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Initial clinical experience with the novel POLARx FIT cryoballoon system for pulmonary vein isolation in patients with atrial fibrillation

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ABSTRACT

Background: The POLARx FIT system (Boston Scientific, MA, USA) is a novel cryoballoon (CB) ablation technology in which the balloon diameter can be expanded from 28 to 31 mm. The aim of this study was to compare the benefits and safety of the new POLARx FIT system to those of the existing POLARx system currently in use for pulmonary vein (PV) isolation (PVI) in patients with atrial fibrillation.

Methods: The first 70 consecutive patients who underwent CB-based PVI with the POLARx FIT system were retrospectively compared with 200 consecutive patients treated with the POLARx system at Sakakibara Heart Institute from October 2021 to May 2023.

Results: The POLARx FIT system yielded a higher mean ± standard deviation nadir temperature in the right inferior PV (−59.2 ± 5.29 °C vs. − 62.0 ± 5.08 °C, p = 0.006), but this required a balloon size reduction to 28 mm in 30 % of cases. No significant differences were detected in the time to isolation and thaw time of any PV between the two groups. After the CB-based PVI procedure, no residual PV carina potentials were observed with the POLARx FIT system, whereas 4/20 were with the POLARx system (p = 0.04).

Conclusions: The POLARx FIT system had comparable effectiveness and safety to the basic POLARx system. This technology may improve the ablation area, including the PV carina. However, the 31-mm balloon alone was not sufficient to isolate certain PVs.

1. Introduction

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) treatment, and can be performed in a shorter time and with results comparable to radiofrequency (RF) ablation by using a cryoballoon (CB) [1–4]. For many years, PVI using the Arctic Front Advance (AFA) or AFA Pro (Medtronic, Minneapolis, MN, USA) cryoablation catheter has been an effective alternative to RF ablation [1,5] and well established, with numerous reports of its efficacy and safety in the treatment of paroxysmal AF [6,7]. Recently, a new CB, the POLARx cryoablation system (Boston Scientific, Marlborough, MA, USA), was introduced. A unique feature of the POLARx balloon is that the pressure remains constant regardless of whether it is frozen, allowing the balloon to remain compliant during ablation. The POLARx system has demonstrated comparable procedural efficacy and safety to the other catheters despite its lower nadir balloon temperature [8–10]. Although the POLARx system reportedly yields a higher incidence of transient phrenic nerve palsy than the AFA Pro catheter, the recurrence rate does not significantly differ between the two [11]. In a recent multicenter study, two CB ablation systems (AFA and POLARx) were compared for PVI, revealing no differences in efficacy or safety at the 12-month follow-up [12]. In addition, the new POLARx FIT cryoablation system (Boston Scientific) allows the same balloon to be increased in size from 28 to 31 mm by changing the internal pressure. Therefore, this system has potential for treatment of larger PVs; however, no clinical data is available in that respect.

Abbreviations: AF, atrial fibrillation; CB, cryoballoon; CBA, cryoballoon ablation; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; PNP, phrenic nerve palsy; PV, pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; TTI, time to isolation.

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[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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1.1. Objective

The purpose of this study was to compare the benefits and safety of the new POLARx FIT system to those of the POLARx system.

2. Methods

2.1. Study population

This was a retrospective, single-center study of PVI as first-line treatment for symptomatic paroxysmal and persistent AF via the POLARx and POLARx FIT systems. In total, 200 consecutive patients underwent CB-PVI via the POLARx system and 70 via the POLARx FIT system at Sakakibara Heart Institute from October 2021 to May 2023. All procedures were performed by five electrophysiologists, each with more than 10 years of training.

2.2. Consent

All patients provided written informed consent prior to catheter ablation. This study complied with the tenets of the Declaration of Helsinki, and the study protocol was approved by the Ethics Committee of Sakakibara Heart Institute (Approval number: 23–024).

