

Cryoballoon Ablation and Bipolar Voltage Mapping in Patients With Left Atrial Appendage Occlusion Devices



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Left atrial appendage occlusion is utilized as a second line therapy to long-term oral anti-coagulation in appropriately selected patients with atrial fibrillation (AF). We examined the feasibility of cryoballoon (CB) pulmonary vein isolation (PVI) subsequent to Watchman device implantation. The study prospectively identified patients with Watchman devices (>90 days old) who underwent CB-PVI ablation between 2018 and 2019. Twelve consecutive patients (male 50%; mean age 71 ± 9 years; CHA₂DS₂-VASc score 3.4 ± 1.1) underwent CB-PVI procedures after Watchman device implantation (mean 182 ± 82 days). Acute PVI was achieved in 100% of patients. All patients had evidence of complete (n = 9) or partial (n = 3) endothelialization of the surface of the Watchman device with conductive tissue properties demonstrated during electrophysiologic testing. There were no major procedure-related complications including death, stroke, pericardial effusion, device dislodgment, device thrombus, or new or increasing peri-device leak. Mean peri-device leak size (45-day postimplant: 0.06 ± 0.09 mm vs Post-PVI: 0.04 ± 0.06 mm; $p = 0.61$) remained unchanged. Two patients had recurrence of AF after the 90-day blanking period (13.2 ± 6.6 months). One patient underwent a redo ablation procedure for recurrent AF. This pilot study suggests the potential feasibility of CB-PVI ablation in patients with chronic Watchman left atrial appendage occlusion devices. Larger prospective studies are needed to confirm the clinical efficacy and safety of this approach. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;135:99–104)

As adoption of left atrial appendage occlusion (LAAO) procedures grows,^{1,2} the number of patients with existing LAAO devices eligible for catheter ablation of atrial fibrillation (AF) is expected to increase substantially. Concomitant LAAO device implantation and AF catheter ablation is feasible, but the risk of developing new peridevice leaks is high.^{3–6} Not all patients referred for evaluation for LAAO are candidates for or desire catheter ablation due to differing procedural indications.^{7,8} While radiofrequency (RF) PVI and LA ablation can be successfully performed, device surface thrombus and other device-related complications have been reported.^{9–11} Endocardial tissue growth with endothelialization of the LAAO device surface has been reported in preclinical and human autopsy studies^{12,13} and may pose a challenge when performing electroanatomic mapping (EAM) guided AF ablation.^{14,15}

Methods

This was a prospective study. Patients that presented for AF ablation post-LAAO device implantation were included. Twelve patients with symptomatic paroxysmal AF

underwent de novo PVI ablation using a second-generation 28 mm cryoballoon device (CB2; Artic Advance, Medtronic Inc., Minneapolis, MN) at Rush University Medical Center ≥ 90 days after Watchman device implantation. Definitions for type of AF were based on established guidelines.^{7,8} The study protocol was approved by Rush University Medical Center's institutional review board. Patients were enrolled into the study and gave written informed consent prior to the day of their ablation procedure.

A TEE was performed on the day of procedure prior to ablation to exclude thrombus on the device surface or within the left atrial (LA) cavity. All patients were intubated and placed under general anesthesia. After a decapolar catheter (for pacing and recording) was placed in the coronary sinus, a transeptal puncture was performed using an SL-1 sheath and Baylis needle system under fluoroscopic and intracardiac echocardiographic (ICE) guidance. Intravenous heparin was administered at time of transeptal puncture followed by an infusion to maintain an activated clotting time of 300 to 400 seconds.

