Pulmonary Vein Re-mapping after Cryoballoon Ablation for Atrial Fibrillation

Short title: Pulmonary Vein Re-mapping after Cryoballoon Ablation

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What's New?

- After cryoballoon PV isolation, PV antral remapping by conventional circular mapping catheter was performed. A residual PV potential was detected in 4.3% of PVs (1.2% of LSPV, 2.5% of LIPV, none of RSPV and 20% of RIPV).
- Almost 60 % of residual PV potential was located around the bottom portion of the RIPV.
- In PVs with residual potential, PV trunk was shorter, minimal balloon temperature was higher, and balloon warming time was shorter than those without.

Abstract

Aims

Establishment of pulmonary vein isolation (PVI) during cryoballoon (CB) ablation is generally confirmed by use of an octapolar inner-lumen mapping catheter (Achieve®). The aim of this study is to evaluate the residual PV potential (PVP) using the conventional circular catheter after CB-PVI.

Methods

A total of 105 consecutive patients (418 PVs) with paroxysmal AF who underwent the initial CB-PVI were prospectively included in this study. Of those, 305 (73%) PVs with real-time

recordings of PVP elimination by Achieve® catheter during successful PVI were included. After isolation of all 4 PVs, PV antral remapping by conventional circular mapping catheter was performed.

Results

After CB-PVI, residual PVP was detected in 4.3% (13/305) of PVs (1.2% of left-superior PV, 2.5% of left-inferior PV, none of right-superior PV and 20% of right-inferior PV). Almost 60 % of residual PV potential was located around the bottom portion of the right-inferior PV. In PVs with residual potential, PV trunk was shorter (12.7±5.7 mm vs. 18.7±7.9, P=0.001), minimal balloon temperature was higher (-46.6±5.9 °C vs. -50.9±8.2, P=0.02), and balloon warming time was shorter (35.6±17.8 sec vs. 50.0±22.8, P=0.006) than those without. All residual potentials were eliminated by additional touch up ablation. After the initial ablation procedure, 1-year AF-free rate was 79.5%.

Conclusions

PV remapping after CB-PVI revealed residual antral PVP in 4.3% of PVs and in 20% of RIPVs in particular. The Achieve® catheter sometimes fails to detect complete PV antral isolation.

Key word

Atrial fibrillation, Cryoballoon, Catheter ablation, Pulmonary Vein Isolation

Introduction

The effectiveness of pulmonary vein isolation (PVI) to treat atrial fibrillation (AF) has been established. [1] In addition to radiofrequency (RF) ablation catheters, cryoballoons (CBs) have proven to be an effective for PVI in patients with AF. Several recent randomized trials have shown the noninferiority of CB ablation to RF ablation, with respect to the treatment efficacy in patients with drug-refractory paroxysmal AF, and there was no significant difference between the two methods with regard to overall safety. [2, 3] An establishment of PVI during CB ablation is generally confirmed by use of an octapolar inner-lumen mapping catheter (Achieve®, Medtronic, Minneapolis, MN, USA). However, Achieve® catheter could not completely describe circumferential antral PV potential (PVP) and real-time PV disconnection during CB-PVI due to its structural constraint. The purpose of this study is to evaluate the presence of residual PVP by PV antrum remapping after CB-PVI.

Methods

Study Subjects

A total of 105 consecutive patients who had undergone an initial catheter ablation using CB for paroxysmal AF were prospectively included in this study. All of the patients underwent a contrast-enhanced CT-scan prior to ablation to establish the anatomy of the left atrium (LA) and

PV. 3-dimensional image of PV and LA was reconstructed from preprocedural contrast-enhanced CT. Size and length of PV trunk (from ostium to the first bifurcation) were measured on 3-dimensional mapping system (Ensite NavX, St. Jude Medical, St. Paul, MN, USA). The definition of antrum was defined as a circumferential area ≥1.5 cm away from the PV ostium as identified by angiography or 3-dimensional electroanatomical reconstruction. [4]

Antiarrhythmic drugs were discontinued for at least 5 half-lives prior to ablation. Transesophageal echocardiography was performed prior to the procedure to rule out LA thrombus. In the present study, “paroxysmal AF” was defined as AF that spontaneously terminated within 7 days. The studies and data collection were performed according to protocols that had been approved by the Human Research Committee of the Jikei University School of Medicine.