2.3. Ablation protocol

The procedures were performed under conscious sedation with pentazocine, buprenorphine, and propofol. In all cases, an esophageal temperature sensor was inserted prior to puncture of the femoral vein. First, two sheaths (8.5-Fr SL-0; Abbott, St. Paul, MN, USA and a 9-Fr 25-cm sheath; Terumo Corp., Tokyo, Japan) were inserted through the femoral vein. Thereafter, 5,000 units of heparin were administered. The atrial septum was observed using a ViewFlex Xtra ICE catheter (Abbott Laboratories, Chicago, IL, USA) from the 9-Fr sheath, and a septal puncture was performed using an RF needle (NRG; Baylis Medical, Toronto, Canada) through the 8.5-Fr sheath. After the septal puncture, a bolus of 5,000 units of heparin was immediately administered, and heparin was added as needed to achieve an activated clotting time of 300–350 s. The 8.5-Fr sheath was exchanged over a guidewire for the 15.5F POLAR sheath (Boston Scientific). A 20-mm inner lumen circular mapping catheter with eight electrodes (POLARMAP; Boston Scientific) was inserted for all PVs, and PV potentials were recorded whenever possible. PVI was performed using a 28-mm CB (POLARx) in 200 patients, and PVI was performed using a 31-mm CB (POLARx FIT) in 70 patients. The POLARx FIT balloon can be enlarged from 28 mm to 31 mm, and all PVs were first treated with a 31-mm balloon size. Cryoablation was initiated after optimal PV occlusion was achieved, as verified using contrast injection. Cooling was generally initiated after a grade 4 occlusion was confirmed, but momentary contrast leakage, e.g., due to breathing, was tolerated. The occlusion grading system consisted of four grades: grade 4: complete occlusion, grade 1: massive outflow leakage from the PV to the left atrium. In cases of minor leakage (grade 3), wherein freezing time and balloon temperature were consistently correlated and time to isolation (TTI) of < 60 s could be achieved, good occlusion was assumed to be ensured during the freezing process. If PVI was not achieved within 60 s, we assumed that favorable contact had not been achieved, and the balloon size was reduced to 28 mm. Time to isolation (TTI) was used to determine the freezing time. Cryoablation was performed on the left PVs first, followed by the right PVs. During left-sided ablation, ventricular pacing was on standby in case of atrioventricular block. During right-sided ablation, pacing was performed from the right subclavian vein to prevent phrenic nerve palsy. Acute PVI was confirmed by the loss or dissociation of the PV signal, and exit block was confirmed by pacing from the proximal PV with the POLARMAP catheter and the absence of atrial capture. After confirming the loss of all PV potentials and bidirectional conduction block, a high dose of isoproterenol (16–17 μg/min) was administered to detect reconnections between the PVs and the left atrium as well as the presence of non-PV foci [13].

2.4. Data collection

Patient laboratory and clinical data were obtained from their medical records. For each CB ablation (CBA), the following parameters were collected: total treatment time, duration of fluoroscopy, duration of CBA, TTI (if available), balloon temperature 30 s after cryoablation was started, balloon nadir temperature, touch-up RF ablation, and the occurrence of transient phrenic nerve palsy. For cases in which the voltage was obtained using the POLARMAP after CBA, we confirmed the isolation of the PVs and evaluated whether residual potentials could be observed in the carina as a simple indicator of the isolated area.

2.5. Evaluation of lesion size

The scar area of the posterior wall (defined as an area with a potential less than 0.1 mV) obtained from postoperative voltage maps was compared among 20 patients who underwent PVI with the 28-mm CB and 20 patients who underwent PVI with the 31-mm CB. These 20 cases were the initial 20 consecutive cases of each balloon, and for the POLARx FIT group, only cases that could be isolated with the 31-mm balloon in a single procedure were included (cases that required RF touch-up or were reapplied with a 28-mm balloon were excluded).

