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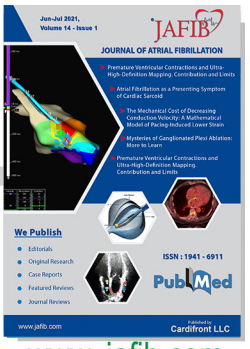

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Procedural Safety and Efficacy for Pulmonary Vein Isolation with the Novel Polarx™ Cryoablation System: A Propensity Score Matched Comparison with the Arctic Front™ Cryoballoon in the Setting of Paroxysmal Atrial Fibrillation

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Abstract

Background. The novel Polarx™ cryoablation system is currently being studied for atrial fibrillation (AF) ablation. To the best of our knowledge, no study comparing the novel cryoablation system with the standard Arctic Front™ cryoballoon is available in today's literature. This study aims to compare Polarx™ and Arctic Front™ cryoballoon in terms of safety and efficacy.

Methods. From a total cohort of 202 patients who underwent pulmonary vein (PV) isolation for paroxysmal AF through cryoablation, a population of 30 patients who used Polarx™ were compared with 30 propensity-score matched patients who used Arctic Front™.

Results. Pulmonary vein occlusion and electrical isolation were achieved in all (100%) veins with a mean number of 1.09 ± 0.3 occlusion per vein using Polarx™ and 1.19 ± 0.5 occlusion per vein using Arctic Front™ (p = 0.6). Shorter procedure and fluoroscopy time were observed with Polarx™ group (60.5 ± 14.23 vs 73.43 ± 13.26 mins, p = 0.001; 12.83 ± 6.03 vs 17.23 ± 7.17 mins, p = 0.01, respectively). Lower cumulative freeze duration per vein was also observed with Polarx™ (203.38 ± 72.03 vs 224.9 ± 79.35 mins, p = 0.02). There was no significant difference in isolation time between the two groups (34.47 ± 21.23 vs 34.18 ± 26.79 secs, p = 0.9).

Conclusion. The novel Polarx™ cryoablation system showed similar efficacy in vein occlusion and isolation and safety profile when compared to Arctic Front™ cryoablation system. Procedure time, fluoroscopy time, and cumulative freeze duration were significantly lower with Polarx™ cryoablation system.

Introduction

The pulmonary veins (PV) play a key role in the pathogenesis of atrial fibrillation (AF) and their isolation is associated with freedom from AF [1]. PV isolation using catheter ablation is achieved through different sources (laser, radiofrequency, cryoenergy) and is being increasingly performed worldwide. Cryoablation has high efficacy in isolating PVs, low rate of complications, more reproducible and less operator dependent outcomes, and is proven superior to antiarrhythmic drugs (AADs) in preventing AF recurrence [2-4], making it standard of care for numerous institutions for AF management. Over the years, Arctic Front™cryoballoon(Medtronic, USA) has been paving the way for the science of AF cryoablation [5-9]. The Polarx™ cryoablation system (Boston Scientific, USA) has been very recently released on the market, with modifications designed to potentially improve workflow for PV isolation. The present study aimed to compare the safety and efficacy of the new Polarx™ cryoablation system with the standard Arctic Front™ cryoablation system.

Key Words

Atrial fibrillation; Cryoballoon; Arctic Front; Polarx.

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Aim of the study

The aim of the study was to compare the new Polarx™ cryoablation system with the standard Arctic Front™ cryoballoon in terms of safety and efficacy during PV isolation for AF.

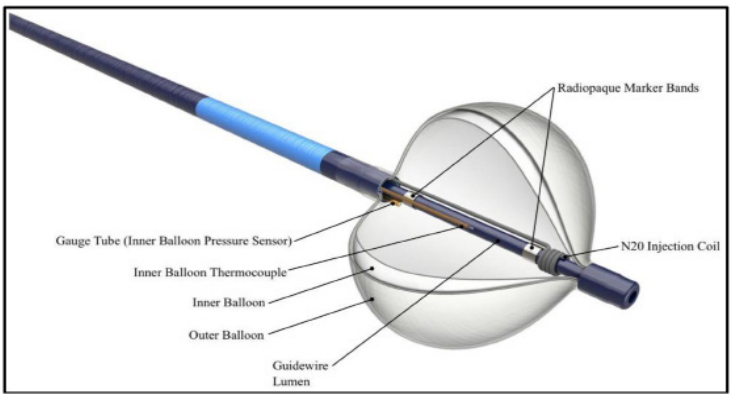

Figure 1: Cross section of the novel POLARx™ cryoballoon catheter, showing integral parts of the balloon catheter. Image courtesy of Boston Scientific.

