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THE FIRST USE OF POLARx CRYOBALLOON CATHETER FOR PULMONARY VEIN ISOLATION IN PATIENTS WITH ATRIAL FIBRILLATION: CASE SERIES

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There is the first clinical use of POLARx cryoballoon catheter for pulmonary vein isolation in patients with atrial fibrillation in Russian Federation.

Key words: atrial fibrillation; catheter ablation; cryoballoon ablation

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Atrial fibrillation (AF) is the most common arrhythmia among the population. This arrhythmia is the cause of an increased risk of mortality. It has been proven that the presence of AF in the anamnesis increases the risk of thromboembolic complications, can lead to the development or deterioration of the heart failure, reduces the quality of life of patients [1]. In accordance with the latest recommendations for the treatment of AF, the main strategy of catheter treatment is isolation of pulmonary veins (PV) [2]. Currently, cryoballon ablation (CBA) and radiofrequency ablation (RFA) are used for this purpose [3, 4]. Large randomized studies have confirmed that CBA is comparable in efficacy and safety with point-by-point RFA [5, 6]. Thus, in the FIRE AND ICE study, the effectiveness of CBA was 65.4% and effectiveness of RFA 64.1% with an average follow-up period of 1.5 years [7]. With a longer follow-up time of more than 1000 days for these patients, various clinical characteristics of patients were evaluated [8]. It was found out that there were a greater number of redo procedures, cardioversions, the total number of hospitalizations and hospitalizations for diseases of the cardiovascular system in the RFA group. Moreover, a subsequent study on a sample of patients from the FIRE AND ICE study revealed a smaller number of PV reconnection in the group where CBA was performed [9]. Also, the advantage of CBA is a reduction in the time of surgical intervention due to the simplified "single-shot" technique compared to the point-by-point technique of RFA [10]. This paper presents the first experience of using the POLARx cryoballon catheter.

Clinical characteristics of patients

Three patients with normal PV anatomy were selected for the CBA procedure using the POLARx system. In one case there was a paroxysmal form of AF, in two – persistent. A brief clinical description of patients is presented in table 1.

POLARx cryoballon ablation system

The POLARx CBA system consists of a deflectable sheath with a size of 15.9 Fr, a circular 8-pole diagnostic catheter with a diameter of 20 mm with an interelectrode distance of 6 mm, a cryoballon catheter with a diameter of 28 mm and a cryoconsole (Fig. 1). It is worth noting that sheath designed with a 155 degree angle of deflection. A double-layer balloon with special «semi-compliant» technology enables to take the shape of the PV ostium, which allows achieve its complete occlusion. There is a sensor inside the balloon catheter which provides a constant pressure level in it, which eliminates its displacement during inflating and during thawing.

The console of this cryoablation system involves switching with temperature sensors in the esophagus and diaphragm motion sensor (DMS). The DMS sensor is fixed to the skin in the greatest amplitude of movement of the abdomen wall during breathing (Fig. 2). This device is configured before the procedure. The physician asks the patient to cough so that the sensor records the amplitude of the diaphragm movement in memory, so that during the ablation on the right PVs it is possible to differentiate the initial contraction of the diaphragm and the stimulated one.

It is important to note that the presence of a controlling pedal provides an opportunity for the surgeon to control the procedure of the CBA all by himself, as well as to mark time to isolation (TTI) of the PV.

Cryoballon ablation procedure

All CBA procedures were carried out according to a single protocol. The procedure was performed under total intravenous anesthesia using 0.05% fentanyl for anesthesia and 1% propofol at a dose of 5 mg/kg/h for sedation. Venous access was performed using the Seldinger method. A 10-pole electrophysiological catheter was inserted into the coronary sinus through the left

subclavian vein. A 4-pole electrophysiological catheter was inserted through the left femoral vein into the right ventricle. A Swartz introducer was installed through the right femoral vein into the right atrium, through which a needle for transeptal puncture was carried out. Puncture of the atrial septum was performed under fluoroscopic control. Heparin was administered based on the patient's weight 100 UI/kg. After the transeptal puncture, the Swartz introducer was replaced with a deflectable sheath, through which a cryoballon catheter with a circular diagnostic electrode was carried out in left atrium (LA). Two types of cryoballon catheters were used: with a short (5 mm) and a long (12 mm) distal tip. Anatomical reconstruction of the LA was performed using the Astrocard navigation system. The degree of PV occlusion was determined by contrast under fluoroscopic control. The duration of cryoapplication in each PV was 180 seconds. The isolation was checked for lack of electrical activity in the PV on the circular electrode. While maintaining PV activity, additional cryotherapy lasting 120 seconds was performed. During ablation in the right PVs, the right phrenic nerve was stimulated under the control of the amplitude of the diaphragm contraction according to the DMS, which served as an additional element of monitoring the development of phrenic nerve palsy.

