Delayed embolization of next-generation left atrial appendage closure device in an asymptomatic patient

Aditi Bhagat, MD, MPH,* Chad Gier, MD,* Paul Kim, MD,* Paul Diggs, MD,†
Erdal Gursoy, MD, PhD†

*From the *Division of Cardiology, Stony Brook University, Stony Brook, New York, and †Division of Cardiology, Northport VA Medical Center, Northport, New York.*

Introduction

Atrial fibrillation is a common cardiac arrhythmia that can lead to potentially adverse events, including ischemic stroke. For patients with nonvalvular atrial fibrillation who are not able to tolerate oral anticoagulation (OAC) for stroke prevention, the left atrial appendage closure (LAAC) device is an alternative method that shows noninferiority in comparison to OAC.[1] Though the first-generation WATCHMAN LAAC have very high technical success rates,[2,3] there was still room for device improvement to minimize complications, including pericardial effusion, device embolization, early or late peri-device leaks, and device-related thrombosis.[4] This led to the innovation of the WATCHMAN FLX (Boston Scientific, Marlborough, MA), which was designed to provide a simpler implantation method as well as increased compatibility with a wider range of anatomies. Herein, we describe the first known case, to our knowledge, of WATCHMAN FLX version 2 embolization found on routine follow-up transesophageal echocardiography (TEE).

KEY TEACHING POINTS

- Transesophageal echocardiography is the current modality of choice to determine adequate placement of the Watchman device (Boston Scientific).
- Embolization of the Watchman FLX can occur in asymptomatic patients.
- Routine transesophageal echocardiogram 45 days after implantation of the next-generation Watchman FLX is imperative to assess for embolization and other device complications.
- Further studies are needed to provide information regarding the safety and efficacy of the next-generation Watchman FLX.

Case report

A 73-year-old male patient with a history of paroxysmal atrial fibrillation (CHA_2DS_2-VASc score 5), 2 cerebrovascular accidents, and a history of an intracranial hemorrhage presented for implantation of the WATCHMAN FLX. He was referred for LAAC device owing to his history of a prior intracranial hemorrhage and was deemed a high-risk candidate for OAC. Baseline TEE left atrial appendage (LAA) diameters demonstrated no exclusionary criteria for device implantation. The patient was deemed to be euvolemic prior to TEE and LAAC implantation and hemodynamic monitoring during the case. Preprocedural TEE showed the LAA had a chicken wing shape and maximum LAA ostial width was measured at 21.3 mm at 135 degrees (measured from top of the mitral valve annulus to 2 cm from the tip of the limbus). A double-curve WATCHMAN access sheath was used. Following transseptal puncture, LAA dimensions were measured in orthogonal views with TEE (Figure 1A–1D). A 27-mm WATCHMAN FLX device was positioned. Only 1 device was used and there was 1 attempt and no recaptures made. Anchoring and seal criteria were confirmed with imaging, adequate tug test, and Doppler, which showed no peri-device leak (Figure 2A). Following release, the location was again verified by TEE (Figure 2B–2E). There were no immediate postoperative complications, and the patient was discharged home the following day.

His implantable loop recorder was interrogated 35 days after the WATCHMAN FLX implantation and did not show any atrial fibrillation or other significant arrhythmia. Follow-up transthoracic echocardiogram and TEE were also performed 35 days after implantation and illustrated that the LAAC device had migrated to the mitral valve and left ventricular outflow tract (Figure 3A and 3B). The patient was transferred to the hospital where the initial implantation was performed and underwent urgent surgical device retrieval with simultaneous LAA ligation.

KEYWORDS Atrial fibrillation; Left atrial appendage occlusion; Embolization; Transesophageal echocardiography
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Address reprint requests and correspondence: Dr Erdal Gursoy, Department of Medicine, Northport VA Medical Center, 79 Middleville Rd, Northport, NY 11768. E-mail address: Erdal.Gursoy@va.gov.

