Issue date: March 2009

NHS
National Institute for
Health and Clinical Excellence

Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

1 Guidance

1.1 Current evidence on the safety and efficacy of percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation (AF) is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance and consent.

1.2 Clinicians wishing to undertake percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG294publicinfo).

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 NHS Information Centre for health and social care runs the UK Central Cardiac Audit Database, and clinicians should enter details about all patients undergoing percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF onto this database (www.ccad.org.uk).

1.7 Clinicians are encouraged to enter patients into research studies that aim to provide more information about patient selection, the use of this procedure as an adjunct to other procedures, freedom from AF in the long term and relief of associated symptoms, and the safety profile of the procedure. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Atrial fibrillation is the most common type of cardiac arrhythmia, and is caused by the irregular and rapid beating of the atria. It can be classified as paroxysmal, persistent or permanent, depending on episode duration and the patient's response to treatment. People with AF may be asymptomatic or they may have symptoms such as palpitations, dizziness, breathlessness and fatigue. Atrial fibrillation is associated with increased risk of death and of embolic stroke from atrial thrombus. Anticoagulation treatment is used to reduce this risk.

2.1.2 Antiarrhythmic medication is used either to help maintain a normal cardiac rhythm following successful cardioversion or to help reduce the heart rate. Ablation procedures can be used when drug therapy is either not tolerated or is ineffective.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

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.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/IP261overview

2.3 Efficacy

2.3.1 In a case series of five patients, all of them had percutaneous epicardial catheter radiofrequency ablation after failed endocardial ablation. Four patients were AF free and not on antiarrhythmic medication at 2-month, 6-month, 13-month and 15-month follow-up, respectively. The fifth patient was AF free but on antiarrhythmic medication at 4-month follow-up.

2.3.2 A case report of a patient with persistent AF (refractory to antiarrhythmic medication and with two previous failed electrical cardioversions) reported that the patient was symptom free at 1 month postoperatively.

2.3.3 One Specialist Adviser thought that the key efficacy outcome was freedom from AF. One Specialist Adviser commented that there was uncertainty about the efficacy of the procedure because of the small number of cases reported in the literature.

2.4 Safety

2.4.1 In the case series of five patients, one patient developed haemopericardium during the percutaneous epicardial puncture, which was successfully drained. In another patient, a tachycardia originating from the left inferior pulmonary vein was observed during the procedure but this was successfully terminated with delivery of further epicardial and endocardial radiofrequency pulses.

2.4.2 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. One Specialist Adviser described an anecdotal report of death because of gastric injury resulting from percutaneous epicardial implantation of pacing leads. Another commented that there was uncertainty about the long-term safety of the procedure.

3 Further information

3.1 NICE has published a clinical guideline on AF and interventional procedures guidance on several procedures for AF, with or without cardiac surgery. NICE has also published interventional procedures guidance on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia. For more information see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG294publicinfo

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1835 for this guidance or N1836 for the 'Understanding NICE guidance'.

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NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treating atrial fibrillation using heat energy delivered to the outside of the heart through a thin tube

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how heat energy delivered to the outside of the heart by a thin, flexible tube (called a catheter) can be used in the NHS to treat people with atrial fibrillation. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe atrial fibrillation or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

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What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use this procedure they should make sure that extra steps are taken to explain the uncertainty about how well it works and about the potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information. There should also be special arrangements for monitoring what happens to the patient after the procedure. NICE has said that a team of specialist doctors experienced in treating heart rhythm disorders should decide who has this procedure. It should include experts in the heart's electrical activity and in removing abnormal tissue. The procedure should only be carried out by cardiologists who have training in the heart's electrical activity, operating on the heart, and removing abnormal tissue. It should only be carried out in units with emergency cardiac surgery support.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at the UK Central Cardiac Audit Database (www.ccad.org.uk) so that the safety of the procedure and how well it works can be checked over time. NICE has encouraged further research into the procedure and may review the procedure if more evidence becomes available.

