Early experiences with three types of balloon-based ablation catheters in patients with paroxysmal atrial fibrillation

Atsushi Kobori, MD, PhD, Yasuhiro Sasaki, MD, Misun Pak, MD, PhD, Taiji Okada, MD, Toshiaki Toyota, MD, Kitae Kim, MD, Takeshi Kitai, MD, PhD, Natsuhiko Ehara, MD, PhD, Makoto Kinoshita, MD, PhD, Shuichiro Kaji, MD, PhD, Yasuki Kihara, MD, PhD, Yutaka Furukawa, MD, PhD

From the Department of Cardiology, Kobe City Medical Center General Hospital, Kobe, Japan.

BACKGROUND Although balloon-based ablation catheters are expected to improve the feasibility and quality of pulmonary vein isolation (PVI) in patients with atrial fibrillation (AF), they must be introduced to physicians in the proper setting to ensure their correct usage.

OBJECTIVE To identify the optimal clinical settings for learning the techniques for 3 balloon-based ablation catheters (Cryoballoon, Hotballoon, and Laserballoon).

METHODS We introduced 3 balloon catheters in 50 consecutive patients with paroxysmal AF each during the introduction periods. Clinical parameters were compared among the groups and between these groups and their steady-state controls.

RESULTS The completion rate of PVI by sole balloon procedures was 56% with the Hotballoon catheter, which was lower than those of the Cryoballoon and Laserballoon catheters (each 88%). Radiofrequency touch-up was most frequently required at the bottom aspect of the inferior pulmonary veins (PVs) in the Cryoballoon group and at the anterior aspect of the superior PVs in the Hotballoon and Laserballoon groups. The Laserballoon catheter had the longest average PVI procedural time (89.2 $\pm$ 40 vs 58.4 $\pm$ 22 minutes for Hotballoon, 65.1 $\pm$ 25 minutes for Cryoballoon, $P < .001$), but the difference was ultimately removed by the learning curve. There was no significant difference in the major complication or recurrence-free survival rates among the catheter types.

CONCLUSIONS All 3 balloon-based catheter types allowed feasibility and quality for PVI, even during the learning period. To introduce these new catheters without complications, an experiences of 20 cases with specific clinical settings should be met for each catheter type.

KEYWORDS Atrial fibrillation; Catheter ablation; Cryoballoon; Hotballoon; Laserballoon

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Introduction

Pulmonary vein isolation (PVI) is recognized as the standard strategy of catheter ablation for atrial fibrillation (AF) and has been commonly performed with a radiofrequency (RF) technology catheter since the first report by Haïssaguerre in 1998.[1] However, the RF catheter is technically difficult to manipulate to complete the PVI and has a high rate of reconduction, requires a long procedural time, and causes unavoidable complications, including cardiac tamponade. Innovative ablation devices based on balloon technologies are expected to improve the feasibility and quality of PVI in patients with AF.[2,3]

Three types of balloon-based ablation catheters are currently available in Japan and have been widely introduced in many centers. The Cryoballoon was launched in 2014, the Hotballoon in 2016, and the Laserballoon in 2018. However, although each type of balloon-based ablation catheter offers advantages, some centers stopped using them during the learning period owing to unexpected ineffectiveness and complications. Learning the techniques required for the new balloon-based ablation catheters while determining the clinical features of each energy source is challenging. Thus, the optimal clinical settings for the smooth introduction of each balloon-based ablation catheter need to be determined. Therefore, we examined the optimal clinical settings for learning the techniques of the 3 balloon-based ablation catheters.

Methods

Study patients

The introduction study groups consisted of 50 consecutive patients each from the first introduction case undergoing their first ablation using the 3 balloon catheter types owing to

Address reprint requests and correspondence: Dr Atsushi Kobori, Department of Cardiology, Kobe City Medical Center General Hospital, 2-1-1 Minatojima-minamimachi, Chuou-Ku, Kobe 650-0047, Japan. E-mail address: kobori@kcho.jp.