Table 1.

Clinical parameters of patients

Parameters	Patient 1	Patient 2	Patient 3
Age	43	64	62
Gender	male	female	female
Body mass index (kg/m²)	35	25	30
Paroxysmal AF		+	
Persistent AF	+		+
Duration of AF (months)	6	120	60
Arterial hypertension	+	-	+
Volume of LA (ml)	139	84.9	211.4
Diametr of LSPV (sm)	15	17	15
Diametr of LIPV (sm)	15	14	18
Diametr of RSPV (sm)	19	16	23
Diametr of RIPV (sm)	15	17	23.5
Vestibule of PV	-	Left PV	-

Note: AF - atrial fibrillation, LA - left atrium, LSPV - left superior pulmonary vein, LIPV - left inferior pulmonary vein, PV - pulmonary vein, RSPV - right superior pulmonary vein, RIPV - right inferior pulmonary vein.

Fig. 1. Cryoconsole POLARx. Main menu on the screen.

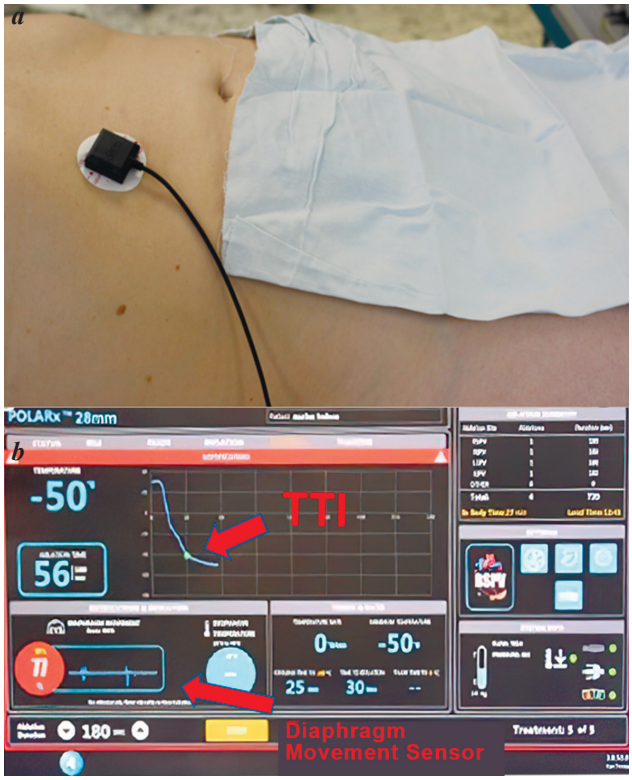

Fig. 2. DMS (Diaphragm Movement Sensor) location on the on the anterior abdominal wall in the greatest amplitude of maximum movement during breathing (a). Cryoconsole screen while ablation (b). There is catheter name and its diameter (28 mm), current temperature in balloon (-50 °C), green point marks time to isolation (TTI) of pulmonary vein. Below is the amplitude of diaphragm contraction when it is stimulated during ablation in right superior pulmonary vein.

RESULTS

Two patients had AF while the ablation, and an electrical cardioversion was performed at the end of the procedures. One patient maintained a sinus rhythm throughout the cryoablation procedure.

During the CBA, it was possible to catheterize all PV and achieve a stable position of the cryoballon. It is important to note that in a patient with a common PV vestibule on the left, it was possible to position the catheter unhindered and perform effective isolation of the left PV without bonus ablation. Residual activity was recorded in two cases (in the right upper PV and the left upper PV), which required additional bonus cryotherapy before isolation was achieved. As a result, PV isolation was achieved in 100% of cases. During the CBA procedure, the moment

a

TREATMENT INFO :

Treatment	Ablation Site	Duration (sec)	Min ESO Temp (°C)	Min Temp (°C)	Time to Target (sec)	Time to Vein Isolation (sec)	Time to Thaw (sec)	Min DMS (%)	Treatment Start Time
1	LSPV	180	--	-65	28	--	24	--	12:15:32
2	LIPV	180	--	-59	26	--	31	--	12:21:51
3	RSPV	180	--	-58	26	--	17	75	12:29:03
4	RIPV	180	--	-55	25	31	22	66	12:33:55
5	RSPV	120	--	-56	25	30	17	76	12:40:34