Treating atrial fibrillation using heat energy delivered to the outside of the heart through a thin tube

This procedure may not be the only possible treatment for atrial fibrillation. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation'. 'Epicardial' refers to the outermost membrane of the heart and 'radiofrequency ablation' means using heat energy to remove tissue. The procedure is not described in detail here – please talk to your specialist for a full description.

Atrial fibrillation is a condition that affects the heart, causing an irregular pulse. It occurs when the electrical impulses controlling the heartbeat become disorganised, so that the heart beats irregularly and too fast. The heart cannot then efficiently pump blood around the body. Some people don't have any symptoms, but if present, symptoms can include palpitations, dizziness, breathlessness and tiredness. Atrial fibrillation increases the risk of blood clots, stroke and death. Treatments include medicine to control the heart rhythm and rate, or to stop blood clots forming. Ablation procedures can also be successfully carried out from the inside of the heart. Surgical procedures can be offered when medicine either does not work or cannot be tolerated.

The procedure is carried out with the patient sedated or under general anaesthetic. A special thin tube is inserted through the skin and positioned next to the epicardium (the outer layer of the heart wall). The surgeon uses X-rays to make sure it is positioned properly. Heat is passed to the tip of the

thin tube and used to break down the parts of the heart where the abnormal electrical impulses are. The patient is given steroids to reduce the risk of inflammation around the heart. Ablation from the inside and outside of the heart may be combined.

What does this mean for me?

If your doctor has offered you this procedure for atrial fibrillation, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at two studies on this procedure.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

How well does the procedure work?

In one study, five patients had the procedure after another heart operation had failed. Between 2 and 15 months after the procedure four of them no longer had atrial fibrillation, and did not need medication. The fifth patient did not have atrial fibrillation but was still taking medication 4 months after the procedure. In a different study one person who had long-lasting atrial fibrillation had no symptoms 1 month after having the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. One

adviser said that the main success factor was freedom from atrial fibrillation. Another said that it is uncertain how well the procedure works because only a few cases have been reported.

Risks and possible problems

In the study of five patients, one patient developed a collection of blood in the sac around the heart. Another patient had a very fast heart rate (known as tachycardia) during the procedure, but this was cured by delivering more heat energy to the inside and outside of the heart.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that theoretical problems were puncturing of the heart muscle and stomach; inflammation of the membranes around the heart; perforation of the heart; damage to the coronary artery, the throat, lungs and the nerve to the diaphragm, and to blood vessels and organs in the abdomen. One adviser said that safety of the procedure in the long term was uncertain.

More information about atrial fibrillation

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG294

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1836).

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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Consultation Comments table

IPAC date: 15th January 2009

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Medical devices company Medtronic	**1**	We believe that the provisional recommendation is reasonable and reflects the current evidence base. When long-term data becomes available we will inform the Institute and request a review of the guidance.	Thank you for your comment.
2	Consultee 1 Medical devices company Medtronic	**2.1**	No comments to be added.	Noted.
3	Consultee 1 Medical devices company Medtronic	**2.2**	No comments to be added.	Noted.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
4	Consultee 1 Medical devices company Medtronic	**2.3 and 2.4**	We have identified one additional study which should have been identified under the inclusion criteria for this IPG. We believe this should be further considered and attach it for your review: “Minimally invasive off-pump video-assisted endoscopic surgical pulmonary vein isolation using bipolar radiofrequency ablation” Piotr Suwalski, Grzegorz Suwalski, Rados Wilimski, Janusz Kochanowski, Piotr Scis, Hanna Gaca, Zbigniew Popiel, Julita Smolarska, Kazimierz Suwalski Â Department of Cardiac Surgery, Medical University, Warsaw, Poland. Kardiologia Polska 2007 65: 4 Key messages/design summary: -Report on the feasibility and early results of the first Polish experience with a novel technique of minimally invasive video-assisted beating heart bilateral surgical ablation for lone paroxysmal AF using irrigated bipolar radiofrequency technique -Patients with highly symptomatic paroxysmal AF, resistant to pharmacological treatment, underwent video-assisted beating heart bilateral pulmonary vein isolation using irrigated bipolar radiofrequency combined with vein of Marshall dissection and left atrial appendage closure.	Thank you for your comment. This study refers to thoracoscopic RF ablation (not percutaneous) for atrial fibrillation on which NICE published guidance in January 2009 (IPG286). The study was included in the overview for IP286, which is available on NICE’s website.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