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KEY FINDINGS

- The learning curve for mastering techniques for balloon-based ablation catheters could eliminate any differences in procedure times.
- All 3 catheters (Cryoballoon, Hotballoon, and Laserballoon) provided equally favorable chronic clinical outcomes even in the introduction periods.
- The shortcut to mastery is preprocedural computed tomography for Cryoballoon, radiofrequency touch-up for Hotballoon, and sufficient irradiation of thick pulmonary vein wall for Laserballoon.

drug-resistant paroxysmal AF at our center. Eligible patients for balloon-based catheter ablation were selected based on the preprocedural computed tomography (CT) images, and ineligible patients who had severely enlarged or thin left atrium (LA) and deformed pulmonary veins (PV) were excluded and treated without using balloon-based catheters. PVI was performed in all cases. Patients requiring additional ablation lesions in the LA were excluded from the study, except for ablations at the superior vena cava (SVC) and cavotricuspid isthmus line. Between September 8, 2014, and February 9, 2015, the Cryoballoon introduction group (Cryo-intro) consisted of 50 consecutive patients, after excluding 3 patients who underwent additional LA ablation. Between July 4, 2016, and January 29, 2018, the Hotballoon introduction group (Hot-intro) consisted of 50 consecutive patients, after excluding 4 patients who underwent additional LA ablation. The Laserballoon introduction group (Laser-intro) consisted of all 50 consecutive patients who underwent PVI from July 24, 2018, to March 4, 2019. To compare with steady-state cohorts, subsequent 25 patients were enrolled as controls (Cryo-control, Hot-control, and Laser-control). Informed consent was obtained from all patients. The study was approved by the Institutional Review Board of Kobe City Medical Center General Hospital, and an opt-out system was used to obtain patients' consent for the use of their clinical data for research purposes. The research reported in this study was conducted according to the principles of the Declaration of Helsinki.

Ablation

Periprocedural management and electrophysiological study

All patients received oral anticoagulation medications between at least 1 month before and 6 months after the procedure. The patients were instructed not to take their medication on the morning of the procedure (except those taking warfarin). All anticoagulation medications were immediately restarted after the procedure. All antiarrhythmic medications were discontinued at least 5 half-lives before the procedure. An activated clotting time of >300 seconds was maintained by continuous heparin infusion during the procedure. Dexmedetomidine and fentanyl were used to achieve conscious sedation in the patients. Multipolar catheters with internal cardioversion (BeeAT; Japan-Life-Line, Tokyo, Japan) were placed at the coronary sinus (CS) through the internal jugular vein, and a deflectable multipolar catheter (Abbott, St. Paul, MN) was placed at the right ventricle or right atrium through the right femoral vein. Transseptal puncture was performed under intracardiac echocardiography guidance, and 1 or 2 sheaths were introduced to the LA. Three-dimensional (3D) voltage maps of the LA and PVs were depicted by 10- or 20-electrode circular catheters during CS pacing with an EnSite Precision mapping system (Abbott) before and after PVI. Temporal right ventricle pacing was performed during left-sided PV ablation, and continuous phrenic nerve pacing with monitoring of compound motor action potentials was performed during right-sided PV ablation. The application of ablation energy was discontinued to prevent a phrenic nerve injury when a >30% reduction in compound motor action potential amplitude or decreased diaphragmatic excursions were detected. Esophageal luminal temperature was monitored using a temperature-sensing probe (Esophastar; Japan-Life-Line).

To confirm the completion of PVI, the bidirectional block of paced or self-activated PV electrograms was assessed using a decapolar or duodecapolar circular catheter after the ablation of all PVs. To assess an acute reconnection of an isolated PV, an adenosine triphosphate (ATP) test using a 20-mg adenosine triphosphate bolus injection was administered after enough long waiting time. If PV reconnection was continuously observed with or without the ATP test, a RF ablation catheter (TactiCath SE; Abbott) was applied for touch-ups to achieve complete PVI. Almost all patients were ablated at the cavotricuspid isthmus line using an RF catheter routinely. If the SVC demonstrated an origin of AF, SVC isolation was performed using an RF catheter. On the other hand, the patients who underwent additional ablations in the LA were excluded from the study. The provocation test of the AF by rapid and decrement pacing at the RA or CS with an infusion of 20–40 μg of isoproterenol was performed, and any continuous AF was terminated by internal cardioversion. A figure-of-8 suture was used before all vein sheath extractions and the patients remained in bed for 6 hours after the procedure. The procedures were performed by 2 operators who have 10 years (70% of cases) and 3 years (30% of cases) of RF ablation experience but without balloon-based catheter ablation experience. The first 2 cases in each group were performed with verbal guidance from instructors.

