Single-Sweep Pulmonary Vein Isolation using the new third-generation laser balloon – Evolution in ablation style using endoscopic ablation system

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Running title: Laser Balloon Single Shot Pulmonary vein isolation

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Word count: 3422

Disclosure: BS, SB and JC received speaking honoraria from Cardiofocus Inc**.**

Structured abstract

Background: The endoscopic ablation system (EAS) is an established ablation device for pulmonary vein isolation (PVI) in patients with atrial fibrillation (AF). The novel X3 EAS is now equipped with a contiguous circumferential ablation mode (RAPID mode).

Aim: To determine the feasibility of single-sweep ablation using X3.

Methods: Consecutive patients who underwent AF ablation using X3 were enrolled.

We assessed the acute procedural data focusing on "Single-sweep PVI" defined as PVI with a single energy application using RAPID mode to complete the circular lesion set, and on "first-pass isolation" defined as successful visually guided PVI after initial circular lesion set.

Results: One-hundred AF patients (56% male, age 68±10 years, 66% paroxysmal AF) were analyzed. A total of 379 of 383 PVs (99%) were isolated with X3. Single-sweep isolation and first-pass-isolation were achieved in 214 PVs (56%) and in 362 PVs (95%), respectively. Single-sweep isolation rates varied across PVs with higher rates at the superior PVs (61.2% vs. inferior PVs:49.5%, P=0.0239) and at PVs with maximal ostial diameter <24mm (57.6% vs. >24mm: 36.8%, P=0.0151). The mean total procedure and fluoroscopy times were 43.0±10 and 4.0±2 mins, respectively. In none of the patients an acute thromboembolic event (stroke or transient ischemic attack) or a pericardial effusion/tamponade occurred. A single transient phrenic nerve palsy was observed.

Conclusion: The new X3 EAS allows for single-sweep PVI in 56% of PVs. The new RAPID ablation mode leads to an improved rate of first-pass isolation associated with very short procedure times without compromising safety.

Key words: endoscopic ablation system, atrial fibrillation, pulmonary vein isolation, balloon ablation, laser balloon

Introduction

Pulmonary Vein Isolation (PVI) remains the key procedural endpoint for any ablation procedure in patients with symptomatic atrial fibrillation (AF)[1]. In an attempt to standardize procedural work-flow and to reduce procedure times various technical innovations have been proposed. In this context single shot balloon devices play a major role with proven efficacy for patients with paroxysmal and persistent AF[2].

The endoscopic ablation system (EAS) represents a hybrid device being a balloon catheter on the one side and offering a point-by-point ablation mode on the other side[3]. Although it has proven similar clinical efficacy compared to other ablation modalities including single shot devices procedure times were longer due to numerous overlapping ablation spots to create contiguous circular lesion sets[4,5]. The latest generation EAS (HeartLight X3, CardioFocus, Marlborough, MA, USA) offers a new rapid ablation mode (RAPID™) during which the laser beam is continuously swept around the PV ostium at a pre-defined speed[6,7]. This allows for PVI by a single laser energy application.

In a prospective all-comer study, we aimed to assess the feasibility and safety of single-sweep-PVI using the novel motor driven EAS.

Methods

The study was approved by the local ethic committee. The study complies with the declaration of Helsinki. Patients had to sign the patient informed consent form prior to enrollment.

Patient population

Patients with symptomatic AF refractory to the treatment of at least one antiarrhythmic drug including beta blockers (class I-III) with an episode duration of >7days and <1 year were eligible to enter the study. Patients had to be 18-85 years old. Mild to moderate left atrial

enlargement up to 50mm was allowed as well as a mildly reduced left ventricular ejection fraction (>45%).

Patients were excluded if they had had previous PVI attempts or were ineligible for treatment with oral anticoagulation. Moreover, presence of an intracardiac thrombus, moderate or severe mitral valve disease led to exclusion from the study. Pre-procedural imaging to assess PV anatomy was not required.

Pre-ablation protocol

In order to exclude intracardiac thrombi and to assess potential mitral valve disease pre-procedural transesophageal echocardiography was performed in patients with a CHA2DS2-VaSc score >/=2. Baseline ECG was acquired and blood testing was performed to exclude secondary causes for AF. Anticoagulation was continued until the morning of the procedure and resumed on the evening after the intervention.

Investigational device

The X3 catheter represents an update of the existing Excalibur™ system. A motor was integrated into the catheter handle to enable controlled, continuous energy delivery in addition to the conventional point by point ablation mode. The compliant balloon is delivered to the left atrium through a 12-French deflectable sheath. Real-time visualization of the target tissue is realized through a 2-French endoscope embedded in the central shaft of the balloon catheter. Due to the eccentric position of the endoscope riding on the central catheter shaft, the endoscopic view to the PV ostium is limited to approximately 300°.