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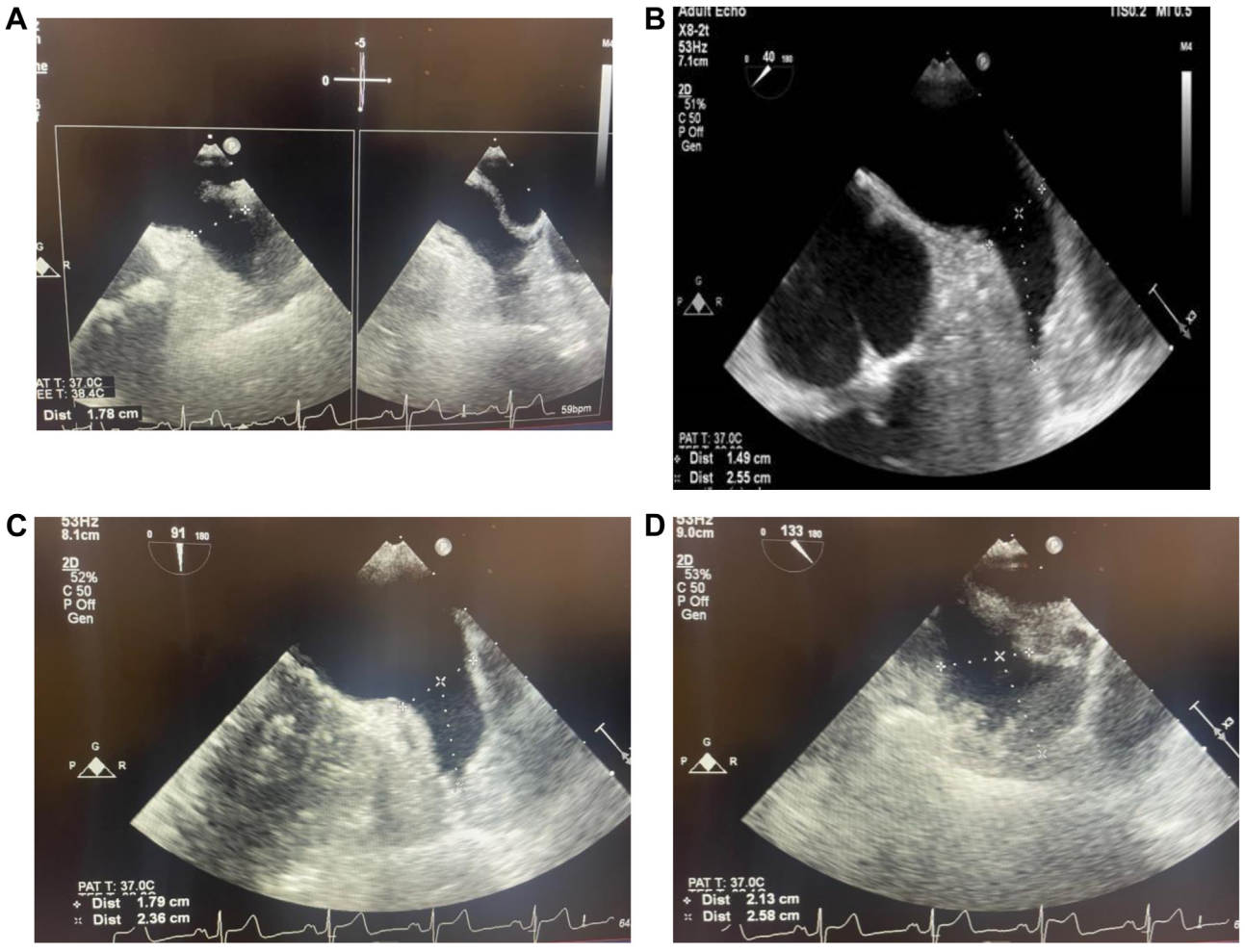

Figure 1 Immediate preimplantation transesophageal echocardiography views of left atrial appendage (LAA). **A:** View illustrates the width of the LAA at 0 degrees. **B:** View illustrates the length and width of the LAA at 40 degrees. **C:** View illustrates the length and width of the LAA at 90 degrees. **D:** View illustrates the length and width of the LAA at 135 degrees.

