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Reoccurrence of Stroke in a Patient With Peri-Device Leak of WATCHMAN Device

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Abstract

Atrial fibrillation is the leading cause of cardioembolic stroke, with emboli most commonly originating from the left atrial appendage. We report the case of a 71-year-old male with left atrial appendage closure via implantation of the WATCHMAN device, due to possible anticoagulation therapy failure and increased bleeding risk, following a stroke. Following a new stroke over a year later, a 1.8-mm peri-device leak was observed. Surgical records noted a minimal (<5 mm jet flow) peri-device leak after the installation, which was considered successful WATCHMAN implantation per protocol. This case highlights the persistent risk of cardioembolic stroke in patients with nonvalvular atrial fibrillation despite device implantation and questions the significance of peri-device leak and further management with anticoagulation for recurrent stroke.

Keywords

atrial fibrillation, peri-device leak, stroke, WATCHMAN

Introduction

Atrial fibrillation puts affected individuals at an increased risk of stroke due to the propensity for clot formation. Specifically, in patients with nonvalvular atrial fibrillation (NVAF), the majority of clots are formed within the left atrial appendage (LAA) due to a combination of fibrosis, inflammation, and blood flow stasis. Additional studies have shown that the specific morphology of the LAA may also affect the chance of clot formation.[1] Consequently, obliteration or occlusion of LAA in NVAF is considered an effective measure for stroke prevention. This nonpharmacological measure is only considered for the patients not suitable for oral anticoagulation. In this case, we present a patient with an LAA occlusion device (WATCHMAN) with a 1.8-mm peri-device leak (PDL) seen 17 months postimplantation for a stroke of suspected thromboembolic origin. A waiver of informed consent was granted by the institutional review board.

Case Presentation

Initially, a 71-year-old right-handed male with a history of NVAF presented with confusion without lateralizing neurological deficits. The patient was compliant on his apixaban, metoprolol, and amiodarone for NVAF. His CHA2DS2-VASc score was 4 (prior stroke, hypertension, age). Brain magnetic resonance imaging showed a left frontal lobe stroke. Computed tomography angiography of head and neck vessels showed patent anterior and posterior circulation without calcification, fibromuscular dysplasia, soft plaques, or stenosis.

Transesophageal echocardiogram (TEE) showed moderate-to-severe left atrial enlargement, and minimal patent foramen ovale (PFO). Doppler ultrasound of the lower extremity was negative for deep vein thrombosis. Blood test showed low-density lipoprotein cholesterol of 61 mg/dL and a hemoglobin A1C of 5.2%. The location of stroke was cortical, and based on the above findings the etiology was suspected to be cardioembolic. His HAS-BLED score was 3 (prior stroke, age, and antiplatelet therapy). Secondary to the high risk of bleeding on anticoagulation, a left atrial appendage occlusive device (WATCHMAN) was implanted, and per protocol, warfarin and aspirin was continued for initial 45 days postimplantation. Repeat TEE after 45 days showed intact device with 3-mm PDL and no thrombus. Thereafter,

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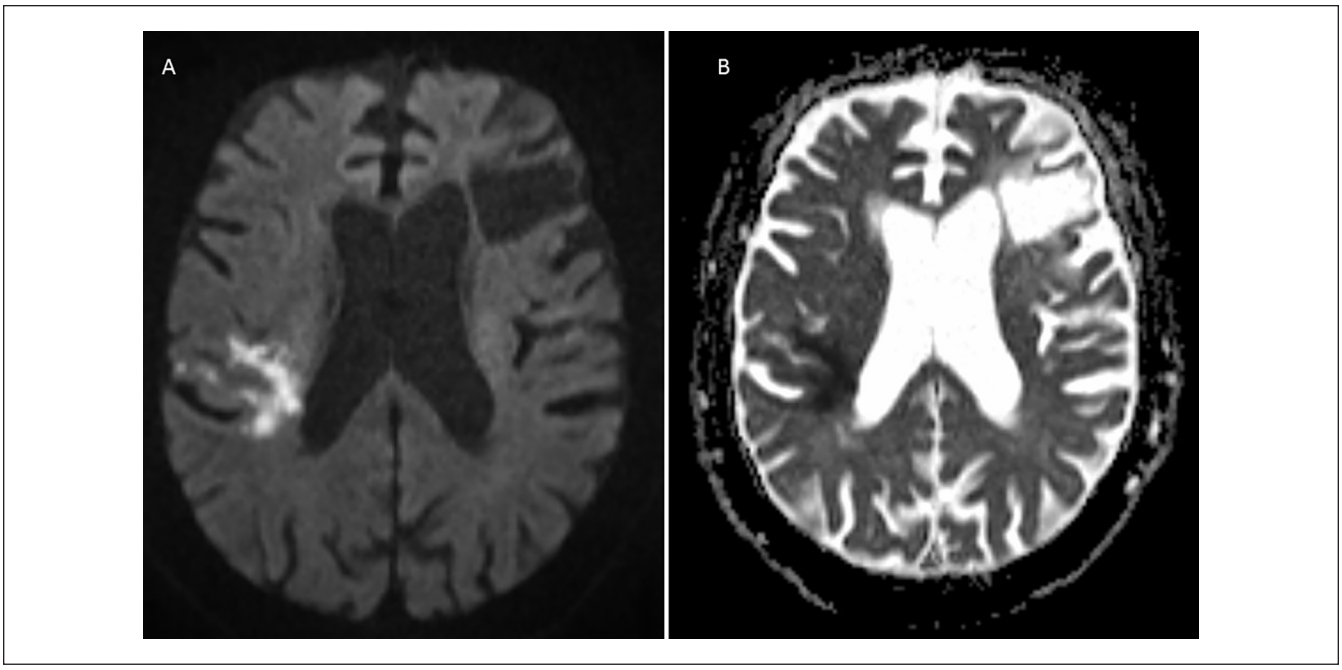

