

A Novel Cryoballoon Technique for Mapping and Isolating Pulmonary Veins: A Feasibility and Efficacy Study

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A Novel Cryoballoon Technique. *Introduction:* The study was designed to evaluate the feasibility and efficacy of a simplified cryoballoon technique in which a microcircular catheter was introduced into the central lumen of a cryoballoon catheter for the purpose of recording pulmonary vein (PV) potentials during ablation procedures and without interchanging catheters.

Methods and Results: A total of 23 consecutive patients with paroxysmal atrial fibrillation (AF) were enrolled. A single transseptal puncture was made and a cryoballoon catheter was inserted into the left atrium. A 6-pole mapping catheter with a 0.035-inch shaft diameter was introduced into the PV through the central lumen of the cryoballoon catheter. In addition to the function as a recording device, the mapping catheter was also used as a “guide-wire” during the procedure. A total of 84 PVs (84/92, 91.3%) were completely isolated using this novel cryoballoon technique. In 43 of the 84 veins (51.2%), isolation was observed in real time during the cryoablation; in the remaining 41 veins (48.8%), isolation was confirmed immediately post ablation attempt with the mapping catheter. Procedure time was 152.7 ± 54.9 minutes, and fluoroscopy time was 33.2 ± 17.3 minutes. At follow-up (7.4 months, range 2–18 months), 17 (73.9%) patients were free from AF. There was 1 occurrence of phrenic nerve palsy during ablation of a right superior PV, which fully resolved after 1 month.

Conclusion: The use of a cryoballoon catheter equipped with a 6-pole micromapping catheter inserted through its central lumen for the purpose of mapping and ablation during PV isolation procedures is both feasible and effective. (*J Cardiovasc Electrophysiol*, Vol. pp. 1-6)

atrial fibrillation, cryoballoon, ablation, pulmonary vein isolation

Introduction

Pulmonary vein isolation (PVI) has become an established treatment for patients with atrial fibrillation (AF).^{1,2} Traditional radiofrequency (RF) catheter ablation is performed using a single-tip, point-by-point technique, which is time-consuming and requires a high degree of operator skill. A significant number of complications are associated with this technique and the use of RF energy, including thromboembolism, PV stenosis, and atrioesophageal fistulae.^{2,3} Consequently, innovative technologies are being developed to make PVI safer and easier.

To that end, cryoballoon catheter technology offers a promising approach since it is relatively easy to use. Moreover, it has been shown that cryothermal energy does not

lead to PV stenosis, is not associated with atrioesophageal fistula, and carries a lower risk of thrombogenicity. However, in addition to the ablation catheter, current cryoballoon technology usually requires the use of a circular mapping multielectrode catheter to record PV potentials.⁴⁻¹¹

The ablation and mapping catheters may be used jointly in one of two ways: with access to the PVs using a double transseptal puncture or a single transseptal puncture. In the case of double transseptal access, the balloon is withdrawn back into the left atrium (LA) after the isolation attempt and the mapping catheter is positioned at the PV ostium to verify isolation.⁴⁻¹² When using single transseptal access, the balloon must be removed and the mapping catheter is inserted to check isolation; if additional lesions are required, the mapping catheter must be removed and the balloon reinserted. There are drawbacks associated with both of these approaches. Making a double transseptal puncture increases procedural risk and complexity; however, a single transseptal approach—with its frequent interchanges between ablation and mapping catheters—also entails risk and complexity.

Ideally, in the interests of simplifying the procedure and reducing risk, it would be desirable to make a single transseptal puncture and use only one device that can both ablate and map. Accordingly, we hypothesized that a cryoballoon catheter and a microcircular mapping catheter might be deployed jointly. Single-channel access to PVs is achievable by inserting the mapping catheter into and through the central lumen of the cryoballoon catheter. Our study evaluates the

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TABLE 1
Baseline Characteristics of Patients

Age	54.7 ± 10.7 years
Male	14 (60.9%)
History of AF	5.9 years (0.8–19 years)
Hypertension	6 (26.1%)
Structural heart disease	8 (37.8%)
Coronary heart disease	5
Cardiomyopathy	1
Valvular heart disease	2
Echocardiography	
Left atrial dimension	49.1 ± 6.7 mm
Ejection fraction	54.3% ± 15.1%

feasibility and efficacy of this novel, combined cryoablation-mapping catheter technique in PVI procedures.

Methods

A cohort of 23 patients undergoing ablation for paroxysmal AF was prospectively studied. Study inclusion criteria included a history of symptomatic paroxysmal AF with a normal left ventricular ejection fraction evaluated by echocardiography. All the patients had unsuccessful treatment with at least 2 antiarrhythmic drugs.