The central shaft also contains lumens for circulating the balloon-filling media (D2O) which cools the balloon, and a maneuverable optical fiber that generates a ~30° arc/spot of both non-ablative visible light and near-infrared ablative light energy. This arc of light can be advanced, retracted, and rotated to any location along the surface of the balloon to allow aiming and then

ablation using diode laser energy (980 nm). The catheter tip is equipped with a flexible tip segment to minimize the risk of catheter-induced trauma. The shaft of the catheter contains a radiopaque marker that can be visualized on fluoroscopy to align the endoscopic image with the fluoroscopic position of the balloon.

In addition to the conventional, manually controlled point-by point ablation mode with preset power (5.5-12W) and lesion duration (20-30 seconds), the X3 offers a novel "RAPID mode". During "RAPID mode" the lesion generator is continuously swept around the PV ostium (either clockwise or counterclockwise) at a preset speed (2.25° per second) by an integrated motor. In this study, ablation power could be titrated between 13 or 15W.

Ablation procedure

Our ablation protocol was based on the previously described streamlined strategy for anatomical PVI[10]. All ablations were carried out under intravenous sedation using propofol, midazolam and sufentanil. After femoral venous access, transseptal puncture was performed using a 8-Fr sheath and a Brockenbrough needle with fluoroscopy guidance. Intravenous heparin was administered as boluses and as a continuous infusion to maintain an activated clotting time ≥300 seconds. The transseptal sheath was then exchanged for the 12-Fr deflectable sheath. Esophageal temperature monitoring was mandatory using a commercial temperature probe (Circa S-Cath™, Circa Scientific, USA or SensiTherm™, Abbott, USA). Ablation was stopped if the esophageal temperature exceeded 39°C.

Using the deflectable sheath, the X3 catheter was positioned at the ostium of the target PV and the balloon was inflated to achieve optimal balloon to tissue contact. As described previously, PV occlusion was graded according to the degree of tissue exposure[8].

Ablation was performed under visual guidance. Ablation consisted of ablative energy delivery segments of either RAPID mode and/or manual mode energy delivery.

Balloon positioning

In an attempt to exclusively use RAPID mode, the operator strived for optimal tissues exposure. The following criteria were assessed before energy deployment (Figure 1): (1) After balloon positioning at the PV ostium, the laser generator was pulled back to obtain a circumferential view to the PV ostium. In case of 360° tissue exposure (2) the catheter shaft was positioned in the region with the broadest tissue corridor (usually posterior LA wall) to visualize the ablation path and subsequently allow for "blind spot" ablation behind the catheter shaft. (3) Then, the ablation path was simulated by manually sweeping the aiming beam behind the shaft from one edge of the shaft to the other. If no or only minimal correction of the laser generator along the z-axis of the shaft was required to keep the beam on exposed tissue on both sides of the shaft, the individual PV qualified for a RAPID ablation attempt.

Energy setting

In pre-clinical studies, it was ascertained that continuous ablation resulted in comparable lesion depth and tissue temperatures as manual spot ablation. Multi physics modelling predicted that 13W and 15W continuous ablation was comparable to 8.5W and 12W manual spot ablation in this regard, respectively[7]. In a turkey thigh model as well as in an *in-vivo* pig model lesion contiguity and transmurality were confirmed by manufacturer. According to suggestion by the manufacturer, the energy setting was basically started with the RAPID mode at 13W. A 15W ablation was used only in case of failed first pass PVI. In cases of suboptimal tissue exposure, e.g., interjacent blood or too close vicinity of blood RAPID mode ablation was interrupted and manual applications with low ablation power (5.5-7 W) were used to complete the circular lesion set.

After placement of the initial anatomically-guided encircling lesion set to all PVs, the navigated circular mapping catheter was used to assess for electrical isolation of the PV in conjunction with an electroanatomical mapping system (CARTO, Biosense Webster, CA, USA, Figure 2).

If the PV was not isolated, RAPID mode was again used to deliver energy on the targeted and surrounding area of electrical breakthrough based on assumed conduction gap.

During ablation of the right-sided PVs, phrenic nerve pacing was always performed from the superior vena cava to monitor diaphragmatic movement. At the right-sided PV, the cauterization was started clockwise from the upper part of the posterior wall so that the anterior upper part, anatomically close to the diaphragmatic nerve, would be the final ablated area to minimize the risk of phrenic nerve injury before complete encircling PV ostium.

Post procedural care

All patients underwent post-interventional transthoracic echocardiography to exclude pericardial effusion. Therapeutic anticoagulation was continued or resumed the day after the procedure. Before discharge an ECG was obtained to exclude arrhythmia recurrence.

It was encouraged to stop all previously ineffective antiarrhythmic drugs (AAD) immediately after the procedure. At day 90 following ablation (blanking period) all AAD had to be stopped.