Figure 1. Magnetic resonance imaging of brain, diffusion-weighted imaging (A) and apparent diffusion coefficient (B), shows multiple areas of diffusion restriction involving posterior superior right middle cerebral artery territory.

dual antiplatelet therapy was continued without anticoagulation therapy.

Seventeen months later, despite compliance with medication, the patient was readmitted after experiencing left upper extremity numbness without weakness. Brain magnetic resonance imaging showed embolic appearing cortical stroke confined in the posterior superior right middle cerebral artery territory (Figure 1). Repeat computed tomography angiography of the head and neck vessels showed no significant change compared with the previous imaging. Hypercoagulability panel that included antiphospholipid antibodies, lipoprotein(a), factor V Leiden, prothrombin G20210A, protein C/S, and antithrombin were negative. Aspirin and clopidogrel response test showed adequate platelet inhibition. The patient's cardiac rate and rhythm were well controlled, and no evidence of atrial fibrillation was found during inpatient stay. Repeat TEE showed an intact WATCHMAN device with 1.8-mm PDL, minimal PFO, and no thrombus (Figure 2). There was no blood flow stasis, no left ventricular dyskinesia, and ejection fraction was 60%. Computed tomography of chest and abdomen showed no mass lesions suggestive of tumor. Previous colonoscopy study, cancer screening test for his age group, was unremarkable. Due to the persistent risk of a cardioembolic stroke, he was treated with continuous heparin while hospitalized and discharged home on rivaroxaban 20 mg daily, aspirin 81 mg, and atorvastatin 80 mg.

Discussion

The WATCHMAN device (Boston Scientific) is the only US Food and Drug Administration–approved LAA closure device in patients with NVAF where warfarin therapy is indicated based on CHADS2 or CHA2DS2-VASc scores, but are not suitable for such therapy secondary to varying degrees of bleeding risk, poor compliance, intolerance, and high fall risk.[2] The contraindications for implanting a WATCHMAN device are visualized intracardiac thrombus, high-risk PFO, Class 4 heart failure, left ventricular ejection fraction $<30\%$, symptomatic coronary artery disease, LAA anatomy that is incompatible, any contraindications for percutaneous catheterization procedures, contraindications to the use of warfarin, aspirin, or clopidogrel, or if the patient has a known hypersensitivity to the device components.[3] The PROTECT AF and PREVAIL, noninferiority (NI) randomized control trials, were conducted for WATCHMAN device compared with warfarin treatment. Antithrombotic regimen postimplantation includes warfarin and aspirin for 45 days, followed by a regimen of aspirin and clopidogrel for 6 months, and finally, a transition to aspirin monotherapy lifelong.[4,5] PROTECT AF trial showed NI margins (NI: probability criterion $\geq 97.5\%$) to primary efficacy endpoint of composite (hemorrhagic and ischemic) stroke (NI $>99.9\%$), systemic embolism (SE), and cardiovascular event/unexplained death (NI $>99.9\%$). However, it did not demonstrate NI to ischemic stroke alone (NI $= 71.8\%$).[5] The primary efficacy endpoint of PROTECT AF trial did not achieve NI in the PREVAIL trial (NI margin: upper boundary of 95% Color Rendering Index ≥ 1.75) but showed NI to warfarin for ischemic stroke prevention or SE >7 days' postprocedure.[4] At 5-year follow-up, the differences in hemorrhagic stroke, disabling/fatal stroke, cardiovascular/unexplained death, all-cause death, and postprocedure