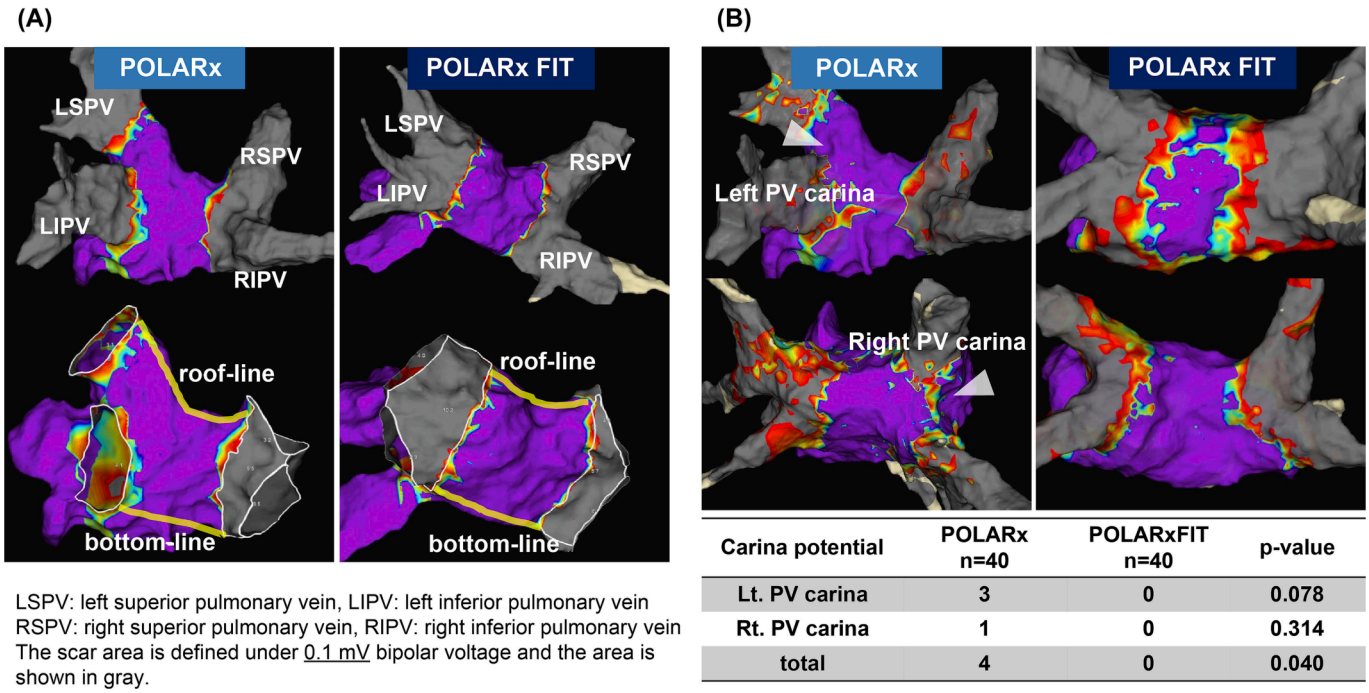
From the obtained 3D voltage map, each PV was cut out. Cases isolated at the distal side of the PV were cut at the site of the scar, and cases isolated at the ostium were cut at the ostium (Fig. 1A). The scar area (the area where the CB would normally make contact) in the left atrial posterior wall was calculated using the “roof line” connecting the upper edge of the upper PV and the “bottom line” connecting the lower edge of the lower PV. For the four PVs that were excised, half of the cross-sectional area was incorporated as the scar area of the posterior wall (Fig. 1A, Supplemental Figure). If a scar was formed distal to the PV ostium, the scar area was defined as half of the PV cross-sectional area at the site of scar formation. Using this method, the scar area of the posterior left atrial wall formed by the cryoballoon was defined as the sum of the gray areas shown in the additional figure (Supplemental Figure). Note that in this study, there was no additional treatment based on the size of the scar.

2.6. Statistical methods

Continuous data were expressed as means ± standard deviations for normally distributed variables or as medians (interquartile ranges) for non-normally distributed variables. Differences in continuous variables were analyzed using Student’s *t*-test or the Wilcoxon rank-sum test. Levene’s test was used to confirm equality of variances for normally distributed variables; where the Kolmogorov–Smirnov test indicated a non-normal distribution, an equivalent nonparametric test was used. All statistical analyses were performed using JMP 15 software (SAS Institute Inc., Cary, NC, USA), and $p < 0.05$ was considered indicative of statistical significance.

3. Results

From October 2021 to May 2023, 270 consecutive patients who underwent CBA for paroxysmal or persistent AF were included in this study. Baseline patient characteristics are presented in Table 1. The baseline variables (age, sex, type of AF, left atrial diameter, left atrial volume, ejection fraction, and $CHADS_2$ score) were similar between the two groups. The procedure time was significantly longer in the POLARx FIT group due to the need to perform PVI with balloon size changes in some pulmonary veins. The POLARx FIT group had significantly lower esophageal temperatures. There were no significant differences in



LSPV: left superior pulmonary vein, LIPV: left inferior pulmonary vein
RSPV: right superior pulmonary vein, RIPV: right inferior pulmonary vein
The scar area is defined under 0.1 mV bipolar voltage and the area is shown in gray.