Cryoballoon ablation

The cryoballoon ablation procedure was performed as previously described.[4] In brief, after voltage mapping of the LA and PV, a 15F steerable sheath (FlexCath Advance; Medtronic Inc, Minneapolis, MN) was placed. A 28-mm second-generation cryoballoon (ArcticFront Advance, Medtronic Inc; Cryoballoon) was inflated at the orifice of each PV anchored using a 20-mm circular mapping wire catheter with 10-pole electrodes (Achieve; Medtronic Inc). An optimal

occlusion was confirmed using the pooling and leakage maneuver (proximal seal technique). The double-freezing protocol (180 seconds and subsequent 120 seconds) was initially applied to each PV in the following order: left superior (LSPV), left inferior, right inferior (RIPV), and right superior. When the esophageal luminal temperature reached <20°C, the application of cryoenergy was stopped.

Hotballoon ablation

The Hotballoon ablation procedure was performed as previously described.[5] After LA voltage mapping, the SATAKE Hot Balloon catheter (Hotballoon; Toray Industries, Tokyo, Japan) was inserted to the proximal portion of the PV supported by a J-tip guidewire. Manual inflation of the balloon with triple-diluted contrast media (10–16 mL, determined by the diameter of each PV) was performed, and optimal occlusion was confirmed. A circular mapping catheter was placed at the distal side of the PV through the occluding balloon to allow for real-time monitoring of the disappearance of the PV potential. RF ablation maintained within 70°C of the balloon's central temperature was delivered for up to 240 seconds for superior PVs and 180 seconds for inferior PVs. When the esophageal temperature exceeded 39°C, it was cooled with an injection of ice water.[6]

Laserballoon ablation

The Laserballoon ablation procedure was performed as previously described.[7] In brief, after LA voltage mapping, a 12F steerable sheath was placed in the LA. The Laserballoon catheter (Heartlight; CardioFocus, Marlborough, MA) was positioned at each individual PV ostium, and optimal PV occlusion with maximal exposure of LA tissue was attempted by continuous flushing with deuterium (D_2O). The laser energy was titrated from 5.5 to 12 W (delivery time of 20–30 seconds) according to the quality of tissue exposure and the segment of PV; 12 W energy was used in the anterior and roof, 8.5 W energy was used in the posterior and inferior, and 5.5 W energy was used at tissues that were poorly visualized owing to floating blood. Ablation lesions were created in a contiguous fashion with 30% overlapping. If PV isolation was not achieved after each initial circular irradiation, additional laser irradiation with real-time PV potential monitoring was performed. When the esophageal temperature exceeded 39°C, energy delivery was stopped.

Follow-up

Follow-up appointments were performed at 1, 3, 6, 9, and 12 months after the procedure and included a physical examination, 12-lead electrocardiogram (ECG), and blood examination. A cardiac ultrasound examination and 24-hour Holter recording were obtained at 6 and 12 months after the procedure. PV stenosis was assessed by CT imaging at 3 months after the procedure. Recurrence was defined as any symptomatic or documented atrial arrhythmias of >30 seconds after the 3-month blanking period.

Statistical analysis

Baseline patient demographics and procedural and clinical characteristics were compared among the cohorts. To assess the learning curve phenomenon, each population was divided into 5 quantiles of 10 consecutive patients (Q1–5). Continuous variables were analyzed using the analysis of variance or *t* test. The Fisher exact test was used for comparing categorical variables. Time-to-event analysis was performed using the Kaplan-Meier curves, utilizing the log-rank tests to compare the differences between the groups. For all analyses, *P* values were 2-sided and statistical significance was set at $P < .05$. JMP version 13 (SAS Institute Inc, Cary, NC) was used for all statistical analyses.

Results

Patients' characteristics

The patients' baseline characteristics were similar among the 3 introduction groups except for the LA appendage flow velocity ($P = .03$) (Table 1). There were no significant differences in the patients' characteristics between the introduction and control groups for each balloon population, except for age and male sex rate, which was significantly different between the introduction and control groups in the Hotballoon population. There were no significant differences in PV diameters and LA size between the introduction and control groups among all balloon populations.

PVI procedures

PVI was successfully achieved in each case. The success rate of PVI using a sole balloon catheter was higher in the Laser-intro (88.0%) and Cryo-intro (88.0%) groups than in the Hot-intro (56.0%) group (Table 2). However, the success rates varied in each PV. In the LSPV, the success rate of PVI was the highest in the Cryo-intro group, followed by that in the Laser-intro group. The Hot-intro group had the lowest success rate of PVI in the LSPV. In the left inferior and right superior PV, the success rates of PVI were similar between the Laser-intro and Cryo-intro groups, but the success rate was the lowest in the Hot-intro group. In the RIPV, the success rate of PVI was comparable among groups. The sites that required touch-up by RF ablation most frequently were the bottom of the RIPV in the Cryo-intro group and the anterior-inferior aspect of the LSPV in the Hot-intro and Laser-intro groups (Figure 1). The reconnection sites unmasked by ATP were observed most frequently in the Hotballoon and successfully eliminated by performing additional RF ablation. The success rate of PVI and distribution of the gap sites in each introduction group were similar to those of the control group.

