Boston Scientific
Advancing science for life™

POLARx™ FIT Proof-of-Concept Study

Early Clinical Outcomes and Advantages of a Novel-Size Adjustable Second-Generation Cryoballoon

CLINICAL PERSPECTIVE

WHAT'S NEW

- First comprehensive assessment of acute performance and balloon-size utilisation of the POLARx FIT dual-diameter cryoablation system in AF ablation in a small study cohort.

WHAT'S IMPORTANT

- The 31mm cryoballoon (CB) configuration was utilised in 51% of applications, and in 66.6% of cases, both balloon sizes were employed to accomplish optimal occlusion.
- POLARx FIT has showcased its ability to help optimal occlusion in challenging anatomies.
- More antral lesions may reduce phrenic nerve palsies.
- No major complications occured, no phrenic nerve palsy reported.

OBJECTIVE

- To assess the acute performance of the Boston Scientific POLARx FIT novel-size, adjustable, second-generation CB system in paroxysmal AF (PAF) ablation procedures.

TRIAL DESIGN AND METHODS

- Single-centre, single-arm, observational investigation (NCT04133168).
- 24 consecutive patients with PAF (91.7%).
- May – Nov 2023.
- 100% esophageal temperature probe used.

STUDY ENDPOINTS

- Primary outcome: rate of 31mm balloon size utilisation.
- Secondary outcomes include acute pulmonary vein isolation (PVI) rate, periprocedural complications, and in-hospital AF recurrences.

PROCEDURAL CHARACTERISTICS AND OUTCOMES

- Procedural characteristics are shown in **Table 1.**
- No major procedural complications, two in-hospital AF recurrences, no phrenic nerve palsy.
- 31mm size POLARx FIT configuration was used for 51% of the overall applications.
- In 66.6% of cases, both balloon sizes were employed to ensure optimal occlusions for all veins.

Table 1: Procedural Characteristics and Study Outcomes

	Overall (n=24)
Overall procedural time (min), median (IQR)	90 (60 – 110)
Overall fluoroscopy time (min), median (IQR)	15.5 (12 – 22.3)
Anatomical variants	
Right common pulmonary trunks, n (%)	2 (8.3)
Left common pulmonary trunks, n (%)	1 (4.2)
Additional PV branches, n (%)	3 (12.5)
Number of applications needing the 31mm size, n (%)	64 (51.6)
Minimal reached temperatures	
LSPV (°C), median (IQR)	-52.0 (-54.5 – -50.5)
LIPV (°C), median (IQR)	-49.0 (-52.0 – -48.0)
RSPV (°C), median (IQR)	-50.0 (-54.0 – -45.5)
RIPV (°C), median (IQR)	-50.0 (-57.0 – -48.0)

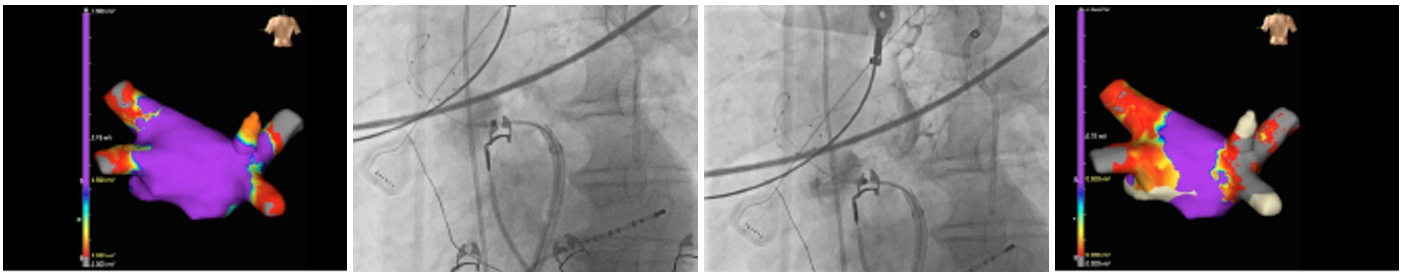
Table 1 (continued): Procedural Characteristics and Study Outcomes

	Overall (n=24)
In-hospital AF recurrences, n (%)	2 (8.3)
Periprocedural complications	
Groin haematoma, n (%)	1 (4.2)
Pericardial effusion, n (%)	0 (0)
Cardiac tamponade, n (%)	0 (0)
Phrenic nerve palsy, n (%)	0 (0)
Thromboembolic complications, n (%)	0 (0)

DISCUSSION AND KEY TAKEAWAYS

- The use of the dual-size feature has helped to reach an easier pulmonary vein isolation (PVI) in various clinical scenarios, such the presence of common PV trunks, accessory PVs, funnel-shaped PV ostia.
- The new generation POLARx™ FIT showed comparable easy maneuverability to POLARx™ Cryoablation System, with an overall high acute success rate and low periprocedural complication rates.
- POLARx FIT may show similar procedure and fluoroscopy times in the presence of standard PV anatomy but offers significant intraprocedural flexibility to the operator.
- In a case-based approach, POLARx FIT enhanced the quality of occlusion, reduced the necessity for cryoballoon (CB) repositioning and segmental approaches for PCTs and veins, which are potential predictors of worse outcomes.
- POLARx FIT may increase the rate of single-shot isolations.
- The increased antral occlusion capability potentially reduces phrenic nerve injury.

Figure 1. High Density Maps of Challenging Anatomy



(a) (b) (c) (d)

Figure 1. CB ablation of an angled posterior and vertical branch of the RSPV, originating from a large-shaped PV ostium. From left to right: **(a)** 3D mapping showing RSPV anatomy. **(b)** Unsuccessful attempt to occlude and isolate this branch with the 28mm size CB. **(c)** Successful attempt to occlude and isolate this branch with the 31mm size CB. **(d)** Three-dimensional mapping showing RSPV after cryoenergy delivery.

CONCLUSION

POLARx FIT distinguishes itself as the sole cryoballoon offering two balloon sizes within a single catheter, presenting the potential to simplify the treatment of complex anatomies and harness all the benefits associated with increased antral occlusion.

Boston Scientific
Advancing science for life™

Schiavone M, Fassini G, Moltrasio M, Majocchi B, Tundo F, Casati F, Tondo C. Early Clinical Outcomes and Advantages of a Novel-Size Adjustable Second-Generation Cryoballoon: A Proof-of-Concept Study. J Clin Med. 2024 Feb 22;13(5):1259. doi: 10.3390/jcm13051259. PMID: 38592089; PMCID: PMC10931948.

www.bostonscientific.eu

EP-1916101-AA

CE 0123