Carina potential	POLARx n=40	POLARxFIT n=40	p-value
Lt. PV carina	3	0	0.078
Rt. PV carina	1	0	0.314
total	4	0	0.040

Fig. 1. Comparison of scar areas created by POLARx and POLARx FIT. **A.** Comparison of lesion size between the 28-mm and 31-mm balloon. The left figure shows a case treated with a 28-mm balloon, and the right figure shows a case treated with a 31-mm balloon. The "roof line" is defined as the line connecting the top of the upper PV and the "bottom line" as the line connecting the bottom of the lower PV. The scar area is defined as that under 0.1 mV bipolar voltage and the area is shown in gray. The total posterior scar area was calculated as the sum of half the cross-sectional area of each pulmonary vein and the scar area of the left atrial posterior wall. **B.** Voltage map obtained using the POLARMAP catheter after pulmonary vein isolation. In the POLARx (28 mm) group, 4 of 20 patients (40 carinae) had residual potentials in the PV carina (3 in the left carina, 1 in the right carina). However, none of 20 patients (40 carinae) in which all PVs were isolated with a 31-mm balloon size using the POLARx FIT CB exhibited residual carina potentials. PV: pulmonary vein.

Table 1
Baseline patient characteristics and procedural parameters.

	POLARx n = 200	POLARx FIT n = 70	p-value
Male (%)	131 (65.5)	47 (67.1)	0.80
Age (years)	66.7 ± 11.4	66.8 ± 11.5	0.75
AF type, paroxysmal (%)	128 (64)	42 (60)	0.55
LA diameter (mm)	38.0 ± 7.0	39.1 ± 7.3	0.38
LA volume (ml)	65.5 ± 26.0	64.8 ± 25.7	0.86
LA volume index (ml/m^2)	42.1 ± 15.3	38.5 ± 14.9	0.07
EF (%)	57.4 ± 8.74	57.6 ± 8.71	0.76
$CHADS_2$ score	0.95 ± 1.00	1.01 ± 0.93	0.46
Procedure time, min	101.7 ± 32.5	119 ± 30.5	<0.001
Fluoroscopy time, min	21.3 ± 11.6	21.9 ± 9.4	0.20
TTI observations (%)	74	76	0.64
Minimum esophageal temperature (°C)	24.8 ± 11.3	22.3 ± 10.5	0.048
RF touch-up, n (%)	3 (1.5)	3 (4.3)	0.17
PNP, n (%)	27 (13.5)	10 (14.3)	0.87
at RSPV, n (%)	19 (70.4)	6 (60)	0.84
at RIPV, n (%)	8 (29.6)	4 (40)	0.53
by 31 mm, n	–	8	–
Cardiac tamponade	1	1	0.43
Puncture site complication	1	0	0.56

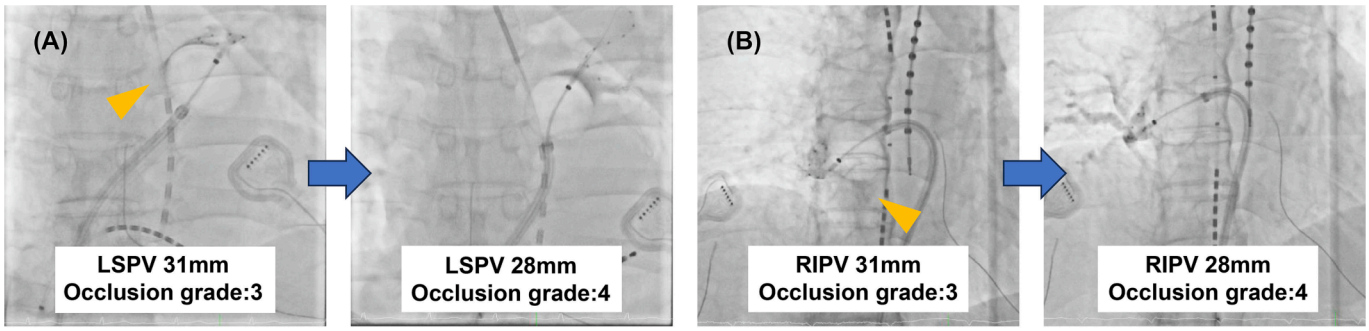
Abbreviations - AF: atrial fibrillation, LA: left atrium, EF: ejection fraction, TTI: Time to isolation, RF: radio frequency, PNP: phrenic nerve palsy, RSPV: right superior pulmonary vein, RIPV: right inferior pulmonary vein

cardiac tamponade or puncture site complications between the two groups.