A 5-spline multipolar mapping catheter with 1 mm electrode size and 2 mm interelectrode spacing (Pentaray, Biosense-Webster, Irving, CA) was introduced through the SL-1 sheath and an endocardial bipolar voltage map of the LA, pulmonary veins (PVs), and ostial surface of the Watchman device was created with a 3D mapping system (Carto 3, Biosense-Webster, Irvine, CA). Special care (assisted by ICE and fluoroscopy) was taken when mapping over the surface of the Watchman and LAA-left superior PV

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(LSPV) ridge. Contact of the mapping catheter's splines over the Watchman surface was confirmed with concomitant ICE imaging. Bipolar voltage atrial tissue amplitude was considered normal if > 0.5 mV, intermediate if between 0.05 and 0.5 mV, and low and/or absent if the amplitude was <0.05 over adjacent points as previously described using multielectrode mapping catheters.^{16,17}

Catheter ablation was performed using a second generation 28 mm CB catheter (Arctic Front Advance; Medtronic, St. Paul, Minnesota, MN) inserted through a 12 French steerable sheath (FlexCath Advance Steerable Sheath, Medtronic, Minneapolis, MN). The CB catheter was guided into each PV over a circular inner lumen mapping catheter (Achieve; Medtronic, Minneapolis, MN) placed within the targeted PV under fluoroscopic and EAM guidance. Prior to delivery of each freeze, PV angiography was performed to assess venous occlusion (Figure 2B). During freeze delivery, attempts were made to record time-to-PV isolation (TT-PVI). A single freeze application (TT-PVI + 120 seconds) was applied to a PV if TT-PVI was <60 seconds. When TT-PVI was >60 seconds, a bonus freeze application of 120 seconds was administered. If TT-PVI was not measurable due to absence of PV recordings, an empiric 180 seconds freeze was delivered followed by a single bonus 90 to 120 seconds freeze. If PV isolation was not obtained after 2 freeze applications, the CB catheter was repositioned and additional bonus freezes were performed until PVI was obtained. Supplemental RF ablation was not utilized to assist with completing PVI.

Freeze applications were stopped when the CB temperature fell below -65°C , and the balloon was repositioned before the next freeze was performed. Luminal esophageal temperature was monitored and freeze applications were stopped if the temperature fell to 15°C . During cryoablation of the right PVs, a decapolar catheter was positioned in the superior vena cava and high output phrenic nerve stimulation was performed while monitoring for loss of capture or attenuation of the diaphragmatic compound motor action potential amplitude.

All PVs were assessed for entrance and exit block after ablation and prior to exiting the left atrium. A postablation voltage map of the LA, PVs and surface of the Watchman device surface was created after PVI ablation was complete. ICE imaging was performed from within the LA to assess positioning of the Watchman device, new peri-device leaks and measure for change in size of preexisting peri-device leaks postablation.

Patients were discharged the following day provided that their clinical status was deemed stable. Oral anticoagulation was initiated the evening of the ablation procedure unless a pericardial effusion was detected and was continued uninterrupted at least 2 months afterwards. Previous antiarrhythmic drug treatment was continued for at least 3 months. Clinic follow up was performed at 3 months, 6 months, and 12 months. All patients had at least one 14-day ambulatory monitor performed after discharge.

Baseline characteristics are summarized using descriptive statistics, that is, mean (standard deviation) for continuous variables and percentage for categorical or nominal variables. Statistical significance was considered at a p value ≤ 0.05 . Analyses were performed with Stata 15 (Stata-Corp, College Station, TX).

Results

Twelve patients with symptomatic AF and previously implanted Watchman devices ≥ 90 days old underwent first-time CB-PVI procedures (mean 182 ± 82 days after device implant). Patient baseline characteristics are shown in Table 1.

PVI was performed using a second generation 28 mm CB device. Total procedural time was 119.3 ± 25.2 minutes and total fluoroscopy time was 16.9 ± 5.8 minutes. Mean number of freeze applications per PV was 1.7 ± 0.6 (LSPV: 1.8 ± 0.5 ; left inferior PV: 1.6 ± 0.7). The mean temperature reached per freeze cycle was $-46.9^{\circ}\text{C} \pm 7.1^{\circ}\text{C}$ (LSPV: $-48.7^{\circ}\text{C} \pm 6.9^{\circ}\text{C}$; left inferior PV: $-43.1^{\circ}\text{C} \pm 7.1^{\circ}\text{C}$). The mean distance of ridge tissue between the Watchmans' edge and the CB placed within the LSPV was 4.4 ± 1.7 mm (measured by EAM; confirmed by ICE in 8 of 12 patients). Acute PVI was successfully achieved 100% of procedures without supplemental RF ablation. Procedural and LAAO device characteristics of the study cohort are shown in Table 2.