Cryoballoon Ablation of Atrial Fibrillation

Each patient gave written informed consent. A heparin (100 IU/kg body weight) was administered immediately after obtaining venous access; heparinized saline was also infused to maintain an activated clotting time of 250–350 seconds. The procedures were performed under mild sedation with flunitrazepam and propofol. An esophageal temperature probe (Esophastar,

Japan Lifeline, Tokyo, Japan) was inserted throughout the ablation procedure to avoid esophageal injury.

A single transseptal puncture was performed using an RF needle (Baylis Medical, Montreal, QC, Canada) and an 8-Fr long sheath (SL0, St. Jude Medical). The transseptal sheath was exchanged over a guide wire for a 15-Fr steerable sheath (Flexcath Advance, Medtronic). Direct visualization of all four PVs was performed using LA angiography and displayed during the procedure to show the venous anatomy and location of the LA-PV junction. (Figure 1A) A 20-30 mm circular catheter (Lasso®, Biosense Webster, Diamond Bar, CA, USA) or a variable-diameter circular mapping catheter (Inquiry Optima®, St. Jude Medical) was used for mapping all of the PVs before and after the CB-PVI to confirm the electrical isolation in all patients. Electrical cardioversion was performed to restore sinus rhythm in all patients with atrial fibrillation. PVI was performed during sinus rhythm in all patients with a single balloon technique using a second-generation CB (Arctic Front Advance, Medtronic). In the present study, a 28-mm CB catheter was used in all cases. A 20-mm Achieve® catheter was used to advance the CB and to map the PVPs. When no PVPs were clearly detected by the Achieve® catheter which was placed distal to the tip of CB, the catheter was advanced and then partially withdrawn repeatedly, alongside with torqueing movements, to displace it backwards and more proximally into the proximity of the balloon. Complete sealing at the antral aspect of the PV was confirmed

by the injection of contrast medium. This was followed by a freeze cycle of 180 seconds. (Figure 1B) In order to avoid phrenic nerve injury [5], the diaphragmatic compound motor action potentials (CMAP) were monitored during phrenic nerve pacing while all of the CB applications were applied. [6] The endpoint of the PVI was the establishment of a bidirectional conduction block between the LA and the PV. The exit block was confirmed by pacing inside the PV with the circular catheter. The presence/absence of residual antral PVP was confirmed in each PV using the conventional circular catheter after the isolation of all 4 PVs. (Figure 1C)

The location of the breakthrough of residual PVP between the PV and the LA was defined as the earliest activation site at the PV ostium under the guidance of the circular catheter, which was confirmed by the elimination of residual PVP by touch-up ablation.

If electrical isolation was not achieved by a total of 3 CB applications (180 seconds for each application) per vein, additional touch-up ablation was performed with a conventional RF or cryothermal (Freezer Max, Medtronic) catheter.

After waiting for at least 30 minutes after the final application of PVI, Adenosine triphosphate (20 mg) was rapidly administered intravenously to induce dormant PV conduction under the continuous infusion of isoproterenol (up to 20 μg/min) in all patients. The reconnection of the PV-LA conduction and presence/absence of dormant PV conduction was evaluated using the conventional circular catheter that was positioned at the PV antrum. If dormant PV

conduction was provoked, additional RF or cryothermal energy (Freezer Max, Medtronic) was applied in order to eliminate the dormant PV conduction. A complete PV disconnection was reconfirmed in all PVs by the repeated injection of ATP under continuous isoproterenol infusion.

