Comparison of Pulmonary Vein Isolation Using Cryoballoon Versus Conventional Radiofrequency for Paroxysmal Atrial Fibrillation

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The aim of this study was to compare the results of pulmonary vein isolation using conventional irrigated radiofrequency (RF) approach versus the cryoballoon (CB) ablation. From January 2008 to December 2011, a total of 426 patients with drug-resistant symptomatic paroxysmal atrial fibrillation underwent pulmonary vein isolation as the index procedure by conventional manual RF or CB ablation at our center. A final population of 396 patients was considered for analysis and divided into 2 groups: conventional RF ablation (n = 260) and CB ablation (n = 136). At a mean follow-up of 23 ± 13 months (median 27, range 4 to 68), the success rate for RF ablation group was 57.3% (149 patients) and was 63.2% (86 patients) for cryoablation group (p = 0.25). Procedural times were significantly shorter in the cryoablation group (192 ± 49 vs 112 ± 58 minutes, p <0.000001) but not fluoroscopy times (36 ± 14 vs 31 ± 17 minutes, p = 0.45). No clinical predictors were found to predict atrial fibrillation recurrences. Complication rates were similar in both groups except for phrenic nerve palsy that was uniquely observed in the CB group (8.1%, p <0.00001). All phrenic nerve palsies resolved during follow-up. In conclusion, on a medium-term follow-up, conventional point-by-point RF ablation and CB ablation showed similar success rates. Procedural times were significantly shorter in the CB approach. The most frequent complication during CB procedures was phrenic nerve palsy, which occurred in 8.1% of patients and resolved in all during the follow-up period. **(Am J Cardiol 2014;113:1509−1513)**

Pulmonary vein (PV) isolation is nowadays the cornerstone of percutaneous transcatheter ablation for drug-resistant paroxysmal atrial fibrillation (AF).[1−4] Traditionally, these procedures are performed with a "point-by-point" ablation technique by means of radiofrequency (RF) energy; however, in the last years, the use of novel alternative technologies such as cryoballoon (CB) ablation is growing rapidly.[5−7] Despite continuous improvements in catheter technology, RF ablation by means of a focal-tip catheter is still a challenging procedure and is highly dependent on operators' skills. In contrast, CB technology might offer more reproducible and standardizable procedures by significantly simplifying the ablation itself.[7,8] To the best of our knowledge, published data on comparison of medium- and long-term results between CB and conventional manual RF ablation are limited. In the present study, we sought to compare the outcomes of both approaches on a medium-term follow-up in a series of consecutive patients who underwent PV isolation at our center for drug-resistant paroxysmal AF.

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Methods

From January 2008 to December 2011, all consecutive patients who underwent PV isolation as the index procedure by RF ablation or CB ablation at our department for documented symptomatic paroxysmal AF were taken into consideration for our retrospective analysis. In all procedures, the acute end point was the achievement of electrical PV isolation in all veins. Paroxysmal AF was defined as self-terminating AF episodes lasting <7 days as per guidelines. Exclusion criteria were repeat procedures for recurrent AF after the index procedure, first-line ablation treatment, acute complications disrupting procedure continuation, and persistent AF. Before the procedure, all patients underwent a 2-dimensional transthoracic echocardiography to assess left ventricular ejection fraction and to rule out any structural and/or valvular disease. A cardiac computed tomography and a transesophageal echocardiography were performed the day before ablation to analyze left atrial (LA) and PV anatomy and to rule out intracardiac thrombus formation.

RF ablation was performed as follows. After having accessed the left atrium with a double transseptal puncture, a 70 UI/kg heparin intravenous bolus was given. A selective PV angiogram was performed to assess all PV ostium positions. A circumferential mapping catheter

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Table 1
Baseline characteristics of the patients

