NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

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. When this happens, the heart cannot efficiently pump blood around the body. This may cause symptoms such as palpitations, chest pain or discomfort, shortness of breath, dizziness and fainting. Atrial fibrillation increases the risk of blood clots and stroke. In thoracoscopic radiofrequency ablation, selected areas of the heart are destroyed using heat, with the aim of preventing the occurrence or conduction of abnormal electrical activity. The procedure is done through small incisions in the chest and using a camera.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 May 2008.

Procedure name

- Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

Specialty societies

- Society of Cardiothoracic Surgeons of Great Britain and Ireland
- British Cardiovascular Interventional 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 <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 seven days and is unlikely to resolve without treatment. Restoration of normal rhythm can be achieved with treatment, however episodes tend to recur. Permanent AF is when restoration of normal rhythm has either failed or has not been attempted (as clinically judged futile). It is usually associated with structural heart disease and is most common in older people.

Patients with AF may be asymptomatic or have symptoms such as fatigue, palpitations, chest pain or discomfort, 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. Firstly, anticoagulation medication is used to prevent stroke and thromboembolism. Secondly, medication can be used to either help maintain a normal rhythm (‘rhythm control therapy’) or to help reduce the heart rate in response to AF (‘rate control therapy’).

Interventional treatments are indicated when drug therapy is either not tolerated or is ineffective. An interventional approach may involve surgical or electro-physiological ablative procedures which aim to isolate or destroy the atrial areas responsible for the generation of AF (pulmonary vein isolation and trigger focus ablation) or its conduction to the rest of the heart (AV nodal ablation and pace). Modification of the electrical character of the atria is the aim of the Cox-Maze procedure (originally made by cutting and re-sewing the atrium and now most commonly with radiofrequency ablation).

What the procedure involves

Thoracoscopic epicardial radiofrequency ablation is carried out under general anaesthesia through two or more small incisions in the chest wall into which surgical instruments and a thoracoscope (camera) are introduced.

The right lung is deflated and the right pulmonary veins are usually accessed first. Blunt dissection is used to enter the oblique sinus beneath the right pulmonary veins. The endoscopic dissector is exchanged for a catheter through which a bipolar radiofrequency clamp is inserted and positioned on

the atrium. Bipolar radiofrequency energy is applied to create full thickness atrial wall ablation in areas of the myocardium around the pulmonary veins, with the aim of electrically isolating these areas from the rest of the atrial myocardium. Intraoperative electrophysiological study may be used to check whether electrical isolation has been successful. The procedure is repeated on the left pulmonary veins.

The left atrial appendage may be excised with a surgical stapler at the same time as ablation of the left pulmonary vein in order to minimise the risk of future atrial thrombus and thromboembolic events.

Efficacy

Sinus rhythm

In two case series, one of 70 patients with paroxysmal or persistent AF and one of 26 patients with paroxysmal or permanent AF who were treated with thoracoscopic epicardial radiofrequency ablation, 93% (65/70) and 81% (21/26) had normal sinus rhythm at 6-month follow-up [1,2].

Two case series of 22 and 20 patients with paroxysmal or persistent AF reported that 91% (20/22) and 90% (18/20), respectively, had normal sinus rhythm at their last follow-up (mean: 18 months and 17 months respectively). One patient in each of the 2 case series had atrial flutter 2 to 7 months postoperatively, requiring an additional ablative procedure using a percutaneous (endovascular) approach [3,4].

In a case series of 27 patients, only 23 were followed up for at least 3 months. Of these patients, 91% (21/23) were free of AF (mean follow-up: 3 months), and 2 patients had episodes of AF on outpatient telemetry monitoring 5 and 6 months (respectively) after the procedure [5].

A case series of 6 patients with paroxysmal AF reported that all patients were admitted to the intensive care unit in sinus rhythm. Four patients had at least one episode of AF in the early postoperative period and required additional treatment (electrical cardioversion or amiodarone infusion). Five patients were in normal sinus rhythm at follow-up of between 3 and 6 months [6].

