Closure of Residual Left Atrial Appendage Communications After a Prior Exclusion Attempt

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May 29, 2021

Abstract

Background: Surgical or percutaneous occlusion of the left atrial appendage (LAA) is increasingly used for thromboembolic protection in atrial fibrillation. Incomplete LAA closure may increase risk of thrombosis and thromboembolism, and therefore approaches to address residual communications are needed. Objective: To analyze the technique of closing an incompletely occluded LAA and subsequent patient outcomes. Methods: We performed a retrospective analysis of 5 consecutive patients who presented for completion of LAA closure. Results: Four patients were male, mean age 75, average CHA2DS2-VASc score 5.4, and four had prior surgical LAA ligation. One patient had previously had a WATCHMAN device placed for whom a 3D printed model was created from preprocedural imaging data to guide Amplatzer occluder device selection for closure. The residual LAA communication maximal diameter averaged 6.2 mm (range 5-8mm). In 4 of 5 cases, an ablation catheter was used to enter the LAA. The residual LAA communication was closed with either an Amplatzer occluder (n=3) or a WATCHMAN device (n=2). No procedural complications occurred, and no residual leak remained afterwards. No neurologic events occurred during follow up (average 603 days, range 155-1177 days). Anticoagulation or dual antiplatelet therapy was stopped following a transesophageal echo (TEE) [3] 6 weeks after the procedure demonstrated no residual communication in 4 of 5 patients, and after 20 weeks in the fifth patient without a follow up TEE. Conclusion: Large residual LAA communications after LAA occlusion attempts can be successfully and safely closed percutaneously using either Amplatzer occluder devices or WATCHMAN devices.

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Running Title: Left atrial appendage occlusion after incomplete prior occlusion attempt

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Word Count: 3821

Disclosures:

W Hucker: none

A Bapat: none

A Hanley: none

S Bernard: none

P Bertrand: none

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S Klassen: none

C Mihos: none

G Ha: none

EK Heist: Consulting fees/honoraria and fellowship support Biotronik, Boston Scientific, Medtronic, Abbott, Pfizer

R Sakhuja: Consulting fees/honoraria: Abbott, Cardiovascular Systems Inc, Edwards Lifesciences, Medtronic; Research Grants: Abbott, Boston Scientific, Cardiovascular Systems Inc, Abiomed

J Galvin: none

J Dal-Bianco: none

D Sanborn: none

J Danik: none

M Fitzsimons: none

K Slattery: none

J Ruskin: Consulting fees/honoraria Cala Health, Jazz Pharmaceuticals, Lantheus Medical Imaging, Medtronic, Milestone Pharmaceuticals, Pfizer Inc, Apple Inc, Gilead Sciences, InCarda Therapeutics, Advanced Medical Education, Element Science, InfoBionic, Boston Scientific, NewPace Ltd, Equity interest Portola Pharaceuticals

B Ghoshhajra: none

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J Hung: none

M Mansour : Consultant: Biosense-Webster, Boston Scientific, Abbott, Medtronic, Johnson and Johnson, Janssen, Philips, Novartis, Sentre Heart. Research Grants: Biosense-Webster, Boston Scientific, Abbott, Pfizer, Boehringer Ingelheim, Sentre Heart, Johnson and Johnson, Medtronic

Equity: EPS Solutions, New Pace Ltd, Affera

Key Words:

Left atrial appendage closure, Atrial Fibrillation, WATCHMAN, Amplatzer

Abstract

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Objective: To analyze the technique of closing an incompletely occluded LAA and subsequent patient outcomes.

Methods: We performed a retrospective analysis of 5 consecutive patients who presented for completion of LAA closure.