In Body Time: 31 min

ABLATION SUMMARY

Ablation Site	Ablations	Duration (sec)
RSPV	2	300
RIPV	1	180
LSPV	1	180
LIPV	1	180
OTHER	0	0
TOTAL	5	840

b

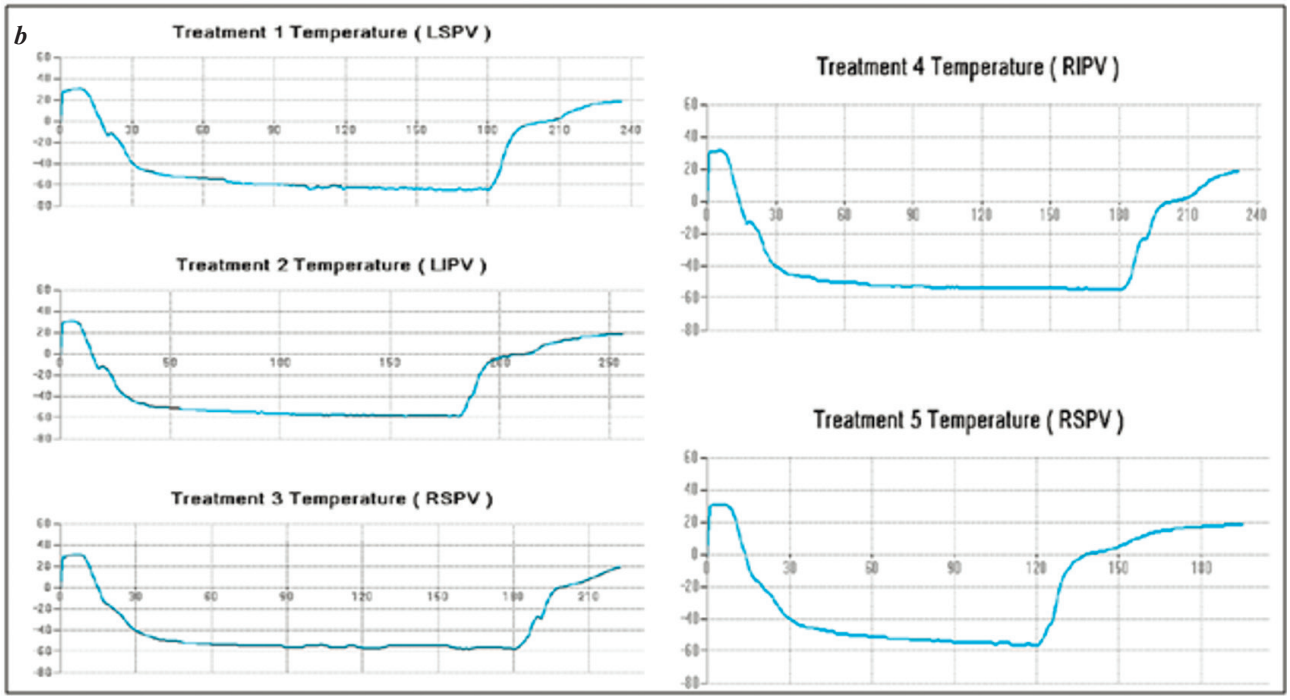

Fig. 3. Ablation procedure report (a). Mentioned number of cryoapplications, name of every pulmonary vein (ablation site), duration of every ablation, minimal temperature in balloon, the time to reach the temperature -40 °C (time to target), time of isolation (time to vein isolation), thawing time to 0 °C (time to thaw), minimum amplitude of diaphragm contraction during stimulation of the phrenic nerve compared to the initial amplitude of contraction (min DMS), time of the start ablation (treatment start time). The time that the cryocatheter was in the body is also recorded (in body time). Below is a table with the calculation of applications and the time of exposure in each vein separately and the total time of ablation. Graph of temperature changes during ablation in each vein (b): treatment 1 temperature (LSPV) - graph of the temperature in the cryoballoon during 1 application in LSPV, treatment 2 temperature (LIPV) - graph of the temperature in the cryoballoon during application in LIPV, treatment 3 temperature (RSPV) - graph of the temperature in the cryoballoon during 1 application in RSPV, treatment 4 temperature (RIPV) - graph of the temperature in the cryoballoon during application in RIPV, treatment 5 temperature (RSPV) - graph of the temperature in the cryoballoon during additional application in RSPV. LSPV - left superior pulmonary vein, LIPV - left inferior pulmonary vein, RSPV - right superior pulmonary vein, RIPV - right inferior pulmonary vein.