In all procedures, cooling was performed to achieve complete occlusion (grade 4 occlusion), but grade 3 occlusion was acceptable if the pulmonary venous potential observed in POLARmap disappeared within 60 s. As shown in Table 1, three patients in the POLARx group required RF touch up: two in the right superior PV (RSPV) and one in the left superior PV (LSPV). All of these cases were grade 3 obstructions in which the loss of pulmonary venous potential was not obtained within 60 s. The number of PVs that were reablated with a 28-mm balloon size for each PV is summarized in Fig. 2. The percentage that required downsizing to 28 mm was 15.7 % for the LSPV, 10 % for the left inferior PV (LIPV), 4.3 % for the RSPV, and 30 % for the right inferior PV (RIPV), indicating that overall, the 31-mm size alone was not sufficient for complete isolation in a significant percentage of cases. No significant differences were detected between the two groups with respect to fluoroscopy time or transient phrenic nerve palsy (PNP). The number of touch-ups required with RF catheters was also did not significantly differ between the groups (Table 1).

Comparisons of the procedural parameters for each PV are summarized in Table 2. Missing data were excluded from these analyses. Patients with a left common PV were also excluded from these analyses; thus, a total of 652 PVs were included (POLARx: n = 460, POLARx FIT: n = 192). Significant differences were observed in the balloon temperature at 30 s in the LSPV (POLARx: −35.8 ± 5.27 °C vs. POLARx FIT: −38.0 ± 5.50 °C, p = 0.02) and the nadir balloon temperature in the RIPV (POLARx: −62.0 ± 5.08 °C vs. POLARx FIT: −59.2 ± 5.29 °C, p = 0.006). Other procedure-related variables were similar between the two groups.

In addition, the POLARMAP catheter was used to obtain voltage maps for 20 patients in each group. For mapping, we used the Ensite NavX (St. Jude Medical, Inc., St. Paul, MN, USA) three-dimensional mapping system. In 20 patients undergoing POLARx CBA, residual carina potentials were detected in 4 (3 in the left carina, 1 in the right carina). However, none of the 20 selected patients undergoing POLARx FIT CBA exhibited residual carina potentials (Fig. 1B). Moreover, the scar area created by the 31-mm balloon was significantly larger than that created by the 28-mm balloon (17.9 ± 4.0 mm^2 vs. 15.1 ± 3.9 mm^2, p = 0.04) (Supplemental Figure).



	Number of vessels that required balloon size reduction to 28 mm, n=70
LSPV, n (%)	11 (15.7)
LIPV, n (%)	7 (10)
RSPV, n (%)	3 (4.3)
RIPV, n (%)	21 (30)

LSPV: left superior pulmonary vein, LIPV: left inferior pulmonary vein
RSPV: right superior pulmonary vein, RIPV: right inferior pulmonary vein
Occlusion grade 4: complete occlusion, Occlusion grade 3: small leakage(▼) of contrast media

Fig. 2. Pulmonary venographs at 31- and 28-mm balloon sizes for the LSPV and RIPV, and the number of vessels requiring balloon-size reduction to 28 mm using the POLARx FIT system. LSPV: left superior pulmonary vein, LIPV: left inferior pulmonary vein, RSPV: right superior pulmonary vein, RIPV: right inferior pulmonary vein. Occlusion grade 4: complete occlusion, occlusion grade 3: small leakage of contrast media.

Table 2
Comparisons of the procedural parameters for each pulmonary vein.