All patients had at least partial device surface coverage with excitable endothelialized tissue demonstrated by presence of normal bipolar voltage (near-field bipolar electrogram recordings, > 0.5 mV amplitude) with splines of the Pentaray catheter over the ostial surface of the Watchman. We also demonstrated capture of the local potentials on the device surface (conducting to the rest of the LA) when pacing at an output of <3 V at 0.4 ms (Figure 1). Nine patients (75%; 94 to 369 days postimplant) had normal bipolar voltage over the entire device surface. Three patients (25%; 102 to 167 days postimplant) demonstrated intermediate or low voltage mostly over the central area of their Watchman with bipolar voltage amplitudes between 0.05 and 0.5 mV

Table 1
Patient baseline characteristics and follow up

Variable	Cryoablation group (N = 12)
Age (years)	71 \pm 9
Men	6 (50%)
Body Mass Index	29.3 \pm 4.6
Hypertension	8 (67%)
DM type 2,	2 (17%)
CAD	5 (42%)
Stroke or TIA	1 (8%)
CHA ₂ DS ₂ -VASc score	3.4 \pm 1.1
HAS-BLED score	2.8 \pm 0.9
Baseline LVEF	57 \pm 10
LA volume index (ml/m ²)	38 \pm 12
Procedure time (minutes)	119.3 \pm 25.2
Total fluoroscopy time (minutes)	16.9 \pm 5.9
AAD after ablation	6 (50%)
Follow up (months)	13.2 \pm 6.6
Recurrence of AF after blanking period	2 (17%)
Maintained oral anticoagulation at least 6 weeks after ablation	12 (100%)

AAD = antiarrhythmic drug; AF = indicates atrial fibrillation; BMI = body mass index; CAD = coronary artery disease; DM = diabetes mellitus; LA = left atrium; LVEF = left ventricular ejection fraction; TIA = transient ischemic attack.

Table 2
Procedural and left atrial appendage occlusion device characteristics

Patient	Days ablation performed after implant	No. of PVs	Device size (mm)	Device surface endothelialized	Peridevice flow size (mm) prior to ablation	Peridevice flow size (mm) after ablation
1	362	4	30	+	0	0
2	112	4	27	+	1	1
3	167	3	27	+	1	1
4	220	4	27	+	0	0
5	177	4	24	+	0	0
6	102	4	33	+	3	2
7	195	5	24	+	0	0
8	369	4	19	+	0	0
9	248	4	27	+	0	0
10	112	4	27	+	1	0
11	94	4	27	+	0	0
12	130	4	30	+	0	0

