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# Outcomes after cryoballoon ablation of paroxysmal atrial fibrillation with the PolarX or the Arctic Front Advance Pro: a prospective multicentre experience

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## Aims

The aim of this study was to compare procedural efficacy and safety, including 1-year freedom from AF recurrence, between the novel cryoballoon system PolarX (Boston Scientific) and the Arctic Front Advance Pro (AFA-Pro) (Medtronic), in patients with paroxysmal AF undergoing PVI.

## Methods and results

This multicentre prospective observational study included 267 consecutive patients undergoing a first cryoablation procedure for paroxysmal AF (137 PolarX, 130 AFA-Pro). Kaplan-Meier curves with the log-rank test was used to compare the 1-year freedom from AF recurrence between both groups. Multivariate Cox model was performed to evaluate whether the type of procedure (PolarX vs. AFA-Pro) had an impact on the occurrence of AF recurrences after adjustment on potentially confounding factors. The PolarX reaches lower temperatures than the AFA-Pro (LSPV  $52 \pm 5$ , vs.  $59 \pm 6$ ; LIPV  $49 \pm 6$  vs.  $56 \pm 6$ ; right superior pulmonary vein:  $49 \pm 6$  vs.  $57 \pm 7$ ; right inferior pulmonary vein:  $52 \pm 6$  vs.  $59 \pm 6$ ;  $P < 0.0001$ ). A higher rate of transient phrenic nerve palsy was found in patients treated with the PolarX system (15% vs. 7%,  $P = 0.05$ ). After a mean follow-up of  $15 \pm 5$  months, 20 patients (15%) had recurrences in AFA-Pro group and 27 patients (19%) in PolarX group ( $P = 0.35$ ). Based on survival analysis, no significant difference was observed between both groups with a 12-month free of recurrence survival of 91.2% (85.1–95.4%) vs. 83.7% (76.0–89.1%) (log-rank test  $P = 0.11$ ). In multivariate Cox model hazard ratio of recurrence for PolarX vs. AFA-Pro was not significant [HR = 1.6 (0.9–2.8),  $P = 0.12$ ].

## Conclusion

PolarX and AFA-Pro have comparable efficacy and safety profiles for pulmonary veins isolation in paroxysmal atrial fibrillation.

## Keywords

Atrial fibrillation • Paroxysmal atrial fibrillation • Atrial fibrillation ablation • Cryoablation • Cryoballoon

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## What's new?

- PolarX and Arctic Front Advance Pro (AFA-Pro) balloons show similar efficacy in terms of recurrences at 1 year after a first ablation procedure of paroxysmal AF.
- The workflow is comparable between the two cryoballoons, without significant differences in procedural and fluoroscopy times.
- The PolarX cryoballoon reaches lower temperatures than the AFA-Pro, with a median difference of  $-7^{\circ}\text{C}$ .
- Despite a low rate of complications, a higher rate of transient phrenic nerve palsy was found in patients treated with the PolarX system.

## Introduction

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) ablation.<sup>1</sup>

Cryoballoon ablation has demonstrated to be as effective as radiofrequency ablation for achieving PVI, being faster, reproducible and less operator dependent.<sup>2,3</sup>

Over the years and until the latest Arctic Front Advance Pro (AFA-Pro) (Medtronic, Minneapolis, MN, USA), upgrades in technical characteristics of this cryoballoon led to improved procedural outcomes.<sup>4</sup>

Different procedural and biophysical markers of this tool have been found to predict acute and durable PVI, specifically the time to pulmonary vein isolation (TTI).<sup>5</sup>

Recently, a novel cryoballoon system, the PolarX (Boston Scientific, St. Paul, MN, USA) has become available. Compared with AFA-Pro, the main difference of this new tool is its ability to maintain a constant pressure inside the balloon before and during the freeze.