	LSPV POLARx (n = 132)	LSPV POLARx FIT (n = 53)	p-value
Time to isolation, s	47.6 ± 21.5	51.8 ± 25.1	0.28
Thaw time (to reach 20 °C), s	67.2 ± 25.2	72.7 ± 30.1	0.26
Balloon temperature at 30 s, °C	−35.8 ± 5.27	−38.0 ± 5.50	0.02
Nadir temperature, °C	−60.9 ± 4.61	−59.8 ± 4.93	0.07
	LIPV POLARx (n = 113)	**LIPV POLARx FIT (n = 47)**	**p-value**
Time to isolation, s	30.6 ± 15.7	30.5 ± 11.6	0.40
Thaw time (to reach 20 °C), s	47.2 ± 16.8	51.6 ± 20.4	0.12
Balloon temperature at 30 s, °C	−38.6 ± 5.48	−38.8 ± 4.01	0.94
Nadir temperature, °C	−56.4 ± 5.20	−54.7 ± 4.84	0.09
	RSPV POLARx (n = 114)	**RSPV POLARx FIT (n = 51)**	**p-value**
Time to isolation, s	38.8 ± 24.6	34.7 ± 19.5	0.85
Thaw time (to reach 20 °C), s	67.6 ± 23.6	72.3 ± 23.7	0.19
Balloon temperature at 30 s, °C	−40.6 ± 5.98	−41.3 ± 4.40	0.95
Nadir temperature, °C	−62.3 ± 4.85	−60.6 ± 5.86	0.11
	RIPV POLARx (n = 101)	**RIPV POLARx FIT (n = 41)**	**p-value**
Time to isolation, s	47.0 ± 25.1	47.9 ± 24.5	0.71
Thaw time (to reach 20 °C), s	64.4 ± 23.3	64.2 ± 22.0	0.96
Balloon temperature at 30 s, °C	−37.5 ± 6.00	−38.1 ± 5.43	0.58
Nadir temperature, °C	−62.0 ± 5.08	−59.2 ± 5.29	0.006

Abbreviations – LSPV: left superior pulmonary vein, LIPV: right inferior pulmonary vein, RSPV: right superior pulmonary vein, RIPV: right inferior pulmonary vein

4. Discussion

The new POLARx FIT balloon system enables the selection of two different balloon sizes in a single catheter. Its maneuverability is equivalent to that of the conventional POLARx system. The use of the balloon and connection to the console remain unchanged from the basic POLARx system. When the balloon is first inflated, the internal balloon pressure of the POLARx FIT catheter is controlled at 2.5 psig and the balloon diameter is maintained at 28 mm. Pressing a newly installed button switches the mode from 28 mm to 31 mm, and the internal balloon pressure is controlled at 7.5 psig.

Balloon-tissue contact is essential for optimal efficacy of CBA, and grade 4 PV occlusion upon contrast injection is recommended prior to freezing [14]. In all cases in which the POLARx FIT system was used, initial occlusion and freezing were attempted at 31 mm. In PVs that were not isolated within 60 s, the size was reduced to 28 mm, and freezing was performed again. This probably explains the difference in procedure time (POLARx: 101.7 ± 32.5 min vs. POLARx FIT: 119.0 ± 30.5 min, $p < 0.001$; Table 1) and highlights the importance of selecting an appropriate balloon size according to the diameter and shape of the vessel. As demonstrated in Table 2, the nadir temperature and balloon temperature at 30 s differed between the two groups. The reason for the difference in the balloon temperature at 30 s in the LSPV cannot be determined with our data. The nadir balloon temperature in the RIPV was significantly higher in the POLARx FIT group. Furthermore, Fig. 2 reveals that the RIPV required balloon size reduction to 28 mm in 30 % of cases. The inferior portion of the RIPV is closest to the septal puncture site and is reportedly the most likely location for residual potentials in CBA [15,16]. These results might have been caused by the increased internal pressure of the 31-mm balloon, complicating the achievement of adequate occlusion of the RIPV. At the start of balloon freezing, complete occlusion of the PV should be confirmed with contrast injection. Patients can be classified into four groups according to occlusion grade (grade 4: complete occlusion, grade 1: massive outflow leakage from the PV to the left atrium) [16,17]. As shown in Fig. 2, grade 3 PV

was detected in several cases at 31 mm, and grade 4 occlusion was achieved by using a balloon size of 28 mm, which ensured complete isolation.

The LSPV also required balloon downsizing in 16 % of cases. The larger balloon and higher internal pressure might not have allowed for adequate fixation. The distal PV tissue is thinner, and the proximal atrial muscle tissue is thicker. In addition, the LSPV tissue is thicker, especially on the anterior wall, owing to the presence of the left atrial appendage. In fact, in one case, acute re-conduction was observed after 180 s of cooling, even though the TTI was less than 60 s with the 31-mm balloon. In the case illustrated in Fig. 3, acute re-conduction was confirmed when the patient was re-evaluated with the POLARMAP catheter after all PVIs were completed, despite a TTI of 21 s. Therefore, clinicians should be aware that re-conduction may be observed after isolation when the 31-mm balloon is used. Further studies are needed to determine whether the initial freezing time should be extended with the 31-mm balloon or whether the balloon size should be reduced to 28 mm for distal freezing.