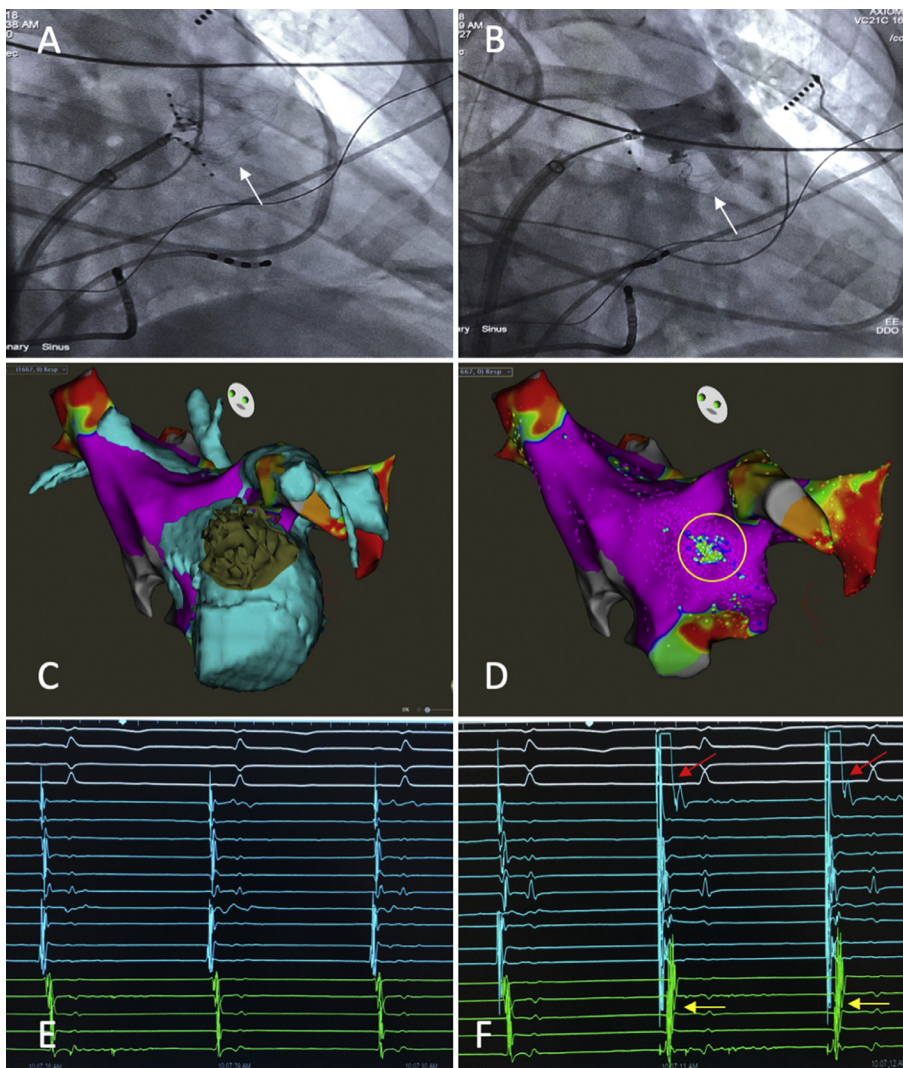


Figure 1. Patient 3. Panel A. Right anterior oblique view. Pentaray catheter splines over ostial surface of 27 mm Watchman device (white arrow) 167 days postimplant. Panel B. Right anterior oblique view. Contrast angiography of the left superior pulmonary vein after cryoballoon inflation. White arrow indicates Watchman device. Panel C. Fusion image of bipolar voltage map and preprocedure Cardiac CT imaging shows location of Watchman device in relation to left atrial and pulmonary vein anatomy acquired with 3D mapping. Panel D. High-density bipolar voltage map (0.05 to 0.5 mV) showing reduced voltage (<0.5 mV) mostly over the central surface of Watchman device. Yellow circular area indicates expected endocardial surface area of the Watchman device based upon CT fusion image. Panel E. Voltage recordings obtained with Pentaray catheter splines over the Watchman device. Panel F. Pacing from splines 1,2 with high amplitude recordings (red arrows) results in local capture and 1:1 capture of electrogram recordings on the decapolar catheter positioned in the coronary sinus (yellow arrows) at paced cycle length of 500 ms. (Color version of figure is available online.)

or <0.05 mV (over consecutive points). Only these 3 patients with reduced voltage during endocardial mapping demonstrated inability to capture excitable local tissue or the rest of the LA when pacing, (Figure 2 A–D) suggesting incomplete endocardial tissue growth over the device's fabric surface. Voltage mapping performed post-PVI showed normal bipolar voltage over the Watchman surface after cryoablation in all patients.

The only procedure-related complication during follow up was a minor groin hematoma in 1 patient. There were no cerebrovascular events, pericardial effusions or deaths

during the peri-procedure period. Postablation ICE imaging within the LA and did not reveal thrombus on the device surface, device perforation, device dislodgement, or new peridevice leaks in any patient.