Transesophageal echocardiography was performed prior to the procedure to exclude left atrial thrombus. A multislice cardiac CT scan (Somatom, Siemens Inc.) was performed in all patients prior to the ablation procedure. Since the diameter of the mapping catheter's circular ring is 15 mm, patients with large common PV ostia were excluded from the study. Informed consent was obtained from all patients, and the study was performed in accordance with the Institutional Research guidelines at the German Heart Institute Berlin. Patient clinical characteristics are shown in Table 1.

Procedure

Procedures were performed under conscious sedation and analgesia with appropriate doses of propofol. A quadrapolar catheter (Josephson-type, Bard) was placed at the right ventricular apex. A 10-pole catheter (Inquiry, St. Jude Medical) was introduced in the coronary sinus for stimulation of the LA.

One transeptal puncture was made using a modified Brockenbrough technique to introduce a steerable 12F sheath (FlexCath, Cryocath). Rotational angiography of the LA was performed to identify the LA-PV anatomy, as reported in a previous study.¹³ A 6F pig-tail catheter was advanced into the LA through the sheath. The right ventricle was rapidly paced (cycle length 300 ms) for 6–8 seconds. Sixty milliliters of diluted contrast medium (Ultravist, Schering) was injected into the LA 2 seconds after the beginning of the rapid pacing. An FD10 flat detector system (Allura Xper FD10, Philips Medical Systems) was rotated isocentrically over a 220° arc, from a right anterior oblique (RAO) 110° to a left anterior oblique (LAO) 110° projection in 4 seconds, at a sampling rate of 30 frames per second. Rotational angiography of LA was achieved.

As a first option in all patients, we selected a 28-mm cryoballoon (Arctic Front, CryoCath Technologies). A microcircular mapping catheter with a 0.035-inch shaft diameter (ProMAP, ProRhythm Inc.) was introduced into the central

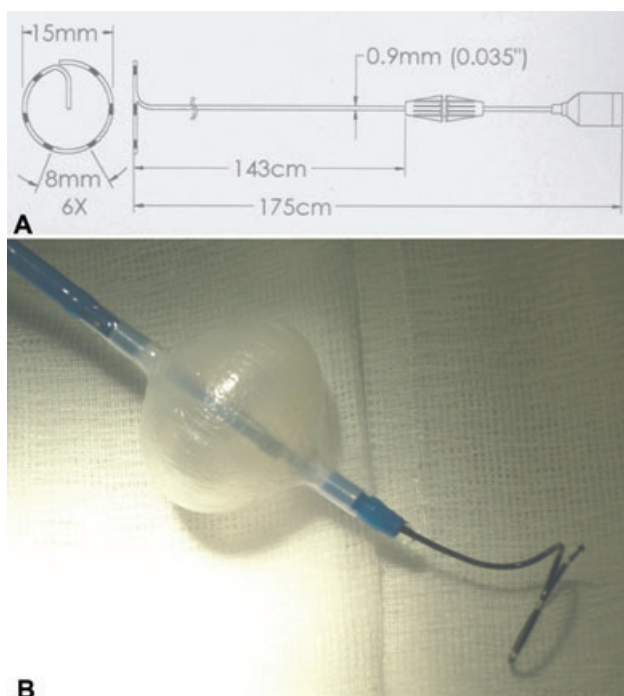


Figure 1. The microcircular mapping catheter is a 6-pole circular catheter with a shaft diameter of only 0.035 inch and a circular ring diameter of 15 mm. The mapping catheter can be introduced into the central lumen of the cryoballoon catheter and can be used as a “guide wire” as well as a recording device. (A) Schematic representation of the mapping catheter. (B) Distal end of cryoballoon catheter equipped with the circular mapping catheter.

lumen of the cryoballoon catheter (see Fig. 1A and B). In turn, the cryoballoon catheter was introduced into the LA via the 12F steerable sheath. In addition to its function as a recording device, the microcircular mapping catheter was also used as a “guide wire.” Using the “over-the-wire” technique with the steerable sheath, the balloon was guided to each PV ostium. The contrast medium (diluted 1:1 ratio with 0.9% saline) was injected into each PV through the central lumen of the cryoballoon catheter to obtain the PV angiogram (see Fig. 2A and B).

Before the balloon was inflated, the mapping catheter was placed in the PV to record the PV potential. The cryoballoon was then inflated and advanced toward the PV ostium. When the balloon was docked with the tissue, the diluted contrast medium was injected from the lumen of the catheter to evaluate the exact position of the balloon in relation to the LA-PV junction and determine the extent of vein occlusion with the cryoballoon.