Follow-up

A blanking period of 90 days was applied. All patients attended outpatient clinic visits including 72h-Holter-ECG at 3 and 6 months. In case of symptoms suggestive of an arrhythmia recurrence 24 h Holter-ECGs were performed or patients received an external event monitor. A recurrence was defined as any documented atrial tachyarrhythmia episode lasting more than 30 seconds.

Study endpoints

Acute procedural endpoints consisted of the rate of PVI achieved by the X3, the rate of PVI exclusively using RAPID mode (*RAPID only*) without manual spot applications and the rate of *single-sweep* PVI, e.g., electrical isolation with a single RAPID mode energy application. In

addition, *first-pass isolation* was assessed, which was defined as documented PVI after the first circular lesion set irrespective of the mode of energy delivery.

Procedure time was defined as "skin-to-skin" starting with venous access and ending with removal of all sheathes.

The safety endpoint was defined as the incidence of peri-procedural complications such as major bleeding requiring intervention, phrenic nerve palsy, pericardial tamponade, thromboembolic events, atrio-to-esophageal fistula or death.

The chronic efficacy endpoint was defined as freedom from of AF or any atrial tachyarrhythmia lasting >30 seconds between day 90 and 180 days after the index procedure.

Statistical analysis

Mean ± standard deviation was used to describe continuous variables with normal distribution. Median and inter-quartile range were used when appropriate. The Student t-test was performed to calculate differences of variable between groups with normal distribution. The Chi squared test or the Fisher exact test were used to perform between group comparisons. The confidence interval and test statistic were constructed for this study according to the adjusted Wald method. For time to event data Kaplan Meier curves and log rank test were computed using custom software.

Results

In this study, one hundred consecutive patients were prospectively enrolled. The mean age was 68 $\pm$10 years and 44% were female. Symptomatic paroxysmal and persistent AF was present in 66% and 34% of patients, respectively. In Table 1, demographic data are depicted. Remarkably, 73% of patients had not received membrane active antiarrhythmic drug therapy before the ablation.

Procedural Data

During ablation 379/383 PVs (99%) were electrically isolated using the X3 EAS (Table 2). In 4 patients touch-up ablation was required due to failure to achieve isolation with X3 (n=1, LSPV) or a balloon pinhole (RIPV; n=3).

The median number of energy applications per patient was 6 (range 3-50; Table 3). On a per PV basis the median number of applications was 1, 2, 2, 1, 2 for the LSPV, LIPV, LCPV, RSPV and RIPV, respectively. This resulted in a mean total ablation time of 706±173 secs per patient. The rates of first-pass isolation, RAPID mode only ablation and single-sweep isolation were summarized in Figure 3. The first-pass isolation rate was 95% (362/383 PVs). In 84 patients all PVs were isolated first-pass, e.g., after the first circular lesion set.

In 357 PVs (93%) RAPID only PVI was accomplished without the need for manual spot lesions. Numerically, the LCPV showed the lowest rate of RAPID only PVI. RAPID only PVI with a single energy application (e.g. single-sweep PVI) was achieved in 214 PVs (56%).

Selective angiography was not performed in 11 patients because of history of contrast allergy or hypothyroidism. On per PV based analysis (Table 4), single-sweep PVI was achieved more readily in superior PVs (63.2% vs. inferior PVs; 36.8%, P=0.0095) excluding common PVs. PV ostium maximal diameter was shorter in successful single-sweep PVI (19.3±3,2mm vs. non-single-sweep PVI, 19.3±3,2mm, P=0.0064). In extra-large PV, such as PV with maximal ostium diameter > 24mm (38 PVs), the rate of achieving successful single-sweep PVI was lower (39.5 % vs other PVs; 58.5%, P=0.0365).

The reason for interrupting the RAPID mode energy application in 214/357 PVs were as follows: 1) suboptimal balloon position with the inability to securely place lesions behind the catheter shaft without visual control (n=132; 62%), 2) suboptimal PV occlusion with interjacent blood between the balloon and the myocardium (n=60; 28%), and 3) esophageal temperature rise >39° (n=22; 10%). Manuel ablation mode with reduced energy (5.5 - 7 W) was applicated in 23 PVs (6.0%) to complete lesion sets.

The total procedure time was 43±10 mins including a fluoroscopy time of 4±2 mins. In 6 patients one (n=5) or two (n=1) additional balloons had to be used due to balloon pinholes.

Procedural Complications

In one patient a femoral pseudoaneurysm was treated by thrombin injection. In another patient phrenic nerve palsy occurred during ablation at the RSPV. Diaphragmatic function had already recovered at the 3 months follow-up visit. In none of the patients an acute thromboembolic event (stroke or transient ischemic attack) or a pericardial effusion/tamponade occurred.

One patient died due to uro-septic shock leading to multi-organ failure 8 days after the uneventful ablation procedure. No evidence of atrio-esophageal fistula or stroke were found.