Several centres already published their initial clinical experience comparing the two balloons.<sup>6–10</sup> These studies mainly focused on acute procedural efficacy, balloon nadir temperature, incidence of phrenic nerve palsy or acute recurrence of AF, but they were limited by their small sample size and/or their single-centre design. Very recently, two new reports, comparing this time both balloons, have also been released.<sup>11,12</sup>

## Objective

The aim of this multicentre study was to compare procedural efficacy, safety and 1-year freedom of AF recurrence, between the PolarX and the AFA-Pro in patients with paroxysmal AF undergoing PVI.

## Methods

### Study design

In this multicentre prospective observational study, 275 consecutive patients undergoing a first cryoablation procedure for paroxysmal AF were included in three high volume cryoballoon ablation centres between April 2020 and February 2021 (Clinique Pasteur Toulouse, France; UZ Brussel, Belgium and CHU Grenoble, France). Both the AFA-Pro and the PolarX were used in all study centres and the choice between them was left to the EP physician discretion for each patient. Patients with a follow-up duration below 3 months were excluded from this analysis, yielding a final population of 267 patients. All patients provided a written informed consent prior to the procedure. The study complied with the Declaration of Helsinki and the research protocol was approved by the local ethics committee.

### Ablation procedure scheme

The procedure was performed under general anaesthesia/deep sedation and on uninterrupted anticoagulation in all patients.

After vascular accesses were obtained, a single transseptal puncture was performed to introduce an 8 F transeptal non-steerable sheath into the left atrium (SLO™). Thereafter, patients received a weight adjusted dose of intravenous heparin (6000–10 000 units), and subsequent administration of heparin was performed to maintain ACT values between 250 and 350 s, checked every 30 min during the procedure.

Depending on the cryoballoon, the non-steerable transseptal sheath was exchanged over a guidewire for the 15.5 F Polar sheath™ (Boston Scientific, St. Paul MN, USA) or the 15F Flexcath Advance sheath™ (Medtronic, Minneapolis, MN, USA); both sheaths were continuously flushed with heparinized saline solution.

Before freezing, each vein was first cannulated with the mapping catheter (Polarmap™ 20 mm for the PolarX or Achieve™ 20 mm for the AFA-Pro), and after the inflation and the positioning of the balloon, complete occlusion of the vein was assessed with contrast injection. In case of suboptimal occlusion, balloon position was adapted in order to obtain a complete occlusion (4/4). To improve the detection of pulmonary vein signals the mapping catheter was pulled as close as possible to the tip of the balloon.

With both balloons, total freezing time was set to 180–240 s for each application, with a target TTI of less than 60 s. When the TTI was > 60 s, freezing cycle was aborted, and the balloon was repositioned, in order to obtain a TTI < 60 s. When no stable pulmonary vein potential could be assessed by the mapping catheter during cryo-application, a bonus freeze was systematically delivered. During freezing of both right pulmonary veins, the right phrenic nerve was stimulated by pacing with a steerable diagnostic catheter positioned in the superior vena cava (10 V, 2 ms); the diaphragmatic movement was monitored by abdominal palpation in all patients, and with an additional DMS™ sensor in patients ablated with the Boston Scientific system. This new sensor is based on an accelerometer placed on an electrode below the right costal cartilage allowing the operator to visualise

**Table 1** Baseline characteristics

Variables	AFA-Pro™ (n = 130)	PolarX™ (n = 137)	P-value
Male	81 (62%)	81 (59%)	0.59
Age	63.2 ± 11.1	63.3 ± 10.7	0.97
Cardiopathy			
No	117 (90%)	128 (94%)	0.25
DCM	2 (2%)	1 (1%)	
HCM	1 (1%)	3 (2%)	
Ischemic	9 (7%)	3 (2%)	
Post-myocarditis	0 (0%)	1 (1%)	
Valvular	1 (1%)	0 (0%)	
CHF	4 (3%)	4 (3%)	0.94
Dyslipidaemia	35 (27%)	28 (20%)	0.21
Hypertension	64 (49%)	57 (42%)	0.21
Diabetes	9 (7%)	10 (7%)	0.90
CAD	14 (11%)	9 (7%)	0.22
Valvular heart disease	3 (2%)	3 (2%)	0.95
COPD	3 (2%)	3 (2%)	0.95
CHA <sub>2</sub> DS <sub>2</sub> VASc			0.67
0	27 (21%)	29 (21%)	
1	31 (24%)	41 (30%)	
2	35 (27%)	26 (19%)	
>2	37 (28%)	41 (30%)	