Methods

Study Population. All patients who underwent PV isolation for paroxysmal AF using Polarx™ cryoablation system and Arctic Front™ cryoablation system from March 2 to October 16, 2020 were included in this study. The study was retrospective in nature and approved by the local ethics committee of our institution. All patients underwent cryoablation procedure with standard protocol in our institution.

Preprocedural management. All patients provided written informed consent to the ablation. A transthoracic echocardiogram (TTE) was performed one week prior to ablation for assessment of structural heart disease. To exclude the presence of thrombi, transesophageal echocardiography (TEE) was performed on the day of the procedure. All patients underwent pre-procedural cardiac computed tomography (CT) scan to assess left atrium (LA) and PV anatomy. The LA anteroposterior diameter was assessed by TTE on parasternal long-axis M mode and indexed to body surface area. Antiarrhythmic drugs (AAD) were discontinued at least 3 days before the scheduled ablation.

Polarx™ cryoablation system. The novel cryoablation system is composed of a Polarx™ cryoballoon (Boston Scientific, USA) that is maneuvered in the left atrium through a steerable sheath (PolarSheath™, Boston Scientific, USA). Aninner-lumen mapping catheter (ILMC) (PolarMap™, Boston Scientific, USA) is placed inside the cryoballoon inner lumen and positioned in the ostium of each PV. The system is connected to a console (SmartFreeze™, Boston Scientific, USA) which controls, monitors, and records the different phases of cryoablation (inflation, freezing, deflation). For this study, we used the short-tip Polarx™ cryoballoon catheter. See Figure 1 for Polarx™ cryoablation system.

Arctic Front™ cryoablation system. The standard cryoablation system is composed of the Arctic Front Advance Pro™ cryoballoon catheter (Medtronic, USA) that is maneuvered in the left atrium through a steerable sheath (FlexCath Advance™, Medtronic, USA). AnILMC (Achieve™mapping catheter, Medtronic, USA) is placed inside the cryoballoon inner lumen and positioned in the ostium of each PV. The system is connected to a console (CryoConsole™, Medtronic, USA) which controls, monitors, and records the different phases of cryoablation. See Table 1 for description and difference between the 2 cryoablation systems. See Figure 2 for Arctic Front™ cryoablation system.

Cryoballoon ablation procedure. All procedures were done by two primary operators who both performed more than1,000 Arctic Front cryoballoon each. Procedures were performed under general anesthesia. Under TEE guidance, an 8.5-Fr transeptal sheath (SL-0, Abbott) with a Brockenbrough needle (BRK-1, Medtronic) was advanced to the LA and exchanged for the cryoballoon steerable sheath. The cryoballoon and ILMC were advanced in each PV ostium to obtain baseline electrical information. The cryoballoon was inflated and gently advanced to occlude each PV. Pulmonary vein occlusion was assessed with contrast injection. Optimal vessel occlusion is when contrast injection showed total contrast retention inside the PV with no backflow to the LA. Activated clotting time was maintained at 250 seconds by an initial intravenous bolus of heparin with supplemental heparin boluses as required. Protamine was administered after the procedure and manual pressure was applied on the access site after removal of sheath and catheters.

Assessment of electrical isolation. Pulmonary vein electrical isolation was recorded with the ILMC positioned at the proximal site in the ostium before cryoablation of each PV. If PV potentials were visible during cryoablation, time to isolation (TTI) was recorded when PV potentials disappear or were dissociated from LA electrical activity. If PV potentials were not visible during ablation due to a distal positioning of the ILMC, the latter was retracted after completion of the cryoablation to a more proximal position to examine the PV potentials.