of disappearance of the PV electrical activity (TTI - time to isolation) was noted in 5/14 applications (35.7%). The most effective determination of TTI occurred with the use of a cryoballon catheter with a short distal end in 3/4 of the ablations (75%). The moment of PV isolation was noted by the operator using a pedal (Fig. 2). Cases when visualization of PV activity was not possible were due to the need to position the circular catheter most distally to ensure the supporting function of the balloon.

During the ablation in the right PVs, a DMS was used, which provided additional control over the safety of the procedure. There were no cases of phrenic nerve palsy. According to the DMS, in all cases, the amplitude of the diaphragm contraction did not fall below 70%.

In the POLARx system, it is possible to receive a report on the ablation procedure in PDF format, which allows for its detailed analysis (Fig. 3). There were not intra- and postoperative complications. There were no complications in the postoperative period. Intraoperative parameters of the cryoablation procedure are shown in table 2.

Patients were discharged on the 3rd day after procedure on the sinus rhythm with recommendations for antiarrhythmic and anticoagulant therapy.

DISCUSSION

A systematic review and meta-analysis has recently been published comparing the efficacy, safety and details of the cryoablation procedure using two catheters: POLARx and Arctic Front Advance Pro [11]. 310 people were included in it: 142 and 168 patients underwent PV isolation using POLARx and Arctic Front Advance Pro, respectively. There was no statistical difference in the ability to isolate PV in the acute period, the time of the procedure, the time of fluoroscopy and the time of ablation. A lower minimum exposure temperature was recorded when using the POLARx cryocatheter, a statistically significant difference was revealed for this indicator, but despite this, the effectiveness of PV isolation and phrenic nerve palsy did not differ. In this regard, it can be assumed that the difference in temperature indicators has no effect on the clinical effect, and the level of the target ablation temperature in the POLARx cryocatheter should be clarified based on biological and clinical effects. In studies evaluating the effectiveness of the POLARx cryoablation system, a longer thawing cycle is noted, which plays an important role in cell apoptosis during cryoapplications.

It is worth noting that all previous studies were one-central, observational [12-15]. Now, two more major studies are underway – Boston Scientific's Cryoballoon in the Treatment of Symptomatic Drug Refraction Paroxysmal Atrial Fibrillation (FROZEN-AF) (NCT04133168) in the USA and POLARx Cardiac Cryoablation System Study (POLAR ICE) (NCT04250714) in Europe.

When analyzing the technical details of the procedure, the following features were revealed. The special conical shape of the sheath dilator provides softer passage through the atrial septum, and the bend provides a more simplified positioning in the RIPV. The circular diagnostic electrode is a soft electrode, which in some cases requires deeper positioning in the PV to improve the support function.

CONCLUSION

Thus, the new cryoballon ablation system has demonstrated its effectiveness and safety of use for PV isolation. The presence of a console controlling pedal allows the surgeon to quickly control the ablation process, as well as to mark the TTI of the PV. The DMS during the stimulation of the diaphragmatic nerve allows additional control over the safety of the procedure. Providing a report on the details of the procedure allows a detailed analysis of each impact and the procedure.

Table 2.

Characteristics of ablation procedures

	PV	T, s	t, °C	DTCC		TTI, s	DP, min	DF, min:s
				Short	Long			
Patient 1	LSPV	180	-61			-	80	14:42
	LSPV*	120	-61			-		
	LIPV	180	-61		+	-		
	RSPV	180	-58			-		
	RIPV	180	-65			-		
Patient 2	LSPV	180	-65			-	90	14:57
	LIPV	180	-59			-		
	RSPV	180	-58		+	-		
	RSPV*	120	-56			30		
	RIPV	180	-55			31		
Patient 3	LSPV	180	-62			26	140	12:11
	LIPV	180	-54	+		24		
	RSPV	180	-61			25		
	RIPV	180	-58			-		

Note: T - time of ablation; t - temperature of ablation; DTCC - distal tip of the circular catheter; TTI - time to isolation; DP - duration of the procedure; DF - duration of the fluoroscopy; * - additional ablation.

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