DCM, dilated cardiomyopathy; HCM, hypertrophic cardiomyopathy; CHF, chronic heart failure; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; AF, atrial fibrillation; LA, left atrium; AFA-Pro, Arctic Front Advance Pro.

the percentage of diaphragm movement during the phrenic nerve pacing on the console screen. Freeze energy delivering was interrupted with a so-called 'double stop' provoking an immediate balloon deflation if a weakening or loss of the diaphragmatic contraction was noticed by tactile feedback, and/or when the DMS™ signal decreased > 40% for the PolarX.

Other situations where the freezing application was discontinued included very low temperatures (<−65°C on AFA-Pro or <−7°C for the PolarX), dislodgment of the balloon, or as previously said, when TTI was > 60 s. In these cases, a repositioning of the balloon, and a new freezing application were performed. We will not use the term of 'bonus application' because in all cases, the first application was shorter than 100 s when aborted.

Acute PVI was confirmed by the disappearance of pulmonary veins signals and the demonstration of the entry block. Exit block was also assessed by pacing with the Achieve™, or the Polarmap™ catheter at the proximal part of the pulmonary vein and checking for any atrial capture.

## Discharge and follow-up

Following each institution's rules, patients were discharged between 8 and 24 h after the procedure. Oral anticoagulation was uninterrupted and kept for at least 2 months according to current international recommendations.<sup>13</sup>

Antiarrhythmic therapy (ADT) was discontinued immediately after ablation. In case of recurrence after blanking period, ADT or a repeat procedure was discussed with the patient.

A transthoracic echocardiography was systematically performed in all patients before discharge.

The femoral access was checked clinically, and in case of haematoma or femoral bruits, a colour doppler ultrasound examination was performed.

All patients underwent a clinical evaluation and a 12-lead electrocardiogram (ECG) at 1, 3, 6, and 12 months along with an ECG Holter monitoring at least at 6 and 12 months.

## Statistical analysis

Continuous variables are reported as mean standard deviation for variable with normal distribution (evaluated with Shapiro-test) and as median and interquartile range in case of non-normal data. Categorical data are shown as frequencies and proportions. Comparisons of patients' baseline characteristics and preprocedural characteristics between AFA-Pro and PolarX groups were based on unpaired T-test (or Wilcoxon test in

case of non-normal distribution) and chi-square test (or Fisher test) as appropriate.

In order to evaluate whether the type of procedure (AFA-Pro or PolarX) had an impact on the occurrence of AF recurrence arising more than 3 months after the procedure, we performed a survival analysis. Survival time was defined as the time starting from the date of procedure to the occurrence of AF recurrence or the most recent clinical evaluation (maximum November 2022). Survival curves free of recurrence were calculated by the Kaplan–Meier method and compared using a log-rank test. To evaluate whether the type of balloon (PolarX vs. AFA-Pro) had an impact on the occurrence of AF recurrence, we performed Cox proportional hazard regressions providing hazard ratios (HRs) (95% confidence intervals, CIs). Multivariate analysis considered the type of balloon and potentially confounding factors (baseline patients' characteristics) preliminarily identified in univariate analysis with corresponding *P*-value < 0.20. *P*-values ≤ 0.05 were considered statistically significant. Statistical analysis was accomplished by operating SAS version 9.4 (SAS Institute Inc, Cary, NC).

## Results

### Study population

From April 2020 to April 2021, 267 consecutive patients underwent a first cryoballoon ablation for paroxysmal AF, 137 with the PolarX and 130 with the AFA-Pro, and were included in the study.

