Comparison of the 1-year clinical outcome of a novel cryoballoon to an established cryoballoon technology

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1 Introduction

Mid 2020, a novel cryoballoon was introduced, the POLARx (Boston Scientific, Marlborough, MA, USA). The design of this cryoballoon is comparable to Arctic Front (Medtronic, Minneapolis, MN, USA), except it has a lower balloon pressure during freezing making it more compliant. Previous studies have compared the procedural outcome of POLARx to Arctic Front Advance Pro (AFA-Pro) [1–5]. The aim of the present study was to compare the 1-year clinical outcome between POLARx and AFA-Pro of our original study cohort.

2 Methods

We prospectively included consecutive patients who underwent cryoballoon ablation (CBA) for the treatment of AF between May and October 2020 in 3 centers. The periprocedural management of our patients was described extensively previously [5]. A time-to-isolation (TTI)-based cryodosing was employed. The primary outcome was the freedom from atrial arrhythmias between 90 and 365 days after the procedure. The primary outcome between both groups was compared using log-rank statistics. A $P$ value of $<0.05$ was considered statistically significant.

3 Results

We enrolled 110 patients in the study period (POLARx: $n = 57$; AFA-Pro: $n = 53$). The POLARx group had less hypertension (31.6% vs. 58.5%, $P = 0.007$), had more use of direct acting oral anticoagulants (100% vs. 90.6%, $P = 0.02$), and used less antiarrhythmic drugs (52.6% vs. 75.5%, $P = 0.02$) in comparison to the AFA-Pro group. Most patients had paroxysmal AF (POLARx: 75.4% versus AFA-Pro: 75.5%, $P = 1.00$). The rate of PV isolation was similar between groups (POLARx: 99.5% of all PVs versus AFA-Pro: 100% of all PVs, $P = 1.00$). The POLARx group had a longer procedure time (median 81 min versus 67 min, $P < 0.001$) and longer balloon in body time (median, 51 min versus 35 min, $P < 0.001$). There was no difference in the magnitude of PV occlusion (grade 4 occlusion: POLARx: 81.6% versus AFA-Pro 77.3%, $P = 0.21$). Balloon nadir temperatures and temperatures at TTI were lower with POLARx (median $-55\, ^\circ\text{C}$ versus $-47\, ^\circ\text{C}$, $P < 0.001$; $-46\, ^\circ\text{C}$ versus $-37\, ^\circ\text{C}$, $P < 0.001$), but the timing of TTI was similar between groups (median 45 s versus 43 s, $P = 0.44$). In both groups, 2 patients had phrenic nerve palsy (PNP) at hospital discharge ($P = 1.00$). During a follow-up of 1 year, there was no difference in freedom from atrial arrhythmias after a blanking period of 90 days (Fig. 1). The 1-year freedom from atrial arrhythmias was 82% and 87% for the POLARx and AFA-Pro group, respectively (log-rank $P = 0.60$). The rate of redo procedures in the first year was similar between groups (POLARx: 7% versus AFA-Pro: 0%, log-rank $P = 0.12$). Of the 4 patients in the POLARx group undergoing a redo procedure, all had at least one reconnected PV. The PV reconnection rate was 33% (5 of 15 PVs). Of the 4 patients with PNP, all recovered.
To the best of our knowledge, this is the first report comparing the 1-year freedom from atrial arrhythmias between the novel POLARx cryoballoon and the fourth-generation AFA-Pro. The freedom of atrial arrhythmias, freedom from redo procedures and rate of persistent PNP was similar between both cryoballoon technologies.

Previous studies with POLARx have established that the balloon nadir temperatures are approximately 10 °C lower in comparison to AFA-Pro [1]. Considering similarities in catheter design and an identical thermal energy source, it was presumed that these lower balloon nadir temperatures reflected a more efficient energy transfer of POLARx resulting in faster and more durable lesions. However, our study seems to indicate that these lower inner balloon nadir temperatures do not improve the acute and long-term efficacy. Many factors influence the measurement of the return gas temperature including the grade of occlusion, balloon-tissue contact area, and balloon-PV ratio. The present study also shows that markers of the biological effect (i.e., TTI, risk of PNP, recurrence of atrial arrhythmias) were similar between both cryoballoons.

From a safety perspective, the incidence of acute PNP was comparable between both systems, and no patient had persistent PNP. Furthermore, previous studies have demonstrated that the minimal esophageal temperatures are similar between POLARx and AFA-Pro, despite a lower balloon nadir temperature with POLARx [4]. These observations suggest that the balloon surface temperature is very likely similar, thus probably resulting in a similar safety profile between POLARx and AFA-Pro. Larger clinical studies are warranted to evaluate the presence of rare complications such as atrooesophageal fistula. Therefore, the long-term results of the POLAR-ICE (n = 400, NCT04250714) and FROZEN-AF (n = 405, NCT04133168) registries are eagerly awaited, but are not expected until 2023.

5 Study limitations

A limitation of our study is the observational study design and the relatively small sample size. Currently, one randomized controlled trial comparing POLARx and AFA-Pro for the treatment of paroxysmal AF is recruiting patients (NCT04704986, COMPARE-CRYO) (estimated study size 200 patients) and will provide more definitive conclusions regarding the long-term outcome, but these results are not expected soon.

6 Conclusion

The 1-year clinical outcome after PVI with POLARx is comparable to AFA-Pro. The lower measured balloon nadir temperatures with POLARx do not seem to be associated with a lower recurrence rate of atrial arrhythmias nor with more procedure-related complications in comparison to AFA-Pro.

Declarations

Conflict of interest SCY, AA, and AL are consultants for Boston Scientific. The other authors have no conflict of interests.

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