Procedural time

Both procedural and application times to complete PVI were the longest in the Laser-intro group. However, the fluoroscopy time to complete PVI was the shortest in the Laser-intro group (Table 2). The procedural and dwelling times were longer in the introduction group than in the control

Table 1 Patient demographics at baseline

Characteristic	Cryoballoon		Hotballoon		Laserballoon		
	Cryo-intro (n = 50)	Cryo-control (n = 25)	Hot-intro (n = 50)	Hot-control (n = 25)	Laser-intro (n = 50)	Laser-control (n = 25)	*P* value (among intro groups)
Age, years	68.8 ± 12.2	68.9 ± 11.4	67.2 ± 11.4*	72.8 ± 8.5	65.2 ± 10.4	65.6 ± 13.1	.28
Male sex, (%)	62.0	68.0	78.0*	68.0	76.0	72.0	.16
Disease periods, months	35.1 ± 7.7	34.8 ± 11	34.8 ± 7.7	36.0 ± 8.0	30.7 ± 7.7	32.7 ± 7.1	.90
$CHADS_2$ score	1 [0,2]	1 [0,2]	1[0,2]	1 [0,2]	1[0,2]	1[0,2]	.10
No. of ineffective antiarrhythmic drugs, n	1.20 ± 1.1	0.91 ± 0.9	1.41 ± 0.6	1.10 ± 0.3	1.19 ± 0.5	1.09 ± 0.3	.49
No baseline disease, (%)	40.0	40.0	26.0	36.0	44.0	40.0	.12
Hypertension, (%)	52.0	49.0	60.0	40.0	42.0	48.0	.19
Heart failure, (%)	6.0	4.0	8.0	0	2.0	0	.12
Cardiomyopathy, (%)	4.0	0	4.0	0	4.0	0	.47
Valvular heart disease, (%)	0	4.0	0	0	2.0	1.0	.50
Renal dysfunction, (%) <no. of HD>	6.0, <2>	0, <0>	2.0, <0>	0, <0>	6.0, <1>	8.0, <0>	.52
Chronic pulmonary disease, (%)	0	0	0	0	0	0	-
Left ventricular ejection fraction, (%)	62.4 ± 5.1	62.7 ± 3.2	62.8 ± 4.2	62.1 ± 5.0	62.5 ± 5.4	63.4 ± 2.7	.91
Left atrial diameter, (mm)	36.5 ± 6.3	35.2 ± 8.9	36.8 ± 5.4	34.3 ± 5.3	35.5 ± 5.5	35.9 ± 6.7	.47
Left atrial volume index, ($mL/m^{2)}$	42.1 ± 20.0	39.0 ± 16.1	37.7 ± 11.2	35.2 ± 10.3	36.5 ± 8.9	36.6 ± 9.0	.11
Left appendage flow velocity, (cm/sec)	60.5 ± 23.8	58.1 ± 20.5	68.5 ± 21.2	62.1 ± 19.4	57.5 ± 17.4	59.1 ± 15.0	.030
Pulmonary vein diameter, (mm)							
Left superior	19.7 ± 3.0	18.2 ± 3.3	19.1 ± 2.8	18.4 ± 33	18.7 ± 3.0	19.9 ± 2.8	.29
Left inferior	17.2 ± 2.7	17.1 ± 2.1	16.6 ± 2.1	16.0 ± 3.0	16.0 ± 2.6	16.8 ± 2.2	.08
Right superior	19.1 ± 3.3	19.4 ± 2.0	19.1 ± 3.4	18.4 ± 2.8	18.5 ± 3.5	19.0 ± 3.4	.57
Right inferior	18.3 ± 2.6	19.0 ± 3.0	17.5 ± 3.1	17.7 ± 3.4	17.7 ± 2.5	17.8 ± 3.3	.33
Left common pulmonary vein, (%)	4.0	8.0	0	4.0	4.0	8.0	.33

HD = patients on hemodialysis.

Continuous variables are shown as mean ± standard deviation or as median [25th, 75th percentile] values.

P value indicates analysis of variance among the introduction groups.

