; VT (n = 30); left- or right-sided accessory pathway (n = 10); inappropriate sinus tachycardia (n = 4); atrial arrhythmias (n = 4) Mean number of previous ablation procedures: 1.4 (range 1–3) No patients had had prior cardiac surgery. <b>n = 48 (30 with VT)</b> Age: 45 years (mean) Sex: 71% male</p> <p>Inclusion criteria: not stated</p> <p>Technique: percutaneous, subxiphoid instrumentation of the pericardial space for electrophysiological mapping and RF ablation</p> <p>Follow-up: <b>25 months (mean)</b></p> <p>Conflict of interest: not stated</p>	<p><i>Results are presented here for only those patients with VT (n = 30).</i></p> <p><b>Site of origin of arrhythmia</b> <i>Assessed by activation and/or pace mapping</i></p> <ul style="list-style-type: none"> <li>• Of the 30 patients with previous VT, 24 (80%) were found to have an epicardial VT substrate. Six patients had VT origins in the endocardium or non-coronary cusp.</li> <li>• Six of the 24 patients with an epicardial VT substrate could not have epicardial ablation due to interference from the left atrial appendage and therefore could only have ablation of the left coronary cusp.</li> <li>• Of the 24 patients with an epicardial VT substrate, 18 went on to have epicardial ablation.</li> </ul> <p><b>Outcome of ablation</b> <i>Results are presented here for only those VT patients who had epicardial ablation (n = 18).</i></p> <ul style="list-style-type: none"> <li>• Successful ablation (with a mean of 3 ± 1 epicardial lesions): 94% (17/18).</li> <li>• One patient had an accessible epicardial site but RF lesions could not be delivered epicardially because of high impedance.</li> </ul> <p><b>Follow-up (mean: 25 months)</b></p> <ul style="list-style-type: none"> <li>• Of the patients with VT (<i>it is unclear what group of patients is referred to here, presumably it includes all 30 patients with VT</i>), repeated ambulatory Holter monitoring showed no recurrence of the target VT.</li> </ul>	<p><b>Mortality</b> One patient with severe ischaemic cardiomyopathy and a history of refractory VT who underwent successful epicardial ablation died from decompensated congestive heart failure several weeks after the ablation procedure.</p> <p><b>Complications</b> Three patients had symptoms of pericarditis that resolved without treatment within 1 week of the procedure. <i>(It is unclear whether these complications occurred in patients with VT.)</i></p>	<p>It is not reported whether the patients had ICDs.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Cesario et al. (2005)<sup>6</sup></p> <p>Study type: <b>case series</b></p> <p>Country: USA</p> <p>Study period: July 2002–June 2004</p> <p>Study population: patients with drug-refractory VT with multiple ICD shocks</p> <p>Mean ejection fraction: 28.3 ± 10.1%</p> <p>Mean number of therapies (anti-tachycardia pacing or shocks) in week prior to ablation: 10 ± 3</p> <p>n = <b>20</b></p> <p>Age: 64 years (mean)</p> <p>Sex: 75% male</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>• Previous failed ablation</li> <li>• Suspected inferoposterior myocardial scars or</li> <li>• Electrocardiogram suggestive of possible epicardial origin</li> </ul> <p>Technique: combined epicardial and endocardial mapping and catheter ablation. Ablation was initially attempted endocardially when pace maps revealed a 12/12 match to the targeted VT foci. Epicardial ablation was attempted in a) patients for whom the targeted VT could still be induced electrophysiologically during the procedure b) patients who did not have an excellent endocardial pace map but did have an excellent epicardial pace map and c) patients with complex epicardial electrocardiograms. The mean procedure duration was 8 hours (range: 6 to 14 hours).</p> <p>17 patients had percutaneous mapping and ablation and in 3 patients the pericardial space was approached surgically via a minithoracotomy (because of adhesions related to previous cardiac surgery).</p> <p>Follow-up: <b>12 months (mean)</b></p> <p>Conflict of interest: not stated</p>	<p>All 20 patients had endocardial catheter ablation and 8 patients also required additional epicardial RF delivery for successful VT ablation. However, the results are reported for all 20 patients together.</p> <p><b>Follow-up</b></p> <ul style="list-style-type: none"> <li>• 75% (15/20) were event free during follow-up (anti-tachycardia pacing or shocks based on assessment of implantable cardioverter-defibrillator logs).</li> <li>• At least one antiarrhythmic drug (in addition to beta-blocker therapy when tolerated) was continued in all patients.</li> <li>• Two patients underwent heart transplantation during follow-up.</li> </ul>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>• One patient developed atrioventricular block during endocardial ablation (in the region of the left posterior fascicle). No information about further treatment or management was reported.</li> <li>• One patient developed an arteriovenous fistula that required surgical repair (the exact anatomical location of the fistula was not reported).</li> <li>• Two patients died during follow-up due to progressive heart failure.</li> </ul>	<p>The outcomes reported here include 12 patients who had endocardial ablation only and 8 patients who had both endocardial and epicardial ablation. Data were not reported separately for each group.