Atrial fibrillation is a condition that affects the heart, causing an irregular heartbeat. It increases the risk of blood clots in the heart and stroke. Electrical impulses (originating from the atria, the small chambers of the heart) control the heartbeat. In atrial fibrillation these impulses become disorganised, so that the heart beats irregularly and too quickly. When this happens, the heart cannot efficiently pump blood around the body. This may cause symptoms such as palpitations, chest pain, shortness of breath, dizziness and fainting. In percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation, selected areas of the heart are destroyed using heat, with the aim of preventing the abnormal electrical impulses responsible for atrial fibrillation. The procedure is carried out through a special catheter which is inserted into the lower chest area and guided to the outer part of the heart.

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 atrial fibrillation

Specialty societies

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

- Heart Rhythm UK

Description

Indications and current treatment

Atrial fibrillation (AF) is irregular and rapid beating of the atria. It is the most common type of cardiac arrhythmia and the incidence increases markedly with age.

AF can be classified as paroxysmal, persistent or permanent. Paroxysmal AF is characterised by self-terminating and relapsing episodes usually lasting less than 48 hours that are often initiated by focal triggers within or near the orifice of the pulmonary veins. It is most common among middle-aged people. Persistent AF is characterised by episodes typically lasting longer than 7 days and is unlikely to resolve without treatment. Restoration of the normal rhythm can be achieved with treatment; however, episodes tend to recur. In permanent AF, restoration of the normal rhythm has either failed or not been attempted (as clinically judged futile). It is usually associated with structural and/or ischaemic heart disease and is most common in older people.

Patients with AF may be asymptomatic or have symptoms such as fatigue, palpitations, chest pain, shortness of breath, dizziness and fainting. There is an increased risk of death and stroke or other thromboembolic events.

Drug therapy for AF has two different aims. First, anticoagulation medication is used to prevent stroke and thromboembolism. Second, medication can be used either to help maintain a normal rhythm following successful cardioversion (‘rhythm control therapy’) or to help reduce the heart rate (‘rate control therapy’).

Interventional treatments are indicated when drug therapy is either not tolerated or ineffective. An interventional approach can involve surgical or endovascular ablative procedures which aim to isolate or destroy the atrial areas responsible for the generation of AF (pulmonary vein isolation and trigger focus ablation). The Cox maze procedure involves cutting and resewing the atrium with the aim of modifying the electrical properties of the atria. Radiofrequency ablation is now more commonly used to achieve this aim.

Percutaneous ablation for AF is usually performed with an intravascular approach to the inside (endocardial surface) of the atrium. The present procedure has been proposed as a means of treating AF in patients in whom an endocardial approach has been unsuccessful (failure to eliminate AF or recurrence of AF) or in whom there is an increased risk associated with a standard procedure (higher risk of trans-septal puncture or subsequent pulmonary vein stenosis). The rationale is that the use of additional energy from the outside of the heart (epicardial surface) provides an adjunctive means to ensure successful ablation in these difficult cases.

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. To identify the location of the needle tip, a small amount of contrast medium may be injected and visualisation of the contrast medium around the cardiac silhouette indicates that the needle has 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 (along a line starting at the junction between the left atrial roof and right superior pulmonary vein and ending at the mitral isthmus).

During the procedure, catheter position is monitored with a 3D 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).

Efficacy

This overview is based on six patients, from one case series of five patients and one case report.

