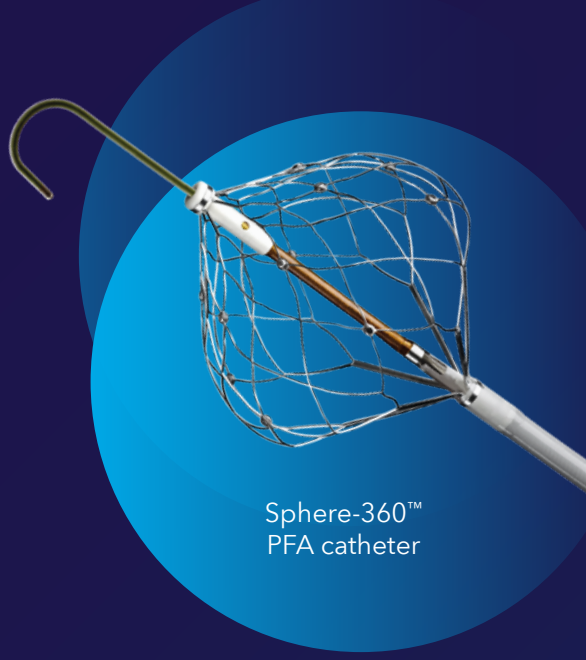
Medtronic

Sphere-360™

pulsed field ablation catheter



Cost savings in AF compared with the pentaspline PFA catheter in the UK[1].

Background

- Technological advancements in atrial fibrillation (AF) ablation have greatly improved procedural safety and efficacy. Pulsed field ablation (PFA) offers the potential for precise myocardial ablation with minimal collateral damage.
- Multiple PFA catheters are currently available, each differing in design and energy delivery. Sphere-360™ pulsed field ablation catheter is a rotation free PFA catheter fully integrated with the Affera™ mapping and ablation system. It streamlines AF treatment and has demonstrated high pulmonary vein lesion durability (98% per vein), predictability, and offers easily reproducible workflow for consistent results across operators[2].
- As PFA adoption grows, understanding the economic impact of each system becomes increasingly important.

Objective

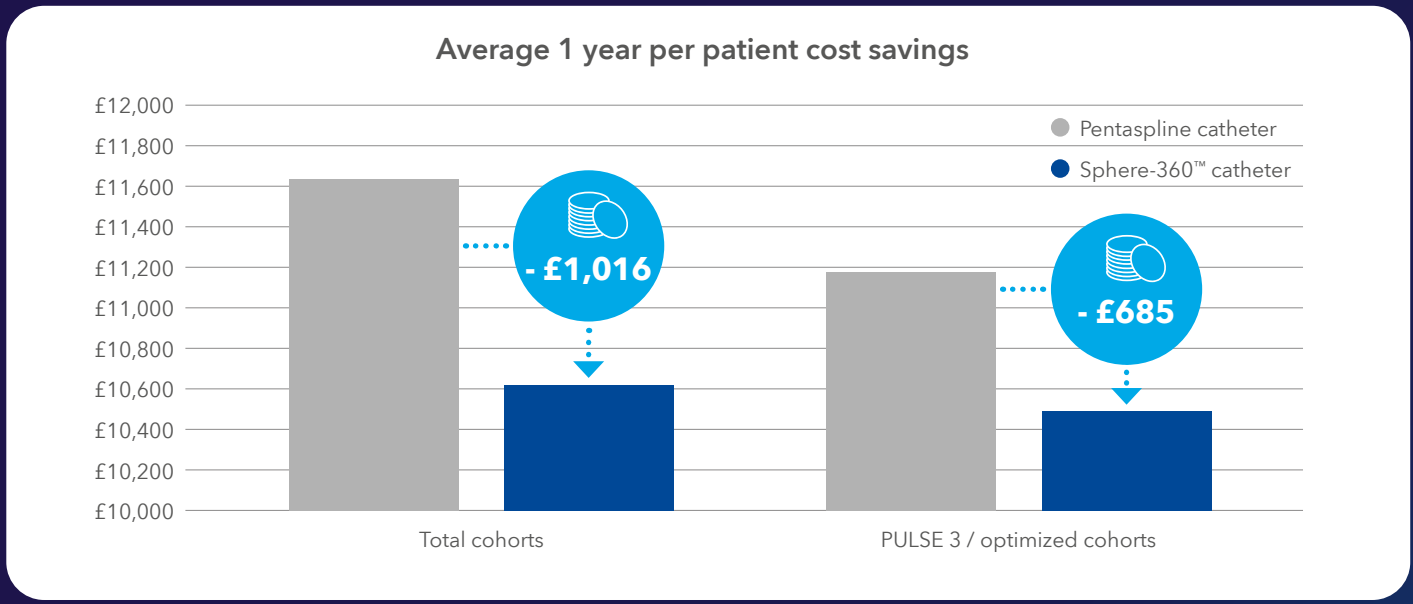
To evaluate the economic implications of the Sphere-360™ pulsed field ablation catheter compared to the pentaspline catheter for the treatment of paroxysmal AF from the NHS perspective.