The PNP was expected to decrease as the balloon was further inflated and more proximally attached; however, no significant difference was observed (Table 1). Although a larger balloon would provide more proximal occlusion and a larger distance to the phrenic nerve, it is possible that the larger balloon may have had a greater effect, thus counteracting these results. In the POLARx FIT group comprising 10 cases of PNP, 2 patients showed improvement in symptoms the next day, 6 showed improvement after 1 month, and 2 having persistent symptoms at the 3-month mark. Unfortunately, the follow-up data in the POLARx FIT group was limited to 3 months due to the short observation period. Meanwhile, the POLARx group comprised 27 PNP cases, with 10 showing improvement in symptoms the next day, 10 showing improvement after 1 month, and 7 having persistent symptoms at the 12-month mark. During the observation period, no significant differences were noted in the occurrence of PNP between the two groups when comparing the data after 3 months. The incidences of phrenic nerve palsy may be higher at our institution. Our balloon ablation technique involved withdrawing the balloon temperature dropped below −40 °C during the cooling process of the right upper and lower pulmonary veins. The elevated incidence of PNP may therefore be attributed to the increased tissue contact, as prioritizing occlusion and isolation was our primary focus. Compared with the ANTARCTICA study [18], our data showed that the minimum balloon and esophageal temperatures were lower at our hospital (Table 2). This data also suggests that the contact force of the balloon on the pulmonary vein may be stronger with our technique. However, no substantial percentage occurrence of phrenic nerve palsy was noted after 3 months in this study.

Post-ablation voltage maps were obtained for 20 patients from each group. No residual carina potentials were observed in any of the cases in the POLARx FIT group, suggesting that this device may be more useful in obtaining extensive ipsilateral PVI (Fig. 1). However, Fig. 2 indicates that 42 of the 277 PVs in 70 patients (15.2 %) could not be isolated with a 31-mm balloon. Thus, using two different sizes, 28 and 31 mm, depending on the morphology of the left atrium and PV, would provide more appropriate PVI.

4.1. Study limitations

The data obtained from the new POLARx FIT system were based on our first experience with it. The technique is similar to that of the POLARx system; however, further studies are needed regarding balloon size selection for optimal PV occlusion. A TTI cut-off of 60 s was used to declare PVI with the 31 mm balloon as ineffective and to change to the 28 mm diameter balloon. However, in the 28 mm group, 60 s was not used as a cut-off to stop the current application. This represents a bias in the treatment and could have clearly influenced some of the variables in the analysis, including procedure time and PNP. Although POLARmap was not sufficient to obtain a high-density voltage map, it was able to calculate the residual carina potentials and ablation area, so this study was also acceptable in terms of simplicity and cost. In addition, due to some cases revealing insufficient potential on the anterior wall side, this study was focused on the posterior wall side. In the future, we aim to consider calculating the entire scar area using a multipolar mapping

