# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

# Pulsed-field ablation for atrial fibrillation

Atrial fibrillation is irregular and rapid beating of the upper chambers of the heart (atria). It happens when the electrical impulses that control the heart beat become irregular. Symptoms include palpitations, dizziness, shortness of breath and fatigue. Complications can include stroke. In this procedure, pulses of electricity (pulsed-field) are used to specifically destroy the heart cells (ablation) that are causing irregular beats. The aim is to avoid damage to surrounding tissues such as the oesophagus and nerves while treating the atrial fibrillation.

NICE is looking at pulsed-field ablation for atrial fibrillation.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.



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NICE interventional procedures consultation document, February 2025

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 March 2025

Target date for publication of guidance: July 2025



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# 1 Draft recommendations

1.1 Use pulsed-field ablation as an option to treat atrial fibrillation with standard arrangements in place for clinical governance, consent and audit.

1.2 Healthcare professionals should enter details about everyone having pulsed-field ablation for atrial fibrillation onto a suitable registry. This should include details of patient selection, the technology used and longer-term outcomes.

### Why the committee made these recommendations

Evidence shows the procedure reduces atrial fibrillation and its symptoms, increases quality of life in the short term, and is safe. More data collection would be useful to guide patient selection and to see how well the procedure works to prevent long-term complications of atrial fibrillation, such as stroke.

# 2 The condition, current treatments, unmet need and procedure

## The condition

2.1 Atrial fibrillation is an irregular contraction of the upper chambers of the heart (atria) and often causes the heart to beat rapidly. This makes the heart less effective at moving blood from the upper to the lower chambers of the heart. Symptoms include palpitations, dizziness, shortness of breath, fatigue and chest pain. It can have a substantial effect on quality of life. Complications of atrial fibrillation include stroke and heart failure. Atrial fibrillation can be transient (paroxysmal), lasting longer than 30 seconds but only up to 7 days or it can be persistent, lasting more than 7 days.


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## Current treatments

2.2 Standard treatments for symptomatic atrial fibrillation include lifestyle modification, drug therapy and procedural interventions. The aim of treatment is to prevent complications like stroke and alleviate symptoms. Drug treatments include anticoagulants to reduce the risk of stroke, and antiarrhythmics to restore or maintain the normal heart rhythm or to slow the heart rate. When medications do not work or are unsuitable, other treatments such as catheter ablation procedures may be used. The current standard catheter ablation techniques are radiofrequency ablation (RFA) and cryoballoon ablation (CBA). Laser balloon ablation is rarely used in the NHS.

## Unmet need

2.3 Atrial fibrillation is the most common heart rhythm disorder, affecting about 2% of the adult population. The prevalence is likely increasing because it is associated with age, underlying heart disease, diabetes, obesity and hypertension, which are also increasing in prevalence in the UK population. If left untreated, it is a significant risk factor for stroke, other morbidities and mortality. When standard medications do not work or are unsuitable, catheter ablation procedures are commonly offered. Most catheter ablation methods use thermal energy, by either burning (in RFA) or freezing (in CBA) heart tissue that conducts the irregular electrical impulses. Thermal ablation carries a risk of damaging neighbouring tissues. Pulsed-field ablation (PFA) uses electrical instead of thermal energy. Heart cells are very sensitive to electrical energy. So, it may be able to target heart tissue more precisely than thermal ablation, which may reduce the risk of damaging surrounding tissues like the oesophagus, nerves, and blood vessels.



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### The procedure

2.4 PFA is a catheter ablation technique that uses electrical energy to destroy the heart cells that transmit abnormal electrical impulses. In the NHS, the procedure is usually done under general anaesthesia but deep sedation is often used in other countries. As in other catheter ablation procedures for atrial fibrillation, a catheter is inserted into the femoral vein and advanced into the left atrium through a trans-septal puncture. The PFA catheter delivers rapid, high-voltage pulsed electrical energy to the tissue it is applied to. This causes pores to form in myocardial cells so they die (irreversible electroporation). Most commonly, PFA is used for isolation of abnormal electrical activity transmitted through the pulmonary vein cells at the entrance to the left atrium. But it can be used on other structures such as the left atrial posterior wall. The aim is targeted destruction and scar formation in the tissue it is applied to, to disrupt the transmission of abnormal electrical impulses that cause atrial fibrillation while avoiding damage to surrounding tissues such as nerves and blood vessels.

## 3 Committee considerations

### The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 1 non-inferiority randomised controlled trial, 4 single-arm trials, an EU retrospective analysis of a prospective registry, a centre-level study done across 101 centres in the EU and Israel, a study that combined 2 single-arm trials, a prospective case series and a retrospective case series. It is presented in the summary of key evidence section in


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the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: return to normal sinus rhythm, recurrence of arrhythmia, improved quality of life, reintervention rate, and long-term outcomes including reduction in stroke.

3.3 The professional experts and the committee considered the key safety outcomes to be: injury to oesophagus or phrenic nerve, pericardial tamponade, perforation, effusion and bleeding.

3.4 Sixteen commentaries from people who have had this procedure and a submission from a patient organisation were discussed by the committee.

## Committee comments

3.5 There are different types of catheter and generators with varying amounts of evidence. The evidence may not be transferable between technologies because of their differences.

3.6 People may have to continue taking anticoagulation medication after the procedure.

3.7 Results may be different for paroxysmal atrial fibrillation and persistent atrial fibrillation.

3.8 The procedure may need to be repeated.

3.9 The procedure is most commonly done under general anaesthesia in the UK.

3.10 The procedure may be associated with less post-procedure discomfort than other types of ablation.



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