One case reported on a patient with permanent AF who underwent thoracoscopic epicardial radiofrequency ablation and was discharged in normal sinus rhythm. Medication was discontinued at 3 months and the patient remained in sinus rhythm for 24 months postoperatively [7].

Anti-arrhythmic medication

In the case series of 70 patients, the percentages of patients with paroxysmal AF (n = 42) who continued to use anti-arrhythmic medication at 3, 6 and 12 months was 43%, 23% and 14%, respectively (raw data not reported). Of the patients with persistent AF (n = 28), 61%, 26% and 38% of patients (respectively) used anti-arrhythmic medication at the same time points [1].

In two case series of 27 and 26 patients, 65% (15 of 23 the patients who had at least 3 months' follow-up) and 57% (12 of the 21 patients who were in sinus rhythm at 6 months' follow-up) respectively were no longer using anti-arrhythmic medication at follow-up [5,2].

The case series of 22 and 20 patients reported that 91% (20/22) and 85% (17/20) were not using anti-arrhythmic medication at their last follow-up (mean: 18 months and 17 months, respectively) [3,4].

Anti-coagulation medication

In the case series of 22 patients, 91% (20/22) were not using anti-coagulation medication at last follow-up (mean: 18 months) [3].

Safety

The case series of 70 patients reported two major complications. One patient required reoperation 10 days postoperatively due to fistula formation between the oesophagus and the left atrium. Another patient required angioplasty and stent insertion due to stenosis of the coronary artery 6 weeks after the procedure [1].

The case series of 27 patients reported one case each of right pneumothorax (which resolved without treatment), right forearm phlebitis (no further information stated), and suspected pericarditis (which resolved with oral steroid administration). In addition, a morbidly obese patient was readmitted to hospital both 3 and 7 months postoperatively due to AF, atrial flutter and congestive heart failure. The patient required direct current cardioversion and an additional electrophysiological procedure [5].

In the case series of 26 patients, one patient required aspiration of pleural effusion and another patient developed transient diaphragm paralysis which was reported to be 'not clinically significant' [2].

In the case series of 22 patients, a patient required an outpatient skin revision and another patient was rehospitalised for pulmonary embolism [3].

The case series of 20 patients reported bleeding complications in 3 patients (15%). One patient had intraoperative bleeding because of injury to the posterior left atrium; two patients required re-exploration for pneumothorax 1 and 4 days postoperatively [4].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to thoracoscopic epicardial microwave ablation for atrial fibrillation. Searches were conducted of the following databases, covering the period from their

commencement to 07/05/08: 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 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	Thoracoscopic epicardial 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.

List of studies included in the overview

This overview is based on approximately 172 patients from six case series and one case report.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

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 (HIFU) 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

Table 2 Summary of key efficacy and safety findings on thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

Abbreviations used: AF, atrial fibrillation;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kottkamp (2002) [1]
Study type: case series
Country: Germany
Study period: not stated
Study population: patients with drug-refractory paroxysmal (n = 42) or persistent (n = 28) AF.
n = 70
Age: 53 years
Sex: not stated

Inclusion criteria:
• AF for more than 2 years
• ‘highly symptomatic’ despite multiple anti-arrhythmic drug-treatment regimens
• ≥ 2 episodes per week lasting > 12 hours (paroxysmal AF)

Technique: thoracoscopic technique via a right anterolateral minithoracotomy.

Follow-up: 18 months (mean)

Conflict of interest: none stated</td>
<td>Sinus rhythm
<table>
<tr><th></th><th colspan="5">Normal sinus rhythm</th></tr>
<tr><th></th><th>Hospital discharge</th><th>6 weeks</th><th>3 months</th><th>6 months</th><th>12 months</th></tr>
<tr><td>Paroxysmal AF</td><td>95% (40/42)</td><td>90% (38/42)</td><td>93% (39/42)</td><td>93% (39/42)</td><td>97% (34/35)</td></tr>
<tr><td>Persistent AF</td><td>86% (24/28)</td><td>89% (25/28)</td><td>89% (25/28)</td><td>93% (26/28)</td><td>95% (18/19)</td></tr>
<tr><td>All patients</td><td>91% (64/70)</td><td>90% (63/70)</td><td>91% (64/70)</td><td>93% (65/70)</td><td>96% (52/54)</td></tr>
</table>
Differences between patients with persistent and paroxysmal AF were not statistically significant.

