First experience of POLARx™ versus Arctic Front Advance™: An early technology comparison

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Abstract

Introduction: Cryoballoon ablation is an established technique to achieve pulmonary vein isolation in patients with atrial fibrillation (AF). Recently, a new manufacturer of cryoballoon achieved regulatory CE marking (POLARx™; Boston Scientific). We describe our early experience of using this new market entrant of the technology and describe procedural aspects in comparison to the incumbent Medtronic Arctic Front Advance™.

Methods: We assessed the first 40 AF ablations performed with the POLARx catheter at the Barts Heart Centre. These patients were compared with a contemporaneous series of patients undergoing ablation by the same operators using the Arctic Front Advance. Procedural metrics were prospectively recorded.

Results: A total of four operators undertook 40 cases using the POLARx catheter, compared with 40 cases using the Arctic Front Advance. Procedure times (60.0 vs. 60.0 min) were similar between the two technologies, however left atrial dwell time (35.0 vs 39.0 min) and fluoroscopy times (3.3 vs. 5.2 min) were higher with the POLARx. Measured nadir and isolation balloon temperatures were significantly lower with POLARx. Almost all veins were isolated with a median freezing time of 16.0 (POLARx) versus 15.0 (Arctic Front Advance) min. The rate of procedural complications was low in both groups.

Conclusion: The POLARx cryoballoon is effective for pulmonary vein isolation. Measured isolation and nadir temperatures are lower compared with the predicate Medtronic Arctic Front Advance catheter. The technology appears similar in acute efficacy and has a short learning curve, but formal dosing studies may be required to prove equivalence of efficacy.

Keywords
atrial fibrillation, catheter ablation, cryoballoon, technology
1 | INTRODUCTION

Catheter ablation is the most effective treatment for atrial fibrillation (AF), particularly if paroxysmal, symptomatic, and refractory to antiarrhythmic drugs. Pulmonary vein isolation (PVI) represents the cornerstone of this procedure. Since its introduction in 2007, cryo-balloon (CB) ablation has emerged as a valid alternative to the point-to-point technique with radiofrequency for achieving PVI and this reproducible and rapid technique has become established as a major technique for index procedures in paroxysmal and persistent AF ablation. Indeed, several landmark studies have demonstrated the feasibility, safety, and efficacy of the CB ablation for both paroxysmal and persistent AF. Compared with radiofrequency, the CB technique offers several advantages such as shorter procedure duration, shorter learning curve and a higher degree of reproducibility. Recently, a new CB technology (POLARx™; Boston Scientific) has achieved regulatory CE marking and has been introduced into the market. The aim of the present study is to describe our early experience with the POLARx cryoablation system and describe procedural aspects in comparison to the incumbent Medtronic Arctic Front Advance™.

2 | METHODS

2.1 | Study design

This was a nonrandomized prospective single-center study. We analyzed clinical procedures from the first consecutive 40 PVI procedures performed using the POLARx in the United Kingdom. The procedures were performed by four operators using the novel POLARx cryoablation system (Boston Scientific). These data were compared with the 40 previous consecutive cases undergoing ablation by the same operators using the Arctic Front Advance CB (Medtronic). We systematically collected procedural metrics including skin-to-skin time, time to PVI, left atrial dwell time, fluoroscopy time and dose, nadir and isolation balloon temperatures, as well as acute efficacy and safety outcomes. All patients provided written informed consent before the procedure. The study complied with the Declaration of Helsinki and was registered and endorsed by the Barts Health NHS Trust Clinical Effectiveness Unit (registration ID: 11496). Prospective approval for the use of the POLARx system was obtained from the Barts Heart Centre New Technologies Committee. Cases where additional ablation was performed, for example, radiofrequency ablation of cavo-tricuspid isthmus, were excluded.

2.2 | The POLARx cryoablation system

The POLARx cryoablation system consists of four dedicated components:

- the ablation console (SMARTFREEZE™), consisting of a cryoblation gas exchange and regulation system, integrated computer, cryoablation touchscreen display, and connectors;
- the POLARSHEATH™, a 15.5F deflectable sheath;
- the POLARx 28-mm balloon catheter;
- a pulmonary vein catheter (POLARMAP™) with eight electrodes, 20-mm loop diameter and 3F shaft diameter.

The SMARTFREEZE console was supplied to our laboratory with a control pedal, allowing a physician operator to control therapy delivery. The design of the POLARx recommended workflow is nearly identical to that of the Arctic Front Advance system, with a test inflation while the balloon is submerged in saline before introduction to the POLARx sheath specified. A novel feature of the system is an accelerometer-based adhesive diaphragm movement sensor. This provides a relative measure of diaphragm movement during phrenic pacing as an on-screen graph of instantaneous movement plus a numeric value of movement during pacing.