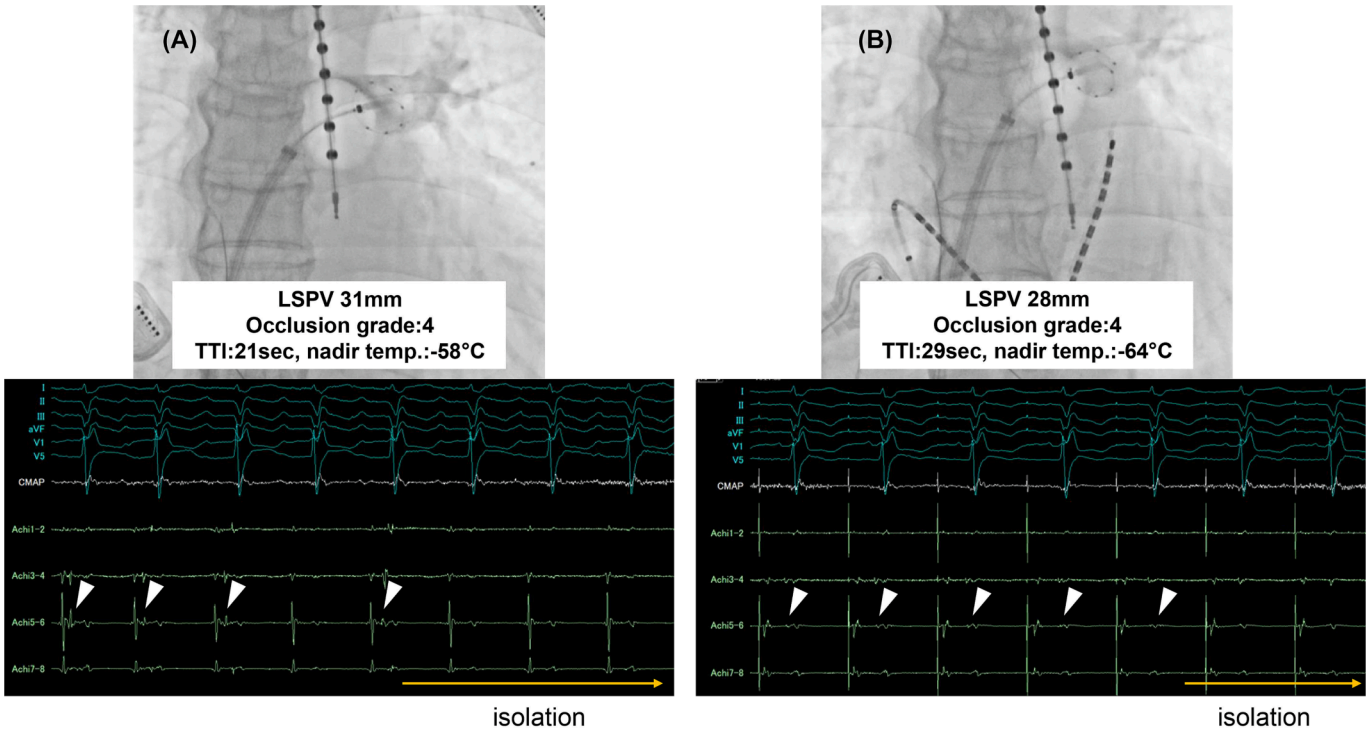


Fig. 3. Acute re-conduction after pulmonary vein isolation with a 31-mm balloon in LSPV. (A) In this case, re-conduction of PV potential was observed after 180 s of freezing despite a TTI of 21 s and a nadir balloon temperature of − 58 °C. (B) Complete isolation was obtained by refreezing with the 28-mm balloon. Additional freezing was performed for 210 s. LSPV: left superior pulmonary vein, PV: pulmonary vein, TTI: time to isolation.

catheter.

Future observations are needed regarding medium- to long-term prognosis, including gastrointestinal problems, PV stenosis, and recurrence. This study was a simple comparison of consecutive cases with a small sample size and did not provide a comparison between two groups with a combined background of clinical data. Therefore, the statistical analyses, and especially the subgroup analyses, may be of limited value. However, our data suggest that the POLARx FIT system may have a wider isolation area, and future studies are needed to determine whether this has an effect on the recurrence rate.

5. Conclusions

The new POLARx FIT system was an effective and safe treatment for PVI in our study, comparable to the basic POLARx system. This new technology may improve the area of ablation, including the PV carina. However, not all PVs can be isolated with a 31-mm balloon; in such cases, the balloon size can be switched to 28 mm. Larger, prospective studies are required to determine the long-term efficacy and safety of this system and to determine the optimal balloon size according to PV characteristics.

Clinical trial registration

Not applicable.

Data availability statement

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

CRediT authorship contribution statement

Hiroshi Fukunaga: Writing – review & editing, Visualization, Formal analysis, Data curation. **Yukio Sekiguchi:** Writing – review & editing. **Jun Sawaguchi:** Methodology. **Yosuke Hayashi:** Investigation, Data curation. **Sou Asano:** Investigation, Data curation. **Kei Mabuchi:** Formal analysis. **Kanki Inoue:** Visualization. **Kohei Tanizaki:** Methodology. **Jun Umemura:** Methodology. **Mitsuaki Isobe:** Supervision. **Junichi Nitta:** Writing – original draft, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2023.101326.

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