</p> <p>In three patients (with previous cardiac surgery and adhesions) epicardial access was achieved via a minithoracotomy rather than percutaneously.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sosa et al. (2000)<sup>2</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Brazil</p> <p>Study period: October 1996–August 1998</p> <p>Study population: consecutive patients with recurrent and drug-refractory post-infarction VT. Two patients had previously undergone unsuccessful standard endocardial RF ablation. One patient had an ICD.</p> <p>Mean left ventricular ejection fraction: 50 ± 12% n = 14</p> <p>Age: 54 years (mean)</p> <p>Sex: 71% male</p> <p>Inclusion criteria: not stated</p> <p>Technique: transthoracic epicardial catheter RF ablation. The mean procedure duration was 3.5 hours.</p> <p>Follow-up: <b>14 months (mean)</b></p> <p>Conflict of interest: not stated</p>	<p><b>Outcome of ablation</b></p> <p>There were a total of 30 inducible VTs of which:</p> <ul style="list-style-type: none"> <li>• 7 inducible VTs (in 7 patients) had electrophysiological evidence of an epicardial circuit; all VTs were successfully terminated by epicardial ablation</li> <li>• 3 inducible VTs were successfully terminated by endocardial ablation</li> <li>• 8 inducible VTs could not be terminated by either endocardial or epicardial ablation</li> <li>• 12 inducible VTs could not be mapped (and ablated) because of poor haemodynamic tolerance.</li> </ul> <p><b>Symptoms</b></p> <p><i>Results are presented here for only the seven patients who had epicardial ablation alone (mean follow-up: 14 months).</i></p> <ul style="list-style-type: none"> <li>• All seven patients were asymptomatic during follow-up.</li> </ul> <p><b>Antiarrhythmic medication</b></p> <p><i>Results are presented here for only the seven patients who had epicardial ablation alone (mean follow-up: 14 months).</i></p> <ul style="list-style-type: none"> <li>• One patient was taking oral antiarrhythmic medication.</li> <li>• One patient continued to take oral sotalol.</li> <li>• Five patients were not taking antiarrhythmic medication.</li> </ul>	<p><b>Complications</b></p> <p>There were no complications during hospital stay.</p>	<p>The authors do not report any outcomes assessed by electrocardiograph or Holter monitoring during follow-up.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sosa et al. (1998)<sup>1</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Brazil</p> <p>Study period: July 1995–March 1996</p> <p>Study population: consecutive patients with drug-refractory VT and Chagas' disease.</p> <ul style="list-style-type: none"> <li>All patients had had at least two prior documented episodes of sustained VT in the previous 18 months despite oral antiarrhythmic drugs.</li> <li>Two patients had palpitations, six patients had syncope or near-syncope and two patients had a history of aborted sudden cardiac death.</li> <li>In one patient, VT occurred 1 month after implantation of an ICD.</li> <li>Five patients had previously had endocardial ablation.</li> <li>Mean left ventricular ejection fraction in patients with structural heart disease: 62 ± 8%.</li> </ul> <p>n = 10</p> <p>Age: 53 years (mean)</p> <p>Sex: 60% male</p> <p>Inclusion criteria: not stated</p> <p>Technique: non-surgical transthoracic epicardial (n = 6) or endocardial (n = 4) radiofrequency ablation. Target sites were identified by epicardial activation mapping.</p> <p>Follow-up: <b>18 months</b></p> <p>Conflict of interest: not stated</p>	<p>There were a total of 18 mappable inducible VTs, of which 14 had an epicardial circuit. Four patients had endocardial ablation and six patients had epicardial ablation.</p> <p><b>Outcome of ablation</b></p> <p><i>Results are presented here for only the six patients who had epicardial ablation.</i></p> <ul style="list-style-type: none"> <li>All inducible VTs were terminated and were not inducible after ablation.</li> </ul> <p><b>Symptoms</b></p> <p><i>Results are presented here for only the six patients who had epicardial ablation (mean follow-up: 14 months).</i></p> <ul style="list-style-type: none"> <li>All patients were asymptomatic 4–9 months after the procedure.</li> </ul> <p><b>Antiarrhythmic medication</b></p> <p><i>Results are presented here for only the six patients who had epicardial ablation (mean follow-up: 14 months).</i></p> <ul style="list-style-type: none"> <li>One patient was taking oral antiarrhythmic medication because of self-limiting palpitations.</li> </ul>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>One patient developed haemopericardium, detected immediately after the procedure, which required drainage by insertion of a pigtail catheter.</li> <li>Three patients developed minimal retrosternal discomfort and pericardial friction rub in the first 24 hours after the procedure which resolved spontaneously.</li> </ul>	<p>The authors do not report any outcomes assessed by electrocardiograph or Holter monitoring during follow-up.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sosa et al. (2004)<sup>5</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Brazil</p> <p>Study period: October 1996 –October 2002</p> <p>Study population: patients with a history of recurrent and drug-refractory VT and previous open-chest cardiac surgery</p> <ul style="list-style-type: none"> <li>• Three patients had coronary artery bypass surgery 7 months, 2 years and 10 years prior.