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CASE REPORT
Coronary heart disease

Case report: percutaneous closure of residual leak following left atrial appendage occlusion

Hussam S. Suradi *, Jeffrey Park , Marie-France Poulin , and Clifford J. Kavinsky

Division of Cardiovascular Medicine, Rush University Medical Center, 1717 W. Congress Parkway, Kellogg 317, Chicago, IL 60612, USA

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Background Transcatheter left atrial appendage occlusion (LAAO) using Watchman device has been demonstrated to be efficacious in decreasing stroke risk in patients with atrial fibrillation who are not suitable for long-term anticoagulation. Residual leaks are frequently encountered following LAAO procedures and their clinical implications and optimal management remain controversial.

Case summary In this report, we describe a case of peri-Watchman device leak treated successfully with percutaneous device closure using an Amplatzer Vascular Plug II device.

Discussion The clinical implications of peri-device leaks remain controversial with general consensus to continue anticoagulation along with serial imaging for larger leaks (>5 mm). As an alternative strategy, percutaneous closure of these leaks has been attempted in hope of avoiding anticoagulation and minimizing the risk of stroke and should be studied further.

Keywords Case report • Atrial fibrillation • Watchman • Stroke • Peri-device leak

Learning points

- Transcatheter left atrial appendage occlusion (LAAO) using Watchman device has been demonstrated to be efficacious in decreasing stroke risk in patients with atrial fibrillation who are not suitable for long-term anticoagulation.
- Catheter-based closure of residual leaks following LAAO is feasible and safe to help avoid anticoagulation and minimize risk of CVA.

Introduction

Left atrial appendage occlusion (LAAO) with the Watchman device has been shown to be an effective treatment for stroke prevention in patients with atrial fibrillation who are not suitable for long-term anticoagulation.[1] The left atrial appendage (LAA) varies in size and shape, therefore, using an endovascular device with a fixed size and shape may result in incomplete sealing of the LAA resulting in persistent leak. In the PROTECT-AF study, residual leak was noted in 40.9%, 33.8%, and 32.1% of the subjects at 45 days, 6 months, and 12 months, respectively.[2] The clinical implications of these leaks remain controversial with general consensus

* Corresponding author. Tel: +1 312 942 6024, Fax: +1 312 942 5829, Email: hussam_suradi@rush.edu
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to continue anticoagulation along with serial imaging studies for larger leaks (>5 mm). Alternatively, percutaneous closure of these leaks has been attempted in hope of avoiding anticoagulation and minimizing the risk of stroke, nevertheless, experience with this approach remains limited.[3,4] In this report, we describe a case of peri-Watchman device leak treated successfully with percutaneous device closure.

Timeline

Dates	Clinical scenario
1990	First diagnosed with paroxysmal atrial fibrillation
2016	First episode of gastrointestinal (GI) bleed due to gastric erosions requiring admission and multiple blood transfusions
2017	Recurrent GI bleed and taken off warfarin, started on aspirin + clopidogrel by after multidisciplinary discussion given intolerance to full-dose anticoagulation
8 March 2018	Left atrial appendage occlusion (LAAO) procedure with 31 mm Watchman device—restarted on warfarin post-procedurally until follow-up 45-day transoesophageal echocardiogram (TOE) without issue
4 May 2018	45-Day post-LAAO TOE follow-up showing suboptimal results with residual leak due to uncovered anterior lobe—continued on anticoagulation due to risk of stroke. No issues noted while on anticoagulation
October 2018	6-Month follow-up TOE showing persistent leak and decision to go forward with leak closure
23 October 2018	LAAO peri-device leak closure with 12 mm Amplatzer Vascular Plug
15 April 19	Follow-up TOE showing no residual leak, device embolization, or thrombus formation

Case presentation

An 82-year-old male with permanent atrial fibrillation [CHA2DS2-VASc score 5 for age, hypertension, history of cerebrovascular accident (CVA)] was referred for the management of residual leak following LAAO. His atrial fibrillation was initially managed medically with rate control and anticoagulation with warfarin, and his clinical course was complicated over the last 2 years with recurrent gastrointestinal bleeding presenting first with melena and subsequently with haematochezia requiring invasive intervention. He was deemed too high risk to continue indefinite anticoagulation in multidisciplinary discussion given his HAS-BLED score of 4 (age, history of CVA, hypertension, antiplatelet use) and was thus referred for transoesophageal echocardiogram (TOE) and LAAO implantation. His anticoagulation was modified pre-procedurally to aspirin and clopidogrel given significant CHADS2-VASc score. Vitals and physical exam was largely unremarkable with a well-nourished male in no acute distress, normal lung exam, and cardiovascular exam with regular rhythm and heart rate in the 70 s. There was a soft II/VI systolic murmur at the right upper sternal border without radiation consistent with known history of mild aortic stenosis.