*$P < .05$ between introduction and control groups of each balloon population.

group. To assess the learning curve phenomenon, each of the introduction groups was divided into 5 quantiles of 10 consecutive patients (Q1–5, Figure 2). The procedural time for PVI, dwelling time in LA, and fluoroscopic time of the Cryo-intro and Laser-intro groups were shortened by Q3 and comparable to those of the controls. The procedural and application times for PVI in the Hot-intro group were gradually shortened by Q4. The procedural and application times for PVI in the Laser-intro group were significantly longer until Q2 (approximately 20 patients); however, the procedural and application times after Q2 learned the technique to maintain balloon stability were comparable among the 3 groups.

Clinical outcomes

Early recurrences of atrial arrhythmias during the blanking period occurred more frequently in the Cryo-intro (n =13) group than in the Hot-intro (n = 4) or Laser-intro (n = 5) group ($P < .05$). The atrial arrhythmia recurrence-free survival rates at approximately 1 year post-procedure were comparable among the 3 introduction groups (92.0% at 350.9 ± 67.6 follow-up days in Laser-intro; 90.0% at 511.0 ± 143 follow-up days in Hot-intro; and 81.9% at 489.3 ± 198 follow-up days in Cryo-intro; log-rank $P = .69$, Figure 3). The recurrence-free survival rate in each introduction group was comparable to the control group. Major adverse events were observed equally among the groups. At 3 months after the procedure, follow-up CT showed asymptomatic PV stenosis (>75% area reduction) at the ostium of the LSPV in 1 patient in each of the Cryoballoon and Laserballoon groups, and asymptomatic PV stenosis at the ostium of the left inferior PV in 1 patient in the Hotballoon group. All stenoses occurred during the first application at the inside of the PV ostium with 18–22 mm diameter; fortunately, no interventions were required. Transient right phrenic nerve palsy occurred in 1 patient in each of the Cryoballoon and Laserballoon groups. One patient in the Hotballoon group experienced transient gastric dysperistalsis.

Discussion

We evaluated our early experiences with 3 different balloon-based ablation catheters, which were each used in 50 patients with AF, to identify how these catheters can be successfully introduced to physicians. This is the first observational study focusing on the early experiences of various balloon-based ablation catheters. We found that all 3 types of balloon catheters have favorable acute and chronic effects and safety outcomes, even during a learning period. The Cryoballoon catheter had a high success rate of PVI and a high rate of gap at the bottom aspect of the inferior PVs. The Hotballoon and Laserballoon catheters frequently required RF touch-up at the anterior aspect of the superior PVs. In the Laserballoon catheter, a relatively long procedural time was required at the initial stage of the introduction period, which has been

Table 2 Procedural outcomes and adverse events

	Cryoballoon		Hotballoon		Laserballoon		*P* value (among intro groups)
	Cryo-intro	Cryo-control	Hot-intro	Hot-control	Laser-intro	Laser-control	
PVI by sole balloon, n (%)	44 (88.0)	23 (92.0)	28 (56.0)	15 (60.0)	44 (88.0)	23 (92.0)	<.0001
Left superior, n/n (%)	48/48 (100)	22/23 (95.7)	36/50 (72.0)	17/24 (70.8)	44/48 (91.7)	21/23 (91.3)	<.001
Left inferior, n/n (%)	46/48 (95.8)	23/23 (100)	43/50 (86.0)	22/24 (91.7)	46/47 (97.9)	22/23 (100)	.050
Right superior, n/n (%)	47/49 (95.9)	24/25 (96.0)	40/50 (80.0)	22/25 (92.0)	49/50 (98.0)	25/25 (100)	.003
Right inferior, n/n (%)	46/49 (93.9)	24/25 (96.0)	50/50 (100)	24/25 (96.0)	46/49 (93.9)	25/25 (100)	.10
Common trunk, n/n (%)	3/3 (100)	2/2 (100)	-	1/1 (100)	3/3 (100)	2/2 (100)	-
Touch-up by radiofrequency ablation, n/n of PVs (%)	7/197 (3.6)	3/98 (3.1)	31/200 (15.5)	13/99 (13.1)	9/197 (4.6)	3/98 (3.1)	<.0001
PV reconnection by adenosine triphosphate test, n/n of pts (%)	4/37 (10.8)	0/15 (0)	10/44 (22.7)	1/8 (12.5)	4/47 (8.5)	1/20 (5.0)	.01
SVC isolation, n (%)	2 (4.0)	2 (8.0)	3 (6.0)	1 (4.0)	3 (6.0)	3 (12.0)	.88
CTI, n (%)	47 (94.0)	24 (96.0)	45 (90.0)	24 (96.0)	48 (96.0)	25 (100)	.48
Time							
PVI, minutes	65.1 ± 24.5*	50.8 ± 19.2	58.4 ± 21.9*	40.1 ± 9.8	87.8 ± 40.3*	61.9 ± 16.0	<.001
Fluoroscopy, minutes	22.3 ± 9.3*	14.8 ± 9.0	18.0 ± 6.7*	12.6 ± 6.1	14.4 ± 9.8	12.0 ± 3.6	<.001
Dwelling in the left atrium, minutes	92.2 ± 29.0*	74.2 ± 19.5	92.0 ± 26.5*	77.2 ± 18.1	122.5 ± 45.1*	96.5 ± 20.0	<.0001
Total procedure, minutes	172.5 ± 37.0*	153.8 ± 38.8	162.5 ± 26.1	151.0 ± 35.5	186.4 ± 49.6*	166.2 ± 30.9	.01
Major adverse events							
Phrenic nerve palsy, n	1	0	0	0	1	0	.44
Gastrointestinal disorder, n	0	1	1	0	0	0	.33
Cardiac tamponade, n	1	0	0	1	0	0	.33
Pulmonary vein stenosis, n	1	0	1	0	1	0	.99
Catheter trouble, n					6	2	