Results: Four patients were male, mean age 75, average CHA_2DS_2-VASc score 5.4, and four had prior surgical LAA ligation. One patient had previously had a WATCHMAN device placed for whom a 3D printed model was created from preprocedural imaging data to guide Amplatzer occluder device selection for closure. The residual LAA communication maximal diameter averaged 6.2 mm (range 5-8mm). In 4 of 5 cases, an ablation catheter was used to enter the LAA. The residual LAA communication was closed with either an Amplatzer occluder (n=3) or a WATCHMAN device (n=2). No procedural complications occurred, and no residual leak remained afterwards. No neurologic events occurred during follow up (average 603 days, range 155-1177 days). Anticoagulation or dual antiplatelet therapy was stopped following a transesophageal echo (TEE) [?] 6 weeks after the procedure demonstrated no residual communication in 4 of 5 patients, and after 20 weeks in the fifth patient without a follow up TEE.

Conclusion: Large residual LAA communications after LAA occlusion attempts can be successfully and safely closed percutaneously using either Amplatzer occluder devices or WATCHMAN devices.

Abbreviations:

ACT: activated clotting time

AF: atrial fibrillation

DAPT: dual anti-platelet therapy

DOAC: Direct oral anticoagulant

GIB: gastrointestinal bleed

HU: Hounsfield unit

IRB: Institutional Review board

LAA: Left atrial appendage

OAC: oral anticoagulation

TEE: Trans-esophageal echo

Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia and is associated with an ischemic stroke risk which is mitigated by anticoagulation. In patients that are not suitable anticoagulation candidates, closure of the left atrial appendage (LAA) is an alternative to reduce the risk of thromboembolic stroke or systemic thromboembolism.[1, 2] In patients with a history of AF undergoing cardiac surgery, the LAA is often either ligated or amputated at the time of surgery, however the rates of incomplete surgical LAA ligation (ISLL) are high,[3, 4] and ISLL is associated with elevated risk of thrombus formation and thromboembolism, likely due to constriction of blood flow into the LAA.[5] In other patients with elevated risk of thromboembolism from AF, endovascular closure of the LAA is often attempted. This approach has been shown to be superior to warfarin for the end point of stroke, systemic embolism, and cardiovascular death, as

well as all-cause mortality.[6] However, residual communications between the LA and the LAA are relatively common. While small communications have been shown not to be associated with elevated thromboembolic risk,[7] leaks >5 mm typically require treatment. In this case series, we report 5 consecutive cases of residual communication between the LAA and the LA which were closed by endovascular techniques.

Methods

Patient Selection

Five consecutive patients (4 men and 1 woman; age 64-91 years) presented for completion of LAA closure (LAAC) after a prior procedure resulted in an unacceptable amount of residual leak. Patients referred for consideration of closure of the residual LAA communication were discussed in an interdisciplinary meeting with representatives from neurology, electrophysiology, cardiac surgery, interventional and general cardiology. The $CHADS_2$, CHA_2DS_2-VASc, and HAS-BLED scores were calculated to estimate ischemic stroke and bleeding risk respectively. Patients that were appropriate for LAAC were scheduled for the procedure. Institutional Review Board (IRB) approval was obtained prior to data collection.

Procedural Details

The procedure was performed under general anesthesia. Femoral venous access was obtained using the Seldinger technique with a micropuncture needle under ultrasound guidance. A transesophageal echocardiogram (TEE) was performed to document the absence of LAA thrombus, define LAA anatomy, and guide the transseptal puncture as well as device implantation. Echo contrast was not required for any of these studies. Transseptal access was performed in the lower, anterior quadrant of the fossa ovalis. Heparin was given prior to transseptal puncture with a goal activated clotting time (ACT) > 250 seconds. Procedural details specific to the different devices used for LAA closure are provided in the Results section. After device deployment, device position and LAA occlusion were verified by TEE and contrast injection. TEE was performed at 6 weeks after the procedure to confirm LAA occlusion.

For the WATCHMAN leak closure, a CT-derived (0.977 mm pixel size x 1.5 mm spacing) 3D printed model was prepared. Segmentation was performed using 3D Slicer software (Brigham and Women's Hospital, Boston, MA): a 5 mm thickened shell model was generated from the contrast-defined volume of the LA and LAA and a model of the WATCHMAN was created using a higher HU threshold (Figure 3). Manual adjustment was used for both elements to improve model quality. Models were printed with a Stratasys Eden 260V printer in FLX930 and RGD720 flexible and rigid resins respectively (Stratasys, Ltd., Rehovot, Israel). The model was used to determine and test the correct type and size of the closure device.