2.3 | Catheter ablation

Procedures were performed under conscious sedation or general anesthesia. A standardized protocol for CB ablation is in use at Barts Heart Centre, aiming to minimize interoperator variance across the department. This was used for all cases, and is provided in detail as Supporting Information. Briefly, 7F and guidesheath venous access was obtained via the femoral vein guided by vascular ultrasound. A single transseptal puncture was performed under fluoroscopic guidance through the flexible guidesheath using an 89-cm BRK™ or BRK-1™ needle (Abbott) and a Safesep’t™ guidewire. Transoesophageal or intracardiac echocardiography was not performed routinely. All patients were on uninterrupted vitamin K antagonist or a direct acting oral anticoagulant. Patients received 7500–10 000 units of intravenous heparin depending on patient weight, with an activated clotting time (ACT) checked after 30 min of left atrial dwell time. Heparin was, thereafter, titrated to achieve an ACT of 300–350 s. The standard freezing time was 180 s; however, this was left at operator discretion depending on time to isolation, temperature lowering speed and nadir. PVI was considered to have been achieved with demonstration of entrance block. Adenosine challenge test was not routinely performed. Phrenic nerve pacing was performed during freezing of the right pulmonary veins via a quadrapolar catheter, and diaphragmatic movement and compound motor action potentials (C-MAP) monitored for phrenic compromise. A Z-suture or Proglide™ (Abbott) closure was used at the end of the case for achieving femoral hemostasis. All suitable procedures were performed as day case according to our protocol, with patients discharged from hospital 4 h after their procedure.

3 | STATISTICAL ANALYSIS

The $\chi^2$ test and Student’s $t$ test were used for comparison of categorical and normally distributed continuous variables, respectively. The Wilcoxon signed-rank test was employed where data were not
Normally distributed. Results with \( p < 0.05 \) were regarded as significant. RStudio (version 1.2.5033) was used for descriptive and inferential statistical analysis.

4 | RESULTS

4.1 | Population

Forty patients underwent ablation using the POLARx system (mean age \( 62.8 \pm 11.7 \), 57.5% male), with 28 paroxysmal AF, and the mean left atrial diameter was \( 39.3 \pm 4.7 \) mm. Baseline demographic characteristics, with a comparison to patients undergoing ablation using the Arctic Front Advance system, are shown in Table 1.

| TABLE 1 Baseline characteristics of the study population |
|--------------------------------------------------------|
| Arctic Front Advance™ | POLARx™ |
| N (%) | N (%) | \( p \) |
| Number of patients | 40 | 40 | - |
| Age (±SD) | 65.0 ± 12.1 | 62.8 ± 11.7 | .41 |
| Gender | | | |
| Male | 24 (55%) | 26 (57.5%) | .64 |
| Operator | | | |
| M. F. | 15 (37.5%) | 16 (40%) | |
| R. J. H. | 13 (32.5%) | 8 (20%) | |
| R. J. S. | 4 (10%) | 9 (22.5%) | |
| M. J. E. | 8 (20%) | 7 (17.5%) | |
| AF type | | | |
| pAF | 19 (50%) | 28 (68%) | .04 |
| PersAF | 21 (50%) | 12 (32%) | |
| LA diameter (mm) | 40.2 ± 6.0 | 38.3 ± 4.1 | .14 |
| LVEF >55% | 31 (77.5%) | 32 (80%) | .78 |
| Hypertension | 14 (35%) | 17 (42.5%) | .49 |
| Diabetes | 1 (2.5%) | 1 (2.5%) | 1.00 |

Abbreviations: AF, atrial fibrillation; LVEF, left ventricular ejection fraction; pAF, paroxysmal atrial fibrillation; PersAF: persistent atrial fibrillation.

4.2 | Procedural outcomes

PVI was achieved for all four veins by the end of the procedure in all but two patients. The median procedure time and total freeze application time were 60 (44–160) and 16 (9–28) min, respectively. The median left atrial dwell time was 39 (25–78) minutes. A median of 7 (3–16) freezing applications were required per patient to achieve isolation of all veins. Single freeze isolation was achieved for 55.0% (22/40) in the left upper pulmonary vein, 72.5% (29/40) in the left lower pulmonary vein, 48.7% (19/39) in the right lower, and 53.8% (21/39) in the right upper pulmonary vein. Nadir temperatures during freezing were 59.0 ± 4.4°C (left upper pulmonary vein), 54.4 ± 4.4°C (left lower pulmonary vein), 56.6 ± 7.1°C (right lower pulmonary vein), and 58.4 ± 6.9°C (right upper pulmonary vein). One procedure (2%) was complicated by cardiac tamponade requiring cardiac surgery; this occurred toward the end of the case following successful isolation of the left pulmonary veins and right lower pulmonary vein, and was felt to be related to the transeptal puncture. Isolation of the right upper pulmonary vein could not be completed. No clear source of bleeding was identified intraoperatively; however, a possible contusion of the left lower pulmonary vein was noted. The patient made an uncomplicated recovery post surgery. One patient (2%) had a temporary phrenic palsy with full recovery in the 24-h post procedure, and another patient (2%) suffered from a femoral hematoma not requiring any intervention. Isolation of the right lower pulmonary vein was not achieved in one patient despite several attempts.