Clinical follow-up

At 6 months 15 patients had had a documented or symptomatic recurrence of an atrial tachyarrhythmia after the 90 days blanking period. Of these, 7 patients underwent a repeat ablation procedure 179±61 days after the index ablation. It was documented, that 19/28 PVs (68%) were still electrically isolated. On a per patient basis 1, 2, 3 and 4 PVs were durably isolated in 1, 2, 2 and 2 patients, respectively. On a per PV basis re-conduction was documented at the RSPV, RIPV, LSPV and LIPV in 2, 3, 1 and 2 cases, respectively.

Discussion

The EAS was originally designed as a hybrid technology combining the advantages of a balloon technology with the ability to flexibly titrate and place spot lesions[3]. While this led to convincing clinical results, procedure times were rather long, thus kindling the desire for continuous laser energy applications[4,5]. In the present study, it was demonstrated, that the new RAPID ablation mode can be applied to all PVs and manual spot applications were required in only 6% of PVs.

In comparison to the predecessor balloon, first-pass isolation rates further improved with the new ablation mode (89% versus 95%)[9,10]. Since the mechanical balloon characteristics have not been changed this is interpreted as a merit of continuous rather than point-by-point ablation leading to fewer acute conduction gaps in the lesion set.

Moreover, this technological innovation enabled the operator to accomplish single-sweep PVI with a single laser energy application in 56% of PVs. In case of a co-axial balloon positioning indicated by the equatorial balloon marker on the target tissue, RAPID mode may be used even behind the catheter shaft without manual adjustment of the laser generator along the z-axis position (Figure 4 A and B) because energy delivery moves on along the equatorial balloon marker. On the contrary, in case of an eccentric position (Figure 4 C and D), blind spot ablation with RAPID mode requires continuous manual adjustment of laser generator along the z-axis to keep the beam on the equatorial line.

The X3 EAS device was not intended to become a single shot device but it offers the option to titrate energy depending on ablation location. In this study the operator chose to deliver a single-sweep at a constant dose, but a momentary discontinuation of energy delivery, dose change and continuation is an alternative approach.

In comparison to competitive single shot devices, 56% single-sweep PVI is still rather low. Using the cryoballoon, experienced operators may be able to achieve single shot isolation rates in up to 86% of PVs[11]. Nonetheless, with a median number of 6 energy applications per patient and a total mean ablation time of 706 secs, procedural data were well comparable.

The most common reason for stopping the first RAPID application was the inability to visually control the ablation behind the catheter shaft. Future innovations enhancing the field of view may overcome this limitation. As a consequence, single shot isolation rates >90% seem realistic given the 94% RAPID mode only isolation rate documented in this study.

In a recent randomized study comparing the second generation cryoballoon and the second generation EAS (Excalibur) offering spot ablation cryoballoon single shot PVI and EAS first-pass isolation were achieved in 82% and 96% of PVs, respectively[12]. Nonetheless, the total procedure time remained significantly shorter using the single shot device with 50.9±21.0min versus 96.0±20.4min, P<0.0001. By introduction of the RAPID mode, the present study provides encouraging data to assume that similar procedure times may be achieved with X3.

In this clinical study, the novel ablation mode does not seem to have compromised efficacy acutely given the high first-pass isolation rates with RAPID. Medium term outcomes were acceptable but long-term outcomes assessing both durable PVI as well as arrhythmia free survival remain to be determined in this study. In a pivotal study comparing X3 to the historical HeartLight EAS, however, the 12 months arrhythmia free survival was favorable at 71.9% versus 61.1%, respectively[7].

Similarly, no excess adverse event rates were observed. In larger cohorts, the phrenic nerve injury rate using EAS was reported to be in the range of 1.4-2%[12,13]. In systematic analyses, thermal esophageal injury occurred in up to 18% but may be mitigated by reduced dose ablation at the posterior LA wall[14,15]. In this study, patients were not systematically referred to undergo endoscopic evaluation. During follow-up, however, no adverse events associated with potential esophageal injury were detected. Close esophageal temperature monitoring, thus appears to be a viable strategy to avoid this complication in the clinical setting.

RAPID mode ablation, in particular if applied behind the catheter shaft, bears the risk of deploying laser energy into blood. This may lead to thrombus formation and/or balloon pinholes. The suggested stepwise approach to qualify for RAPID ablation led to a low rate of balloon pinholes (6/100 patients) and no strokes were observed. This is numerically less in comparison to previous studies using the first generation EAS (HeartLight, CardioFocus) with manual spot

ablation (8%) or the X3 pivotal study (13.3%)[7]. It may be speculated, however, that elimination of the "blind spot" by improving the field of view could further decrease the rate of pinhole.