Patient follow-up

No antiarrhythmic drugs were prescribed after the procedure. The patients underwent continuous, in-hospital ECG monitoring for two to four days after the procedure. The patients underwent careful observation (two weeks after discharge, then every month thereafter) at the cardiology clinic. The outcome of AF ablation was evaluated based on the patient's symptoms, ECG at periodical follow-ups, and periodic 24 hours or 7 days ambulatory monitoring (at 1, 3, 6, 9, and 12 months after the procedure). A cardiac event recorder or a portable electrocardiogram was used to define the causes of symptoms that were suggestive of tachycardia. The recurrence of AF was defined as AF lasting for more than 60 seconds after a blanking period of 90 days.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation. An unpaired Student's *t*-test or the Mann-Whitney U test was used for continuous variables. Categorical variables, expressed as numbers or percentages, were analyzed using the chi-squared test unless

the expected values in any cells were less than 5, in which case Fisher's exact test was used. P values of <0.05 were considered to indicate statistical significance. In comparison among 4 PVs, a P value of 0.05/6 (equivalent to a Bonferroni-adjusted [6 tests] P value of 0.05) was considered significant. Survival curves were created using the Kaplan-Meier method. All of the statistical analyses were performed using the SPSS software program (version 21.0.0; SPSS, Chicago, IL).

Results

Residual Pulmonary Vein Potential

Overall patient characteristics were shown in Table 1. The mean age of the patients was 57.4 ± 10.9 years and the mean LA diameter was 35.8 ± 4.9 mm. Of 418 PVs (including 2 left common (LC) PVs) in 105 patients, PVP was documented in all PVs by the conventional circular catheter at baseline. Flowchart of patient selection was shown in Figure 2. Five (2 LCPVs, 3 RIPVs) and 23 PVs (8 LSPVs, 4 LIPVs, 2 RSPVs, and 9 RIPVs) were excluded because no CB-PVI was attempted due to anatomical constraint and the PVP was failed to be eliminated by CB-PVI, respectively. Furthermore, 85 (22%) PVs (9 LSPVs, 20 LIPVs, 13 RSPVs, and 43 RIPVs) were excluded because the elimination of PVP could not be recorded in real-time during CB-PVI using an Achieve® catheter. Thus, 305 PVs (86 LSPVs, 79 LIPVs, 90 RSPVs and 50

RIPVs) with real-time recordings of PVP elimination on Achieve® catheter during successful PVI were included in this study.

After CB-PVI, residual PVP was detected by the conventional circular catheter in 4.3% (13/305) of PVs. In each PV, residual PVP remains in 1.2% of LSPV, 2.5% of LIPV, none of RSPV and 20% of RIPV (Overall P< 0.0001, **Figure 3**). In pairwise comparison, the residual PVP was more frequently observed in RIPV than LSPV (P<0.001), LIPV (P=0.003) and RSPV (P<0.001). Almost 60% of residual PV conduction gap was detected around bottom region of RIPV (**Figure 4**). All of a residual PVP was eliminated by touch-up ablation (3.5 ± 1.3 times / PV). After the initial ablation procedure, 1-year AF-free rate was 79.5% (**Figure 5)**.

The Associated Factors of Residual Pulmonary Vein Potential after Cryoballoon Ablation

Anatomical factors and procedural details associated with the presence of residual PVP were investigated (Table 2). In the PV with residual potential, while length of PV trunk was shorter (12.7±5.7 mm vs. 18.7±7.9, P=0.001) than the PV without, circumferential length of the PV was similar between 2 groups (51.7±8.0 mm vs. 50.6±17.7, P=0.79). Minimal balloon temperature was higher (-46.6±5.9 °C vs. -50.9±8.2, P=0.02), and balloon warming time from nadir to +20 °C was shorter (35.6±17.8 sec vs. 50.0±22.8, P=0.006) than those without. Time to

the elimination of PVP was similar between the PV with and without residual potentials (44.6±30.0 sec vs. 50.2±40.7, P=0.58)

Discussion

Study Results

In the present study, residual PVP after CB-PVI was detected by the conventional circular catheter in 4.3% of all PVs, especially 20% in RIPV. Residual PV conduction was mostly common in bottom region of RIPV. Earlier PV branching, higher minimal balloon temperature, and shorter balloon warming time were related to the presence of residual PVPs. To the best of our knowledge, this is the first study to report the results of PV antral re-mapping after CB-PVI for AF.