</li> <li>• One patient had mitral valve replacement 40 months prior and one patient had dilated cardiomyopathy and an ICD with an epicardial patch implanted after cardiac arrest 8 years prior.</li> <li>• Three patients had previously undergone unsuccessful standard endocardial RF ablation.</li> <li>• Mean left ventricular ejection fraction in patients with structural heart disease: 40 ± 4%.</li> </ul> <p>n = 5</p> <p>Age: 67 years (mean)</p> <p>Sex: 80% male</p> <p>Inclusion criteria: not stated</p> <p>Technique: transthoracic epicardial catheter RF ablation. Failure to interrupt the VT with RF pulses delivered at the best endocardial or epicardial site prompted changing from one approach to the other.</p> <p>Follow-up: <b>not stated</b></p> <p>Conflict of interest: not stated</p>	<p>In the first three patients, epicardial mapping was carried out after endocardial mapping failed to identify a good ablation target. In the last two patients, endocardial mapping followed epicardial mapping.</p> <p><b>Outcome of ablation</b></p> <p>There were a total of 14 inducible VTs of which:</p> <ul style="list-style-type: none"> <li>• 2 were eliminated by epicardial ablation after failed endocardial ablation</li> <li>• 3 were eliminated by endocardial ablation after failed epicardial ablation</li> <li>• 1 could not be eliminated by either endocardial or epicardial ablation</li> <li>• 8 could not be mapped (and ablated) because of poor haemodynamic tolerance.</li> </ul>	<p><b>Complications</b></p> <p>There were no intra- or postprocedural complications.</p>	<p>It is not clear whether these patients are a different group from those reported in earlier publications from the same centre (there is some overlap in the study period).</p> <p>The authors do not report any outcomes assessed by electrocardiograph or Holter monitoring during follow-up.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Brugada et al. (2003)<sup>3</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Brazil</p> <p>Study period: not stated</p> <p>Study population: patients with persistent, recurrent, sustained VT (for at least a 24-hour period despite at least two intravenous antiarrhythmic drugs, electrical cardioversion and/or overdrive stimulation).</p> <ul style="list-style-type: none"> <li>• Eight patients had previous failed endocardial ablation.</li> <li>• Eight patients had coronary artery disease and previous myocardial infarction.</li> <li>• One patient had dilated cardiomyopathy.</li> <li>• One patient had idiopathic VT.</li> <li>• Mean left ventricular ejection fraction in patients with structural heart disease: <math>0.28 \pm 0.10\%</math>.</li> </ul> <p>n = <b>10</b></p> <p>Age: 69 years (mean)</p> <p>Sex: 90% male</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>• recurrent, sustained VT for a 24-hour period or longer despite two or more intravenous antiarrhythmic drugs, electrical cardioversion and/or overdrive stimulation</li> </ul> <p>Technique: non-surgical transthoracic epicardial radiofrequency ablation. Target sites were identified by activation mapping.</p> <p>Follow-up: <b>18 months</b></p> <p>Conflict of interest: not stated</p>	<p><b>Outcome of ablation</b></p> <p><i>Assessed by attempts to induce VT by programmed ventricular stimulation 30 minutes after the procedure</i></p> <ul style="list-style-type: none"> <li>• In eight patients, ablation was successful in terminating the VT (seven ablations were successful on the first attempt; one patient required a second epicardial session the next day to ablate VT).</li> <li>• In one patient (with coronary artery disease) the VT was finally ablated through standard endocardial access that had failed previously.</li> <li>• In one patient (with cardiomyopathy) the VT could not be terminated by either endocardial or epicardial ablation and urgent heart transplantation was required because of haemodynamic instability and refractory heart failure.</li> </ul> <p><b>Symptoms</b></p> <ul style="list-style-type: none"> <li>• No patients had any episodes of syncope after discharge.</li> </ul> <p><b>Antiarrhythmic medication</b></p> <ul style="list-style-type: none"> <li>• Oral antiarrhythmic medication was continued after ablation in three patients.</li> </ul> <p><b>Follow-up</b></p> <ul style="list-style-type: none"> <li>• A VT (with a different morphology and rate from the one originally treated) recurred 2 years after the procedure in one patient. The VT was successfully ablated endocardially.</li> </ul>	<p><b>Complications</b></p> <p>The authors state that no significant complications were observed.</p> <ul style="list-style-type: none"> <li>• Two patients had thoracic pain for 3 days after the procedure which required analgesia with paracetamol.</li> <li>• Five patients were in heart failure during the procedure. In four patients with effective ablation, the haemodynamic state compensated immediately after ablation. (No heart failure decompensation was observed immediately after the procedure nor in the following days.) The fifth patient had urgent heart transplantation.</li> </ul>	<p>It is not reported whether the patients had ICDs.</p> <p>The authors do not report any outcomes assessed by electrocardiograph or Holter monitoring during follow-up.</p>

