

Pulsed-field ablation for atrial fibrillation

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg806

Your responsibility

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

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

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

1 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 Clinicians should enter details about everyone having the procedure onto the National Institute for Cardiovascular Outcomes Research (NICOR) database and review local clinical 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 raises no major safety concerns. 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.

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 electric field energy instead of thermal energy. Heart cells are very sensitive to electric field 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.

The procedure

- 2.4 PFA is a catheter ablation technique that uses electric field 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 electric field energy to the tissue it is applied to. This causes pores to form in myocardial cells so they die (irreversible electroporation). PFA is currently used most for isolation of abnormal electrical activity transmitted through the pulmonary vein cells at the entrance to the left atrium. But it is also used on other structures such as the left atrial posterior wall and cavo-tricuspid isthmus. 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 19 sources, which was discussed by the committee. The prioritised evidence included 4 systematic reviews and meta-analyses, 2 non-inferiority randomised controlled trials, 5 single-arm trials, an EU retrospective analysis of a prospective registry, a UK nationwide 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, a prospective cohort study, a retrospective case series, and a case report. It is presented in the [summary of key evidence section in 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 damage to adjacent structures and less post-procedure discomfort than other types of ablation.
- 3.11 The committee was told that pulsed-field ablation targets heart tissue more specifically than thermal ablation.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).