Real-time Recordings of Pulmonary Vein Potentials

Real-time recordings during CB-PVI offer valuable information regarding time to PVI. These can be visualized by Achieve® catheter that is used in conjunction with the CB. However, due to anatomical variations of the PVs, Achieve® is often positioned more distally to the PV sleeve extension in order to offer stability to the balloon catheter in the PV ostium, and real-time recordings visualization of PVP during CB-PVI is sometimes difficult. In the present study, a

rate of real-time recordings visualization during CB-PVI was 78%. Even this rate is higher than the recent publications using second-generation CB (50–60%) [7, 8] by moving Achieve® catheter to a more proximal position, it is so far impossible to record real-time PVP during CB application in all cases. Furthermore, PVP failed to be eliminated by CB-PVI alone in 5.5% of PVs. In some health systems, reimbursement is permissible for only one technique, and the procedure must be performed using that one tool. Having to touch-up lesions using other catheters or different energy sources may make CB ablation less attractive as an ablation technique.

The length of myocardium extending from the LA onto the PV varied among the PVs. Since the myocardium usually extends more distally in the superior PVs compared to the inferior PVs [9], the real-time PVP was less frequently visualized in the inferior PVs than the superior PVs. The shaft of second-generation CB catheter extends 1 cm beyond the balloon tip creating a distance between Achieve® and the site of ablation. The use of third-generation CB with a 40% shortened tip length compared to second-generation CB may resolve the problem. [10, 11]

Presence of Residual Pulmonary Vein Potential

Residual PVP after CB-PVI was detected by PV remapping using the conventional circular catheter in 4.3% of PVs. Although we excluded the PVs without real-time visualization

of PVP elimination using an Achieve® catheter, residual PVP may have caused a conduction gap after incomplete CB-PVI. A higher minimal balloon temperature during freezing in PVs with residual potential indicated less sealing contact by CB.

An acute reconnection of PV-LA was also explanation of residual PVP. In the present study early branching of the PV, minimal balloon temperature and warming time were associated with the presence of PVP. Higher minimal balloon temperature and shorter warming time usually related to insufficient PV occlusion resulted in acute PV reconnection. Additionally, the presence of short PV trunk and adjacent PV bifurcation may lead blood leakage and interrupt the complete circumferential occlusion of PV.

The other explanation of residual PVP was the remaining antral (proximal) PVP after complete PV ostium (distal) isolation. Since the isolation line of CB-PVI is sometimes located more inner than that of a RF catheter ablation, PVP may remain at the PV antrum after CB isolation. Miyazaki et al. reported that the areas ablated by CB were significantly smaller than the conventional RF circumferential PVI areas after quantitative analysis using high-resolution electroanatomical mapping. [12]

Sites of Residual Pulmonary Vein Potential

In the present study, the residual PVP after CB-PVI most commonly remained around the bottom region of the RIPV. In comparison to the superior PVs, the inferior PVs have a worse alignment for CB. Additionally, the CB tends to be coaxial to the venous course when being positioned in the antrum of both upper veins, while more catheter manipulation is usually needed to occlude the inferior veins. Previous studies have already reported that an increased tendency for PV electrical reconnection in repeat ablation procedures was observed in the inferior quadrants of both the LIPV and RIPV. [13-15]

