POLARx™ Cryoablation System
POLAR ICE Registry Results

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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-randomized, multicenter international registry (NCT04250714).
- 399 patients were enrolled across 19 centers between August 2020 and May 2021.

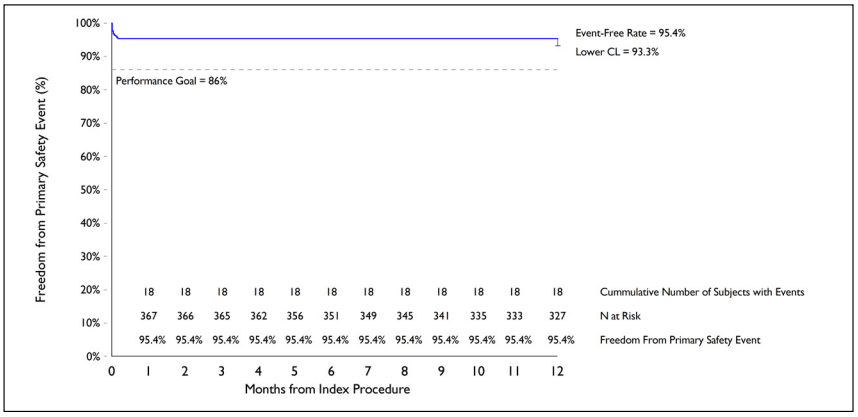
PROCEDURAL CHARACTERISTICS[1]

- 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.

SAFETY[2]

- 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%).

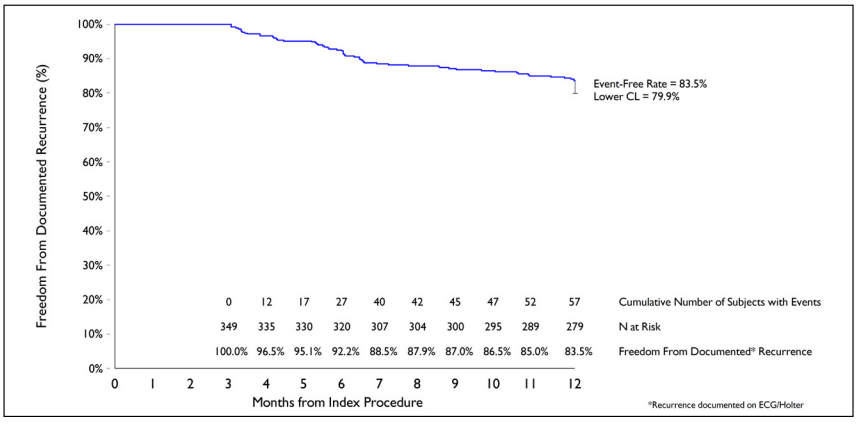
Figure 1. Freedom from Primary Safety Event



EFFICACY[2]

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

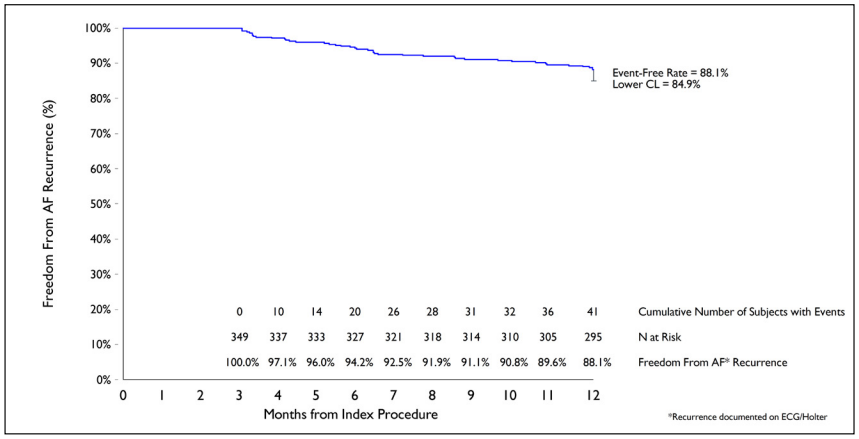
Figure 2. Freedom from Documented Arrythmia Recurrence



83.5%
Arrhythmia Recurrence Free

EFFICACY (*cont.*)

Figure 3. Freedom from AF Recurrence



88.1%
AF Recurrence Free

- Redo procedures were conducted on 19 patients. In 14/19 patients 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.

POLARx™ Cryoablation System
Indications, Safety, and Warnings

1. Martin CA, Tilz RRR, Anic 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. *J Cardiovasc Electrophysiol*. 2023;34:833-840.
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. Presented at: ESC 2023; August 2023; Amsterdam, NL.

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EP-1668804-AA