In the case series of five patients, four patients had percutaneous epicardial catheter radiofrequency ablation after previous failed procedures of endocardial ablation. These patients were AF free and without any antiarrhythmic medication at 2, 6, 13 and 15 months' follow-up (method of assessing AF not reported). In the fifth patient, epicardial ablation was done immediately after failed endocardial ablation. The patient was in sinus rhythm with antiarrhythmic medication at 4 months' follow-up[1].

A case report described a patient who had persistent AF despite amiodarone and in whom a pacemaker had been implanted for sinus pauses. The procedure was successful and the patient remained in sinus rhythm one month post-operatively[2].

Safety

In the case series of five patients, one case of haemopericardium developed during the percutaneous epicardial puncture which was successfully drained. In another patient, a tachycardia originating from the left inferior pulmonary vein was observed during the procedure but this was successfully terminated with further epicardial and endocardial energy delivery[3].

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 27 June 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

Characteristic	Criteria
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 atrial fibrillation.
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.

Interventional procedures

- High-intensity focused ultrasound for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 184 (2006). Available from www.nice.org.uk/IPG184
- Percutaneous radiofrequency catheter ablation for atrial fibrillation. NICE interventional procedures guidance 168 (2006). Available from www.nice.org.uk/IPG168
- Cryoablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 123 (2005). Available from www.nice.org.uk/IPG123
- Microwave ablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 122 (2005). Available from www.nice.org.uk/IPG122
- Radiofrequency ablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 121 (2005). Available from www.nice.org.uk/IPG121

Clinical guidelines

- Atrial fibrillation. NICE clinical guidelines 36 (2006). Available from www.nice.org.uk/CG36

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

Abbreviations used: AF, atrial fibrillation; PV, pulmonary vein

Study details	Key efficacy findings	Key safety findings	Comments
Pak et al. (2007)[4] Study type: **case series** Country: Korea Study period: not stated Study population: patients with persistent (n = 4) or permanent (n =1) AF *'Redo' ablation procedures for persistent AF (n = 4:* one patient had endocardial catheter ablation for persistent AF (plus left atrial antral ablation with electrical isolation of all four pulmonary veins and cavotricuspid isthmus block) 6 months previously. The AF returned and become highly symptomatic. One patient had endocardial ablation for persistent AF 10 months previously. The AF became paroxysmal and the procedure was carried out because of a risk of PV stenosis. In the other two patients PV potentials had recurred during the endocardial ablation and they had PV stenosis. Epicardial ablation was done on average 22 months (± 18 months) after endocardial ablation. *De novo ablation of permanent AF (n = 1)*: the patient had had two failed external cardioversions. Despite creating an endocardial ablation line during the current procedure AF recurred repeatedly immediately after cardioversion so epicardial ablation was attempted. n = **5** Age: 49 years (mean) Sex: 100% male Inclusion criteria: not stated Technique: left atrial linear ablation from the roof to the perimitral isthmus, or localised ablation at the junction between the left atrial appendage and left pulmonary veins or ligament of Marshall, using an open irrigation tip catheter. Follow-up: **8 months (mean ± 6.3 months)** Conflict of interest: not stated	***Freedom from AF at last follow-up*** (Method of assessing AF not reported) The four patients for whom this was a redo procedure were AF free and without any antiarrhythmic medication for 2, 6, 13 and 15 months of follow-up. The patient for whom this was the first ablation procedure was in sinus rhythm with antiarrhythmic medication (200 mg amidarone) for 4 months of follow-up.	***Complications*** In one patient a haemopericardium developed during the percutaneous epicardial puncture. However, the ablation procedure took less than 10 minutes and the haemopericardium was successfully drained. In one patient, a PV tachycardia continued from the left inferior PV so more energy was delivered both epicardially and endocardially and the PV tachycardia was eliminated.	

