



POLARx™ Cryoablation SystemPOLAR ICE Registry Results

OBJECTIVE

Post-market clinical follow-up study to evaluate the safety and effectiveness of the POLARx Cryoablation Balloon for pulmonary vein isolation (PVI) to treat paroxysmal atrial fibrillation (PAF) using real-world data.

METHODS

- Prospective, non-randomised, multicentre international registry (NCT04250714).
- 399 patients were enrolled across 19 centres between August 2020 to May 2021.

PROCEDURAL CHARACTERISTICS¹

- Data on 372 de novo PVI procedures (n = 2190 ablations) were collected.
- Acute PV isolation occurred in 96.8% of PVs.
- The procedure time was 68.2 ± 24.6, left atrial dwell time was 46.6 ± 18.3 minutes and the fluoroscopy time was 15.6 ± 9.6 minutes.
- Grade 3 or 4 occlusion was achieved in 98.2% of PVs with a 71.2% rate of single-shot isolation.
- The average nadir ablation temperature was -56.3 ± 6.5 °C.

SAFETY²

The safety endpoint event rate was 4.6% (Figure 1). Endpoint events included serious vascular access complications (2.6%), cardiac tamponade/perforation (0.5%), thromboembolism/air embolism (0.5%), myocardial infarction (0.3%), persistent gastroparesis/ vagus nerve injury (0.3%) persistent phrenic nerve injury (0.3%), and stroke/cerebrovascular accident (0.3%).



Figure 1. Freedom from Primary Safety Event

POLARx[™] Cryoablation System

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EFFICACY²

The 12-month freedom from any arrhythmia was 83.5% and freedom from atrial fibrillation 88.1% (Figures 2, 3).

Figure 2. Freedom from Documented Arrythmia Recurrence



83.5% Arrhythmia Recurrence Free

Figure 3. Freedom from AF Recurrence



- Redo procedures were conducted on 19 patients. In 14/19 pts reconnection of at least one PV could be identified (RSPV n=8, RIPV n=12, LSPV n=9, LIPV n=11).
- Freedom from any arrhythmia was associated with lower nadir temperature (p=0.008) and longer time to thaw (p=0.05) during the index procedure.

CONCLUSION

- In the POLAR ICE real-world registry there was a low safety event rate (4.6%).
- The one-year arrhythmia recurrence free rates were 83.5%, with an AF recurrence free rate of 88.1%.
- Lower nadir temperatures and a longer thawing time were acute predictors of long-term clinical success.

1. Martin, Claire A., et al. "Acute procedural efficacy and safety of a novel cryoballoon for the treatment of paroxysmal atrial fibrillation: Results from the POLAR ICE study." Journal of Cardiovascular Electrophysiology 34.4 (2023): 833-840.

2. Luik *et al.* Long-term Success Rates of a Stable, Low Pressure Cryoballoon for the Treatment of Paroxysmal Atrial Fibrillation: Results of the Prospective, International, Multicenter POLAR-ICE Study. ESC, 2023.

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