Limitation

This study has several limitations. First, this is a single-center study with large experience in EAS procedures. In addition to shortening the application time using RAPID mode, the learning curve using X3 for operators and assisting stuff should be taken into account. Further studies are required to assess the X3 learning curve characteristics as well as generalizability. It has to be also acknowledged no waiting period to assess recurrence of PV conduction and no provocative maneuvers were completed. However, our ablation strategy was based on the lower incidence of acute PV reconnection using adenosine provocation[18] and the numerically equivalent index lesion durability compared to other modalities[6,19]. Further studies should be conducted about need for additional maneuver. Second, this study was not designed to assess chronic efficacy. Remapping data showed durable electrical PVI in 68% of PVs and complete durable PVI in 2/15 (33%) patients. In comparison, remapping data after PVI with the ICE-T cryoballoon dosing strategy or after high-power short duration ablation with irrigated radiofrequency current showed 61% and 78% complete durable PVI, respectively[16,17]. Thus, future studies will need to investigate if RAPID mode ablation using 15W will be associated with an improved PVI durability without compromising safety. On the other hand, the 12 months arrhythmia free survival in the X3 pivotal study were favorable.

Conclusion

The new X3 EAS allows for single-sweep PVI in 56% of PVs. The new RAPID ablation mode leads to an improved rate of first-pass isolation associated with very short procedure times without compromising safety.

Acknowledgement:

none

Conflicts of interest:

BS, SB and JC received speaking honoraria from Cardiofocus Inc.

Funding:

none

Data availability:

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Tables

Table 1. Demographic data.

Table 2. Procedural data. * RFC Touch up required for failed ablation success or balloon pinhole. [1] PVI after the first circular lesion set; [2] PVI without spot lesion applications; [3] PVI with a single RAPID application

Table 3. Ablation data per Pulmonary Vein. PV: Pulmonary Vein. LS: Left superior; LI: Left inferior; LC: Left common; RS: Right superior; RI; Right inferior; RC: Right common.

Table 4. Analysis for the success rate of single-sweep PVI at individual parameter.

Figure legends

Figure 1: Stepwise approach to achieve single-sweep RAPID PVI. (A) Upper panel: Endoscopic view to the ostium of the right superior pulmonary vein (RSPV). After balloon positioning at the PV ostium, the laser generator was pulled back to obtain a circumferential view to the PV ostium. Lower panel: Schematic drawing. The circular white line indicates the equatorial line on the EAS balloon and will be used for orientation for the ablation lesion set. (B) In case of 360° tissue exposure the catheter shaft was positioned in the region with the broadest tissue corridor (usually posterior LA wall). Then, the ablation path was simulated by manually sweeping the aiming beam behind the shaft from one edge of the shaft to the other. If no or only minimal correction of the laser generator along the z-axis of the shaft was required to keep the beam on exposed tissue on both sides of the shaft, the individual PV qualified for a RAPID ablation attempt. (C) RAPID mode ablation starting at one side of the catheter shaft.

Figure 2: A left atrial voltage map in posterior-anterior oblique after PVI using X3 with RAPID mode.

Figure 3: Procedural results. The bar graphs indicate the (A) percentage of first-pass isolation, (B) RAPID mode only isolation and (C) single-sweep isolation per each PV and in total (dark blue bar).

Figure 4: Tipps for blind spot ablation. Example of different balloon positions at the right inferior pulmonary vein (RIPV). A) Endoscopic view during a co-axial balloon positioning with the shaft at the inferior section of the RIPV. The white equatorial balloon marker is surrounded by myocardial tissue. Thus, RAPID mode may be used behind the catheter shaft without manual adjustment of the laser generator along the z-axis position. B) Schematic drawing illustrating the ablation path.

C) Endoscopic view during an eccentric balloon positioning with the shaft at the superior section of the RIPV. The white equatorial balloon marker is ***not*** surrounded by myocardial tissue behind the catheter shaft. Thus, "blind spot" ablation is strongly discouraged. D) Schematic drawing illustrating the ablation path.

Table 1: Patient characteristics

Patient characteristics, n = 100	
Age, years	68 ± 10
Gender	
Male, %	56 %
Female, %	44 %
BMI, n	29 ± 7
Type of AF	
Paroxysmal, %	66 %
Persistent, %	34 %
Hypertension, %	69 %
Coronary artery disease, %	14 %
Heart failure, %	3 %
Diabetes mellitus, %	11 %
History of stroke, %	7 %
Left atrial diameter, mm	41 ± 6
Ejection fraction, %	60 ± 10
Failed anti-arrhythmic drugs	
Class I, %	14 %
Class II, %	69 %
Class III, %	13 %