Methods

- The economic analysis was based on arrhythmia recurrence, repeat ablations and safety rates. In the absence of head-to-head studies, matching-adjusted indirect comparison (MAIC) was implemented to compare efficacy outcomes from the first-in-human studies of both the Sphere-360™[2] PFA catheter (NCT05144503, NCT05115214) and the pentaspline[3] PFA catheter (NCT03700385, NCT03714178, NCT04170608). MAIC analysis was done in both the total (Sphere-360™ catheter: N=100, pentaspline catheter N=121) and optimized cohorts (Sphere-360™ catheter: N=50, pentaspline catheter N=49).
- A cost comparison based on these MAIC results was performed with a one-year time horizon. One of the studies reported zero safety event rates[2], and given MAIC cannot be completed with zero event rates, unadjusted safety rates were used for the cost analysis. For repeat ablations, the relative difference in repeat ablation rates derived from the MAIC analysis was applied to the rate reported in the National Institute for Health and Care Excellence (NICE) AF guidelines (NG196)[4]. Repeat ablations were assumed to be performed using a radiofrequency (RF) catheter, with associated safety event rates sourced from NG196.
- Cost estimates for safety events were sourced from NG196 and inflated to 2024 values. Ablation procedure costs were based on the 2023/24 NHS National Cost Collection day-case unit price. Catheter costs were derived from an NHS real-world study.[5]

Results

- The results of this study show that ablation with the Sphere-360™ PFA catheter for the treatment of paroxysmal AF is cost saving compared with the pentaspline catheter in the UK.
- Cost savings with Sphere-360™ PFA catheter were £1,016 in the total cohorts and £685 in the PULSE3/ Optimized cohorts.
- Key driver of the results was the efficacy of the catheters, arrhythmia recurrence and repeat ablations.
- In all scenarios ablation with Sphere-360™ PFA catheter remained cost-saving.



Conclusion

Sphere-360™ PFA catheter is cost-saving compared to the pentaspline PFA catheter for the treatment of paroxysmal AF patients, from the UK NHS perspective.

References:

1. Ahsan et al. Economic evaluation of two pulsed field ablation systems, a conformable large-lattice catheter versus a pentaspline catheter, for the treatment of paroxysmal atrial fibrillation. Presented at EHRA 2026 Paris. https://esc365.escardio.org/Ehra-congress/speakers/1413050.
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3. Reddy VY, Dukkipati SR, Neuzil P, et al. Pulsed field ablation of paroxysmal atrial fibrillation: 1-year outcomes of IMPULSE, PEFCAT, and PEFCAT II. Clinical Electrophysiology 2021; 7(5): 614-27.
4. NICE guideline NG196 (atrial fibrillation: diagnosis and management). https://www.nice.org.uk/guidance/ng196/evidence/full-guideline-pdf-9081927326.
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