Variable	RF Ablation (n = 260)	CB Ablation (n = 136)	p Value
Men	181 (69.6)	98 (72.1)	0.61
Age, yrs (median, range)	58.3 ± 8.7 (60, 30−77)	57 ± 13.3 (56, 15−78)	0.08
AF duration (mo)	25.4 ± 37.1 (10)	25.1 ± 24 (10.5)	0.30
Body mass index (kg/m^2)	27.4 ± 4.8 (26.2)	26.2 ± 3.8 (25.5)	0.08
Follow-up (mo)	24.0 ± 13.4 (27)	22.1 ± 14 (24)	0.10
LA diameter (mm)	42.8 ± 6.7 (42.6)	41.6 ± 6.8 (42)	0.26
Left ventricular ejection fraction ≥50%	248 (95.4)	131 (96.3)	0.66
Left ventricular ejection fraction <40%	6 (2.3)	2 (1.5)	0.57
Arterial hypertension	90 (34.9)	35 (25.7)	0.07
Diabetes	18 (6.9)	4 (2.9)	0.10
Dyslipidemia	64 (24.4)	45 (33.1)	0.07
Previous stroke/TIA	20 (7.6)	6 (4.4)	0.21
CHA_2DS_2-VASc score	1.44 ± 1.28	1.16 ± 1.28	0.13
Coronary artery disease	25 (9.6)	7 (5.1)	0.12
Cardiomyopathy	13 (5)	6 (4.4)	0.79
Valve disease	4 (1.5)	2 (1.5)	0.96
Previous cavotricuspid isthmus ablation	45 (17.3)	11 (8.1)	0.01
Previous accessory pathway ablation	2 (0.8)	2 (1.5)	0.51

Data are presented as n (%), mean ± SD, or mean ± SD (median), unless otherwise specified.
TIA = transient ischemic attack.

Table 2
Procedural complications

Variable	RF Ablation (n = 260)	CB Ablation (n = 136)	p Value
Death	0	0	
Stroke/transient ischemic attack	0	0	
Tamponade	4 (1.5)	1 (0.7)	0.50
Pericardial effusion (not hemodynamically significant)	26 (10)	10 (7.3)	0.38
PV stenosis	0	0	
Atrial-esophageal fistula	0	0	
Femoral artery pseudoaneurysm	2 (0.8)	0	0.30
Groin hematoma	0	2 (1.5)	0.05
Sinus arrest/third-degree atrioventricular block	2 (0.8)	0	0.30
Transient ST elevation	2 (0.8)	2 (1.5)	0.51
Phrenic nerve palsy	0	11 (8.1)	<0.00001
Contrast reactions	1 (0.4)	0	0.47

Data are presented as n (%).

(Lasso; Biosense Webster Inc., Diamond Bar, California) was positioned into the proximal portion of the PV ostium to get baseline electrical information. Then an electroanatomic map of the left atrium was performed with a nonfluoroscopic navigation system (CARTO; Biosense Webster Inc.). RF ablation was performed with an open irrigated cool tip 3.5-mm catheter (NaviStar ThermoCool; Biosense Webster Inc.) in a power-controlled mode with a power limit of 35 W and at a maximum temperature of 48°C. Each application lasted a maximum of 60 seconds. Power was reduced to 25 W during ablation of LA posterior wall to prevent esophageal injury. The ablation strategy consisted in creating contiguous focal lesions at a distance of >5 mm from the ostia of the PVs resulting in circumferential lines around ipsilateral PVs. During the whole procedure, activated clotting time was maintained at >300 seconds by supplementing heparin infusion.

CB ablation was performed as follows. A single transseptal puncture was achieved under fluoroscopic guidance, using the right femoral venous approach. After gaining the LA access, a 70 UI/kg heparin intravenous bolus was given. A 0.32Fr Emerald exchange wire (Cordis, Johnson and Johnson, Diamond Bar, California) was advanced in the left superior PV and a steerable 15Fr over-the-wire sheath (FlexCath; Cryocath, Montreal, Quebec, Canada) was positioned in the left atrium. A circular mapping catheter (Lasso; Biosense Webster Inc.) was then advanced in each PV ostium to obtain baseline electrical information. After withdrawing the mapping catheter, a first-generation 28-mm double-walled CB (Arctic Front; Cryocath) was advanced over the wire to the left atrium, inflated, and positioned in the PV ostium of each vein. Vessel occlusion was evaluated according to a semiquantitative grading ranging from grade 0 (very poor occlusion) to grade 4 (perfect occlusion) in 2 different fluoroscopic projections; after dye injection, optimal vessel occlusion was deemed as total contrast retention with no backflow in the atrium. For each vein, cryoablation consisted of a minimum of 2 applications lasting 5 minutes each. Whenever possible, we tried to engage 2 different branches of the same vein and to orient the balloon differently, to cover a wider ostial surface. However, if successful occlusion could be obtained in only 1 branch, both applications were delivered by leaving the guidewire in the same branch. Usually, the left PVs were treated first followed by the right-sided veins. To avoid phrenic nerve palsy, a quadripolar catheter was inserted in the superior vena cava, and diaphragmatic stimulation was achieved by pacing the ipsilateral phrenic nerve with a 1,000-ms cycle and a 12-mA output. The reason for pacing at such a slow rate was to prevent catheter displacement due to diaphragmatic contraction during the early phases of