In 18/28 (64%) of patients with persistent AF, AF or atrial flutter occurred between the second and tenth postoperative day, compared with 16/42 (38%) of patients with paroxysmal AF (p < 0.005).

Medication
<table>
<tr><th></th><th colspan="5">Patients using anti-arrhythmic drugs</th></tr>
<tr><th></th><th>Hospital discharge</th><th>6 weeks</th><th>3 months</th><th>6 months</th><th>12 months</th></tr>
<tr><td>Paroxysmal AF</td><td>38% (16/42) *</td><td>45% *</td><td>43% *</td><td>23%</td><td>14%</td></tr>
<tr><td>Persistent AF</td><td>64% (18/28)</td><td>68%</td><td>61%</td><td>26%</td><td>38%</td></tr>
</table>
* P < 0.005 (persistent vs. paroxysmal AF).
Some raw data were not reported.</td>
<td>Mortality
No deaths during the complete follow-up period (6 months).

Complications: 6% (4/70)
• One patient developed neurologic and septicaemic symptoms. A fistula was found between the oesophagus and left atrium which required revision surgery 10 days after the procedure.
• One patient was found to have significant stenosis of the circumflex coronary artery 6 weeks after the procedure and required percutaneous transluminal coronary angioplasty and stent implantation.
• Two patients had minor bleeding complications (no further information stated).</td>
<td>All patients had complete follow-up to at least 6 months.</td>
</tr>
</table>

Abbreviations used: AF, atrial fibrillation;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Wolf (2005) [5] Study type: **case series** Country: USA Study period: Aug 2003 – Aug 2004 Study population: patients with drug-refractory, symptomatic paroxysmal (n = 18), permanent (n = 5) or persistent (n = 4) AF. n = **27** Age: 57 years (mean) Sex: 81% male Inclusion criteria: • age 18 to 80 years • drug-refractory AF or inability to tolerate anti-arrhythmic therapy (n = 25) or, • inability to tolerate anticoagulation therapy (n = 2) • left ventricular ejection fraction ≥ 30% • life expectancy ≥ 2 years • able to attend scheduled follow-up visits Technique: bilateral thoracoscopic, off-pump epicardial pulmonary vein isolation and exclusion of left atrial appendage. No heparin was used. Patients continued using anti-arrhythmic medication for 3 months postoperatively and were then weaned off as tolerated. Follow-up: **6 months (mean)** Conflict of interest: none stated	***Sinus rhythm*** *- of 23 patients who have minimum 3 months of follow-up data.* *- assessed by 12-lead electrocardiography (n = 10) or outpatient telemetry monitor (n = 11) (duration of telemetry not stated.)* • 91% (21/23) of patients were free of AF at 3 months and all are asymptomatic. • 2 patients had episodes of AF on outpatient telemetry monitoring at 5 and 6 months postoperatively (one of these patients had pre-operative paroxysmal AF and the other had permanent AF). ***Medication*** • 65% (15/23) of patients were off anti-arrhythmic medication at 3 months. • 26% (6/23) of patients were being weaned off medication at their 3-month visit. • 2 patients continued to received anti-arrhythmic medication (amiodarone and sotalol). ***Pulmonary vein stenosis*** • No occurrence of pulmonary vein stenosis was observed in 12 patients who had magnetic resonance imaging 3 to 6 months postoperatively.	***Mortality*** There were no perioperative or late deaths. ***Complications: 15% (4/27)*** • Right pneumothorax which resolved without treatment (n = 1). • Right forearm phlebitis (n =1) (no further information stated). • Suspected pericarditis which resolved after oral steroid administration (n =1). • A morbidly obese patient required two hospital readmissions with atrial fibrillation/flutter and congestive heart failure at 3 and 6.5 months, requiring direct current cardioversion and an additional electrophysiological procedure.	Outcomes for the 4 patients who did not have at least 3 months follow-up are not reported.