4.3 | POLARx versus Arctic Front

We compared procedures performed with the POLARx system with a preceding 40 consecutive PVI cases performed with the Arctic Front Advance CB (Table 2). Duration and fluoroscopy use were slightly higher for the POLARx cases, which also had lower indicated nadir temperatures than Arctic Front Advance cases. Furthermore, more ablations were performed with the POLARx system, specifically for the right pulmonary veins (\( p = .02 \)). Times to isolation were similar overall; however, when broken down by individual veins, isolation of the right upper pulmonary vein with POLARx required more than double the time (36 vs. 91 s; \( p = .06 \)). These results are shown in Table 3.

| TABLE 2 Procedural details |
|---------------------------|
| System                   | Arctic Front (n = 40) | POLARx (n = 40) | \( p \) |
| Procedure time, min (range) | 60 (30–160) | 60 (44–160) | .12 |
| Fluoroscopy time, min (range) | 3.3 (0.1–14.5) | 5.2 (0.2–27) | .07 |
| Dose area product, cGy/cm² (range) | 37 (0.8–330) | 47.5 (1.8–900) | .36 |
| Freeze time, min (range) | 15 (4–30) | 16 (9–28) | .07 |
| Left atrial dwell time, min (range) | 35 (20–54) | 39 (25–78) | <.01 |
| Cryoablation application number (range) | 5 (4–11) | 7 (3–12) | .03 |
In the Arctic Front group, isolation of the left lower pulmonary vein was not achieved despite several attempts in one patient; switching from a 28- to a 23-mm balloon was required in another patient to achieve isolation of the left upper pulmonary vein. Periprocedural complications occurred in two patients (4%): one suffered from a transient phrenic nerve palsy with complete recovery after 10 min and another one suffered from haemoptysis on Day 1 post procedure, this self-resolved and there were no further sequelae.

5 | DISCUSSION

We present our early real-world clinical experience of the novel POLARx CB system for AF ablation. Our preliminary data suggest that this technology is effective and safe, with PVI achieved in almost all patients using a workflow identical to that developed for use with Arctic Front Advance cryoablation. Subjectively, the quality of the electrograms with the POLARMAP pulmonary vein catheter was felt to be excellent. Our key findings were (1) the POLARx system appears safe and is able to be used in a similar workflow to our prior experience with the Arctic Front Advance CB system; (2) acute procedural metrics were somehow comparable to those achieved by using the incumbent device, with some differences likely due to the learning curve; and (3) reported temperatures were significantly lower for a given physiological effect, that is, PV isolation.

Overall procedural success was extremely high, with all veins isolated, and a low rate of complications. This strongly indicates that the device is likely to be safe to use by those already versed in CB ablation during clinical use. Our results are consistent with the preliminary data from Anic et al. in a 30-patient study with paroxysmal AF. Procedural metrics including overall procedure duration, atrial dwell time, number of freezes, and fluoroscopy time/dose were all comparable, but slightly worse, than those gained in routine clinical use with the Arctic Front Advance. This is impressive, particularly in that this represents the first report of the use of the POLARx system technology in the United Kingdom. No major learning curve was observed, again indicating the similarity of this to the incumbent system.

Subjectively, we found the system platform easy to use and the minor variances in workflow required were simple to accommodate into our standard procedural workflow. The footpedal user interface did appear to risk decreasing catheter lab team interactions, and the absence of the operator calling out instructions to "inflate," "freeze," or "stop" had a surprisingly isolating effect; we found an effort had to be made to keep other members of our cath lab team informed as to the stage, and the risks of the stage, of the procedure. Although use of the footpedal may increase operator autonomy, it may be wise to continue some functions as "console operated" by a lab assistant.

The standout procedural difference from previous technologies apparent from our study is that of indicated balloon temperature. We consistently observed temperatures of between 5°C and 10°C below what would be indicated by a physiological effect. Indeed, it was apparent that an achieved temperature of ~40°C would not necessarily be sufficient to indicate a sufficient cryodose, an observation borne out by our finding that the median indicated temperature at isolation was ~57°C with the POLARx system compared to ~49°C with the Arctic Front.