Mean peridevice leak size remained statistically unchanged after CB PVI (Preablation: 0.06 ± 0.09 mm vs Postablation: 0.04 ± 0.06 mm; $p=0.61$) suggesting that device micro-dislodgement did not occur after ablation in any procedure (Table 2). Two study patients actually had a 1 mm decrease in size of their peri-device leaks, likely due to edema after CB ablation. On subsequent transesophageal

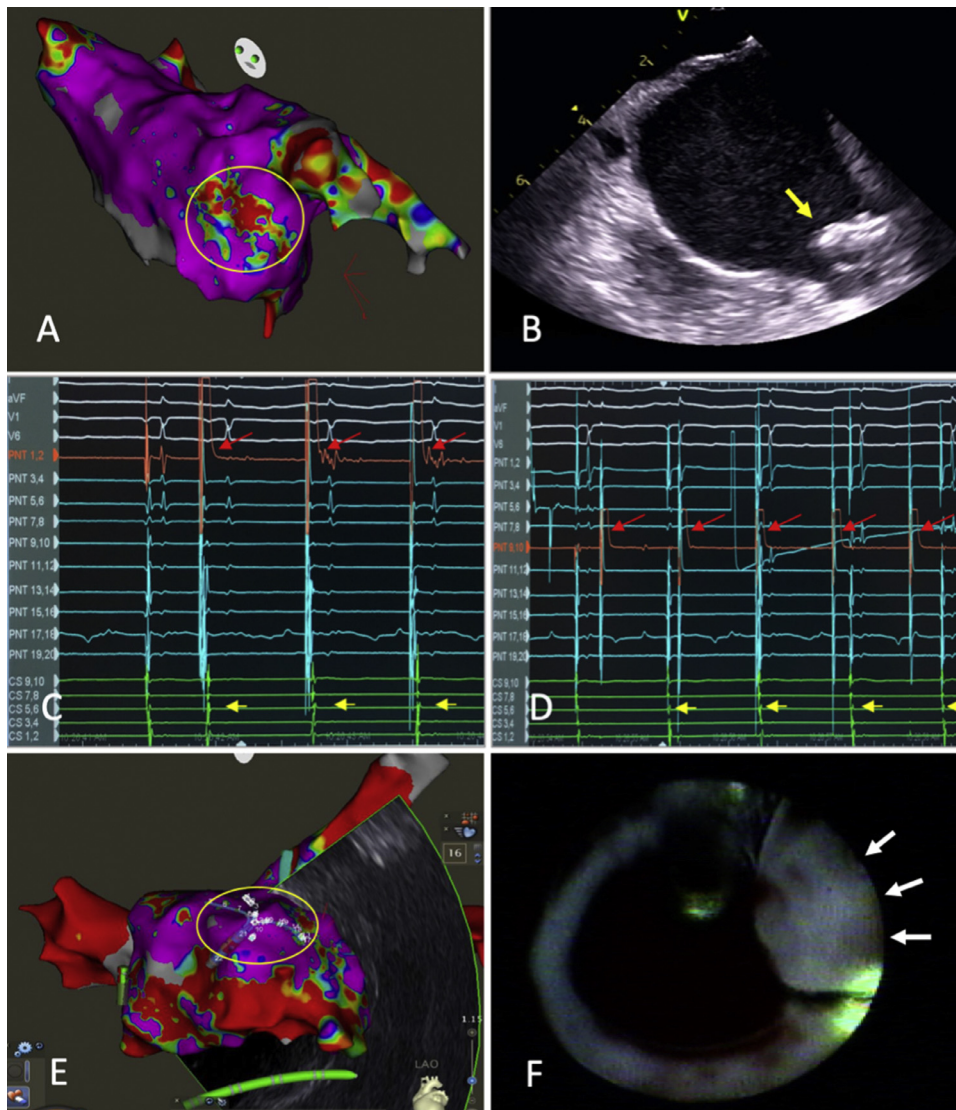


Figure 2. Patient 6. Panel A. Bipolar voltage map (0.05 to 0.5 mV) shows reduced voltage (<0.5 mV) over large area of the ostial surface of the 33 mm Watchman device at 102 days postimplant. Panel B. Intracardiac echocardiography image showing 33 mm Watchman device with prominent shoulder (yellow arrow) exposed beyond the left atrial appendage ostium. Panel C. Pacing from electrode pair 1,2 of Pentaray catheter spline (red arrows) where high amplitude near-field electrogram recordings are present at paced cycle length of 500 ms results in local and 1:1 capture of electrograms on decapolar catheter positioned in the coronary sinus (yellow arrows). Panel D. However pacing from electrode pair 9,10 from a spline recording low amplitude, far-field appearing electrograms (red arrows) does not result in local or 1:1 capture of decapolar catheter coronary sinus electrogram recordings (yellow arrows) even at high output (10 V at 2.0 ms). Panel E. Repeat voltage mapping during redo ablation procedure 182 days later shows bipolar voltage >0.5 mV over the device surface (yellow circular area). Panel F. Endoscopic image during re-isolation of left superior pulmonary vein showing indentation of the LSPV-LAA ridge and tissue appearance of the surface of watchman device similar to rest of myocardium. White arrows: Indicate location of Watchman device. (Color version of figure is available online.)

(TEE) imaging performed during follow up, the peridevice leak remained absent in 1 patient (Case 10) but returned to its preablation size in the other patient (Case 6).

All patients were discharged the day after ablation and maintained oral anticoagulation for at least 8 weeks afterwards. Two patients had AF recurrence after the 90-day blanking period. One of these patients underwent redo-ablation. This patient had reconnection of the LSPV (posterior-carina) and RIPV (anterior-superior location).

Discussion