Abbreviations used: VT, ventricular tachycardia; RF, radiofrequency			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sharada et al. (2005)<sup>4</sup></p> <p>Study type: <b>case series</b></p> <p>Country: India</p> <p>Study period: not stated</p> <p>Study population: patients with postinfarction recurrent, drug-refractory VT. One patient had coronary heart disease and one patient had previous inferior and right ventricular infarction. One patient had a large posterobasal aneurysm and left ventricular thrombus and was unwilling to undergo a revascularisation procedure.</p> <p>n = <b>3</b></p> <p>Age: 65, 53, 70 years</p> <p>Sex: 100% male</p> <p>Inclusion criteria: not stated</p> <p>Technique: non-surgical transpericardial catheter-based epicardial RF ablation via a subxiphoid approach to the pericardial space.</p> <p>If haemodynamically stable VT was induced, endocardial mapping was carried out and if electrograms were found suboptimal, a mapping catheter was introduced into the pericardial space. One patient had an elective epicardial approach due to a large posterobasal left ventricular aneurysm with thrombus.</p> <p>Follow-up: <b>24 months (mean)</b></p> <p>Conflict of interest: not stated</p>	<p><b>Outcome of ablation</b></p> <ul style="list-style-type: none"> <li>In two patients, ablation successfully terminated the VT. They remained in sinus rhythm and VTs were not inducible with programmed ventricular stimulation.</li> <li>In one patient, ablation was successful in modifying the arrhythmia circuit to be controllable with a single antiarrhythmic drug.</li> </ul> <p><b>Symptoms</b></p> <p><i>Mean follow-up: 24 months</i></p> <ul style="list-style-type: none"> <li>All patients were well during follow-up without symptomatic recurrences of VT while taking a single antiarrhythmic drug.</li> </ul>	<p><b>Complications</b></p> <p>The authors state that there were no serious acute or long-term complications related to the procedure.</p>	<p>It is not reported whether the patients had ICDs.</p> <p>The authors do not report any outcomes assessed by electrocardiograph or Holter monitoring during follow-up.</p>