Discussion

The WATCHMAN FLX offers significant advancements in the design of the device compared to its predecessor, the WATCHMAN 2.5 (Boston Scientific). These include an increase in strut frame from 10 to 18, reduced device length, 2 rows of the J-shaped anchors, a closed distal end with fluoroscopic marker, and a more permeable polyester fabric that extends down to the distal row of the anchors.[5] The intention of these changes was to decrease complications that were seen with the first-generation WATCHMAN 2.5 device, including device embolization. The first version of the WATCHMAN FLX device was retracted from the market owing to a high number of device embolization complications.[6] However, the FLX version 2 device was approved by the U.S. Food and Drug Administration on July 21, 2020, based on the data from the randomized controlled PINNACLE FLX trial (The Protection Against Embolism for Non-valvular AF Subjects: Investigational Evaluation of the WATCHMAN FLX™ LAA Closure Technology). PINNACLE FLX had a low rate of major procedure-related safety events (0.5% at 7 days postprocedure) and a high rate of effective LAAC (100% with peri-device flow <5 mm at 45 days and 1 year postprocedure), in addition to a high implant success rate (98.8%).[7] No device embolization events were observed during the trial. Several other small studies have evaluated the WATCHMAN FLX device, 1 of which uses intracardiac echocardiography for implantation. No complications related to device embolization were reported in these studies.[6,8]

A thorough evaluation of the LAA size and shape is critical in selecting the appropriate device size for implantation. Prior to WATCHMAN implantation, a TEE evaluating LAA size/shape, number/location of lobes, and measurements of the LAA ostium and length (recorded through multiple imaging planes) should be performed. LAA thrombus should also be ruled out. Selecting the proper WATCHMAN device size

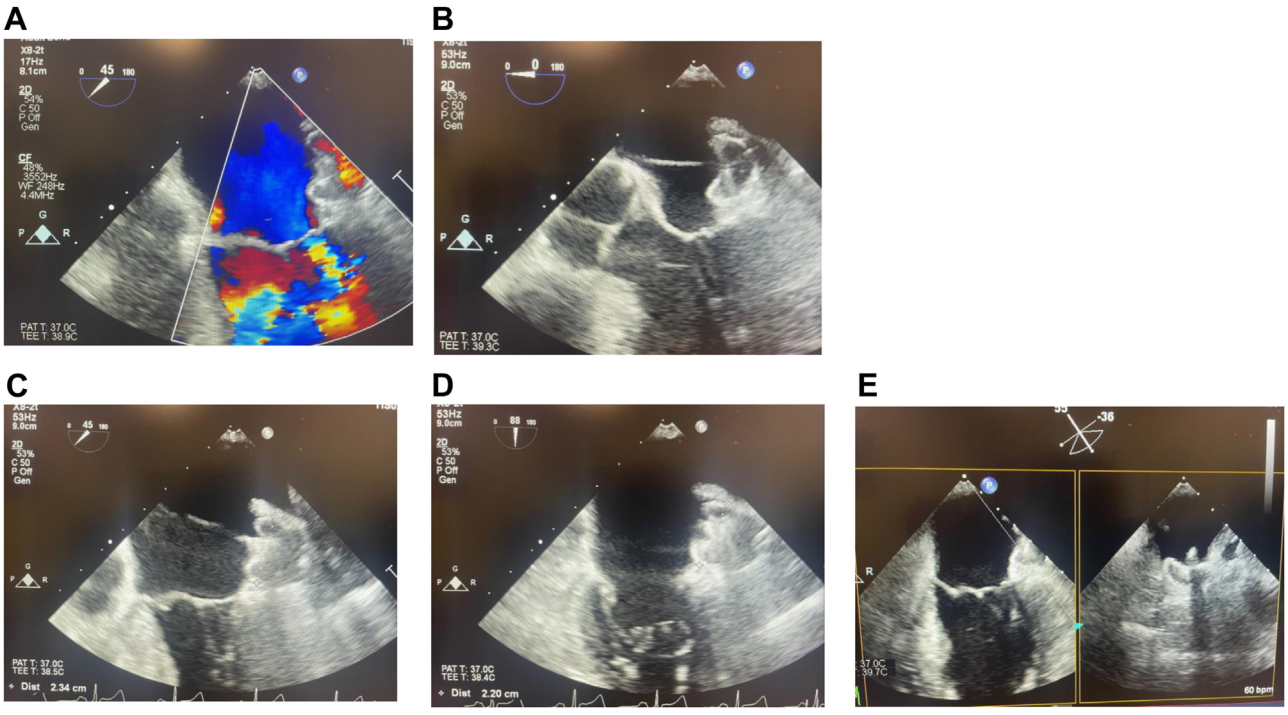

Figure 2 Immediate postimplantation views of the Watchman FLX version 2 device (Boston Scientific). **A:** Immediately postimplantation of Watchman device shows no peri-device leak at 45 degrees. **B:** View illustrates the width of the left atrial appendage (LAA) at 0 degrees. **C:** View illustrates the length and width of the LAA at 40 degrees. **D:** View illustrates the length and width of the LAA at 90 degrees. **D:** View illustrates the length and width of the LAA at 135 degrees.