Cryoballoon catheter ablation was initiated with the freezing cycle set at 300 seconds. Internal proximal balloon temperature was continuously monitored. During the procedure, heparin boluses were repeatedly administered to maintain the activated clotting time between 250 and 300 seconds. After each ablation attempt, PV potentials were reevaluated with the mapping electrode at the same site. If the PV was not isolated, an additional application of cryothermal energy was made. The ablation endpoint was complete isolation of all PVs.

While ablating at the right PVs, the decopolar catheter was withdrawn from the coronary sinus and repositioned in

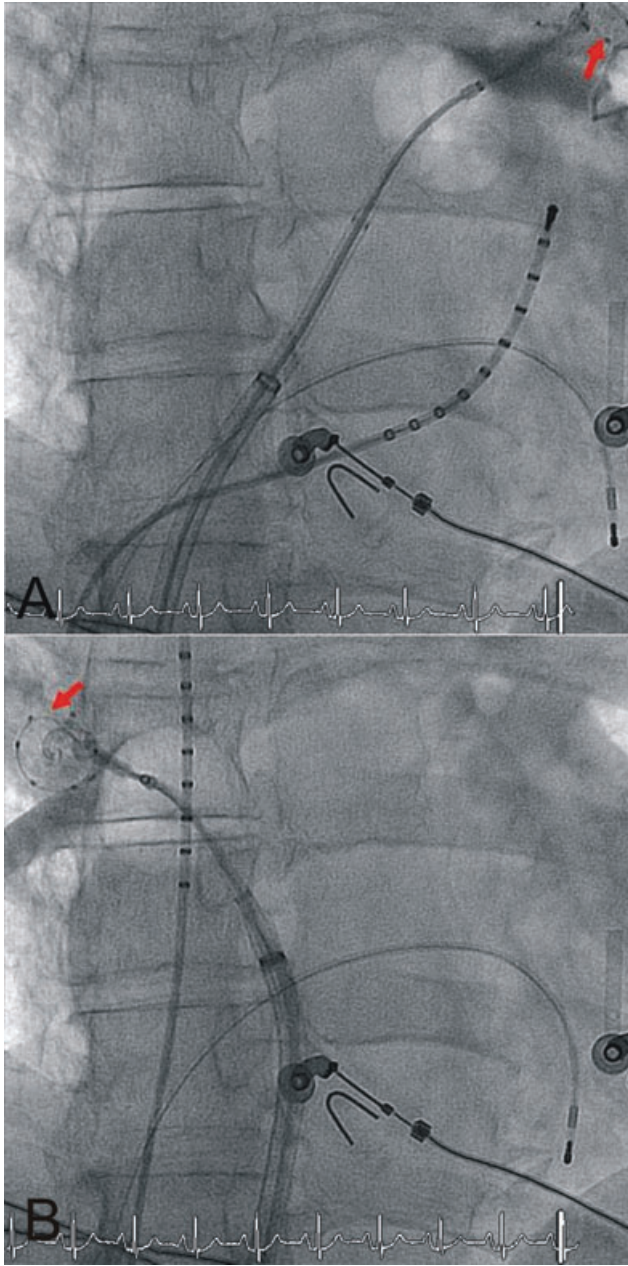


Figure 2. Fluoroscopic images showing complete occlusion of pulmonary veins (PVs) with the simplified cryoballoon technique. (A) Occlusion of the left superior PV with inflated cryoballoon in anterior-posterior projection. The mapping catheter is shown at red arrow. (B) Occlusion of the right superior PV with cryoballoon catheter in anterior-posterior projection. Decapolar catheter is placed in the superior vena cava. Mapping catheter is shown at red arrow.

the superior vein cava to pace the phrenic nerve (cycle length 1,000 ms, 12 mA for 1.5 ms). If the capture of phrenic nerve stimuli was lost, the ablation procedure was immediately stopped.

Follow-Up

On the first postprocedural day, warfarin was restarted and low-molecular heparin was administered until the international normalized ratio (INR) was > 2 . Warfarin was continued for at least 3 months. Also on the first postpro-

cedural day, patients underwent surface ECG, transthoracic echocardiography, and continuous ECG monitoring for at least 24 hours. Antiarrhythmic drugs were stopped 4 weeks post ablation procedure. Follow-up visits at the outpatient clinic were planned at 4 weeks and at 3, 6, and 9 months post ablation, at which time patients were asked about their symptoms and a 24-hour Holter ECG was performed. A cardiac magnetic resonance imaging examination was performed at each follow-up visit.