### ***Validity and generalisability of the studies***

- Patients were selected for this procedure for a variety of reasons, usually because endocardial ablation was not possible or successful.
- The ICD status of most patients is not adequately described.
- In most studies, it is not clear whether the assessment of freedom from recurrent VT activity postprocedurally included Holter or ECG evidence.
- The duration of follow-up in the studies is short.

### **Specialist Advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Richard Schilling (British Cardiovascular Intervention Society), Dr Stephen Furniss, Dr Derick Todd (Heart Rhythm UK).

- One Specialist Adviser provided the same advice for this procedure for both VT and atrial fibrillation (IP261). He stated that he regularly performs an epicardial approach catheter ablation in cases where an endocardial approach is not successful. The other two Specialist Advisers had also performed the procedure before.
- Two Advisers thought the procedure was established practice and had no comparator. One Adviser thought it was a minor variation of an existing technique and that the comparator was endocardial VT ablation.

### **Safety**

- Potential safety concerns included myocardial puncture, pericarditis, gastric puncture, coronary artery damage, damage to the oesophagus, bronchi and phrenic nerve, damage to abdominal vessels and organs when accessing the pericardial space, and perforation of the right ventricle.
- One Adviser described a case in which, despite detailed mapping, ablation could not be performed because of proximity to the coronary artery. Another Adviser described an anecdotal report of a death in a patient who had had epicardial implantation percutaneously of a pacing lead where access caused gastric damage.
- One Adviser commented that uncertainty about the safety of this procedure was due to the small number of cases that have been reported in the literature. He thought that there was no uncertainty about efficacy.

### ***Efficacy***

- The Advisers thought efficacy outcomes included termination of VT acutely (and making it non-inducible), and lack of recurrence and reduction of the need for ICD treatment.
- One Adviser thought there was some uncertainty about which energy source to use in the pericardial space. He states that closed loop irrigated tip catheters have the best data but many centres use the commoner open irrigation systems. Lesion geometry is different and there are issues about monitoring of haemodynamics and fluid removal with this system. He also comments that he has limited experience with epicardial cryo-ablation which may be safer but he has had 2 recurrences using this system.

### ***Training***

- Specialist Advisers stated that formal training in the procedure should be recommended and that pericardial puncture/access requires training. One Adviser commented that the procedure can safely be performed in an electrophysiology laboratory where endocardial ablation is performed.

### ***General***

- One Specialist Adviser stated that Paolo Della Bella from Milan is trying to produce a European Registry.
- All Advisers thought that the impact of this procedure on the NHS would be minor.

## **Issues for consideration by IPAC**

- Consider alternative titles: Non-surgical transthoracic epicardial radiofrequency ablation for VT or Percutaneous (non-surgical) epicardial catheter radiofrequency ablation for VT.
- The evidence base is small.

## References

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3. Brugada J, Berruezo A, Cuesta A et al. (2003) Nonsurgical transthoracic epicardial radiofrequency ablation: an alternative in incessant ventricular tachycardia. *Journal of the American College of Cardiology* 41: 2036–43.
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6. Cesario DA, Vaseghi M, Boyle NG et al. (2006) Value of high-density endocardial and epicardial mapping for catheter ablation of hemodynamically unstable ventricular tachycardia. *Heart Rhythm* 3: 1–10.
7. Sosa E, Scanavacca M, d'Avila A et al. (1998) Endocardial and epicardial ablation guided by nonsurgical transthoracic epicardial mapping to treat recurrent ventricular tachycardia. *Journal of Cardiovascular Electrophysiology* 9: 229–39.