Baseline patient's characteristics are presented in Table 1. Mean age was 63.2 ± 10.9 years, and the two groups were comparable in terms of baseline characteristics (Table 1).

### Procedural and biophysical parameters

The procedural data are presented in Table 2.

For all the pulmonary vein (PV) operators were able to achieve a 4/4 occlusion, except for one case in which a 3/4 occlusion was obtained in the right superior pulmonary vein (RSPV). PVI was acutely achieved in all patients for all four veins, except for two PVs: in one case, the RSPV disconnection could not be achieved, due to the occurrence of a phrenic nerve palsy that recovered after the procedure, and in another case, due to the impossibility to achieve a good occlusion of the RSPV already mentioned above. The mean procedural time was 76.7 ± 24.7 min and

**Table 2** Procedural details

Variables	AFA-Pro™ (n = 130)	PolarX™ (n = 137)	P-value
Procedure time, min	78.8 ± 25.4 (35–210)	74.8 ± 24.0 (30–238)	0.18
Fluoroscopy time, s	16.5 ± 8.3 (4.0–36.0)	14.8 ± 8.4 (4.6–26.0)	0.12
Freeze time, s	946 ± 184 (470–1770)	952 ± 277 (131–2258)	0.83
Cryoablation application number >4	44 (35%)	45 (33%)	0.76
Baseline rhythm			0.17
SR	119 (92%)	131 (96%)	
AF	9 (7%)	3 (2%)	
FLA	2 (1%)	3 (2%)	
Left common trunk	17 (13%)	9 (7%)	0.07
CTI ablation			0.23
No	108 (84%)	117 (85%)	
Yes, during procedure	13 (10%)	17 (12%)	
Yes, precedent procedure	8 (6%)	3 (2%)	

Note: Values are presented as median (range interquartile) or as count (%)

SR, sinus rhythm; AF, atrial fibrillation; FLA, atrial flutter; CTI, cavo-tricuspid isthmus; AFA-Pro, Arctic Front Advance Pro.

**Table 3** Procedural and biophysical parameters

Variable	AFA-Pro™ (n = 130)	PolarX™ (n = 137)	P-value
Freeze time, s			
LSPV	242 ± 70	235 ± 90	0.45
LIPV	237 ± 53	236 ± 64	0.91
RIPV	253 ± 89	231 ± 73	<b>0.03</b>
RSPV	237 ± 79	230 ± 117	<b>0.05</b>
Signal visible (%)			
LSPV	107 (82%)	114 (83%)	0.84
LIPV	84 (68%)	104 (81%)	<b>0.02</b>
RIPV	101 (78%)	105 (77%)	0.92
RSPV	104 (81%)	111 (82%)	0.94
Time to isolation, s			
LSPV	44 ± 22	42 ± 19	0.38
LIPV	32 ± 20	39 ± 30	0.09
RIPV	38 ± 18	45 ± 25	<b>0.03</b>
RSPV	33 ± 22	40 ± 34	0.08
Cryo-abortion when TTI > 60 s, (%)			
LSPV	3 (3%)	6 (4%)	0.35
LIPV	3 (3%)	4 (3%)	0.75
RIPV	7 (6%)	11 (8%)	0.39
RSPV	4 (4%)	6 (4%)	0.59
Nadir temperature (°)			
LSPV	52 ± 5	59 ± 6	<b>&lt;0.0001</b>
LIPV	49 ± 6	56 ± 6	<b>&lt;0.0001</b>
RIPV	49 ± 6	57 ± 7	<b>&lt;0.0001</b>
RSPV	52 ± 6	59 ± 6	<b>&lt;0.0001</b>
>1 n of applications (%)			
LSPV	13 (10%)	9 (7%)	0.31
LIPV	9 (7%)	13 (9%)	0.45
RIPV	25 (19%)	22 (16%)	0.49
RSPV	19 (15%)	20 (15%)	0.99

LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; AFA-Pro, Arctic Front Advance Pro.

