



## Topic Exploration Report <sup>1</sup>

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number	TER547
Topic	Pulsed field ablation for atrial fibrillation
Summary of findings	<p>Atrial fibrillation is the most common heart rhythm disturbance in the UK, affecting approximately 1.4 million people. Currently, catheter ablation using thermal energy is used to treat atrial fibrillation in circumstances where drug treatment has not been effective or tolerated. Pulsed field ablation (PFA) may be a more effective alternative to thermal energy ablation for treating atrial fibrillation.</p> <p>Health Technology Wales identified one relevant piece of UK guidance, one systematic review and meta-analysis, two meta-analyses, a cost-comparison analysis, a prospective, single-arm multi-centre study and a randomized, single-blind non-inferiority trial. Results show that pulsed field ablation is associated with shorter procedure times and a lower incidence of adverse outcomes but may have higher fluoroscopy times compared to thermal energy ablation. Similarly, cost-comparison analysis concluded that pulsed field ablation may be as affordable for the NHS as standard practice cryoablation.</p> <p>Areas of uncertainty relate to whether the use of specific catheters affects the overall costs of performing PFA compared to thermal energy ablation, whether PFA is currently used in NHS Wales, and whether atrial fibrillation recurrence outcomes are lower for PFA compared to thermal energy ablation.</p>

<sup>1</sup> [Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg](#)  
Translation of published technical HTW documents from English into Welsh

## Introduction and aims

Atrial fibrillation is a heart rhythm disturbance that causes an irregular and abnormally fast heart rate. It is the most common heart rhythm disturbance in the UK, affecting approximately 1.4 million people. Catheter ablation is a procedure that targets arrhythmia by passing catheters through veins or arteries to the heart and using thermal energy (either radiofrequency or cryoablation) to destroy the heart muscle at the affected site, creating scar tissue. Catheter ablation is recommended when drug treatment has been unsuccessful or not tolerated.

Pulsed electrical field ablation (PEFA or PFA) is an alternative to thermal energy ablation, and may be a more effective technique for performing ablation for atrial fibrillation. PFA uses rapid, high-voltage pulsed electrical energy to induce cell death in the affected area of the heart, and may be more focused than thermal energy ablation, reducing the risk of damage to other areas of the heart. CENTAURI™ was identified by the topic proposer as a specific example of such a technology.

Health Technology Wales researchers searched for evidence on pulsed field ablation for atrial fibrillation.

## Evidence overview

### Guidance

HTW identified one potentially relevant piece of UK guidance.

NICE Guideline NG196 (2021) 'Atrial fibrillation: diagnosis and management' recommends that for left atrial ablation (1.7.19), if drug treatment is unsuccessful or otherwise unsuitable in people with paroxysmal or persistent atrial fibrillation, radiofrequency point-by-point ablation is used. If this is not suitable, then cryoballoon ablation or laser balloon ablation should be used.

1.7.19 'Left atrial ablation' states 'If drug treatment is unsuccessful, unsuitable, or not tolerated in people with symptomatic paroxysmal or persistent atrial fibrillation: consider radiofrequency point-by-point ablation or if radiofrequency point-by-point ablation is assessed as being unsuitable, consider cryoballoon ablation or laser balloon ablation. [2021]'

NICE are currently producing an IPG (interventional procedures guidance), GID-IPG10267, on pulsed field ablation, with publication expected in June 2025.

### Systematic Review

A systematic review and meta-analysis by Aldaas, et al (2024) compared the procedural efficiency, safety and efficacy of PFA and thermal energy ablation. Six studies were included, with data from 1012 participants. The review reported significantly shorter procedure times ( $p=0.0003$ ), but significantly longer fluoroscopy times ( $p=0.01$ ) for PFA compared to thermal energy sources. The review found no statistically significant differences in peri-procedural complications (RR 1.20, 95% CI 0.59 to 2.44) or recurrence of atrial tachyarrhythmias (RR 0.64, 95% CI 0.31 to 1.34) between cohorts. The review concludes that larger randomised controlled trials are necessary to make conclusions about the efficacy, safety and efficiency of PFA compared to thermal energy ablation.

### Meta-analysis

## Evidence overview

A meta-analysis by Zhang, et al (2024) compared the efficacy, safety and procedural efficiency of PFA compared to cryoablation for atrial fibrillation. 15 studies were included, with data from 1880 participants. The analysis found no significant differences in recurrent atrial arrhythmia (OR 0.83, 95% CI 0.64 to 1.07) or periprocedural complications (OR 0.78, 95% CI 0.46 to 1.30) between PFA and cryoablation. The analysis reports significantly shorter procedure times (MD -7.17, 95% CI -13.60 to -0.73) and significantly longer fluoroscopy times (MD 2.53, 95% CI 0.87 to 4.19) for PFA compared to cryoablation. The analysis found that PFA is significantly associated with a lower incidence of phrenic nerve palsy (OR 0.20, 95% CI 0.07 to 0.59), but a higher incidence of cardiac tamponade (OR 4.07, 95% CI 1.15 to 14.39). The analysis also reported a significant reduction in S100 protein (MD -64.41, 95% CI -105.46 to -17.36) and heart rate (MD -8.76, 95% CI -15.12 to -2.40) for PFA than with cryoablation. The analysis concludes that PFA is a safer, time-saving procedure compared to cryoablation with comparable success rates.

A meta-analysis by Aldaas, et al (2023) compared the safety and acute efficacy of PFA and thermal energy ablation. 24 studies were included, with data from 5203 participants. The meta-analysis reported significantly fewer ( $p=0.001$ ) peri-procedural complications in the PFA group ( $n=2842$ ) (2.05%, 95% CI 0.94 to 3.46) compared to the thermal ablation group (7.75%, 95% CI 5.40 to 10.47). The meta-analysis concludes that PFA is associated with lower rates of peri-procedural complications, with similar rates of acute procedural success and recurrent atrial fibrillation to thermal energy ablation within 12 months.