Table 2: Procedural characteristics

Procedural characteristics, n	X3, n =100
Duration of overall procedure, mins	
Mean ± SD, n	43 ± 10
Median (min, max)	40 (28, 80)
Overall fluoroscopy time (mins)	
Mean ± SD (n)	4 ± 2
Median (min, max)	3.8 (2, 9.4)
Undergoing selective pulmonary vein angiography	89 (89%)
Number of catheters used	
1, n, %	90 (90%)
2, n, %	5 (5%)
3, n, %	1 (1%)
Number of u RF-touch-up catheter, n, %	4 (4%)
Number of veins attempted, n	383
Number of PVs isolated with X3, n, %	378 (99 %) *
First-pass isolation[1], n, %	362 (95 %)
PVI with RAPID only[2], n,%	357 (94 %)
Single-sweep PVI[3], n, %	214 (56 %)
Patients with all PVs first-pass isolation, n, %	84 (84 %)
Number of PVs, in which reduced energy were applicated, n, %	23 (6%)
Esophageal temperature rise > 39℃, n , %	23 (23 %)
Additional ablation	
Cavotricuspid isthmus ablation, n, %	4 (4.0%)

* RF-touch-up catheter was required for failed ablation success or balloon pinhole

[1] PVI after the first circular lesion set;

[2] PVI without spot lesion applications;

[3] PVI with a single RAPID application

Table 3:

PV	Ablation Time (secs)	Applications Median (range)	PVI without balloon repositioning	Blind ablation
LS (n=84)	180 ± 49	2 (1-5)	62 (74 %)	73 (87 %)
LI (n=84)	178 ± 41	2 (1-5)	48 (57 %)	55 (65 %)
LC (n=16)	211 ± 49	1 (1-6)	7 (44 %)	10 (63 %)
RS (n=99)	197 ± 82	1 (1-25)	71 (72 %)	82 (83%)
RI (n=99)	191 ± 60	2 (1-19)	71 (72 %)	77 (78 %)
RC (n=1)	222	NA	1 (100 %)	1 (100 %)
Total (per patient)	706±173	6 (3-50)		

Table 4:

	Achieving single-sweep PVI (n = 214)	Other non-single-sweep PVI (n = 169)	P Value
PV location			
- Septal PVs, %	58.9 %	41.1%	0.245
- Lateral PVs, %	53.0 %	47.0%	
- Superior PVs, %	63.2 %	36.8%	0.0095
- Inferior PVs, %	49.7 %	50.3%	
Without pulmonary angiography, % 33 PVs	51.5 %	48.5%	0.585
PV ostium maximal diameter, mm, 349PVs	19.3 ± 3.2 mm	20.3 ± 4.1 mm	0.0064
Small (<18mm) size PV, 112 PVs, (%)	62.7 %	37.3 %	0.174
Midium (18-21mm) size PV, 139 PVs, (%)	56.2 %	56.2 %	
Large (>21mm) size PV, 104 PVs, (%)	50.0 %	50.0 %	
Extra-large PV diameter > 24 mm, 38 PVs, %	39.5 %	58.5 %	0.0365
PV diameter < 24 mm, 311PVs, %	58.5 %	41.5%	