Duration of cryoenergy application. A single 180-second application was delivered for each vein with TTI or temperature of less than -40 ºC within one minute of cryoablation, otherwise a bonus freeze was delivered. Cryoablation was immediately terminated if there was weakening of diaphragmatic contraction.

Phrenic nerve monitoring. Right phrenic nerve function was monitored during right-sided PV cryoablation by locating and pacing the right phrenic nerve with a 1200-ms cycle and 20-mA output. The diaphragmatic capture was monitored by the operator's hand on the patient's abdomen for both Arctic Front™ and Polarx™ cryoablation and through the diaphragmatic movement sensor (DMS) accelerometer attached on the patient's right upper abdomen for the Polarx™ cryoablation. Cryoablation was terminated when weakness

Table 1: Description and difference between Polarx™ and Arctic Front™ cryoablation system

	Polarx™	Arctic Front™
Cryoballoon	Polarx™ Diameter: 28mm	Arctic Front Advance Pro™ Diameter: 28mm
Steerable sheath	PolarSheath™ 155° deflection	FlexCath™ 135° deflection
Mapping Catheter	Polarmap™ Diameter: 20mm Electrode: 8	Achieve Advance™ Diameter: 25mm Electrodes: 10
Console	SmartFreeze™ Foot pedal option Diaphragm movement sensor	CryoConsole™

Table 2: Baseline characteristics

	Polarx™ (N, 30)	Arctic Front™ (N, 30)	P value
Gender, male	20 (66)	18 (60)	0.5
Age, years	57.47 ± 15.24	53.53 ± 16.24	0.3
Hypertension	10 (33)	9 (30)	0.7
Dyslipidemia	9 (30)	8 (26)	0.7
Diabetes	1 (3)	2 (6)	0.5
Heart failure	3 (10)	1 (3)	0.3
Coronary artery disease	1 (3)	3 (10)	0.3
Prior embolic event	0	1 (3)	0.3
Left atrium volume index	31.5 ± 8.23	31.87 ± 7.31	0.8
CHA_2DS_2VASc score	1.27 ± 1.33	1.13 ± 1.40	0.7

Data presented as N (%) or mean ± SD; AF, atrial fibrillation

of diaphragmatic movement was noted.

Post ablation management. Patients were admitted in the intensive care unit and continuously monitored with electrocardiogram (ECG) telemetry for at least 18 hours. Post-procedure lower extremity ultrasound and TTE were performed the day after the procedure to assess complications such as pseudoaneurysm, hematoma, cardiac structural damage, or pericardial effusion. If without complication, patients were discharged the day after the procedure. Oral anticoagulation was resumed on the evening of the procedure and continued for at least 3 months.

Statistical analysis. Continuous variables were expressed as mean ± standard deviation (SD) and significant differences were analyzed by Student t-test. Categorical data were expressed as number and percentages and compared by Chi square test. Propensity-score matching was performed in order to compare the outcome between Arctic Front™ group and Polarx™ group. Patients were matched in a 1:1 ratio based on propensity scores calculated for each patient using multivariable logistic regression based on age, gender, CHA_2DS_2VASc score, and presence of LA dilatation (LAVi>34 ml/m2) as covariates. A 2-tailed probability value of <0.05 was deemed significant. Statistical analyses were conducted using SPSS software (SPSS version 27, Armonk, NY, USA).

Results

Baseline characteristics. A total of 202 consecutive patients with paroxysmal A Funderwent cryoablation and were included in our study. Thirty patients who underwent cryoablation using Polarx™ and 172 using Arctic Front™ were included in the matching process. Of that cohort, all the 30 Polarx™ patients were matched to 30 Arctic Front™ patients in a 1:1 ratio based on propensity scores which resulted in two balanced groups. Table 2 shows baseline characteristics of the matched patients.