### *Health Economic Assessments*

A cost-comparison analysis by Duxbury, Begley and Heck (2024) compared the 12-month costs of treating atrial fibrillation with pulsed field ablation (via pentaspline catheter) compared to cryoablation. The analysis reported costs for a single, hypothetical patient treated with pulsed field ablation were £343 less (-3%) over 12 months than with cryoablation, but catheter costs were 16% higher using the pentaspline catheter. PFA showed lower (over 50%) repeat ablation costs compared to cryoablation due to a reduction in the number of repeated treatments required. The study also reported that costs of managing complications associated with PFA were £211 lower than cryoablation over 12 months. The study concluded that routine adoption of PFA and use of the pentaspline catheter is as affordable for the NHS as standard practice of cryoablation.

### *Primary Evidence*

A prospective, single-arm multi-centre study by Anić, et al (2023) evaluated the safety and pulmonary vein isolation durability of the CENTAURI™ pulsed field ablation system in 82 participants. 322 pulmonary veins were isolated (100%) with first-pass isolation achieved in 297 veins (92.2%). The study reported four serious adverse events associated with pulsed field ablation: three incidents of vascular access complications and one lacunar stroke. The study concluded that PFA is a viable treatment option for AF with a favourable safety profile.

A randomized, single-blind non-inferiority trial by Reddy, et al (2023) evaluated the efficacy and safety of pulsed field ablation compared to conventional thermal ablation, with data from 607 participants with paroxysmal atrial fibrillation. The study concluded that PFA was non-inferior to conventional thermal ablation.

## Areas of uncertainty

Areas of uncertainty include:

- Whether, and to what extent the specific catheter used for PFA affects overall costs
- How much training is required for the delivery of PFA and the impact of learning curves on outcomes
- Whether PFA is currently used in NHS Wales
- Whether AF recurrence outcomes are lower for PFA compared to thermal energy ablation
- Any difference between PFA systems or range of systems available

## Literature search results

Health technology assessments and guidance	
<p>NICE. (2021). Atrial fibrillation: diagnosis and management. Clinical guideline NG196. National Institute for Health and Care Excellence. Available at: <a href="https://www.nice.org.uk/guidance/ng196/chapter/Recommendations">https://www.nice.org.uk/guidance/ng196/chapter/Recommendations</a> [Accessed 30/05/2024].</p>	
Evidence reviews and economic evaluations	
<p>Aldaas OM, Malladi C, Han FT, et al. (2024). Pulsed field ablation versus thermal energy ablation for atrial fibrillation: a systematic review and meta-analysis of procedural efficiency, safety, and efficacy. <i>J Interv Card Electrophysiol.</i> 67(3): 639-48. doi: <a href="https://doi.org/10.1007/s10840-023-01660-3">https://doi.org/10.1007/s10840-023-01660-3</a></p> <p>Zhang H, Zhang H, Lu H, et al. (2024). Meta-analysis of pulsed-field ablation versus cryoablation for atrial fibrillation. <i>Pacing Clin Electrophysiol.</i> 47(5): 603-13. doi: <a href="https://doi.org/10.1111/pace.14971">https://doi.org/10.1111/pace.14971</a></p> <p>Duxbury C, Begley D, Heck PM. (2024). Pulsed field ablation with the pentaspline catheter compared with cryoablation for the treatment of paroxysmal atrial fibrillation in the UK NHS: a cost-comparison analysis. <i>BMJ Open.</i> 14(5): e079881. doi: <a href="https://doi.org/10.1136/bmjopen-2023-079881">https://doi.org/10.1136/bmjopen-2023-079881</a></p> <p>Aldaas OM, Malladi C, Aldaas AM, et al. (2023). Safety and acute efficacy of catheter ablation for atrial fibrillation with pulsed field ablation vs thermal energy ablation: A meta-analysis of single proportions. <i>Heart Rhythm O2.</i> 4(10): 599-608. doi: <a href="https://doi.org/10.1016/j.hroo.2023.09.003">https://doi.org/10.1016/j.hroo.2023.09.003</a></p>	
Individual studies	
<p>Reddy VY, Gerstenfeld EP, Natale A, et al. (2023). Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. <i>N Engl J Med.</i> 389(18): 1660-71. doi: <a href="https://doi.org/10.1056/NEJMoa2307291">https://doi.org/10.1056/NEJMoa2307291</a></p>	
Evidence supplied by topic proposer	
<p>Anic A, Philips T, Breskovic T, et al. (2023). Pulsed field ablation using focal contact force-sensing catheters for treatment of atrial fibrillation: acute and 90-day invasive remapping results. <i>Europace.</i> 25(6). doi: <a href="https://doi.org/10.1093/europace/euad147">https://doi.org/10.1093/europace/euad147</a></p>	

Date of search	30/05/2024
Concepts used	Pulse field ablation, pulsed field ablation, CENTAURI, cardiac arrhythmia, atrial fibrillation, catheter ablation, ablation

## Proposed research question and evidence selection criteria (if selected)

<b>Proposed Research question</b>	<b>What is the clinical and cost-effectiveness of pulsed field ablation for atrial fibrillation?</b>
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	<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
<b>Population</b>	Adults with atrial fibrillation	
<b>Intervention</b>	Pulsed field ablation	
<b>Comparison/ Comparators</b>	Thermal energy ablation	
<b>Outcome measures</b>	Procedure success Non-recurrence of atrial fibrillation Incidence of adverse events Health related QoL Resource use Economic outcomes	

<b>Proposed speciality</b>	<b>Cardiovascular System</b>
<b>Proposed specialities</b>	