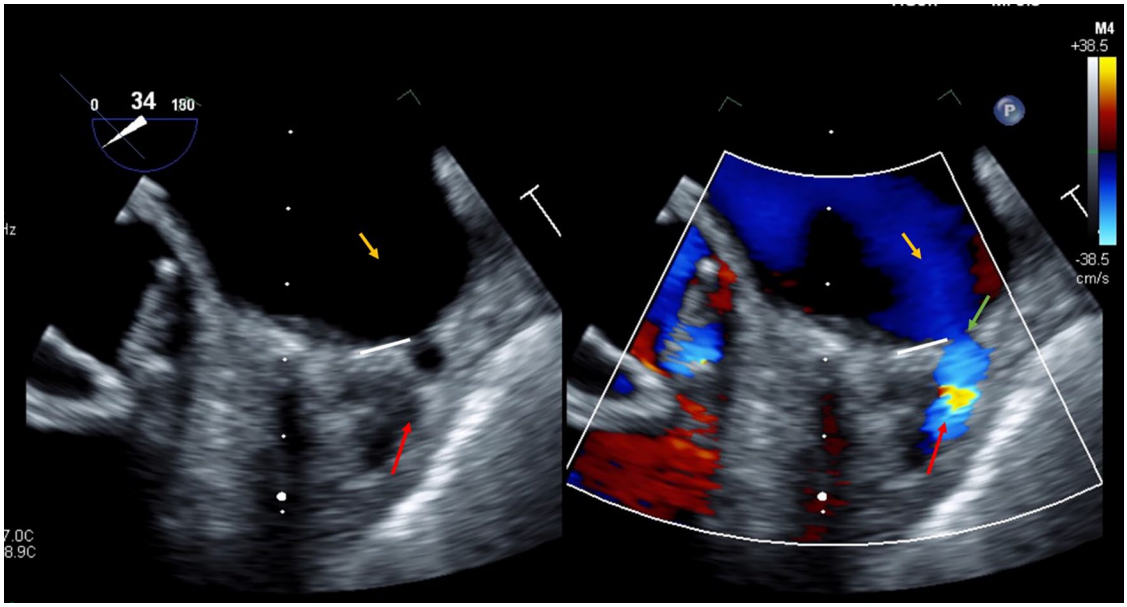

Figure 2. Transesophageal echocardiogram shows left atrium (yellow arrow), left atrial appendage (red arrow), intact WATCHMAN device (white line), and peri-device leak (green arrow).

bleeding favored WATCHMAN device compared with warfarin therapy.[6]

So far, the incidence of WATCHMAN device failure leading to a stroke is rare.[7] There are low rates of device-related thrombus,[8,9] intradevice leak,[10] device dislocation to the aortic arch causing acute heart failure,[11] and LAA perforation.[12] In PROTECTAF and PREVAIL trials, PDL with jet width <5 mm (single lobe) was seen up to 32% and 10%, respectively, after 1-year postimplantation of the device.[4,5] Neither study classified these leaks as clinically worrisome and considered these as successful implantation.

This case highlights the persistent risk of cardioembolic stroke in NVAF despite successful WATCHMAN implantation. One of the landmark clinical trial for WATCHMAN device (PREVAIL) had failed to show noninferiority to prevent ischemic stroke. It is possible in NVAF, clots could still originate from the left atrial cavity.[13] Several other mechanisms that could create a thromboembolism, including blood flow stasis, left ventricular dyskinesia, hypercoagulable state, and ulcerated atherosclerotic plaques, should be considered. In the absence of such mechanisms, a PDL could be the source of an embolic stroke considering the left atrial appendage is the primary source of clot formation.[14] Knowledge gap exists regarding stroke with PDL and treatment strategy for recurrent strokes with WATCHMAN device. The clinical significance of PDL regarding various LAA morphologies, accurate assessment of uncovered lobes, accurate LAA sizing, ideal antithrombotic therapy, ideal patient selection, and management of recurrent stroke with LAA occlusive device warrants further studies.

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Declaration of Conflicting Interests

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Ethics Approval

Our institution does not require ethical approval for reporting individual cases or case series.

Informed Consent

Informed consent for patient information to be published in this article was not obtained because a waiver was obtained by the institutional review board.

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