Clinical implication

One year AF free rate after the initial ablation in this study was better than the previous multicenter trials. [2, 3] Whether this is due to an incremental effect of additional elimination of residual PVP or not is unclear. RF-PVI performed with a wide antral approach is more effective than ostial RF-PVI in achieving freedom from total atrial tachyarrhythmia recurrence at long-term follow-up. [4] Same as RF-PVI, the wider antral approach might be more effective for maintenance of sinus rhythm after CB-PVI. The residual antral PVP remained in 20% of RIPV after CB-PVI in this study. Even RIPV is usually considered as the least arrhythmogenic PV, [1, 16] PV remapping and additional ablation for the residual potential might be considered after CB

ablation. On the other hand, CB ablation has been shown to be sufficiently effective for paroxysmal AF without the need for additional re-mapping and eventual touch up ablation with another catheter. Further studies to confirm the incremental effect of such PV remapping after CB-PVI are recommended

Study limitations

The present study is associated with several limitations. This study was an observational, and single center study; thus, selection biases were undoubtedly present. Since the sample size was small due to the lower incidence of residual PVP after CB-PVI, we could not conduct the multivariate analysis to predict the presence of residual antral PVP. Mapping of antral PVP using an Achieve® catheter was not performed. We also did not compare the PVPs measured by different catheters at the same level.

Conclusions

PV remapping after CB-PVI revealed residual antral PVP in 4.3% of PVs and in 20% of RIPVs in particular. A shorter PV trunk, higher minimal freezing temperature of CB and shorter balloon warming time were associated with the presence of residual PVP.

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Disclosures: None

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Figure Legends

Figure 1.

A. LA angiography was performed to identify the location of the LA-PV junction.

B. Before cryoballoon ablation, the antral PVP was identified using a circular mapping catheter.

C: After verifying the complete occlusion of the LSPV, 180 seconds of cryoballoon application was performed. PV potential (arrow) disappeared during cryoballoon ablation.

D. After cryoballoon ablation of all four PVs, bi-directional block at the PV antrum was confirmed using a circular mapping catheter. Residual potential on Lasso 11-12 was confirmed to be far-field potential from the LA appendage.

LA, left atrium; LSPV, left superior pulmonary vein; CS, coronary sinus; SVC, superior vena cava; d, distal; m, mid; p, proximal.

Figure 2.

The Flow chart of this study

Of 418 PVs, 5 PVs and 23 PVs were excluded from the study because CB ablation was not attempted due to anatomical constraint and PV potential on Achieve® was not eliminated by CB

ablation, respectively. CB, cryoballoon; LCPV, left common PV; RIPV, right inferior PV; PVI pulmonary vein isolation.

The other abbreviations are the same as in the previous figure.

Figure 3.

Presence of residual PV antral potential after CB ablation in each PV was shown.

LI, left inferior; RS, right superior.

The other abbreviations are the same as in the previous figures.

* indicates Bonferroni adjusted P< 0.05/6 which was considered significant in pairwise comparison.

Figure 4. Location of the breakthrough of residual PV-LA conduction was shown.

The other abbreviations are the same as in the previous figures.

Figure 5. The AF-free rate after the initial ablation procedure.

AF indicates atrial fibrillation.

Table 1

The overall patient characteristics

	N=105
Sex (male)	89 (87%)
Age (years)	57.4 ± 10.9
History of AF (years)	6.1 ± 5.3
LA diameter (mm)	35.8 ± 4.9
LV ejection fraction (%)	65.1 ± 4.1
BNP (pg/ml)	48.5±82.6
No. of antiarrhythmic drugs	0.9 ± 0.6
$CHADS_2$ Score	0.6 ± 0.8

The data are presented as the mean ± SD or n (%).

AF, atrial fibrillation; LA, left atrium; LV, left ventricle; BNP, B-type natriuretic peptide.

Table 2

Anatomical factors and Procedural details between PV with and without residual potential

	Residual potential (+) N=13	Residual potential (-) N=292	P-Value
Anatomical factors of PV			
Circumferential length of PV (mm)	51.7±8.0	50.6±17.7	0.79
Length of PV trunk (mm)	12.7±5.7	18.7±7.9	0.001
Procedural details			
Minimal balloon temperature (ºC)	-46.6±5.9	-50.9±8.2	0.02
Balloon warming time (nadir to +20ºC)(sec)	35.6±17.8	50.0±22.8	0.006
Time to PV isolation (sec)	44.6±30.0	50.2±40.7	0.58

The data are presented as the mean ± SD or n (%). The abbreviations are the same as those in the previous table.