PV = pulmonary vein; PVI = pulmonary vein isolation.
Continuous variables are shown as mean ± standard deviation.
P value indicates analysis of variance among the introduction groups.
*$P < .05$ between introduction and control groups of each balloon population.

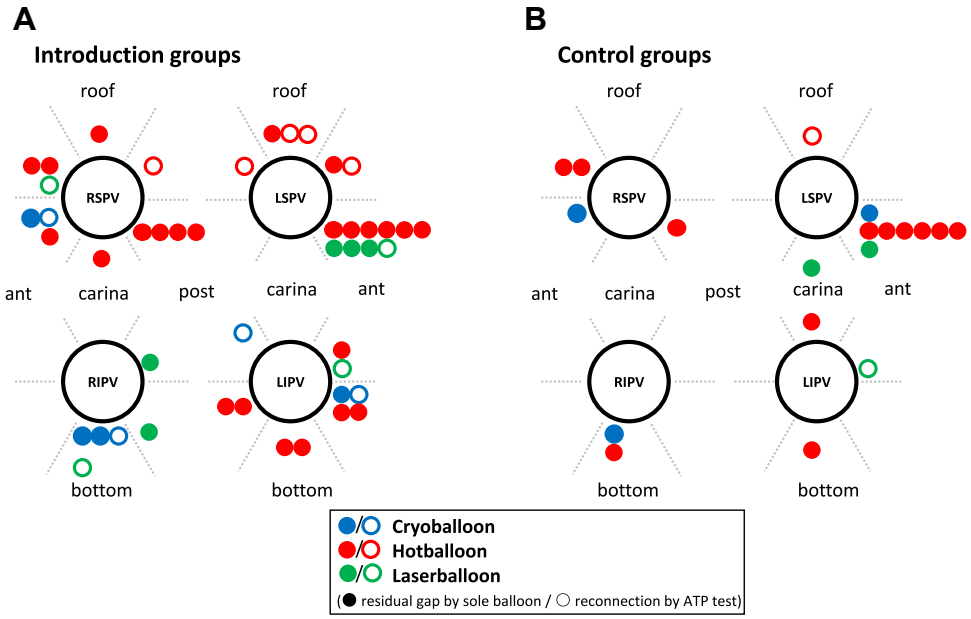

Figure 1 Distribution of the touch-up site by radiofrequency (RF) catheter. **A:** Introduction groups (Cryo-intro, Hot-intro, and Laser-intro; n = 50 each). **B:** Control groups (Cryo-control, Hot-control, and Laser-control; n = 25 each). The closed circles indicate the gap sites requiring RF touch-up after failure to complete pulmonary vein isolation by using a sole balloon catheter. The open circles indicate the reconnection sites provoked by the adenosine triphosphate (ATP) test. The blue, red, and green markers indicate the Cryoballoon, Hotballoon, and Laserballoon groups, respectively. ant = anterior side; LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; post = posterior side; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein.