Abbreviations used: AF, atrial fibrillation; PV, pulmonary vein			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Reddy et al. (2003)[5] Study type: **case report** Country: USA Study period: not stated Study population: one patient with persistent AF despite treatment with antiarrhythmic medication. The patient had had two failed electrical cardioversions within the previous 12 months. n = **1** Age: 55 years Sex: male Technique: combined endocardial and epicardial ablation using a percutaneous subxiphoid puncture approach to the pericardial space. Epicardial radiofrequency ablation was performed immediately after failed endocardial irrigated radiofrequency ablation (endocardial ablation was unable to eliminate a residual electrical breakthrough across an encircling lesion set and failed to achieve extraostial pulmonary vein isolation). The radiofrequency ablation catheter was moved to the epicardial aspect of the breakthrough site. Standard ablation isolated the left-sided lesion set within seconds and entrance block was confirmed. The right-sided lesion set was completed by endocardial ablation alone. Follow-up: **not stated** Conflict of interest: not stated	Freedom from AF The patient was well and without symptoms at a 1-month postoperative visit (the patient reported having no symptoms of fatigue or syncope before the procedure but did report presyncopal spells).	No safety outcomes were reported.	

Validity and generalisability of the studies

- The case report described a combined endocardial and epicardial approach.
- In the case series, four patients had epicardial ablation after other failed ablation procedures. One patient had combined endocardial and epicardial ablation as the first interventional procedure for AF.
- In both studies in table 2, it is not clear how AF was assessed during follow-up.

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 Derick Todd (Heart Rhythm UK).

- One Specialist Adviser provided the same advice for both this procedure (for AF) and the same procedure for ventricular tachycardia (IP709). He stated that he regularly performs an epicardial approach catheter ablation in cases where an endocardial approach is not successful. The other Specialist Adviser had never performed the procedure.
- One Specialist Adviser thought that the procedure was established practice and had no comparator. The other thought that it was novel and that the comparator was endocardial or thoracoscopic AF ablation.
- The Advisers thought 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 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 thought that the key efficacy outcome was freedom from AF.
- One Adviser commented that audit would not be meaningful or possible because it is such a rare procedure.
- One Adviser commented that there was uncertainty about the long-term safety of this procedure. He thought that there was also uncertainty about efficacy of the procedure because of the small number of cases that have been reported in the literature.
- One Adviser thought that formal training in the procedure should be recommended. The other thought that it can safely be performed in an electrophysiology laboratory where endocardial ablation is performed and that training and experience in pericardial puncture is necessary.

Issues for consideration by IPAC

- Consider alternative titles: Non-surgical transthoracic epicardial radiofrequency ablation for AF or Percutaneous (non-surgical) epicardial catheter radiofrequency ablation for AF.
- The evidence base is very small.
- There are only two Specialist Advisers.

References

1. Pak HN, Hwang C, Lim HE et al. (2007) Hybrid epicardial and endocardial ablation of persistent or permanent atrial fibrillation: a new approach for difficult cases. Journal of Cardiovascular Electrophysiology 18: 917–23.

2. Reddy VY, Neuzil P, Ruskin JN (2003) Extra-ostial pulmonary venous isolation: use of epicardial ablation to eliminate a point of conduction breakthrough. Journal of Cardiovascular Electrophysiology 14: 663–6.

Appendix A: Additional papers on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

There were no additional papers identified.

Appendix B: Related NICE guidance for percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