Figure 1.

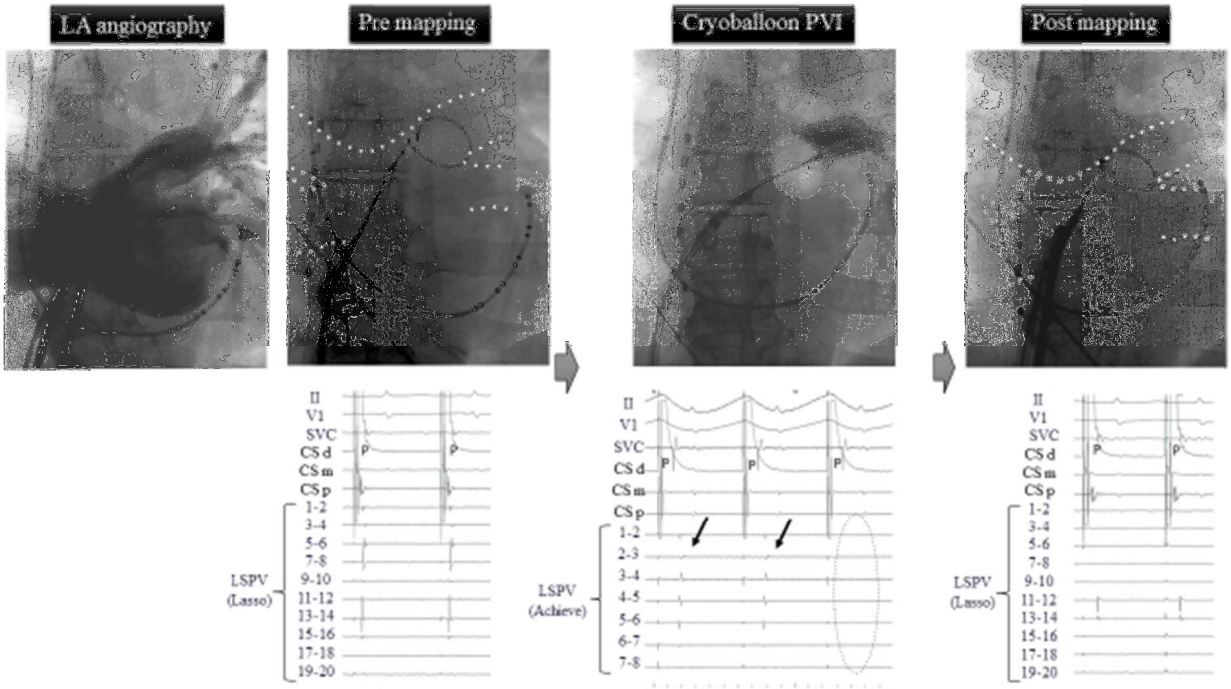
LA angiography
Pre mapping
Cryoballoon PVI
Post mapping
II
V1
SVC
CS d
CS m
CS p
1-2
3-4
5-6
7-8
9-10
11-12
13-14
15-16
17-18
19-20
LSPV
(Lasso)
2-3
4-5
6-7
7-8
LSPV
(Achieve)