Procedural characteristics. The matched 60 patients underwent PV isolation by cryoablation using either Arctic Front™ cryoablation system or Polarx™ cryoablation system. Acute PV isolation was achieved in all veins (100%) without the need for additional focal catheter application. No significant difference was found in total cryoballoon applications with Polarx™ and Arctic Front™(1.09 ± 0.3 vs 1.19 ± 0.5, p = 0.6).Significant differences were found in procedure and fluoroscopy time when comparing Polarx™ and Arctic Front™ (60.5 ± 14.23 vs 73.4 ± 13.26 mins, p = 0.001; 12.83 ± 6.03 vs 17.23 ± 7.17 mins, p = 0.01). There was no significant difference in amount of contrast used with Polarx™ and Arctic Front™ (62.17 ± 7.84 vs 60.17 ± 8.03 mL, p = 0.9).There was also significant difference in cumulative freeze duration in both groups (203.38 ± 72.03 vs 224.9 ± 79.35, p = 0.02). For all PVs that underwent cryoballoon applications between Polarx™ and Arctic Front™, there were significant differences in time to reach 0°C (13.76 ± 2.11 vs 10.69± 1.66 secs,p< 0.001), time to reach -40°C (30.43± 12.53 vs 47.96± 16.91 secs, p<0.001), temperature at 60 seconds (-51.57 ± 5.09 vs -42.87 ± 4.41 °C, p<0.001), nadir temperature (-58.13± 6.26vs -49.63± 6.19 °C, p<0.001), thaw time to 0°C (19.31± 7.9vs 10.0± 4.13 secs,p<0.001) and isolation temperature (-35.5 ± 13.36 vs-29.58± 11.27 °C,p< 0.002). There was no significant difference in isolation time between the two groups (34.47 ± 21.23 vs 34.18 ± 26.79 secs, p = 0.9).When performing head-to-head analysis using Student t-test, comparing the Polarx™ and Arctic Front™ for each vein, no significant differences were found for isolation temperature of the left inferior pulmonary vein (LIPV) (-29.52 ± 11.83 vs -25.28 ± 11.17 °C, p = 0.2), right superior pulmonary vein (RSPV) (-31.71 ± 12.07 vs -26.75 ± 10.65 °C, p = 0.1) and right inferior pulmonary vein (RIPV) (-35.64 ± 14.21 vs -30.35 ± 7.88 °C, p = 0.1).Electrical activity visualization enabling real time isolation was significantly different between Polarx™ and Arctic Front™ (84% vs 70%, p = 0.009). Tables 3 and 4 show procedural and cryoablation characteristics of the matched patients.

Complications. There was no significant difference between Polarx™ and Arctic Front™ groups in terms of complications. The most frequent complication noted was transient right-sided phrenic nerve palsy, with incidence of 3% in the Polarx™ group and 3% in the Arctic Front™ group(p = 1.0). Diaphragm weakness was noted in 1 RSPV application in the Polarx™ group, and 1 RSPV application in the Arctic Front™ group. Diaphragm contraction completely recovered during the same procedure. No lower extremity hematoma, pericardial effusion, cerebrovascular accident, or cardiac structural damage were noted.

Discussion

To the best of our knowledge, this is the first study comparing the acute efficacy and safety outcome of Polarx™ cryoablation system with

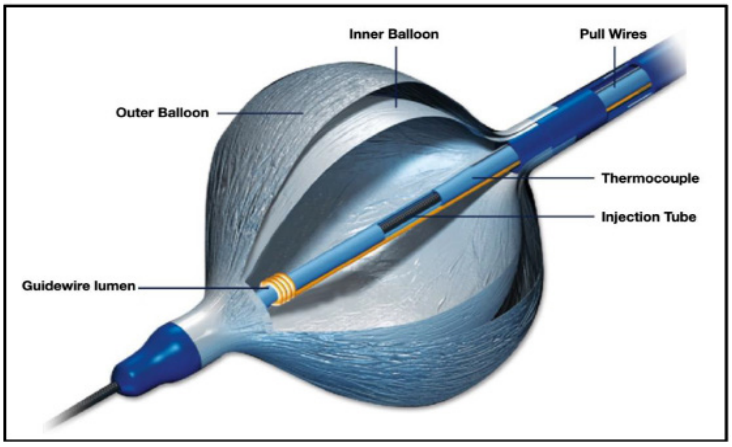

Figure 2: Cross section of the Arctic Front™ cryoballoon catheter, showing integral parts of the balloon catheter. Image courtesy of Medtronic.