His pre-operative TOE showed the LAA to be of windsock type measuring 28 mm at the ostium and he underwent LAAO with a 31 mm Watchman device (Boston Scientific, Marlborough, MA, USA) and was amenable to short-term anticoagulation therapy post-procedurally. After initial device placement, angiography showed mild residual leak of ~7 mm.

On routine 45-day follow-up TOE, significant peri-device leak was noted in an uncovered anterior lobe (*Figure 1A and B*) and warfarin was continued per guidelines. A repeat TOE at 6 months showed persistent residual peri-device leak and given patient's intolerance to long-term anticoagulation, percutaneous leak closure was planned. To minimize the risk of device embolization, leak closure was performed 6 months after the original LAAO procedure to allow time for endothelialization and provide more stable anchoring of the Watchman device in the LAA. After transseptal puncture, an 8 Fr Agilis steerable sheath with medium curve (St. Jude Medical, Saint Paul, MN, USA) was advanced into the left atrium and the defect was crossed with a 0.035 inch Wholey wire (EV3, Plymouth, MN, USA) and a 5 Fr multipurpose catheter under fluoroscopic and TOE guidance. The Wholey wire was then exchanged with a 0.018 inch V-18 wire (Boston Scientific). An 8 Fr × 90 cm Flexor sheath (Cook Medical, Bloomington, IN, USA) was then advanced over the V-18 wire and was used to deliver a 12 mm Amplatzer Vascular Plug II (St. Jude Medical). Satisfactory position was confirmed by TOE (*Figure 1C and D*) and angiography (*Figure 1E and F*) (Supplementary material online, *Videos S1 and S2*).

Post-procedurally he was continued on anticoagulation with warfarin without complication until his planned 45-day follow-up. At his 45-day TOE visit, no residual leak was visualized and there was no evidence of device embolization or thrombus formation and thus warfarin was discontinued with plans to continue high-dose aspirin indefinitely.

Discussion

Leaks remain an inherent complication of LAAO procedures and their clinical implications are still debated.[5] Potential causes include the elliptical-shaped orifices resulting in malapposition of the circular devices, device undersizing or migration, and the inability to cover multiple lobes with one device such as in this case. Although leaks have been reported in as many as 59%, 47%, and 32% following PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion; Appriva Medical Inc., Sunnyvale, CA, USA), Amplatzer Cardiac Plug (St. Jude Medical), and Watchman device implantation, respectively, no study to date has proved that their presence is associated with thromboembolic events and at what size threshold.[6,7] The clinical impact of incomplete LAA closure was examined in a sub-study of the PROTECT-AF trial.[6] In this retrospective analysis of patients who received the Watchman device, residual leak occurred in