Figure 2

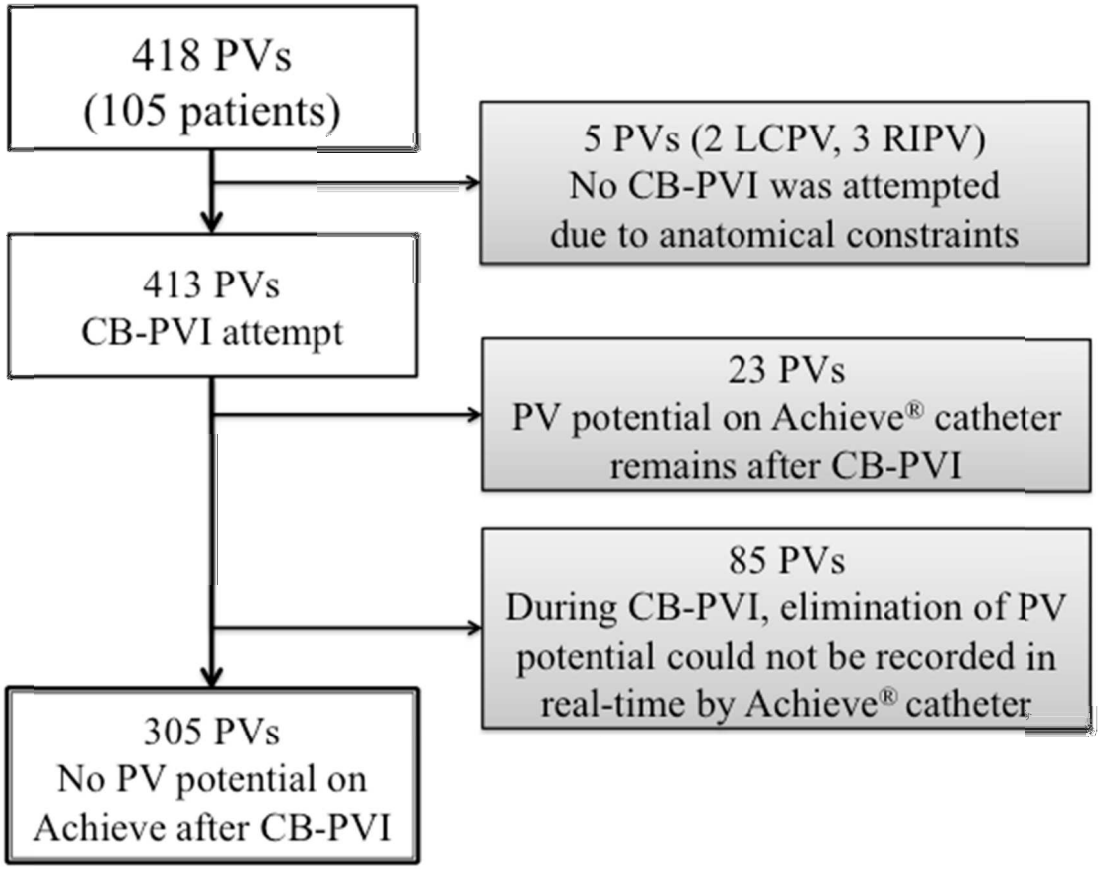
418 PVs
(105 patients)
5 PVs (2 LCPV, 3 RIPV)
No CB-PVI was attempted
due to anatomical constraints
413 PVs
CB-PVI attempt
23 PVs
PV potential on Achieve® catheter
remains after CB-PVI
85 PVs
During CB-PVI, elimination of PV
potential could not be recorded in
real-time by Achieve® catheter
305 PVs
No PV potential on
Achieve after CB-PVI

Figure 3.