Table 3: Procedural characteristics

	Polarx™ (N, 30)	Arctic Front™ (N, 30)	P value
Procedure duration, minutes	60.50 ± 14.23	73.43 ± 13.26	0.001
Fluoroscopy duration, minutes	12.83 ± 6.03	17.23 ± 7.17	0.01
Contrast used, mL	62.17 ± 7.84	60.17 ± 8.03	0.9
Phrenic Nerve Injury	1 (3)	1 (3)	1.0

Data presented as N (%) or mean ± SD

Arctic Front™ cryoablation system. The main findings were: (1) PV isolation with either Polarx™or Arctic Front™ cryoablation system provided acute isolation in 100% of all PVs, (2) Polarx™ was associated with shorter procedure and fluoroscopy time, (3) in all PVs, Polarx™ showed slower time to reach 0º, faster time to reach -40ºC, lower temperature at 60 seconds, lower nadir temperature, longer thaw time to 0 ºC, shorter cumulative freeze duration,and no significant difference in time to isolation, and (4) there were no difference in procedure-related complications between the 2 groups.Optimal placement and contact with the PV ostium are important in creating a well-defined cryothermal lesion. Diminished contact between the cooling zone and PV ostium can lead to gaps and PV electrical reconnection. Several modifications in Arctic Front™'s cryoballoon design over the years have led to a larger ablation area [10-16]. In our study, adequate occlusion during contrast administration and eventual isolation were achieved in all PVs (100%) with no significant difference between the number of cryoballoon applications per vein between Polarx™ and Arctic Front™. While Polarx™ theoretically presents with more stable balloon positioning due to its uniform size and pressure throughout all cryoablation phases (inflation, freezing, thawing), there was no significant difference with the number of occlusions per vein to achieve isolation when using either Polarx™ or Arctic Front™ cryoablation system. In assessing number of occlusions as a measure of learning curve, the insignificant difference is probably due to the large experience accumulated during the years by our operators in performing cryoballoon ablation with the Arctic Front™. Duration of procedure and fluoroscopy time was significantly shorter with Polarx™ when compared to Arctic Front™. Shorter procedure time may be partly due to the inherent set-up of the Polarx™ console where the main steps of inflation, freezing, and deflation are all controlled by the primary operator through the foot pedal attached to the console or through the slide switch on the cryoballoon catheter. This precludes the need for the primary operator to instruct a console operator to inflate, freeze, or deflate the cryoballoon. More importantly, the Polarx™ cryoballoon catheter's body is made of an innovative semi-elastic, thermoplastic material that eases balloon delivery and placement in different PV anatomies, possibly contributing to the shorter procedure and fluoroscopy time as well. Cryothermal energy causes vasoconstriction with a consequent reduction in blood circulation and ischemia. Simultaneously, as the catheter reaches a temperature of -40 ºC, irreversible cell damage is observed due to formation of intracellular and extracellular ice. Furthermore, with subsequent rewarming, endothelial damage occurs which leads to microthrombi formation [17]. Cryoballoon temperature during freezing provides reliable information on balloon-tissue contact, highlighting the relationship between low temperatures and ablation efficiency. The study by Ciconteet al [18] and Watanabe et al [19] showed that nadir temperature reached during freezing (< -51 ºC) represents an independent predictor of absence acute PV reconnection. Furthermore, failure to reach -40 ºC in the first minute of application of cryoenergy represents an independent predictor for late reconnection. Scala et al [20] identified that PV reconnection was associated with longer time to -40 ºC and to reach this temperature in the first minute represents an independent predictor for late reconnection. Warmer temperature at 60 seconds and warmer nadir temperature was associated with PV reconnection. Chierchia et al [21] illustrated that early PV reconnection was associated with a significantly longer TTI. Similarly, Chun et al [22] showed that TTI associated with a durable PV isolation was significantly shorter than in those with electrical reconnection. A recent multicenter study has shown that thaw temperature to 0 ºC of >10 seconds significantly predicts PV isolation [23]. Ghosh et al showed that predictors of PV reconnection include shorter warming time [24]. In the Polarx™ group, the time to reach 0 ºC compared to the Arctic Front™ group was slower, time to reach -40 ˚C was faster, temperature reached at 60 seconds and the nadir temperature were lower, and thaw time to 0 ˚C was longer. Also, there was a significant difference in the isolation temperature between Polarx™ and Arctic Front™. In our study, the nadir temperature and thaw time to 0˚C in Polarx™ met the most marked predictive criteria for successful PV isolation. Furthermore, there were no significant differences in time to isolation between Polarx™ and Arctic Front™.We could infer that these temperature differences might be due to a number of technical factors. The difference in time to reach 0˚C, with Polarx™ being significantly slower than Arctic Front™, is due to the gradual increase in N_2O flow over approximately 10 seconds at the start of cryoablation, enabling the cryoballoon to maintain its size and shape (and therefore occlusion) as therapy is delivered. During this period, there is cryoballoon cooling, but no significant temperature drop until the desired N_2O flow is reached, after which the temperature drops quickly. We could also infer that these temperature differences might be due to different freezing kinetics of the system. Measuring temperature at probe-tissue interface or impedance drop during cryoablation may enhance assessment on the ability of both cryoballoon catheters to create lesions within the ostium for PV isolation.Despite having shorter time to reach -40 ˚ C in Polarx™,both groups reached -40 ˚ C within 60 seconds. This not only represents an acute indicator of PV isolation but also a significant predictor of permanency of PV isolation on the long term. Cumulative freeze duration was also significantly lower with Polarx™. This again might be the result of the adaptable and compliant semi-elastic, thermoplastic material the Polarx™ is made of; therefore facilitating its placement and occlusion in PV ostia despite varying PV drainage patterns. Visualization of PV electrical activity and real time PV isolation was significantly higher in the Polarx™ group than in the Arctic Front™ group. Inner-lumen mapping catheter must be positioned in a proximal portion of the PV in order to maximize the likelihood of visualizing real time recordings without sacrificing cryoballoon stability. Once more, the very nature and design of the Polarx™ played a pivotal role in this setting. Phrenic nerve (PN) palsy is the most common complication of cryoballoon ablation [25] with an incidence of 0.37 - 1.61% [26]. The course of the PN varies from each patient and it is difficult to assess each prior to the procedure. A larger RSPV diameter, a deeper balloon position outside the cardiac silhouette, and rapid temperature drops are known predictors of PN injury [27-30]. In our study, there is no significant difference with the rate of PN injury between Polarx™ and Arctic Front™. All patients who had transient PN injury defined by decrease or abrupt cessation of