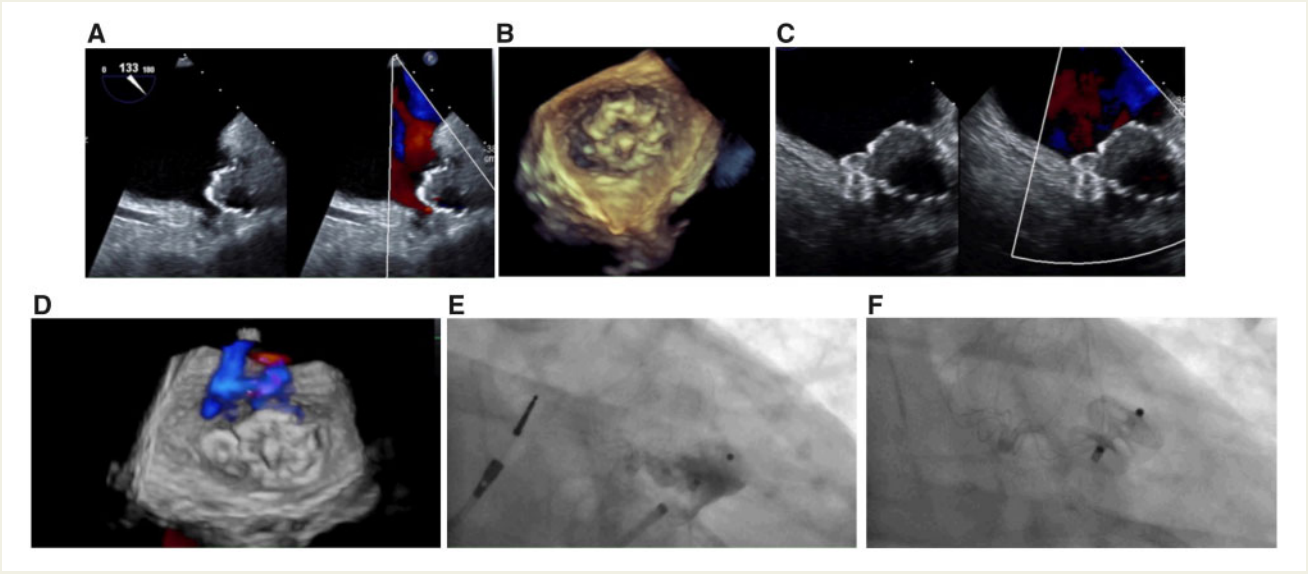

Figure 1 Transoesophageal echocardiogram and cine imaging before and after peri-Watchman leak closure. (*A* and *B*) Two- and three-dimensional transoesophageal echocardiogram images demonstrating large peri-device leak measuring 7 mm. (*C* and *D*) Two- and three-dimensional transoesophageal echocardiogram images following leak closure using 12 mm Amplatzer Vascular Plug II device. (*E*) Angiogram prior to Amplatzer Vascular Plug II device release showing no residual leak. (*F*) Amplatzer Vascular Plug II remains in stable position following device release.

32.1% of patients at 12-month TOE follow-up with no significant increase in the primary endpoints of stroke, systemic embolism, or cardiovascular or unexplained death compared to those with complete closure. Furthermore, there was no association between the severity of peri-device leaks and the primary endpoints. However, definite conclusions cannot be made as the number of patients with major leaks (>3 mm) who were not treated with anticoagulation was small.

In order to obviate the need for long-term anticoagulation and minimize the hypothetical risk of cardioembolic events with large peri-device leaks, percutaneous closure of these leaks has been attempted. The largest experience reported by Hornung *et al.* included 12 patients with large peri-device leaks (>3 mm) who underwent peri-device leak closure with high success rate (83% complete sealing) and low procedural risk, however, long-term follow-up data are lacking.

Due to continued remodelling of the LAA and the tissue around the device, the size of the leak may improve with time, therefore it is generally recommended to wait following the original LAAO procedure before proceeding with leak closure. Moreover, delaying the timing of leak closure procedure will allow time for endothelialization to provide more secure anchoring of the original device in the LAA and in turn reducing the risk of device embolization. Variety of devices can be used for closure based on the size and shape of the residual leak. Three-dimensional TOE is essential in delineating the defect and guiding proper device selection. For larger leaks or uncovered lobes, implantation of a second LAA closure device is feasible. For smaller defects, implantation of Amplatzer Vascular Plug II or III is preferred (AVP III not available in the USA). Oversizing of the plugs is recommended to ensure stability and complete closure of the defect.

Given the significantly elevated CHADS2-VASc score and hypothetical risk of complications from atrial fibrillation and intolerance to long-term anticoagulation, the benefits of pursuing LAAO outweighed the procedural risks after multidisciplinary discussion. The potential benefits were discussed thoroughly with the patient and family in addition to the feasibility of continued clinical monitoring given the limited number of cases and data regarding the utility of peri-device leak closure. The patient ultimately wished to proceed.

Conclusion

Catheter-based closure of residual leaks following LAAO is feasible and safe, nevertheless, experience remains limited. Long-term randomized studies are needed to determine whether leak closure will indeed reduce risk of thrombus formation or thromboembolic events.

Lead author biography

Dr Hussam S. Suradi is a Structural Cardiologist at Rush University Medical Center in Chicago, IL, USA. He is currently the Director of the Structural Hybrid Lab and Assistant Professor of Medicine and Pediatrics in the Division of Cardiovascular Medicine. He has numerous publications in Structural and Interventional Cardiology and has a keen interest in Adult Congenital Heart Disease and forthcoming structural interventions in the management of patients with all types of cardiovascular disease.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: none declared.

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