Results

Patient characteristics are listed in **Table 1.** All patients had a strong indication for stroke prophylaxis with an average CHA_2DS_2-VASc score 5.4 (range 3-8), and 4 patients had a history of prior bleeding complications while on anticoagulation (2 with prior intracranial hemorrhage, 2 with prior gastrointestinal bleeding requiring transfusions). Four patients had previously undergone surgical LAA ligation with an average time between surgical and endovascular LAA closure of 6.4 ± 3.6 years. Of these four patients, three had anticoagulation stopped after the surgical LAA ligation. Of these three patients, one had a subsequent TEE as part of a cardioversion and was found to have the residual connection and a thrombus in the LAA. Another experienced a thromboembolic event. The fifth patient had a previous WATCHMAN device placed but had a persistent communication of the LAA to the LA. Of the five patients, three presented to the percutaneous closure procedure on uninterrupted therapeutic anticoagulation; the other 2 were on ASA monotherapy (**Table 2**).

Device Selection

Selection of the device to close the residual LA-LAA communication was dependent on the anatomy in each case, with specific emphasis on the available depth beyond the persistent communication and the residual appendage orifice area. With regards to WATCHMAN implantation, sufficient depth is necessary

to accommodate the umbrella-like device and the orifice must be large enough to accommodate the delivery sheath**(Figure 1).** Of the five patients, two patients underwent WATCHMAN implantation (both with prior surgical LAA ligation, Table 2). In the other three cases, two of whom had a prior surgical ligation, an Amplatzer occluder device was used (**Figure 2, Table 2**) with the size and type of device chosen based on TEE assessment of the gap and the "waist" of the device. In the final patient, an Amplatzer occluder was chosen to fill the residual gap next to an existing WATCHMAN (**Figure 3, Table 2**). In this patient, the gap around the WATCHMAN was complex, and was reproduced using a 3D printed model. The narrowest neck of the gap appeared to be approximately 8 mm, and the model allowed physical testing of feasibility of closure and selection of the optimal device (**Figure 3B and C**).

Entering the LAA

Entering the LAA is difficult in these cases because of the small size of the residual communications. After confirming no residual thrombus in LAA, in 4 of 5 cases, a 4mm ablation catheter (Biosense Webster, Irvine, CA) was used to enter the LAA through the residual communication under TEE guidance. Once the catheter tip was advanced into the LAA, it provided the necessary support to advance the requisite delivery sheath into the LAA through the narrow neck of the communication (**Figures 1A, 2A, 3E**). In the patients with prior surgical closure, the neck was small and either the ablation catheter or the sheath were occlusive of the communication as noted by contrast injection (**Figure 1A, Figure 2B**). For Amplatzer placement, an Agilis sheath (Abbott, St Paul MN) was used for device delivery (n=3, large curl Agilis in 2 cases). For placement of a WATCHMAN device, the Boston Scientific WATCHMAN sheath (Boston Scientific, St Paul MN) was advanced into the LAA over the ablation catheter (**Table 2**). In all cases, when the sheath tip was visualized in the LAA, the ablation catheter was withdrawn.

Device Delivery

Once the sheath had traversed the neck of the LAA opening, a small amount of contrast dye was injected to assess the depth of the remaining part of the LAA. WATCHMAN devices were deployed by advancing the sheath deeper into the LAA over a pigtail catheter until the sheath depth within the LAA was adequate for WATCHMAN placement. The sheath was then slowly retracted to deliver the WATCHMAN device behind the residual connection to the LAA (**Figure 1C, 1E**). For the Amplatzer devices, the sheath was advanced into the LAA and the distal disc of the Amplatzer was exposed from the sheath. The device was then retracted until it was seated against the LAA side of the residual connection. The delivery sheath was then slowly withdrawn to expose the proximal disc of the device on the LA side of the connection (**Figure 2C, 2E**).

