Resizable cryoballoon vs. standard cryoballoon in atrial fibrillation ablation: preliminary findings from a multicenter randomised controlled trial

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Introduction: Atrial fibrillation (AF) is the most prevalent cardiac arrhythmia; significantly affecting healthcare services.[1] Pulmonary vein isolation (PVI) has emerged as the standard treatment for AF, with radiofrequency energy historically being the primary method employed. The second most common ablation technique has been cryoenergy, particularly using cryoballoon (CB) technology, which has demonstrated superiority over drug therapy in patients with paroxysmal atrial fibrillation (PAF)[2]. Recently, an expandable CB capable of adjusting its size from 28 to 31 mm has been developed. Our study aimed to compare two different CB technologies: the legacy 28 mm fixed-size balloon and the new expandable CB.

Patients and Methods: This multicenter randomized controlled trial has so far enrolled 136 of the planned 200 patients with PAF indicated for PVI. Participants were randomly assigned in a 1:1 ratio to either the Medtronic 4th generation CB (Arctic Front Advance Pro) (MDT group) or the Boston Scientific resizable CB (PolarXFit) (Polar group). Follow-up visits and 24-hour ECG recordings were scheduled at 3, 6, and 12 months, with subsequent visits every six months.

Results: Among the 136 patients, 57 (41.9%) were female, with an average age of 60.78±12,29 years. Both groups were similar regarding sex and age. Procedure durations were similar: 65.5 ± 19.9 minutes for the Polar group vs. 61.8 ± 21.1 minutes for the MDT group (p=0.375). Fluoroscopy times were comparable as well, with 10.6 ± 7.5 minutes in the Polar group and 9.4 ± 7.7 minutes in the MDT group (p=0.414). Complete pulmonary vein isolation was achieved in 98.5% of Polar cases and 95.6% of MDT cases (p=0.303). Only minor complications were reported, including 4 large hematomas (3 in the Polar and 1 in the MDT group), along with 2 transient phrenic nerve palsies (1 in each group).

Conclusion: The new resizable PolarXFit CB is comparable to the MDT CB regarding procedure duration, fluoroscopy time, radiation dose, and acute PVI rate. Complications were minimal and primarily related to venous access. Follow-up data will be needed to confirm non-inferiority in terms of long-term success.

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LITERATURE

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