Abbreviations used: AF, atrial fibrillation;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>
Sagbas (2007) [2]
Study type: case series
Country: Turkey
Study period: April 2004 – Feb 2006
Study population: patients with drug-refractory lone permanent (n = 18) or paroxysmal (n = 8) AF.
n = 26
Age: 56 years
Sex: 62% male

Inclusion criteria:
• under 70 years of age
• highly symptomatic AF that interfered with daily life
• no evidence of accompanying cardiac disease
• unable to tolerate anti-arrhythmic or anticoagulation therapy

Exclusion criteria:
• detected thrombus in left atrial appendage
• left ventricular ejection fraction < 30%
• sick sinus syndrome
• several pleural adhesions

Technique: bilateral thoracoscopic, off-pump epicardial radiofrequency ablation of both pulmonary veins. Some patients underwent endoscopic stapling of the left atrial appendage (n = 16). Anti-arrhythmic medication was discontinued for patients who were in sinus rhythm 6 months postoperatively.

Follow-up: 8 months (mean)
Conflict of interest: One author has a financial relationship with a relevant manufacturer (Medtronic).
</td>
<td>
Sinus rhythm
- assessed by surface electrocardiography and 24-hour Holter monitoring
<table>
<tr><th></th><th colspan="3">Normal sinus rhythm</th></tr>
<tr><th></th><th>Immediately after the procedure</th><th>3 months</th><th>6 months</th></tr>
<tr><td>Permanent AF</td><td>55% (10/18)</td><td>67% (12/18)</td><td>72% (13/18)</td></tr>
<tr><td>Paroxysmal AF</td><td>100% (8/8) *</td><td>100% (8/8)</td><td>100% (8/8)</td></tr>
<tr><td>All patients</td><td>69% (18/26)</td><td>77% (20/26)</td><td>81% (21/26)</td></tr>
</table>
* 2 patients with paroxysmal AF were in AF at the time of the procedure.

Medication
- of 21 patients who were in sinus rhythm at 6 months
• 57% (12/21) of patients were not using anti-arrhythmic medication.
• 43% (9/21) of patients continued to use medication (warfarin) because they had other risk factors for stroke.

Pulmonary vein stenosis
• No pulmonary vein stenosis was detected by magnetic resonance imaging at 3 and 6 months.
</td>
<td>
Mortality
There were no hospital deaths.

Complications:
• one patient required a thoracic puncture for left-sided pleural effusion.
• one patient had transient diaphragm paralysis (‘which was not clinically significant’).
</td>
<td></td>
</tr>
</table>

Abbreviations used: AF, atrial fibrillation;