Guidance	Recommendations
Interventional procedures	**High-intensity focused ultrasound for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 184 (2006).** 1.1. Current evidence on the safety and efficacy of high-intensity focused ultrasound (HIFU) for atrial fibrillation in association with other cardiac surgery is insufficient for this procedure to be used without special arrangements for consent and for audit or research. 1.2. Clinicians wishing to undertake HIFU for atrial fibrillation in association with other cardiac surgery should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG184publicinfo). • Audit and review clinical outcomes of all patients undergoing HIFU for atrial fibrillation in association with other cardiac surgery. 1.3. Patient selection and follow-up should be carried out by a multidisciplinary team. Cardiac surgeons undertaking this procedure should have specific training in the use of high-intensity focused ultrasound equipment. 1.4. Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence. **Percutaneous radiofrequency catheter ablation for atrial fibrillation. NICE interventional procedures guidance 168 (2006).** 1.1. Current evidence on the safety and efficacy of percutaneous radiofrequency ablation for atrial fibrillation appears adequate to support the use of this procedure in appropriately selected patients (see section 2.1.4) provided that normal arrangements are in place for audit and clinical governance. 1.2. Clinicians should ensure that patients fully understand the potential complications, the likelihood of success and the risk of recurrent atrial fibrillation associated with this procedure. In addition, use of the Institute's Information for the public is recommended (available from www.nice.org.uk/IPG168publicinfo). 1.3. This procedure should only be performed in specialist units and

	with arrangements for cardiac surgical support in the event of complications. 1.4. This procedure should only be performed by cardiologists with extensive experience of other types of ablation procedures. 1.5. The Department of Health runs the Central Cardiac Audit Database (CCAD), and clinicians are encouraged to enter all patients undergoing percutaneous radiofrequency ablation for atrial fibrillation onto this database (www.ccad.org.uk). **Cryoablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 123 (2005).** 1.1. Current evidence on the safety and efficacy of cryoablation for atrial fibrillation in association with other cardiac surgery appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2. Patient selection and follow-up should be carried out by a multidisciplinary team. Cardiac surgeons undertaking this procedure should have specific training in the use of cryoablation equipment. **Microwave ablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 122 (2005).** 1.1. Current evidence on the safety and efficacy of microwave ablation for atrial fibrillation in association with other cardiac surgery appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2. Patient selection and follow-up should be carried out by a multidisciplinary team. Cardiac surgeons undertaking this procedure should have specific training in the use of microwave energy equipment. **Radiofrequency ablation for atrial fibrillation in association with other cardiac surgery. NICE interventional procedures guidance 121 (2005).** 1.1. Current evidence on the safety and efficacy of radiofrequency ablation (RFA) for atrial fibrillation in association with other cardiac surgery appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2. Patient selection and follow-up should be carried out by a multidisciplinary team. Cardiac surgeons undertaking this procedure should have specific training in the use of radiofrequency equipment.

Appendix C: Literature search for percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

Source	Date searched	Title, year and link
Notification and specialist advisors papers	20 June 2008	Pak HN et al. (2007) Hybrid epicardial and endocardial ablation of persistent or permanent atrial fibrillation: a new approach for difficult cases. Journal of Cardiovascular Electrophysiology 18: 917–23.
FDA (MAUDE database)	27 June 2008	Nothing found
ASERNIP	20 June 2008	Systematic review of intraoperative ablation for the treatment of atrial fibrillation. July 2004
ANZHSN	20 June 2008	Nothing found
Cochrane reviews (CDSR)	27 June 2008	3
Conference websites	24 June 2008	Nothing found
General Internet search	24 June 2008	Nothing found

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Surgical Procedures, Minimally Invasive/ (9245)
2	(surgic$ procedur$ adj3 minimal$ invasiv$).tw. (262)
3	percutan$.tw. (66525)
4	epicardial$.tw. (9343)
5	or/1-4 (83910)
6	exp Electrocoagulation/ (20731)
7	electrocoag$.tw. (1982)
8	RFA.tw. (1386)
9	RFCA.tw. (152)
10	((radio$ or cathet$) adj3 (ablat$ or remov$ or eradicat$ or destruct$ or cut$)).tw. (15372)
11	or/6-10 (29955)
12	exp Atrial Fibrillation/ (21836)

13	(atrial$ adj3 fibrill$).tw. (21882)
14	AF.tw. (11053)
15	(auricul$ adj3 fibrill$).tw. (766)
16	or/12-15 (34558)
17	5 and 11 and 16 (262)
18	Animals/ (4287246)
19	Humans/ (10480715)
20	18 not (18 and 19) (3227844)
21	17 not 20 (224)