## **Appendix A: Additional papers on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia**

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Berruezo A, Cano L, Mont L et al. (2006) Epicardial ablation of syncope ventricular tachycardia. Utility of the electrocardiogram. <i>Europace</i> 8 (5): 338–40.	n = 1  Follow-up: 1 year	23-year-old male. VT was successfully terminated and not inducible after ablation. Normal sinus rhythm on Holter monitoring during first 24 hours. The patient has remained asymptomatic without recurrence of VT.	Larger studies are included in table 2.
d'Avila A, Scanavacca M, Sosa E (2006) Transthoracic epicardial catheter ablation of ventricular tachycardia. <i>Heart rhythm</i> 3 (9): 1110–11.	n = 1  Follow-up: 10 days	63-year-old male who had been awaiting heart transplant for 6 months. VT was successfully terminated after ablation. The patient was asymptomatic until heart transplant (10 days later).	Larger studies are included in table 2.
De Ponti R, Tritto M, Marazzi R et al. (2003) How to approach epicardial ventricular tachycardia: electroanatomical mapping and ablation by transpericardial nonsurgical approach. <i>Europace</i> 5 (1): 55–6.	n = 1  Follow-up: 2 years	53-year-old male. VT was successfully terminated and not inducible after ablation. The patient has remained asymptomatic without antiarrhythmic medication.	Larger studies are included in table 2.
Liew R, Rajappan K, Gupta D et al. (2007) Percutaneous epicardial ablation reverses ventricular tachycardia mediated cardiomyopathy. <i>Journal of Interventional Cardiac Electrophysiology</i> 18 (3): 265–7.	n = 1  Follow-up: 4 months	18-year-old female. VT was successfully terminated and not inducible after ablation.	Larger studies are included in table 2.
Sosa E, Scanavacca M (2007) Percutaneous pericardial access for mapping and ablation of epicardial ventricular tachycardias. <i>Circulation</i> 115: e542–4.	n = 1  Follow-up: not stated	26-year-old male. VT was successfully terminated and not inducible after ablation. The patient has remained asymptomatic without antiarrhythmic medication.	Larger studies are included in table 2.
Sosa E, Scanavacca M, d'Avila A et al. (1999) Radiofrequency catheter ablation of ventricular tachycardia guided by nonsurgical epicardial mapping in chronic chagasic heart disease. <i>Pacing and Clinical Electrophysiology</i> 22 (1): 128–30.	n = 1  Follow-up: 1 year	63-year-old female. VT was successfully terminated and not inducible after ablation. A distinct VT was induced 2 weeks later and the patient has remained asymptomatic with antiarrhythmic medication.	Larger studies are included in table 2.
Sosa E, Scanavacca M, d'Avila A et al. (2000) Nonsurgical transthoracic mapping and ablation in a child with incessant ventricular tachycardia. <i>Journal of Cardiovascular Electrophysiology</i> 11 (2): 208–	n = 1  Follow-up: 10 months	11-month-old male. VT was successfully terminated and not inducible after ablation. The patient was discharged in sinus rhythm and with no signs of heart failure 2 days later. No ventricular ectopy was noted during 24-hour Holter monitoring	Larger studies are included in table 2.

10.		10 months later.	
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## Appendix B: Related NICE guidance for percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia

Guidance	Recommendations
Technology appraisals	<p data-bbox="565 478 1360 573"><b>Implantable cardioverter defibrillators (ICDs) for the treatment of arrhythmias. NICE technology appraisal 95 (2006).</b></p> <p data-bbox="565 615 1284 678">1.1. ICDs are recommended for patients in the following categories:</p> <p data-bbox="621 730 1369 1224">1.1.1. ‘Secondary prevention’, that is, for patients who present, in the absence of a treatable cause, with one of the following:</p> <ul data-bbox="727 846 1369 1224" style="list-style-type: none"> <li>• having survived a cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF)</li> <li>• spontaneous sustained VT causing syncope or significant haemodynamic compromise</li> <li>• sustained VT without syncope or cardiac arrest, and who have an associated reduction in ejection fraction (LVEF of less than 35%) (no worse than class III of the New York Heart Association functional classification of heart failure).</li> </ul> <p data-bbox="621 1276 1300 1339">1.1.2. ‘Primary prevention’, that is, for patients who have:</p> <ul data-bbox="727 1350 1300 1413" style="list-style-type: none"> <li>• a history of previous (more than 4 weeks) myocardial infarction (MI) and:</li> </ul> <p data-bbox="727 1423 808 1455"><b>either</b></p> <ul data-bbox="768 1465 1344 1749" style="list-style-type: none"> <li>– left ventricular dysfunction with an LVEF of less than 35% (no worse than class III of the New York Heart Association functional classification of heart failure), <b>and</b></li> <li>– non-sustained VT on Holter (24-hour electrocardiogram [ECG]) monitoring, <b>and</b></li> <li>– inducible VT on electrophysiological (EP) testing</li> </ul> <p data-bbox="727 1759 760 1791"><b>or</b></p> <ul data-bbox="768 1801 1344 1896" style="list-style-type: none"> <li>– left ventricular dysfunction with an LVEF of less than 30% (no worse than class III of the New York Heart Association functional</li> </ul>

	<p>classification of heart failure) <b>and</b></p> <ul style="list-style-type: none"><li>- QRS duration of equal to or more than 120 milliseconds</li><li>• a familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia (ARVD), or have undergone surgical repair of congenital heart disease.</li></ul>
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## Appendix C: Literature search for percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia

Database	Date searched	Version/files	Number retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	9 July 2008	Issue 2, 2008	-
Database of Abstracts of Reviews of Effects – DARE (CRD website)	8 July 2008	-	2
HTA database (CRD website)	8 July 2008	-	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	9 August 2008	Issue 2, 2008	2
MEDLINE (Ovid)	8 July 2008	1950 to June Week 4 2008	165
MEDLINE In-Process (Ovid)	8 July 2008	July 07, 2008	10
EMBASE (Ovid)	8 July 2008	1980 to 2008 Week 26	110
CINAHL (Dialog DataStar, NLH)	8 July 2008	1982-date	16
BLIC (Dialog DataStar)	9 July 2008	-	1
National Research Register (NRR) Archive	9 July 2008	Archive	2
UK Clinical Research Network (UKCRN) Portfolio Database	7 July 2008	-	-
Current Controlled Trials <i>meta</i> Register of Controlled Trials – <i>m</i> RCT	7 July 2008		Substrate Mapping and Ablation in Sinus rhythm to Halt Ventricular Tachycardia 2006
Clinicaltrials.gov	7 July 2008	-	Dynamic Substrate Mapping (DSM) for Ischemic VT 2007  NAVISTAR® THERMOCOOL®

			Catheter for the Treatment of Atrial Fibrillation 2006
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The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Strategy used:
2	exp Tachycardia, Ventricular/ (8831)
3	Tachycardia/ (16725)
4	tachycard\$.tw. (37267)
5	tachyarrhy\$.tw. (6078)
6	Arrhythmias, Cardiac/ (45387)
7	Ventricular Flutter/ (3)
8	(cardia\$ adj3 arrhythmia\$).tw. (10117)
9	(ventricul\$ adj3 (flutt\$ or tachycard\$ or tachyarrhy\$)).tw. (16832)
10	((rapid\$ or fast\$ or quick\$) adj3 (heartbeat\$ or heart beat\$ or heart-beat\$ or heart rhyth\$ or heart-rhyth\$ or heart rate\$ or heart-rate\$ or heartrate\$ or cardia\$)).tw. (2099)
11	or/1-9 (93988)
12	epicardial\$.tw. (9356)
13	exp Electrocoagulation/ (20859)
14	electrocoag\$.tw. (2012)
15	RFA.tw. (1396)
16	RFCA.tw. (152)
17	((radio\$ or cathet\$) adj3 (ablat\$ or remov\$ or eradicat\$ or destruct\$ or cut\$)).tw. (15445)
18	or/12-16 (30141)
19	10 and 11 and 17 (207)
20	animals/ (4297276)
21	Humans/ (10548308)
22	19 not (19 and 20) (3233613)
23	18 not 21 (165)
24	from 22 keep 1-10 (10)
25	24 from 22 keep 1-165 (165)