Post procedural management and follow up

Post procedural anti-thrombotic management is also listed in**Table 2** . All patients were discharged on post-procedural day 1. The two patients who received a WATCHMAN device were discharged with aspirin and an anticoagulant. One patient who received an Amplatzer had been noted previously to have a LAA thrombus that resolved with apixaban, and he was maintained on apixaban after device placement. The two other patients who had an Amplatzer placed were discharged on ASA and clopidogrel (**Table 2**).

Follow up TEE was performed [?] 6 weeks after device placement. In the 4 ISLL patients, no residual leaks were noted and no device related thrombus was present. In the fifth patient who had a WATCHMAN and Amplatzer in place, a small leak was noted by TEE ($<$ 4mm) with no thrombus. Patients on an anticoagulant were transitioned to aspirin/clopidogrel for an additional 6 weeks, then transitioned to aspirin monotherapy. The median follow up time since closure of the residual connection was 888 days (range 468 – 1490 days). No strokes or systemic embolic events occurred. One patient had recurrent GIB requiring transfusion on dual antiplatelet therapy 8 weeks after device placement and clopidogrel was stopped.

Discussion

We performed a retrospective analysis of 5 consecutive patients who presented for closure of a residual communication between the LAA and the LA after prior closure attempts. Depending on the anatomy and

the size of the residual communication, either Amplatzer closure devices or WATCHMAN devices were used successfully to achieve LAA occlusion. No patients experienced a subsequent stroke or systemic embolism after closure with a median follow up of 888 +- 426 days. One patient had a recurrent GIB requiring transfusion while on dual antiplatelet therapy after device placement.

Incomplete closure of the LAA after attempted surgical LAA ligation is common, and is associated with increased risk of thromboembolism by causing sluggish flow into the remaining LAA.[3–5] While this has most commonly been reported after a surgical attempt to close the LAA, residual LAA connections have also been described after percutaneous closure attempts with the Lariat and WATCHMAN devices.[8] While peri-device leaks smaller than 5 mm around WATCHMAN devices are not associated with increased risk of thromboembolism, larger leaks have generally required treatment.[7] Because of the varied anatomy of the LAA, variable sizes of residual connections, and the location of the residual connection (edge vs. central), several different interventional approaches have been published to address this problem. Similar to 3 of our patients, the Amplatzer Septal Occluder was successfully used in 6 of 7 cases in a series of patients with incomplete surgical LAA ligation, [9] as well as in 5 of 6 patients with persistent LA-LAA connection after an initial Lariat procedure.[10] Other case series have demonstrated the use of alternate devices for this purpose, including the Gore Helex septal occluder,[11] a vascular plug,[12] the AGA Cardiac plug,[13] and the WATCHMAN device.[14]

Our study adds to this body of literature and provides a useful method of entering the LAA through a small neck using an ablation catheter for support. In addition, we present a case of closing a residual leak after WATCHMAN placement. Closure of edge leaks is challenging given the anatomy of the gap, and placement of certain devices would be precluded by the size and morphology of the residual connection. Our 3D printed LA/LAA and WATCHMAN models allowed testing of device types and sizes; this pre-procedural planning led to a successful deployment of the Amplatzer device to close the gap for this patient.

Antithrombotic management after device placement was individualized. These were patients who were at both high thromboembolic and bleeding risk with elevated CHA_2DS_2-Vasc and HAS-BLED scores, respectively. Fortunately, no strokes or systemic emboli were noted in follow up of our patients, but there was one GIB while on dual antiplatelet therapy. ASD occlusion devices such as the device used in this study are routinely managed with post-procedural dual antiplatelet therapy in the absence of atrial fibrillation. It should be noted, that there has been growing use of DOACs after WATCHMAN placement despite the fact that they were not studied in the trials leading to approval of the device, and we used apixaban after placement of a WATCHMAN device in this case series. Device related thrombosis (DRT) has been reported in up to 3.7% of patients in the year after WATCHMAN implant, but only 0.8% of patients at six weeks after device placement [15]. In our study, these patients only had a TEE performed at 6 weeks and we observed no DRT.