Statistical Analysis

Continuous variables were expressed as the mean value \pm SD and were compared with the one-way analysis of variance or *t*-test. A Pearson chi-square test was used for categorical variables. Nonparametric tests were used when appropriate. Statistical analysis was performed using SPSS, version 13.0 (SPSS Inc.).

Results

Total procedure time was 152.7 ± 54.9 minutes. Fluoroscopy time was 33.2 ± 17.3 minutes. Following the first 9 procedures, procedure time decreased from 191.4 ± 51.5 minutes to 132.1 ± 23.1 minutes ($P < 0.001$), and fluoroscopy time dropped from 44.4 ± 11.3 minutes to 26.21 ± 10.9 minutes ($P = 0.017$). Total cryoablation time was 44.3 ± 14.2 minutes per patient. The number of cryoballoon applications per PV was 1.7 ± 1.0 (range: 1–5) for the right superior pulmonary vein (RSPV); 1.3 ± 0.8 (1–9) for the right inferior pulmonary vein (RIPV); 2.0 ± 1.4 (1–6) for the left superior pulmonary vein (LSPV); and 2.8 ± 1.9 (1–9) for the left inferior pulmonary vein (LIPV) ($P = 0.12$).

A total of 84 PVs (84 of 92, 91.3%) were isolated using this novel cryoballoon technique: RSPV, 23 of 23 (100%); RIPV, 19 of 23 (82.6%); LSPV, 22 of 23 (95.7%); and LIPV, 20 of 23 (87.0%). Statistically, the rate of isolation in the RIPV was less than that of the other PVs ($P = 0.036$). In the other 8 PVs, complete isolation could not be achieved as early branching of the vein hindered full deployment of the microcircular catheter in conjunction with the cryoballoon. In these cases, a conventional rigid guide wire was used, and complete PVI was achieved in all of these veins (4 RIPVs, 1 LSPV and 3 LIPVs).

In the 84 PVs that were isolated with this cryoballoon technique, PV isolation was monitored in real time during cryoablation in 43 PVs (51.2%) (see Figs. 3A–D and 4, Table 2) and the isolation was checked immediately post ablation attempt in 41 PVs (48.8%). In the 41 PVs, the microcircular mapping catheter had to be advanced deeply inside of the veins to achieve complete occlusion during cryoablation; the catheter was immediately withdrawn to the PV ostia to confirm PV isolation after the ablation attempt.

In 1 patient, a phrenic nerve palsy was detected during RSPV isolation. The phrenic nerve palsy resolved 1 month post ablation (as documented with fluoroscopic evaluation of the diaphragm movement). No incidence of PV stenosis was observed during follow-up.

In addition, we performed a linear ablation of the right atrial isthmus in 2 patients in whom typical atrial flutter occurred during PVI. Bidirectional conduction block was achieved in all patients.