Study details	Key efficacy findings	Key safety findings	Comments
Wudel (2008) [3] Study type: **case series** Country: USA Study period: April 2004 – July 2005 Study population: consecutive patients with refractory, symptomatic paroxysmal (n = 14) or persistent (n = 8) AF. n = **22** Age: 63 years Sex: 68% male Inclusion criteria: • drug-refractory AF (n = 21) and/or • inability to tolerate anti-arrhythmic therapy (n = 7) • and/or failed percutaneous (endovascular) catheter based ablation (n = 1) Exclusion criteria: • greater than mild mitral regurgitation • severe systolic dysfunction • untreated coronary disease • morbid obesity • significant enlarged left atrium Technique: bilateral thoracoscopic pulmonary vein isolation. 21 patients also underwent stapling of the left atrial appendage. Anticoagulation and anti-arrhythmic drugs were discontinued at the discretion of the referring cardiologist. Follow-up: **18 months (mean)** Conflict of interest: none stated	***Sinus rhythm*** *- assessed by electrocardiography and 24-hour Holter monitoring at last follow-up (mean 18 months)* • 91% (20/22) of patients had normal sinus rhythm, were asymptomatic, had no palpitations and felt well. • 9% (2/22) of patients had 4 beats each of paroxysmal atrial tachycardia. • 9% (2/22) of patients (who remained on anti-arrhythmic medication) had sinus rhythm with periods of AF for durations of 30 seconds to 25 minutes respectively. Neither patient showed evidence of atrial flutter. ***Medication*** *- at last follow-up* • 91% (20/22) of patients (that is, all asymptomatic patients) had not used anti-arrhythmic medication for at least 6 months (mean: 13 months, range 6 – 24 months). • 91% (20/22) of patients were not using warfarin at last follow-up. • 9% (2/22) of patients had fewer complaints of AF postoperatively than pre-operatively but remained on anti-arrhythmic medication and warfarin. ***Further treatment*** One patient had typical atrial flutter 7 months postoperatively requiring right-sided catheter ablation.	***Mortality*** There were no hospital deaths. ***Complications: 9% (2/22)*** • 1 patient required rehospitalisation for pulmonary embolism (n =1). • 1 female patient required outpatient incision revision (n = 1) (no further formation stated).	It was not possible for a patient to undergo left atrial appendage excision because of adhesions secondary to a previous catheter ablation. All patients were followed-up for at least 1 year.

Abbreviations used: AF, atrial fibrillation;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Matsutani (2008) [4] Study type: **case series** Country: Japan Study period: Jan 2006–Jan 2007 Study population: patients with refractory paroxysmal (n = 16) or persistent (n = 4) AF. Mean duration of AF despite anti-arrhythmic medication: 76 months n = **20** Age: 57 years Sex: 75% male Inclusion criteria: not stated Exclusion criteria: not stated Technique: thoracoscopic 'mini-maze' including bilateral pulmonary vein isolation and ablation of the epicardial ganglionated plexi and excision of the left atrial appendage. Patients remained on anti-arrhythmic medication for approximately 3 months postoperatively and were weaned from medication as tolerated. Follow-up: **17 months (mean)** Conflict of interest: none stated	***Sinus rhythm*** *- assessed by 24-hour Holter electrocardiography at last follow-up (mean 17 months)* • 90% (18/20) of patients had normal sinus rhythm • 10% (2/20) of patients had continued episodes of paroxysmal AF ***Medication*** *- assessed at last follow-up* • 85% (17/20) of patients were successfully weaned from anti-arrhythmic medication ***Further treatment*** One patient (20%) required re-intervention (percutaneous catheter ablation to create an isthmus lesion) for persistent typical right-sided atrial flutter which developed 2 months after discharge).	***Mortality*** There were perioperative or late deaths. ***Complications: 15% (3/20)*** There were three episodes of bleeding: • One case occurred intraoperatively, resulted from injury to the posterior left atrium, and required conversion to sternotomy with cardiopulmonary bypass via the femoral vessels to control bleeding. The heart was kept beating and the procedure was completed. • Two patients required subsequent re-exploration for pneumothorax: one occurred 1 day postoperatively from a presumed trochar site that was not bleeding at the time of thoracoscopic evacuation; one occurred on postoperative day 4 when a chest tube was removed, which led to a haemothorax requiring evacuation. The patient had supratherapeutic anticoagulation with heparin and coumadin.	

Abbreviations used: AF, atrial fibrillation;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Suwalski (2007) [6] Study type: **case series** Country: Poland Study period: Feb 2006 – Dec 2006 Study population: patients with highly symptomatic, drug-refractory, paroxysmal AF. n = **6** Age: 63 years Sex: 33% male Technique: thoracoscopic, beating heart, bilateral pulmonary vein isolation using irrigated bipolar radiofrequency ablation combined with vein of Marshall dissection and left atrial appendage closure. Follow-up: **at least 3 months (n = 4)** Conflict of interest: none stated	***Sinus rhythm*** *- assessed by electrocardiography and 24-hour Holter monitoring at 3 (n = 4) and 6 months (n = 1)* • 5 (of 6) patients who were followed up at 3 (n = 4) or 6 months (n = 1) were in stable sinus rhythm. • All 6 patients were admitted to the intensive care unit in sinus rhythm • At least one episode of AF was observed in 4 patients in the early postoperative period: - in 3 of these patients electrical cardioversion was performed - in 1 patient sinus rhythm was restored following low-dose amiodarone infusion - all 4 patients were in sinus rhythm at discharge from hospital. ***Medication*** • The 4 patients who had episodes of AF postoperatively took oral amiodarone for 3 months after the procedure.	There were no deaths or complications.	