P-values significant (in bold).

the mean fluoroscopy time was  $15.6 \pm 8.4$  min and comparable between both groups ( $P = 0.18$  and  $P = 0.12$ , respectively). Likewise, for the number of applications for each patient and total freezing time.

The procedural and biophysical parameters for each vein are presented in Table 3.

Targeted freeze temperatures were achieved in all cases with a median below  $-50^\circ\text{C}$ .<sup>14</sup> Lower temperatures were observed in all PVs with the PolarX cryoballoon than with the AFA-Pro, with a median lower temperature for the PolarX group of  $-7^\circ\text{C}$  ( $P < 0.001$ ).

While PV signals were recorded with both mapping catheters, a higher rate of PV signals recording was observed with the Polarmap than with the Achieve, during freezing in the LIPV (81% vs. 68%;  $P = 0.02$ ).

As per protocol, the freeze was discontinued in case of a TTI > 60 s and a new freeze was attempted after repositioning. Overall, no

**Table 4** Comparison in safety and efficacy

Variable	AFA-Pro™ (n = 130)	PolarX™ (n = 137)	P-value
Transient phrenic nerve palsy	9 (7%)	20 (15%)	<b>0.048</b>
Other complications	2 (2%)	2 (1%)	0.96
Recurrences in the first 3 months	7 (6%)	9 (7%)	0.74
Total follow-up, in months (25th percentile—75th percentile)	$16 \pm 5$ (12–19)	$15 \pm 5$ (12–17)	0.06
Recurrences after 3 months	20 (15%)	27 (19%)	0.35
Re-do procedure	4 (3%)	23 (17%)	<b>0.0002</b>

AFA-Pro, Arctic Front Advance Pro.

P-values significant (in bold).

significant difference in cryo-abortion was observed between the two groups whatever the PV. Although no significant difference was found in the superior PVs and the LIPV, longer TTI was recorded with the PolarX in the RIPVs ( $45 \pm 25$  s vs.  $38 \pm 18$  s,  $P = 0.03$ ). Furthermore, in cases where more than one application per PV was needed, total number of applications for each PV was comparable between the two groups.

## Complications

In both groups, 2% of complications were observed ( $P = 0.96$ ) as indicated in Table 4. One persistent phrenic nerve palsy (PNP) was observed after a procedure in the PolarX group whereas 29 (9%) transient PNP were registered: 9 cases in the AFA-Pro group and 20 cases in the PolarX group (7% vs. 15%,  $P = 0.048$ ). PNP was defined by a complete disappearing of the pacing induced diaphragmatic contractions, assessed by manual abdominal palpation, and confirmed by X-ray visualization. All the transient PNPs recovered before the end of the procedure. In one case with the AFA-Pro, the occurrence of the PNP did not allow to achieve the complete isolation of the RSPV. Despite the number of PNP was limited, no correlation between nadir temperature, or application duration, and PNP occurrence was observed.

## Outcomes

During the blanking period (0–3 months), 16 recurrences (6%) were observed, 7 and 9 patients respectively in the AFA-Pro and the PolarX group (6% vs. 7%,  $P = 0.74$ ). The mean follow-up was similar in both groups:  $16 \pm 5$  months vs.  $15 \pm 5$  months for AFA-Pro and PolarX respectively ( $P = 0.06$ ). We observed 47 recurrences (18%) after the 3 months blanking period: 20 patients in the AFA-Pro group and 27 patients in the PolarX group (15% vs. 19%,  $P = 0.35$ ). In addition, 27 patients (10%) underwent a repeat procedure during the follow-up, with a difference between the two groups (4 patients in the AFA-Pro group (3%) vs. 23 patients (17%) in the PolarX group,  $P = 0.0002$ ), despite the absence of significant difference in terms of recurrences. All repeat procedures were performed with radiofrequency.

Kaplan–Meier survival curves for AFA-Pro and PolarX groups are presented in Figure 1 and the log-rank test indicated no significant differences between curves ( $P = 0.11$ ). One year after procedure, 91.2% (85.1–95.4%) in AFA-Pro group and 83.7% (76.0–89.1%) in PolarX group were free of AF recurrence. In multivariate Cox analysis (Table 5), the risk of AF recurrence for PolarX compared with AFA-Pro remained non-significant [HR = 1.61 (0.90–2.89),  $P = 0.12$ ].