### Table 3: Cryoablation ablation metric comparison

| Vein         | Arctic Front | POLARx | Vein comparison p | Group comparisons p |
|--------------|--------------|--------|-------------------|---------------------|
| Number of freezes required, n ± SD | LLPV         | 1.5 ± 0.8 | 1.4 ± 0.9 | .44 | LLPVs: .79 |
|              | LUPV         | 1.5 ± 0.7 | 1.7 ± 0.9 | .21 |                      |
|              | RIPV         | 1.4 ± 0.7 | 1.9 ± 1.5 | .08 | LPVs: .79 |
|              | RUPV         | 1.4 ± 0.8 | 1.8 ± 1.0 | .05 |                      |
| Nadir temperature, n ± SD | LLPV         | 48.3 ± 7.7 | 54.4 ± 4.4 | <.001 | All temperatures: <.001 |
|              | LUPV         | 47.3 ± 6.3 | 59.0 ± 4.4 | <.001 |                      |
|              | RIPV         | 48.6 ± 6.7 | 56.6 ± 7.1 | <.001 |                      |
|              | RUPV         | 50.6 ± 6.5 | 58.4 ± 6.9 | <.001 |                      |
| Time to isolation, s [range] | LLPV         | 74 [2–743] | 54 [21–1020] | .55 | All isolation times: .84 |
|              | LUPV         | 45 [16–240] | 52 [23–224] | .40 |                      |
|              | RIPV         | 37 [9–310] | 73 [18–441] | .429 |                      |
|              | RUPV         | 36 [14–302] | 91 [17–923] | .06 |                      |

Abbreviations: LLPV, left lower pulmonary vein; LUPV, left upper pulmonary vein; RIPV, right inferior pulmonary vein; RUPV, right upper pulmonary vein.
Given that both balloon catheters report temperatures of the return nitric oxide gas from a near identical position, and are of similar construction and geometry, how can this marked difference in apparent temperatures be explained? When taken in context with the increased numbers of cryoablation deliveries required for isolation, the design or materials of the POLARx CB may provide less energy exchange than the Arctic Front Advance CB during clinical use. The resulting therapy could be seen as less aggressive, trading a lower risk of cryoablation impinging on extracardiac structures for slightly longer therapy times. Alternatively, the compliant nature of the POLARx balloon might promote a more antral lesion, more tissue being treated may require longer more therapy. Whatever the underlying reason, this does indicate that dosing schedules for the POLARx should not be assumed to be identical to those established for the Arctic Front Advance system. Until such data are available, routine rechecking of veins for persisting isolation, such as with adenosine or by observing a waiting period, could be prudent.

Furthermore, without a clear understanding of the tissue/indicated temperature interactions, increased caution may be observed regarding system safety. Extensive experience using the Arctic Front system has allowed a nuanced understanding of target temperatures and safety margins to be developed; these lessons may not be directly transferable to the POLARx system. Our preliminary finding of lower indicated temperatures for a given physiological effect was without complication or observation of persistent phrenic nerve palsy.

We have identified that more ablations were required to isolate the RPVs during our early experience with the POLARx technology. The design and handling of the POLARx Sheath appear to the user very similar to the FlexCath, but with an increased maximal bend. The increased number of freezes required for isolation may be attributed to two factors. First, the POLARMap multipolar mapping catheter is somewhat less stiff than the Achieve catheter. Although signals are excellent, it may provide less support. On the flip side, the excellent signals achieved with the POLARMap catheter may reveal very small residual connections which could be missed by the Achieve signals, hence, promoting extra freezes. The technique required for achieving consistent isolation also appears different with POLARx than with the predicate. Unlike the Arctic Front Advance, the POLARx does not increase in size once an ablation is commenced. Whereas a marginally acceptable occlusion would often fully occlude during balloon expansion in the Arctic Front, with the balloon being expelled from the vein as cryoadherence commenced, a full occlusion is mandated before commencing the freeze of the POLARx. In the right-sided veins, stability is usually lower and in our experience a minor adjustment in technique is required to achieve consistent occlusion with the POLARx system. Furthermore, the POLARx balloon appears marginally more delicate, aggressive maneuvers (pull-downs, hockey-sticks, catheter flexion) are not recommended by the manufacturer and the avoidance of these may be reflected in our results.

6 | LIMITATIONS

This represents a short report of our initial experience with this new technology. Comparisons have been performed with consecutive cases rather than by randomization, observed differences between the two technologies could, therefore, arise either by hidden bias or be due to learning curves experienced with the POLARx technology. A randomized study powered for clinically meaningful endpoints would be required to definitively show superiority or equivalence between these technologies.

7 | CONCLUSION

The POLARx CB is effective for PVI. Measured isolation and nadir temperatures are lower compared with the predicate Arctic Front Advance catheter. The technology appears similar in acute efficacy and has a short learning curve, but detailed dosing studies will be required to prove equivalence.

DATA AVAILABILITY STATEMENT

Data are available on request due to privacy/ethical restrictions.

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SUPPORTING INFORMATION
Additional Supporting Information may be found online in the supporting information tab for this article.

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