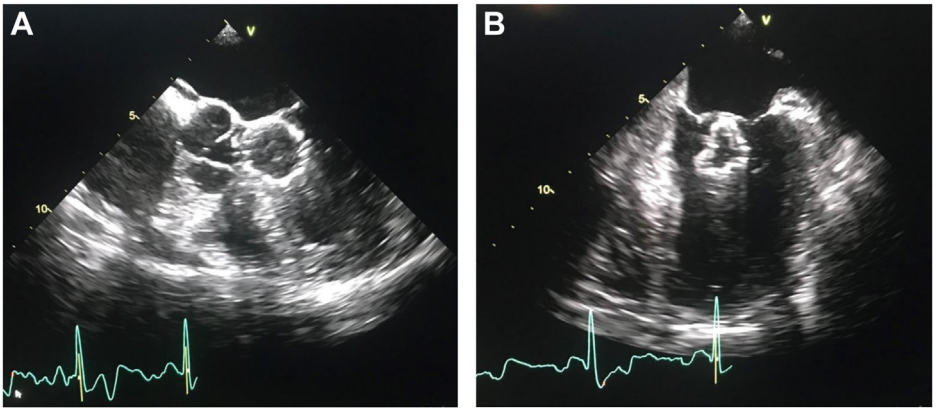

Figure 3 Follow-up transesophageal echocardiogram 35 days after the Watchman FLX version 2 device (Boston Scientific) is implanted. Images illustrate the device position at the left ventricular outflow tract and mitral valve.

is dependent upon the measurements of the maximum LAA ostium taken during preprocedural TEE.

Device embolization risk depends on operator experience, the choice of device size, and the final position. Patient-related characteristics such as LAA morphology and length, ostium size, or unusual morphologies are also important criteria.[9] Intraprocedurally, all 4 PASS criteria must be met prior to device release. The PASS criteria include position (device at the ostium of the LAA), anchor (device is stable and fixation anchors engaged), size (device is compressed to 10%–30% for FLX devices and 8%–20% of original size for 2.5 devices), and seal (device spans ostium and covers all lobes of the LAA). Once all 4 PASS criteria are met, the device can be deployed. TEE images should also be obtained postdeployment to check device position, compression, and LAA sealing. Possible mechanisms of device migration include inappropriately sized device, atrial contractility, and conversion from sinus rhythm to atrial fibrillation (and vice versa). The patient in this case report presented for evaluation after the device placement, so not all preprocedural and intraprocedural information was available for our review, and therefore it was challenging to comprehensively evaluate

the potential causes of device embolization. Notably, our patient had an implantable cardiac monitor that did not show any atrial fibrillation for the 35 days after the procedure until the device migration was seen.

As illustrated with this patient, it is important to perform routine postprocedural TEE to survey for complications in asymptomatic patients. Routine postprocedural electrocardiogram (ECG) and chest radiograph prior to discharge should also be done. ECG is strongly recommended to be routinely performed before discharge, as changes can reveal possible migration. This was reported by Pérez Matos and colleagues,[10] who describe the case of post–Watchman implant routine ECG that showed intermittent left bundle branch block, which triggered performing transthoracic echocardiogram and TEE to eventually find device migration to the left ventricular outflow tract. Device embolization requires immediate intervention to retrieve the device. Percutaneous retrieval of the device is most feasible when the device migrates to the left atrium and aorta, but embolization to the left ventricle usually requires surgical intervention.[11]

Conclusion

This is the first case documented in the literature of embolization of the next-generation WATCHMAN FLX. Although a rare complication, device embolization should be considered in asymptomatic patients. Currently, the PINNACLE FLX is the only study to date that has assessed the WATCHMAN FLX device. The anticipated CHAMPION-AF trial, a randomized prospective multicenter trial, will provide further information to compare the safety and efficacy of the WATCHMAN FLX device to OAC for stroke prevention in patients with nonvalvular atrial fibrillation.

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