Abbreviations used: AF, atrial fibrillation;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Grandmougin (2007) [7] Study type: **case report** Country: France Study period: not stated Study population: patient with lone permanent AF. n = **1** Age: 68 years Sex: female Patient characteristics: The patient was referred with a severe haemothorax attributed to over-anticoagulation, with warfain prescribed for AF diagnosed 5 years earlier and refractory to 5 direct current cardioversion attempts and amiodarone treatment. The patient was also treated with chemotherapy for lymphoma. Technique: thoracoscopic radiofrequency epicardial pulmonary vein isolation. Follow-up: **at least 3 months (n = 4)** Conflict of interest: none stated	The patient was discharged in sinus rhythm. At 3 months, a stable sinus rhythm was assessed with Holter monitoring (duration of monitoring not stated) and amiodarone was discontinued. At 24 months, the patient remained in sinus rhythm with reportedly efficient atrial contraction and no thrombus within the left atrial cavity.	There were no adverse events reported.	

Validity and generalisability of the studies

- Studies included a mix of patients with paroxysmal, persistent and permanent AF.
- The majority of the patients in the reviewed studies were in their late 50s or early 60s.

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.

Peter O'Callaghan, Mr M Dalrymple-Hay, Steven Hunter, Paul Ridley (Society for Cardiothoracic Surgeons of Great Britain and Ireland).

- Three Specialist Advisers had never performed this procedure and one had. One Adviser thought it was a minor variation of an established procedure and the other two thought it was novel.
- Specialist Advisers thought that comparators included open (surgical) epicardial ablation, the Cox-Maze III procedure and percutaneous catheter-based ablation.

Safety

- Theoretical and anecdotal adverse events included: injury to the heart or adjacent structures (including the oesphagus and phrenic nerve), bleeding from the atrial appendage, wound infection, coronary artery occlusion, stroke, pulmonary vein stenosis, increased risk of arrhythmias in the first few months postoperatively, and risks associated with general anesthesia.
- One Specialist Adviser stated that there were no uncertainties about the safety or efficacy of this procedure. Another thought that better results would be expected in young patients with small atrial and paroxysmal rather than permanent AF.

Efficacy

- Specialist Advisers thought that key efficacy outcomes included: freedom from AF or any sinus rhythm tachycardia, reduced use of anti-arrhythmic medication, decreased burden of AF for patients with intermittent AF, and pulmonary vein isolation.
- A Specialist Adviser commented that this procedure has the advantage over catheter-based endocardial procedures because the left atrial appendage can be closed epicardially which should decrease rate of stroke.
- A Specialist Adviser stated that uncertainties about the procedure were around: whether the procedure can effectively isolate the pulmonary veins electrically, variability in practice and use of different energy sources from centre to centre and the lack of standardised method of defining success or

long-term outcomes. Another Adviser thought long-term efficacy was uncertain because the procedure is new.

Training

- Advisers thought that surgeons should be competent in thoracoscopy and cardiac surgery.

- A Specialist Adviser thought that supervision should initially be by an experienced operator and that video-assisted thoracoscopy skills should already have been acquired.

Other

- Two Advisers thought the potential impact of the procedure in the NHS was minor, one thought it was moderate and one thought it was major.

Issues for consideration by IPAC

- The majority of AF patients have chronic, permanent AF because of underlying cardiac conditions (vascular or valvular). This is a very large group of patients who are under-represented in the available evidence that was included in the overview.
- Studies where epicardial radiofrequency ablation was performed in combination with other thoracoscopic cardiac surgery (such as mitral valve surgery) were not included in this overview.