Conclusions

This case series presents the successful closure of residual connections between the LAA and LA using either the Amplazter Septal Occluder device or a WATCHMAN device. We also demonstrated the use of a 3D printed model to facilitate the choice of the appropriate device type and size for successful closure.

Limitations

This case series represents a small series of patients and is meant to demonstrate possible management strategies for a difficult, yet common, clinical scenario. Long-term outcomes, including freedom from ischemic stroke and DRT cannot be extrapolated. Given the small sample size and limited follow-up time, the conclusions that can be drawn from this population are limited.

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Figure Legends

Figure 1: Placement of Watchman past incompletely closed LAA orifice. A: A 4 mm ablation catheter was used to access LAA, the Agilis sheath was advanced over the ablation catheter, the catheter was retracted, and contrast was injected to visualize the LAA. B: Agilis exchanged for Watchman sheath and Pigtail catheter. C: Contrast injection showing Watchman (outlined by black dashed line) placed distal to orifice of the LAA. D: TEE image of the persistent connection between LAA and LA. Dimensions of the LAA were suitable for placement of a 24mm Watchman device. E: TEE image of 24mm Watchman placed in the LAA. F: TEE image of Watchman device 6 weeks after implant demonstrating closure of the LAA.

Figure 2: Placement of an Amplatzer device to close residual LAA communication. A: An ablation catheter was advanced across the persistent connection into the LAA. Contrast injection from the sheath in the LA highlights that the ablation catheter was occlusive of the persistent LAA connection. B: An Agilis sheath was advanced over the ablation catheter into the LAA and contrast was injected into the LAA. The sheath occluded the connection to the main body of the LA. C: Contrast injection highlights the Amplatzer plug that was placed at the persistent connection to the LAA. The narrow neck of the connection (outlined) can be seen due to the contrast. D: TEE image of persistent LAA connection, 4.4 mm in diameter in this view, with flow entering the LAA. E: TEE image of Amplatzer plug in place, occluding the connection seen in panel D. F: 3D TEE image of Amplatzer plug after release from the delivery mechanism

Figure 3: Placement of an Amplatzer device to close residual LAA communication with a preexisting WATCHMAN in place. A: Preprocedural CT with an 8mm gap noted at the inferoposterior border of the Watchman device. B: A 3D model was created from the pre-procedural CT to guide device choice for closure (Scale in cm). C: Internal view of 3D model with Watchman device model printed as a separate piece to allow it to be removed from the model LAA (Scale in cm). D: Pre-procedural TEE demonstrating the persistent gap with flow into the LAA. E: Contrast injection of the LAA. The LAA was entered using a 4mm ablation catheter and the delivery sheath was then advanced over the ablation catheter (WATCHMAN outlined by black dashed line, extent of LAA outlined in white). F: TEE image of Amplatzer plug in place, occluding the connection seen in panel D.