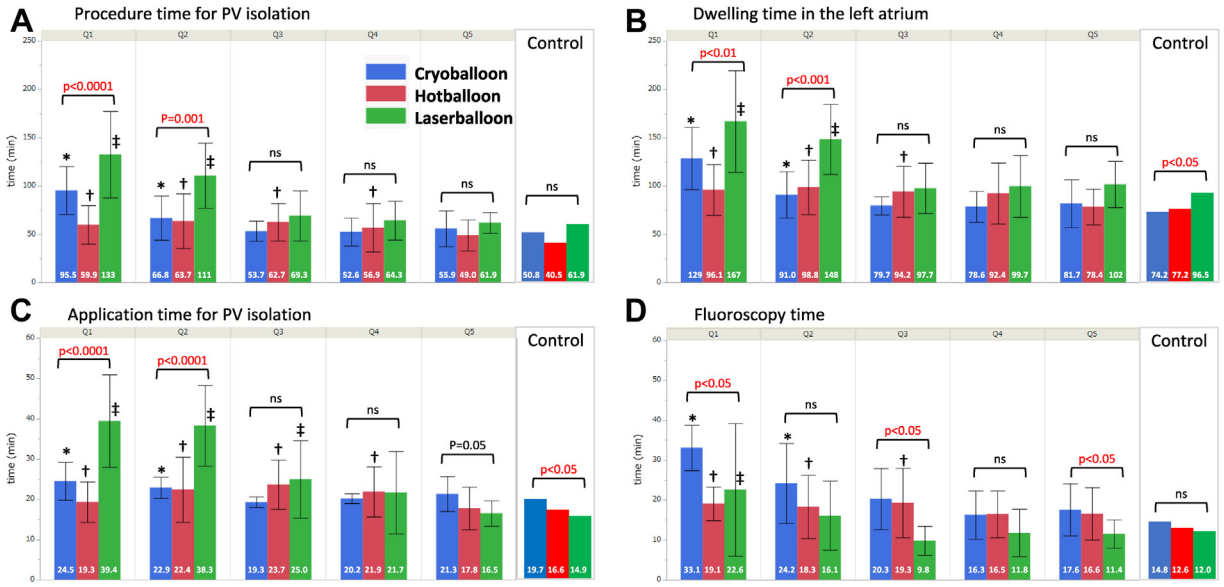

Figure 2 Learning curve of pulmonary vein (PV) isolation procedural time. The average procedural time of the 5 quantiles each containing 10 consecutive introduction group patients (Q1–5) and each control group (Cryo-control, Hot-control, and Laser-control). **A:** The procedural time for PV isolation. **B:** The dwelling time in the left atrium. **C:** The application time of PV isolation. **D:** The fluoroscopy time. The Cryoballoon group is represented by blue bars, the Hotballoon group by red bars, and the Laserballoon group by green bars. White numbers on the bar indicate the average time in minutes. *$P < .05$ vs the Cryo-control; †$P < .05$ vs the Hot-control; ‡$P < .05$ vs Laser-control.

shortened after the operator has acquired a certain number of experiences.

Clinical outcomes

PVI by RF catheters is the standard strategy for AF ablation.[2] Balloon-based ablation catheters have been shown to be as effective and safe as the RF catheter, but data on the introduction and learning periods of these devices are limited.[3,8] This study shows that the success rate of PVI achieved with each balloon catheter and clinical outcome is high enough even during the introduction period (Table 2, Figure 3). Although complications were expected to occur more frequently during the learning period, the complication rates of each catheter in this study are equivalent to those after long-term use. The procedural times for balloon ablation are expected to be shorter, which was proved to be achieved with a short-term learning period in this study. In this study, the dwelling times in the LA improved with a steep learning curve until those of previous reports performed by experienced operators were achieved.[3]

Cryoballoon

The Cryoballoon ablation catheter is very effective at the superior PVs, which are often the origin of AF, owing to the tissue adhesion feature of the balloon that allows for easy PV occlusion, even in the introduction period (Figure 1). In contrast, the bottom and inferior aspects of the RIPV and left inferior PV frequently required RF touch-up ablation. This may be owing to the thin oval orifice of the catheter or the posterior compression of the inferior PV by the vertebrae, and this is especially problematic in beginner users. To overcome this difficulty, patients without morphologic difficulties that occlude the inferior PVs, as determined by preprocedural 3D CTs, should be selected for Cryoballoon ablation.[9,10] Although acute recurrences during the blanking period were observed frequently, the recurrence-free survival rate in the chronic phase was high and relatively equal to those of the other 2 balloon-based ablation catheters.