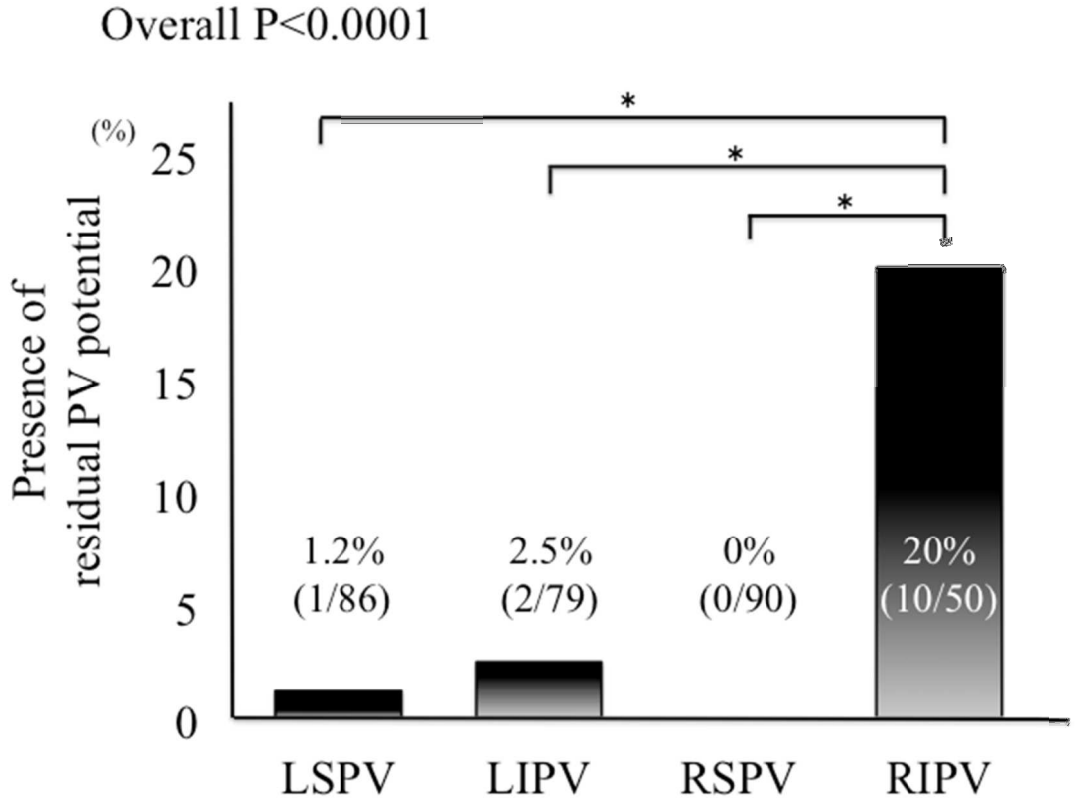
Overall P<0.0001
Presence of residual PV potential
(%)
25
20
15
10
5
0
*
*
*
1.2% (1/86)
2.5% (2/79)
0% (0/90)
20% (10/50)
LSPV
LIPV
RSPV
RIPV

Figure 4.

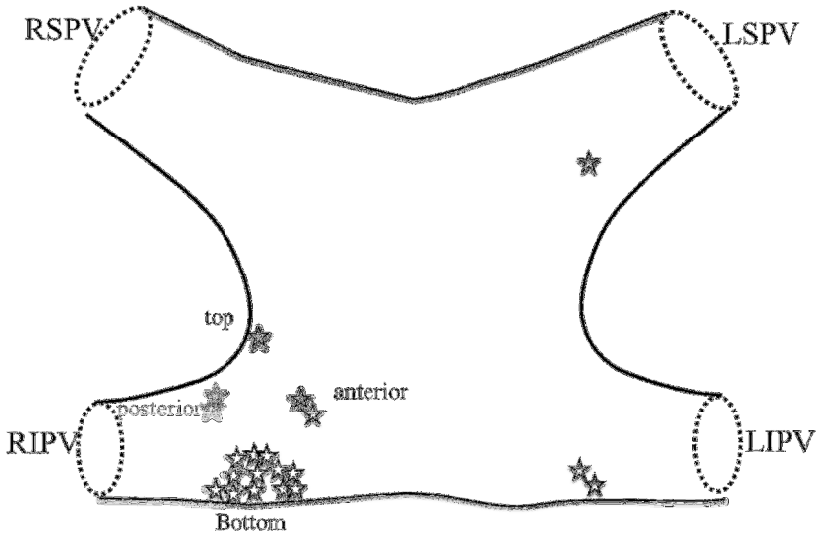

Figure 5.