Figure 1

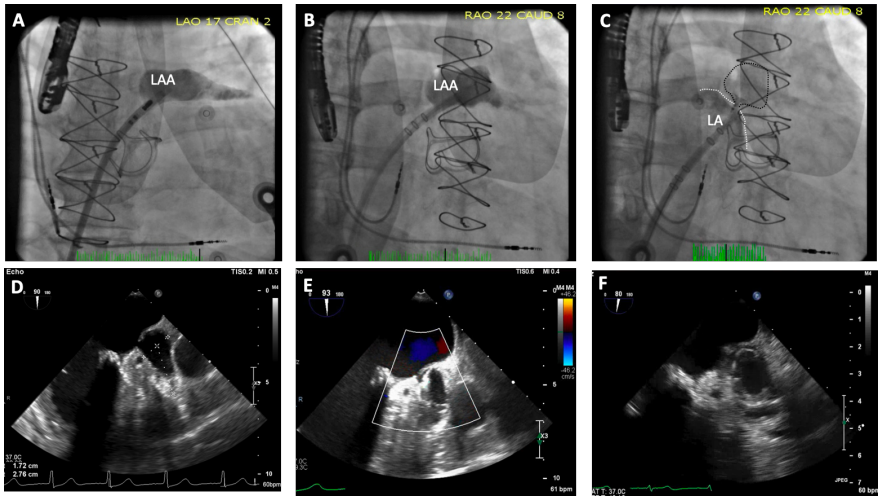

Figure 2

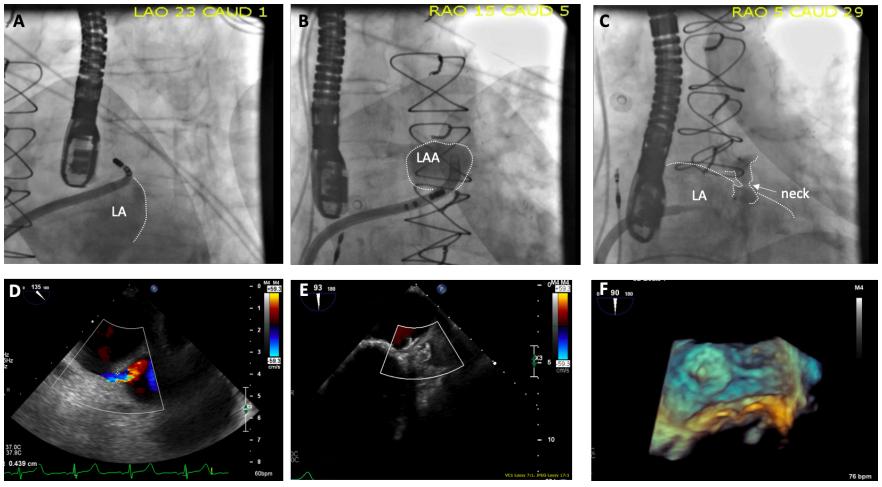

Figure 3

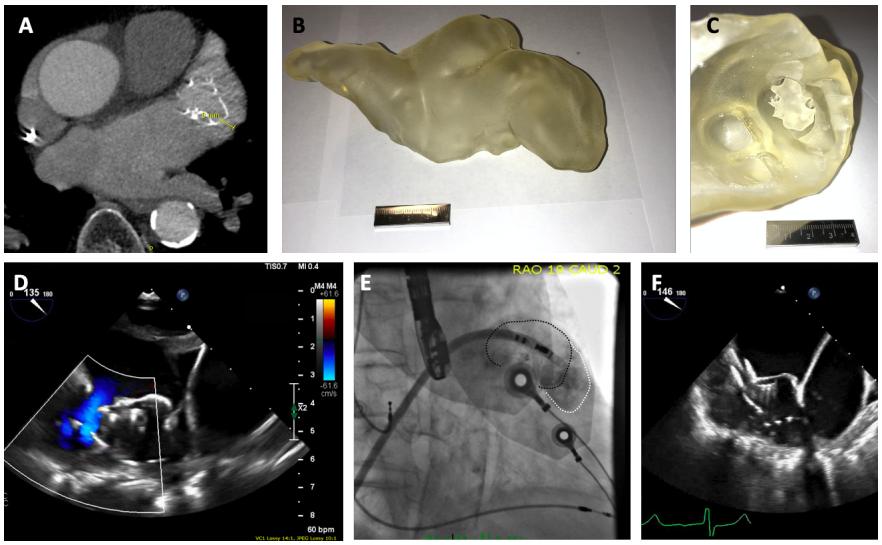

Table 1. Patient Characteristics

AF: atrial fibrillation; CHF: congestive heart failure; DM: diabetes mellitus; EF: ejection fraction; HTN: hypertension; GIB: Gastrointestinal bleed; ICH: intracranial hemorrhage

Table 2. Procedural Characteristics

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`image5.emf` available at https://authorea.com/users/416521/articles/524037-closure-of-residual-left-atrial-appendage-communications-after-a-prior-exclusion-attempt

CABG: coronary artery bypass grafting; AVR: aortic valve replacement; MVR: mitral valve replacement; SL-1: Swartz left transseptal guiding sheath; TVr: tricuspid valve repair; ASA: aspirin