Hotballoon

The Hotballoon catheter is composed of a compliant balloon with a 1-shot thermal energy device. As PV occlusion can be easily obtained with a compliant balloon, the procedural time

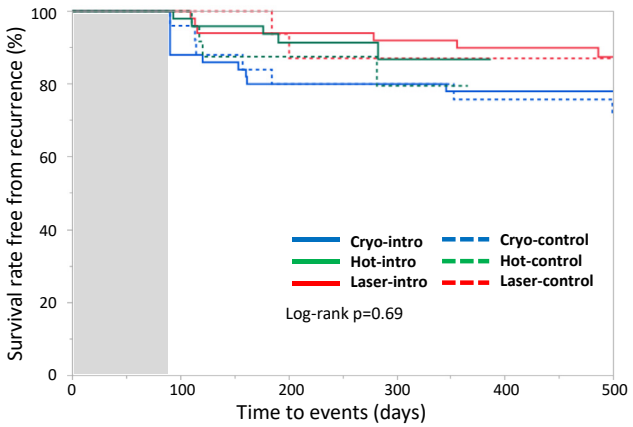

Figure 3 Kaplan-Meier plot of recurrence-free survival rates. The recurrence-free survival rate was similar between the Cryo-intro (blue solid line), Hot-intro (red solid line), and Laser-intro (green solid line) groups. The recurrence-free survival rate was comparable between each introduction group (solid line) and control group (dashed line). Atrial arrhythmia recurrences were measured after the 3-month blanking period (gray field).

is the shortest among the 3 balloon catheters at the initial stage of introduction (Figure 2). However, the PVI completion rates of a single application of the Hotballoon catheter were unsatisfactory, which is consistent with a finding of a previous report.[11] Residual gaps were distributed widely except at the RIPV, and the most frequent site that required RF touch-up was the anterior aspect of the LSPV with a thickened wall (Figure 1). Although a high balloon temperature setting has been reported to improve the Hotballoon catheter's success rate at the LSPV, additional RF touch-up is recommended to avoid severe PV stenosis, especially in the introduction period.[12] Despite the fact that RF touch-up was frequently required, the Hotballoon catheter was very effective in the long term (Figure 3).

Laserballoon

The Laserballoon ablation catheter provides endoscopic visualization of the endocardial surface with a compliant balloon and an adjustable laser energy ablation system.[7] The site that required RF touch-up most frequently was the anterior-inferior aspect of the thick portion of the LSPV, which is the same in the Hotballoon group (Figure 1). The thick wall of the myocardium between the left PV and the LA appendage requires high power and sufficient irradiation.[13] The Laserballoon catheter requires proper catheter placement to obtain good PV occlusion and for the creation of reliable continuous lesions by point-by-point application. However, the learning techniques including slow inflation to maintain a clear endoscopic view of PV with experiences of 10 to 20 cases improved the procedural time, which was consistent with the findings of previous reports (Figure 2).[14,15] The Laserballoon catheter has the lowest fluoroscopy exposure time and eliminates the need for contrast media owing to the use of an endoscopic guide.

Limitations

As this study is a retrospective single-center observational study and the timing of each device group is different and not randomized, the uneven skill level of the operators and the bias of patient selection cannot be denied. This study was conducted at the time of postmarketing surveillance of each balloon catheter, and some regulated procedures were imposed upon the users, including the double-freezing protocol of the Cryoballoon catheter (3 minutes plus an additional 2 minutes). Furthermore, the recurrence of asymptomatic arrhythmia may be underestimated owing to the limited assessment with a regular ECG and Holter ECG. The durability of PVI has not been fully verified owing to a short follow-up period and few patients requiring treatment for recurrence. Therefore, multicenter controlled studies with a larger patient population are required.

Conclusion

Each of the balloon-based catheters allows for a feasible and effective PVI procedure with satisfactory outcome, even during the learning period. To introduce these devices smoothly, patients should be selected based on the findings of preprocedural CT examinations for the Cryoballoon catheter, touching up by RF should be performed without hesitation in Hotballoon catheter procedures, and the thick wall of the PV should be irradiated sufficiently with learning the technique to stabilize the endoscopic view in Laserballoon catheter procedures. An adequate experience of 20 cases would lead to steady state in each balloon-based catheter.

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Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

Informed consent was obtained from all patients.

Ethics Statement

The research reported in this study was conducted according to the principles of the Declaration of Helsinki. The study was approved by the Institutional Review Board of Kobe City Medical Center General Hospital.

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