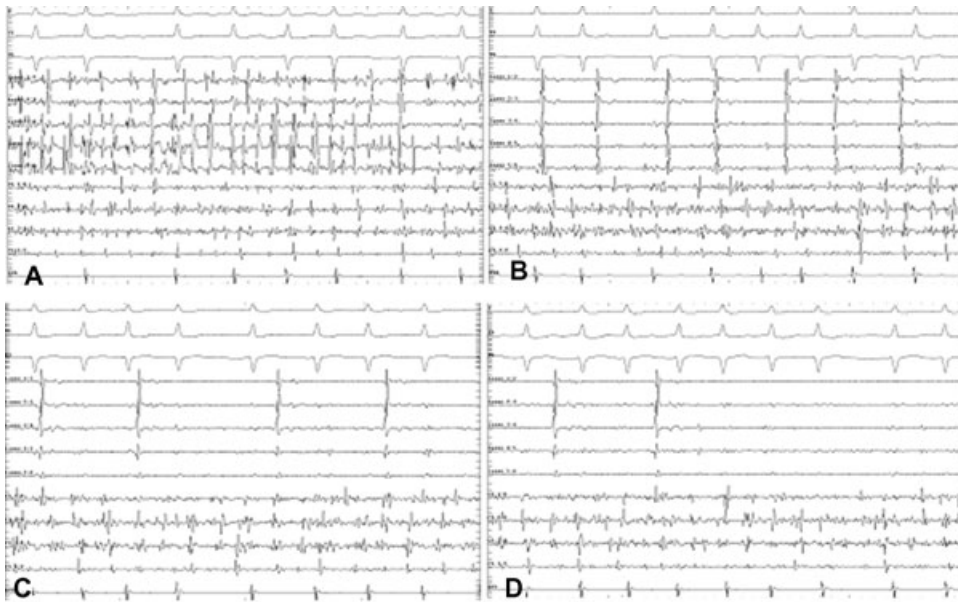


Figure 3. Complete isolation of a left inferior PV (LIPV) in atrial fibrillation rhythm with the simplified cryoballoon technique. From the top to the bottom: surface ECG leads I, II, V1; endocardiograms in the 6-pole microcircular mapping catheter (lasso 1–2 to 5–6); endocardiograms in the coronary sinus (CS 1–2 to 7–8); signals in the right ventricular apex (RVA). (100 mm/s) (A) Irregular activity in the LIPV before ablation. (B) Progressive organization of activity and partial entrance block in the LIPV during ablation. (C) Residual PV potentials in the vein during further ablation. (D) Complete isolation of the LIPV.

At follow-up (7.4 months, range 2–18 months), 17(73.9%) of the 23 patients were free from AF.

Discussion

Our study demonstrates that mapping and isolating PVs can be achieved with just one transseptal puncture and a single-channel device consisting of a cryoballoon catheter and a microcircular mapping catheter.

PVI using a cryoballoon catheter system has been performed in many studies.^{8,14} However, conventional cryobal-

loon technique requires either 2 transseptal punctures (to accommodate both an ablation catheter and a PV-potential mapping catheter) or a single transseptal puncture (in which the operator must interchange the cryoballoon catheter and mapping catheter to verify if the PV has been isolated). Since neither approach is ideal, there is a need for a technique that facilitates both PV mapping and cryoablation.

In response to this need, we introduced a mapping catheter into the cryoballoon catheter through its central lumen. By combining the catheters in this way, the procedure can be carried out with just 1 transseptal puncture, making this novel



Figure 4. Complete isolation of a left superior pulmonary vein in sinus rhythm with the simplified cryoballoon technique. From the top to the bottom: surface ECG leads I, II, V1; endocardiograms in the 6-pole microcircular mapping catheter (Lasso 1–2 to 5–6); endocardiograms in the coronary sinus (CS 1–2 to 7–8); signals in the right ventricular apex (RVA). (25 mm/s).

TABLE 2

Confirmation of Pulmonary Vein Isolation Using Microcircular Mapping Catheter

	Monitor in Real Time During Ablation	Check Immediately After Ablation Attempt
LSPV (n = 22)	15	7
LIPV (n = 20)	10	10
RSPV (n = 23)	15	8
RIPV (n = 19)	3	16
P = 0.003		

LSPV = left superior pulmonary vein; LIPV = left inferior pulmonary vein; RSPV = right superior pulmonary vein; RIPV = right inferior pulmonary vein.

and unique approach ideal in comparison with established techniques.^{5-11,14}

In 46.7% of the veins, isolation was observed in real time during ablation; in 53.3%, the mapping wire had to be positioned deep inside the target PV during ablation to achieve complete occlusion of the vein, but was withdrawn immediately after each ablation attempt to test the PV potential. With this approach, the operator does not need to interchange the 2 catheters, which is of considerable practical benefit. Though innovative, this is a relatively easy-to-perform technique. When we started our study, we observed that procedure and fluoroscopy times decreased significantly after only 9 procedures.

There were 8 veins in which complete occlusion could not be achieved using this technique as the early branching of PVs hindered the full deployment of the cryoballoon on the PV ostium. However, this problem will certainly be resolved with future development in microcircular mapping catheters.

Limitations

There are some limitations in this study. Due to the mapping catheter's small loop size (15 mm), patients with large common ostia were excluded. This limitation will certainly be overcome once microcircular mapping catheters of different formats become available.

Ours was a small study designed primarily to evaluate the effectiveness, feasibility, and safety of a cryoballoon catheter equipped with a mapping catheter for PVI. Larger and randomized studies are needed for a fuller comparison of procedure times, effectiveness, and safety between this new cryoballoon technique and conventional approaches. It is promising, however, that total procedure and fluoroscopy times in this study were relatively shorter compared with previous reports.^{4-6,14} If this finding is confirmed in future randomized studies, it would constitute an additional advantage for this novel technique in comparison with conventional cryoballoon approaches.

The relatively short duration of the follow-up (7.4 months) does not allow to establish correctly the clinical outcome of this novel cryoablation technique.¹⁵ This is a limitation in this study.

Conclusion

The study shows that a single-channel device consisting of a cryoballoon catheter and a 6-pole microcircular mapping

catheter can be used effectively and safely for recording and ablating at the LA-PV junction to achieve PVI.

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