This study's findings include (1) evidence that CB-PVI is feasible 90 days after Watchman implantation, (2) CB ablation did not result in any device-related complications, and (3) after 90 days, all Watchman devices had evidence of endocardial tissue growth over the fabric surface demonstrating excitability and conductive properties during electrophysiologic testing.

Although concomitant catheter ablation and LAAO device implantation has been demonstrated to be feasible,³⁻⁶ this approach may be limited by several factors including: the length and complexity of the combined procedure, reimbursement constraints, and lack of patient readiness for ablation at the time of referral for LAAO given differing procedural indications. In addition, risk of developing new peri-device leaks on 45-day TEE is higher after hybrid procedures than with LAAO device implantation alone.⁴ Frank device dislodgement has also been reported following hybrid procedures.^{3,18}

While RF ablation in the LA has been reported as early as 45 days postimplant,⁹⁻¹¹ optimal timing for LA ablation remains unclear.^{12,14} In a retrospective multicenter registry of patients who underwent RF ablation for AF after Watchman implant, 30% of patients had new peridevice leaks on postprocedure imaging. One-third of new peri-device leaks were >5 mm in size, potentially compromising long term efficacy of the LAAO device.¹¹ Heeger et al reported a 12.5% incidence of acute device thrombus formation complicating RF ablation after Watchman placement.⁹

In our study all patients demonstrated evidence of endocardial tissue growth over the device surface after 90 days

based on presence of near-field, high amplitude normal voltage recordings (>0.5 mV) over the device surface. These findings are supported by histopathologic evidence of neo-endocardial tissue growth over the device's fabric surface during the latter stages of healing after implantation.^{12,13} Schwartz et al reported that healing occurs in a predictable, staged manner: (1) initial formation of an organized thin layer of laminar fibrin and thrombus on top of the fabric membrane as early as 48 hours postimplantation; (2) endothelialization of the fabric surface with a cellular monolayer and tissue ingrowth containing a mixture of smooth muscle cells and collagen matrix sealing the gaps in the LAA-device interface at 45 days, (3) and finally neointimal proliferation with a mixture of smooth muscle-like cells and connective tissue eventually covering the entire device surface.¹² Similar findings were also observed in the Watchman FLX[®] device which demonstrated endothelialized endocardial tissue growth in canines after 90 days.¹³