References

1. Kottkamp H, Hindricks G, Autschbach R. et al. (2002) Specific linear left atrial lesions in atrial fibrillation: intraoperative radiofrequency ablation using minimally invasive surgical techniques. Journal of the American College of Cardiology 40 (3): 475–480.

2. Sagbas E, Akpinar B, Sanisoglu I. et al. (2007) Video-assisted bilateral epicardial pulmonary vein isolation for the treatment of lone atrial fibrillation. Annals of Thoracic Surgery 83 (5): 1724–1730.

3. Wudel JH, Chaudhuri P, and Hiller JJ. (2008) Video-assisted epicardial ablation and left atrial appendage exclusion for atrial fibrillation: extended follow-up. Annals of Thoracic Surgery 85 (1): 34–38.

4. Matsutani (2008)

5. Wolf RK, Schneeberger EW, Osterday R. et al. (2005) Video-assisted bilateral pulmonary vein isolation and left atrial appendage exclusion for atrial fibrillation. Journal of Thoracic and Cardiovascular Surgery 130 (3): 797–802.

6. Suwalski P, Suwalski G., Wilimski R. et al. (2007) Minimally invasive off-pump video-assisted endoscopic surgical pulmonary vein isolation using bipolar radiofrequency ablation – preliminary report. Kardiologia Polska 65 (4): 370–374.

7. Grandmougin D, Tiffet O. (2007) Video-assisted thoracoscopic epicardial ablation of left pulmonary veins for lone permanent atrial fibrillation. Interactive Cardiovascular and Thoracic Surgery 6 (1): 136–138.

Appendix A: Additional papers on thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

There were no additional papers identified.

Appendix B: Related NICE guidance for thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

Guidance	Recommendations
Interventional procedures	**High intensity focused ultrasound (HIFU) 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 thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	06/05/2008	Issue 2, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	06/05/2008	-
HTA database (CRD website)	06/05/2008	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	06/05/2008	Issue 2, 2008
MEDLINE (Ovid)	06/05/2008	1950 to April Week 4 2008
MEDLINE In-Process (Ovid)	06/05/2008	May 05, 2008
EMBASE (Ovid)	06/05/2008	1980 to 2008 Week 18
CINAHL (Dialog DataStar)	06/05/2008	-
BLIC (Dialog DataStar)	07/05/2008	-
National Research Register (NRR) Archive	07/05/2008	-
UK Clinical Research Network (UKCRN) Portfolio Database	06/05/2008	-
Current Controlled Trials metaRegister of Controlled Trials - mRCT	06/05/2008	-
Clinicaltrials.gov	06/05/2008	-

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

1	exp Thoracoscopy/
2	Thoracoscopes/
3	Endoscopy/
4	Surgical Procedures, Minimally Invasive/
5	thoracoscop$.tw.
6	endoscop$.tw.
7	(surgic$ procedur$ adj3 Minimal$ invasiv$).tw.
8	or/1-7

9	Microwaves/
10	exp Ultrasonic Therapy/
11	(microwav$ adj3 (ablat$ or remove$ or eradicat$ or destruct$ or cut$)).tw.
12	(MV or MWA or MCT).tw.
13	(ultrason$ adj3 therap$).tw.
14	or/9-13
15	Catheter Ablation/
16	Radio Waves/
17	RFA.tw.
18	RF.tw.
19	radiofrequen$.tw.
20	((radio$ or cathet$) adj3 (ablat$ or remove$ or eradicat$ or destruct$ or cut$)).tw.
21	(radio$ adj3 waves$).tw.
22	or/15-21
23	Atrial Fibrillation/
24	(atrial$ adj3 fibrill$).tw.
25	AF.tw.
26	(AURICUL$ adj3 FIBRILL$).tw.
27	or/23-26
28	8 and (14 or 22) and 27
29	Animals/
30	Humans/
31	29 not (29 and 30)
32	28 not 31