Figure 1: Step wise approach for single-sweep isolation

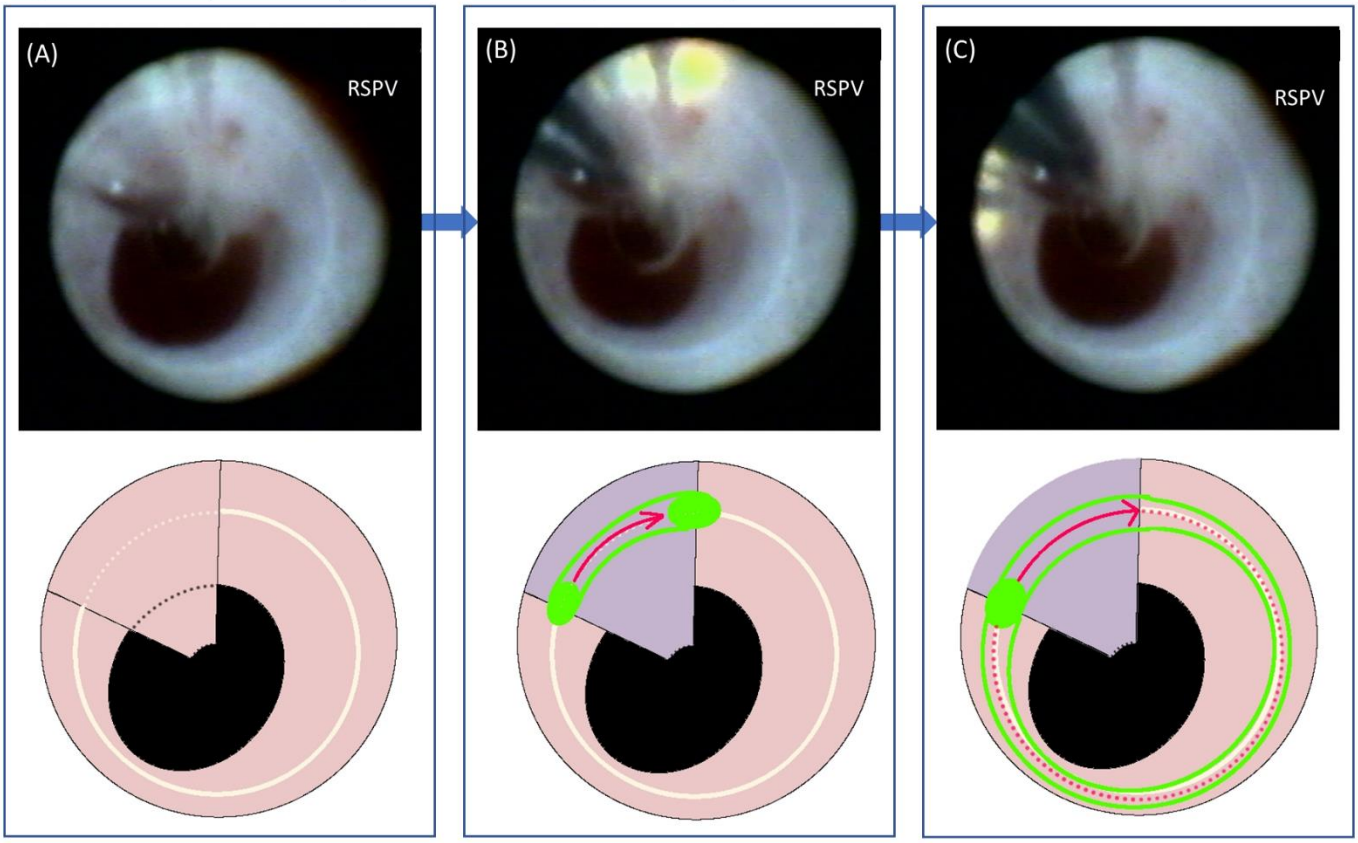

Figure 2: A left atrial voltage map in posterior-anterior oblique after PVI using X3 with RAPID mode.