Table 4: Cryoablation characteristics

	Polarx™ (N, 30)	Arctic Front™ (N, 30)	P value
LSPV			
Number of occlusion	1.17 ± 0.46	1.07 ± 0.25	0.3
Cumulative freeze duration	225.13 ± 112.86	214.0 ± 78.28	0.65
Time to 0°C, seconds	15.0 ± 1.53	11.93 ± 1.68	< 0.001
Time to -40°C, seconds	30.7 ± 4.35	44.17 ± 10.71	< 0.001
Temperature at 60 secs, °C	-52.33 ± 4.17	-45.0 ± 4.25	< 0.001
Nadir temperature, °C	-57.7 ± 5.42	-52.8 ± 4.57	< 0.001
Real time isolation	27 (90%)	22 (73%)	0.09
Isolation time, seconds	43.81 ± 19.30	48.43 ± 39.98	0.6
Isolation temperature, °C	-44.3 ± 10.6	-35.50 ± 12.59	0.01
Thaw time to 0°C, seconds	19.34 ± 6.92	11.50 ± 4.01	< 0.001
LIPV			
Number of occlusion	1.0 ± 0	1.27 ± 0.64	0.02
Cumulative freeze duration	180.43 ± 19.76	249.07 ± 91.78	< 0.001
Time to 0°C, seconds	13.27 ± 2.28	10.47 ± 1.54	< 0.001
Time to -40°C, seconds	33.30 ± 14.0	54.93 ± 22.37	< 0.001
Temperature at 60 secs, °C	-49.90 ± 5.24	-41.0 ± 4.22	< 0.001
Nadir temperature, °C	-55.33 ± 5.96	-45.37 ± 6.86	< 0.001
Real time isolation	25 (83%)	18 (60%)	0.04
Isolation time, seconds	26.24 ± 9.65	26.11 ± 18.56	0.9
Isolation temperature, °C	-29.52 ± 11.83	-25.28 ± 11.17	0.2
Thaw time to 0°C, seconds	17.71 ± 5.99	8.63 ± 3.8	< 0.001
RSPV			
Number of occlusion	1.13 ± 0.34	1.23 ± 0.62	0.4
Cumulative freeze duration	205.9 ± 71.31	214.27 ± 78.5	0.6
Time to 0°C, seconds	13.4 ± 2.41	10.07 ± 1.31	< 0.001
Time to -40°C, seconds	30.53 ± 13.7	43.74 ± 15.0	0.001
Temperature at 60 secs, °C	-52.47 ± 5.72	-43.83 ± 4.52	< 0.001
Nadir temperature, °C	-59.67 ± 6.83	-51.77 ± 5.66	< 0.001
Real time isolation	24 (80%)	24 (80%)	1.0
Isolation time, seconds	32.83 ± 28.64	24.96 ± 13.97	0.2
Isolation temperature, °C	-31.71 ± 12.07	-26.75 ± 10.65	0.1
Thaw time to 0°C, seconds	20.81 ± 10.36	10.36 ± 4.76	< 0.001
RIPV			
Number of occlusion	1.07 ± 0.25	1.20 ± 0.4	0.1
Cumulative freeze duration	202.07 ± 45.13	222.27 ± 65.38	0.1
Time to 0°C, seconds	13.37 ± 1.69	10.33 ± 1.51	< 0.001
Time to -40°C, seconds	27.2 ± 14.91	49.28 ±16.0	< 0.001
Temperature at 60 secs, °C	-52.0 ± 4.92	-41.57 ± 3.62	< 0.001
Nadir temperature, °C	-58.83 ± 6.17	-48.60 ± 4.73	< 0.001
Real time isolation	25 (83%)	20 (66%)	0.1
Isolation time, seconds	34.16 ± 20.58	36.95 ± 20.38	0.6
Isolation temperature, °C	-35.64 ± 14.21	-30.35 ± 7.88	0.1
Thaw time to 0°C, seconds	19.41 ± 7.93	9.52 ± 3.52	< 0.001
Total			
Number of occlusion	1.09 ± 0.3	1.19 ± 0.5	0.6
Cumulative freeze duration	203.38 ± 72.03	224.9 ± 79.35	0.02
Time to 0°C, seconds	13.76 ± 2.11	10.69 ± 1.66	< 0.001
Time to -40°C, seconds	30.43 ± 12.53	47.96 ± 16.91	< 0.001
Temperature at 60 secs, °C	-51.67 ± 5.09	-42.87 ± 4.41	< 0.001
Nadir temperature, °C	-58.13 ± 6.26	-49.63 ± 6.19	< 0.001
Real time isolation	101 (84%)	84 (70%)	0.009
Isolation time, seconds	34.47 ± 21.23	34.18 ± 26.79	0.9
Isolation temperature, °C	-35.5 ± 13.36	-29.58 ± 11.27	0.002
Thaw time to 0°C, seconds	19.31 ± 7.9	10.0 ± 4.13	< 0.001

Data presented as N (%) or mean ± SD. LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RIPV, right inferior pulmonary vein

diaphragm muscle contraction during the cryoablation had resolution of PN function after cryoablation was discontinued.

Limitations

This study compares the novel Polarx™ cryoablation system with the standard Arctic Front™ cryoablation system. This study was conducted in a small cohort of patients and was retrospective in nature. Larger studiesare needed to compare the safety and efficacy of the Polarx™ cryoballoon catheter on a longer follow-up period.

Conclusion

The novel Polarx™ cryoablation system showed similar efficacy in vein occlusion and isolation and safety profile when compared to Arctic Front™ cryoablation system. Procedure time, fluoroscopy time, and cumulative freeze duration were significantly lower with Polarx™ cryoablation system.

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