This is the first demonstration that late tissue growth on the device surface has electrical excitability and conductive properties similar to other LA myocytes. In addition to a playing a role in reduction of thrombogenicity and improving device stability postimplant, endothelialized tissue growth may have several relevant implications for subsequent ablation procedures. First and foremost, presence of electrically conductive tissue inhibits differentiation between the endothelialized surface of the Watchman from other LA tissue during EAM-guided ablation (based upon bipolar electrograms), increasing the chances of inadvertent ablation over the Watchman surface, particularly along the LSPV-LAA ridge where normal anatomy may be distorted post device implant. Given delayed endothelialization in some patients (Figure 2), catheter trauma and/or thermal heating may increase risk of thrombus formation over areas with only a thin monolayer protecting fibrin deposits on the device surface (Figure 3). Although we observed no arrhythmias involving the Watchman surface, the electrical excitability and conductive properties demonstrated suggest device surface tissue could participate in macroreentrant arrhythmias by bridging from the LSPV or LAA to the rest of the LA.

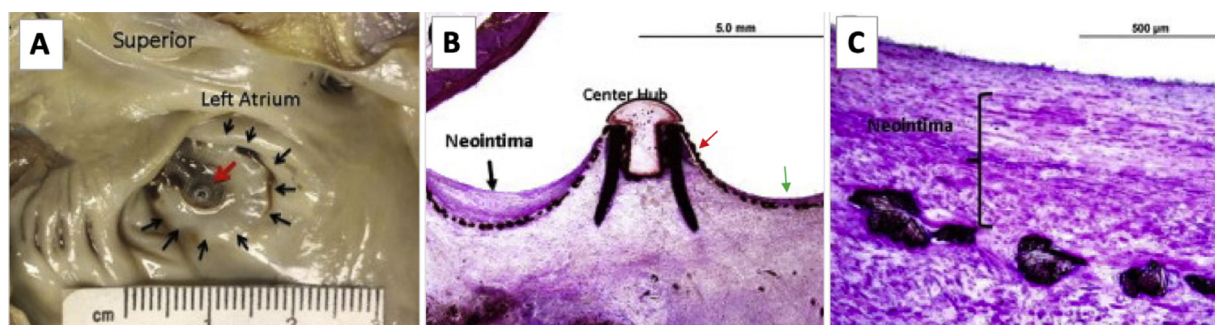


Figure 3. Postmortem images of Watchman device. Panel A. Black arrows indicate endothelialized tissue with neointimal growth partially covering the device surface. Center (red arrow) and surface near carina-ridge is without endocardialized tissue growth. Panel B. Sagittal sections through center of device. Toliudine blue and basic fuchsin stain shows neointimal growth with smooth muscle cells contained within collagenous matrix over one side of device surface. Methyl methacrylate staining shows exposed fibrin coating (red arrow) on surface of fabric membrane uncovered by monolayer of endothelial tissue (green arrow). Panel C. Organized endocardial layer with fibrin deposits deeply buried. Toliudine blue and basic fuchsin stain. Images reproduced with permission from Schwartz et al.¹² (Color version of figure is available online.)

Our results suggest CB ablation may be superior to RFA for PVI in patients with existing Watchman devices. One particular advantage of CB PVI is minimization of contact with the Watchman's surface given balloon placement within the PV antrum. Therefore, inadvertent ablation over the Watchman is less likely to occur during ablation of the left PVs than with EAM-guided RF ablation. Importantly, there were no new peri-device leaks or change in leak size following CB-PVI. This is potentially advantageous as new or large peri-device leaks may limit LAAO long term efficacy.

In conclusion, CB PVI is feasible in patients with pre-existing LAAO devices and may be safer than RF PVI. Although no procedure-related complications were observed, larger studies are needed to verify the acute and long-term safety of CB PVI in this population.

Authors' Contributions

Henry Huang: Conceptualization, funding acquisition, methodology, investigation, writing -original draft. Kousik Krishnan: Writing - review and editing. Clifford Kavinsky: investigation, Writing- review and editing. Ravi Venkatesh: data acquisition, formal analysis. Jason Rodriguez: data acquisition. Parik Sharma: Writing - review and editing. Tim Larsen: Writing- review and editing. Richard Trohman: Writing - review and editing, supervision.

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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