## Discussion

Recently a novel cryoablation system (PolarX) has become available, with few data on its mid-term efficacy and safety.

On another hand, the more established AFA-Pro cryoballoon is already very well described in the literature, with notably high number of studies reporting its outcomes in term of efficacy and safety, in the setting of paroxysmal AF ablation.<sup>4,14–16</sup>

Concerning the novel cryoballoon, Guckel *et al.*<sup>10</sup> reported no differences in acute ablation success and safety, in 65 patients treated with the PolarX, compared with the AFA-Pro, without follow-up. Similarly, the Antartica Study included 317 patients ablated with the PolarX, with promising results in terms of safety and efficacy after 7.5 months of mean follow-up, this time without control group.<sup>17</sup>

Finally, very recently, two publications suggested a comparable safety and 1 year outcome between both cryoballoons, in respectively, 110 (57 PolarX vs. 53 AFA-Pro) and 80 patients (40 PolarX vs. 40 AFA-Pro).<sup>11,12</sup>

In the continuation of these recent reports, our study aimed to prospectively compare the new PolarX with the AFA-Pro, the latter considered as the reference tool, in three high volume centres performing cryoballoon ablation. Therefore, we have increased the number of included patients (267 in total), as well as the mean follow-up period ( $15 \pm 5$  months) in order to get a better insight of the safety and effectiveness of the new device.

Subjectively, the operators found easy to start working with the new PolarX ablation system, finding the workflow very similar to the AFA-Pro, with a short initial learning curve.

The two cryoballoons technologies slightly differ, mainly in the ability of the PolarX balloon to maintain a constant inner pressure before and during the freezing. This characteristic was thought to be an advantage to improve PV occlusion and avoid the pop-out phenomenon, improving balloon-to-tissue contact.<sup>8,18</sup> Despite that, our study confirmed that

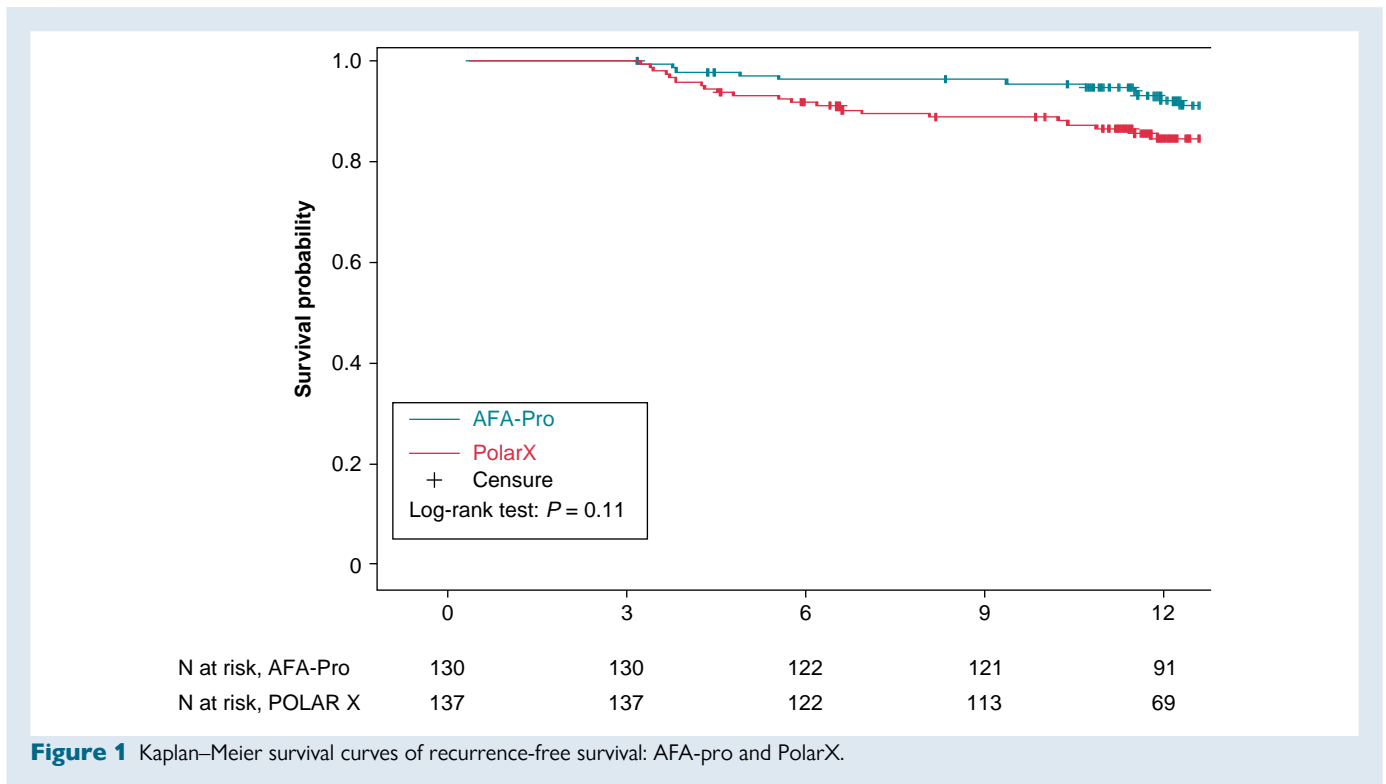
in experienced hands, the total number of freeze applications, and the applications for each PV did not differ between the two technologies.