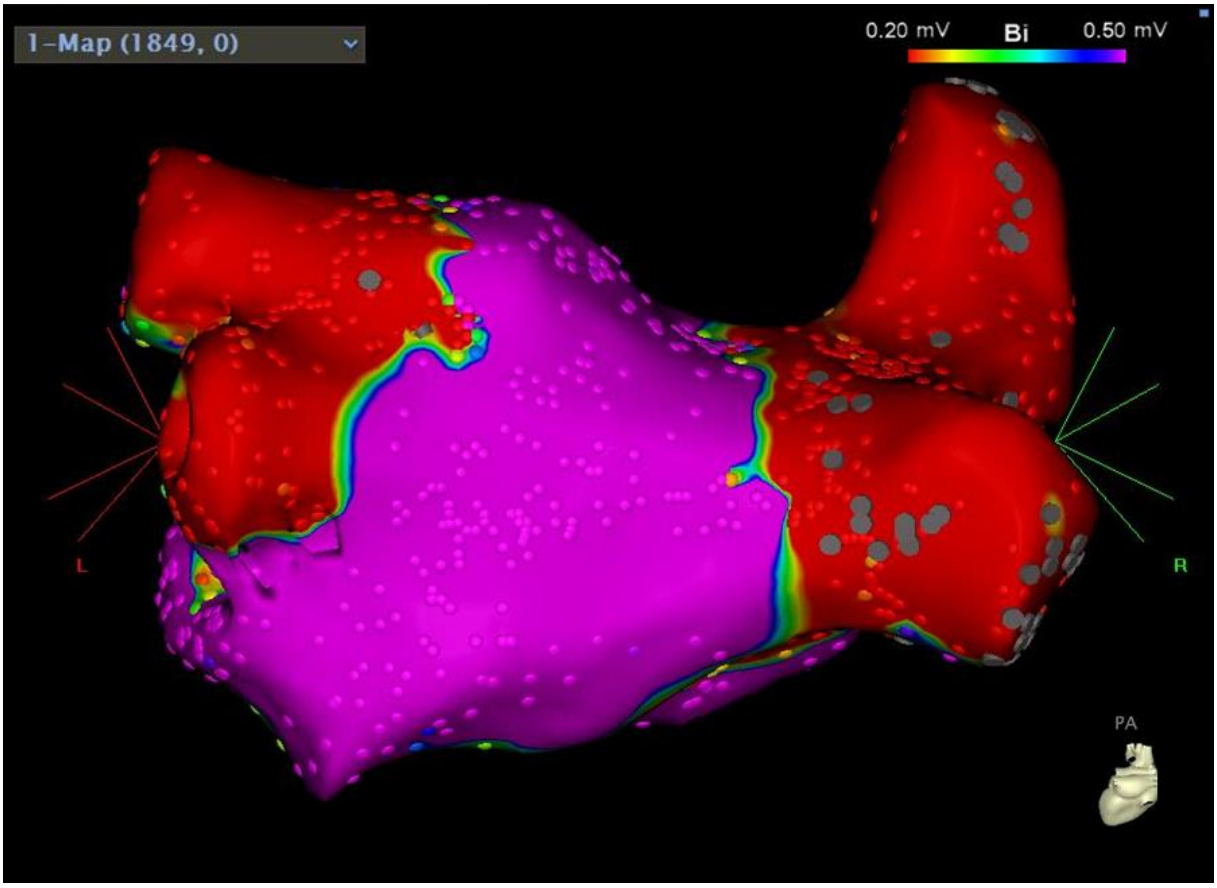

Figure 3: Procedural results

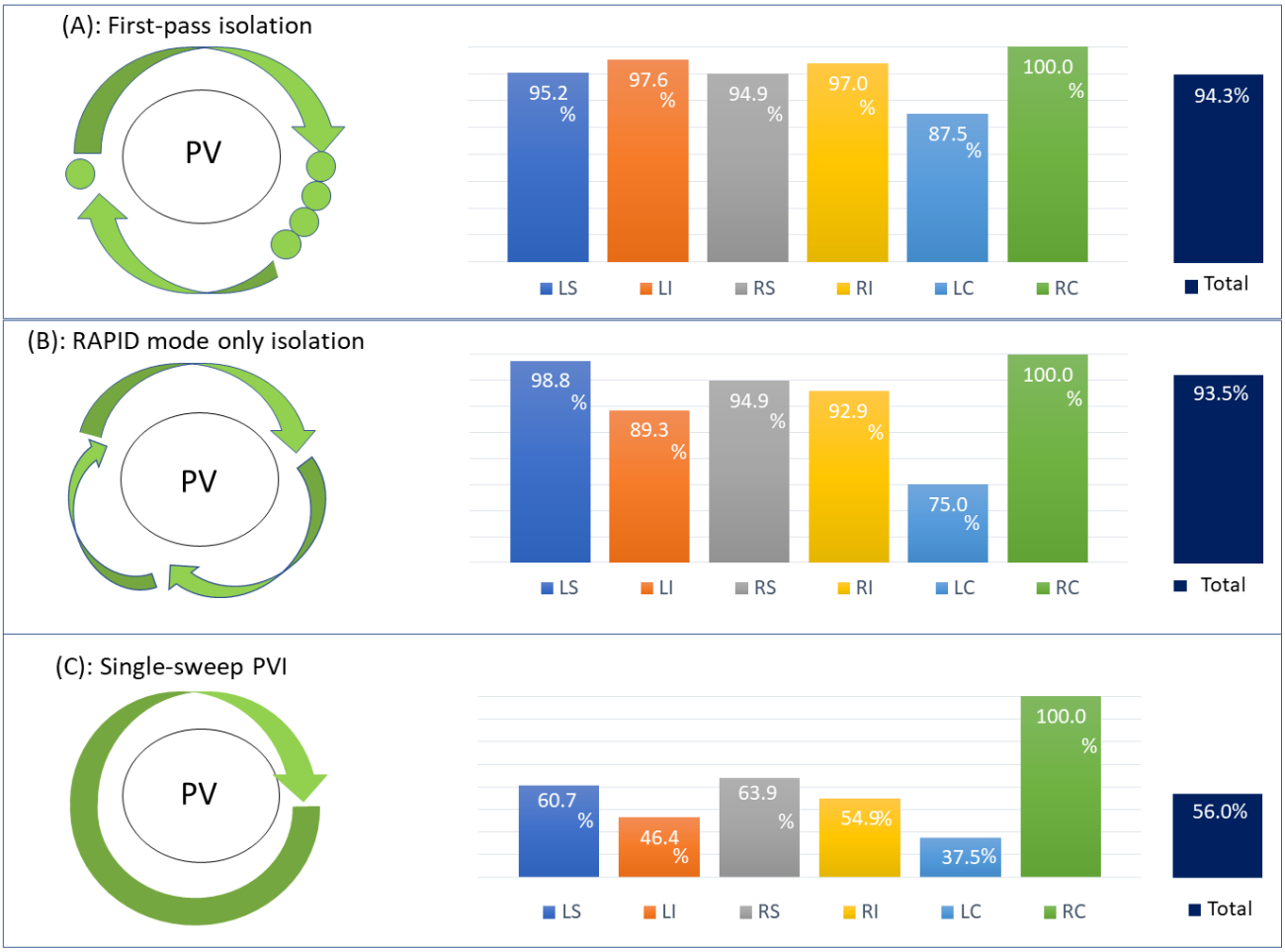

Figure 4: Tipps for blind spot ablation