Interestingly, abortion rate of cryo-application when TTI > 60 s was not significantly different without both balloons (Table 3). This finding is important because it confirms that dosing, as well as TTI workflows, which have been both developed with the AFA-Pro, seem also routinely applicable with the PolarX. However, this does not imply that there are no different parameters that could be more adapted to the PolarX workflow. In this setting, an effort should be produced in further studies dedicated to the PolarX cryoballoon.

In line with previous studies,<sup>6,7,9,19</sup> we confirmed that the PolarX reached lower minimal temperatures during freezing than the AFA-Pro, with a median difference of  $-7^\circ\text{C}$ . Given that both balloons have a similar refrigerating system and location of the thermocouple (21.5 mm between thermocouple and injection coil), architecture of the balloons is not explicative. Whether the more compliant nature of the PolarX, due to the constant inner pressure before and during the application, could induce a closer interface between the balloon and the tissue, resulting in a lower balloon temperature is still speculative. Indeed, such a characteristic should logically induce a shorter TTI, which is not observed in our trial, similarly to other published experiences.<sup>7,9</sup> It is noteworthy that cooler temperature registered by PolarX system may not correspond to a real cooler temperature at the tissue level.

Furthermore, shorter freezing times were recorded with the PolarX in the treatment of the right PVs. This finding, however, should be counterbalanced by the higher rate of phrenic nerve palsy with the PolarX that obliged, in such cases, to shorten the freezing application.

The rate of transient phrenic nerve palsy was consistently higher with the PolarX than with the AFA-Pro. A reasonable explanation could be the lower temperature reached with the PolarX which could be more aggressive for neighbouring structures. On the other hand, the DMS<sup>TM</sup> sensor on PolarX system may be more sensitive to partial phrenic



**Figure 1** Kaplan–Meier survival curves of recurrence-free survival: AFA-pro and PolarX.

**Table 5** Cox analysis

	Univariate analysis: HR (95% CI)	P-value	Multivariate analysis HR (95% CI)	P-value
POLAR X (vs. AFA-Pro)	1.59 (0.89–2.85)	0.12 <sup>a</sup>	1.61 (0.90–2.89)	0.12
Centre (BR as reference)		0.35		
CP	0.66 (0.31–1.41)			
GR	0.61 (0.29–1.25)			
Age	1.01 (0.98–1.04)	0.62		
Male (vs. female)	1.71 (0.96–3.03)	0.07 <sup>a</sup>	1.71 (0.96–3.05)	0.07
Cardiopathy	0.57 (0.18–1.84)	0.35		
CHF	0.49 (0.07–3.56)	0.48		
Dyslipidaemia	1.09 (0.57–2.11)	0.78		
Hypertension	1.08 (0.61–1.92)	0.79		
Diabetes	1.47 (0.53–4.11)	0.46		
CAD	0.65 (0.21–2.10)	0.47		
Valvular heart disease	2.13 (0.52–8.82)	0.30		

<sup>a</sup>included in multivariate analysis.

AFA-Pro, Arctic Front Advance Pro; BR, Brussels; CP, Clinique Pasteur; GR, Grenoble; CHF, chronic heart failure; CAD, coronary artery disease.

nerve palsy compared to the standard tactile feedback used with AFA-Pro, leading to an increased number of transient PNP detected. However, the use of this new DMS™ sensor may need some learning curve, as for example, avoid exerting too much pressure with the abdominal palpation, in order not to disturb the DMS™ measurements. In addition, in seven cases in the PolarX group, the pacing catheter was dislodged, rendering the DMS™ ineffective. On another hand, pacing lead dislodgment is not specific to the PolarX, and it could also occur in the AFA-Pro group. Despite this difference, only one of these PNP evolved to a persistent form (lasting during 4 weeks) in the PolarX group, maintaining an overall low rate of total complications with both systems.

Both mapping catheters were comparable in registering PV signals during ablation with a similar rate of that described in other studies,<sup>20</sup> and a good sensibility (~80% in all PVs) for both mapping catheters. Notably, the difference in PV signal visualization was only significant for the LIPV, and a bonus cryo-application has been delivered in 124/520 (24%) vs. 114/548 (21%) ( $P = 0.23$ ) of the pulmonary veins respectively for the AFA-Pro and the PolarX, which did not influence the global workflow of PV isolation based on TTI in both groups. Additionally, operators did not report any subjective differences in the quality of the signals recorded with the two systems.

Although, overall freedom from recurrence during follow-up was high and comparable between groups, a higher rate of repeat procedures was performed in the PolarX group. Concerning this significant difference in the rate of re-do cases between both balloons, we cannot explain it by a difference in AF burden: the diagnosis of recurrence was assessed in all cases on tracings (ECG or Holter monitoring), and patients were not reporting more symptoms in the PolarX group.

This difference in the rate of reoperations is probably biased by the fact that the PolarX because it was recently introduced, was 'under the radar', and in the patients presenting a recurrence, a second procedure was rapidly planned, in order to better learn about the efficacy of this novel tool. On another hand, in case of recurrences with the AFA-Pro, antiarrhythmic drugs were firstly reintroduced in most patients before planning a second operation, which explains the significant difference in terms of short term re-do procedures.

All in all, this study suggests that in term of efficacy and safety, the PolarX balloon is comparable to the AFA-Pro.

## Limitations

Although this study is not randomized, all patients were consecutively and prospectively included in a multicentric fashion. The size of the population was limited although this is the largest study ever published regarding 1-year free of AF recurrence comparing both balloons. Further larger studies with longer follow-up remain needed to confirm the similar efficacy in terms of recurrences that we observed in our study. In addition, the patients were not followed with a continuous monitoring, so the rate of recurrences could have been underestimated. However, considering that this limitation is applicable for both groups, it looks rather acceptable for the conclusion of the study.

Finally, the presence of the DMS™ sensor could have 'artificially' increased the sensibility of transient phrenic nerve palsy in the PolarX group during the procedure, making the comparison with the AFA-Pro biased.

## Conclusions

This multicentre prospective study suggests that PolarX and AFA-Pro cryoballoons show 1-year comparable efficacy and safety profiles for pulmonary veins isolation in paroxysmal atrial fibrillation.

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## Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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