Device-Related Thrombus: A Reason for Concern?

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INTRODUCTION

In 2010, atrial fibrillation (AF) affected approximately 5 million individuals in the United States and 33.5 million worldwide. It is estimated that nearly 12 million will be affected by year 2030 in the United States alone. Among the many adverse events of AF, stroke is the most devastating and is 4- to 5-fold more common in patients with AF compared to the general population. Because this risk varies among patients, the American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS) guidelines recommend using the CHA2DS2-VASc score as a risk assessment tool. Patients with a score of zero have a risk of only 0.2%, whereas a score of 9 confers a 12.2% risk. Thus, the guidelines recommend using anticoagulation in all patients with scores ≥ 2. However, anticoagulation may lead to major bleeding in up to 5% of patients on warfarin and in 2.1% to 3.6% of those on novel oral anticoagulants (NOACs). Risk models such as HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile International Normalized Ratio, Elderly, Drugs/Alcohol), ATRIA (Anticoagulation and Risk Factors in Atrial Fibrillation), and HEMORR2HAGES (Hepatic or Renal Disease, Ethanol Abuse, Malignancy, Older Age, Reduced Platelet Count or Function, Re-Bleeding, Hypertension, Anemia, Genetic Factors, Excessive Fall Risk and Stroke) were developed to identify patients at increased risk for bleeding. However, many of the clinical factors that contribute to increased stroke risk are associated with bleeding as well.

To mitigate the risk of stroke and bleeding, several left atrial appendage (LAA) occlusion devices have been introduced. These devices isolate the LAA from the left atrium, which is the source of up to 90% of nonvalvular AF-associated emboli. The WATCHMAN Left Atrial Appendage Closure Device (Boston Scientific) is the only device approved by the U.S. Food and Drug Administration for stroke prevention. It is associated with lower rates of hemorrhagic stroke and bleeding and similar rates of all-cause stroke and systemic embolism when compared with warfarin. On the other hand, the device has its own unique set of complications, including but not limited to peridevice leak, device migration, and device-related thrombus. Although a rare entity, device-related thrombus may have a significant impact on patient treatment and outcomes.

In this article, we present a case of device-related thrombus and review the available literature on its incidence, risk stratification, and management.

CASE PRESENTATION

A 76-year-old male with a history of permanent atrial fibrillation underwent a WATCHMAN device implantation due to increased risk of thromboembolism (CHA2DS2-VASc score of 3) and recurrent hematuria. The procedure was successful, and the patient was then placed on apixaban. A surveillance transesophageal echocardiogram (TEE) was performed 45 days post implant and showed a well-seated device without evidence of peridevice leak. At this point, the patient was switched to dual antiplatelet therapy (DAPT) with aspirin and clopidogrel. Four months post implant, the patient presented with loss of peripheral vision in the left eye. On examination, his blood pressure was 148/63 mm Hg and his pulse was 73 bpm. Physical exam was significant for left homonymous hemianopia and irregularly irregular heart rhythm. Magnetic resonance imaging of the brain showed a subacute ischemic stroke with hemorrhagic conversion in the right posterior cerebral artery territory.

Due to the rarity of stroke after WATCHMAN device implantation, a workup was initiated to identify the embolic source. A transthoracic echocardiogram revealed normal left and right ventricular systolic function with no hemodynamically significant valvular disease or identifiable source of embolism. Therefore, a TEE was performed, showing a 1 × 1 cm mass on the WATCHMAN device consistent with a device-related thrombus (Figure 1, arrows). Mild (< 5 mm) peridevice leak was seen anteriorly. After 48 hours, the patient was started on heparin and transitioned to enoxaparin after 48 hours as a bridge to warfarin; however, he developed a headache on day 7. A repeat brain computed tomography showed worsening intracranial hemorrhage with extension into the ventricles, necessitating discontinuation of all anticoagulants. Over the next 3 days, the patient remained clinically stable and the intracranial hemorrhage remained unchanged. The patient was initiated on DAPT with aspirin and clopidogrel. He had
no further changes in his clinical status and was subsequently discharged.

DISCUSSION

The incidence of device-related thrombus (DRT) from WATCHMAN implantation ranges from 3.7% to 6.6%. While most cases occur in the first year after implantation, it may occur up to 10 years post implant. DRT is often asymptomatic and diagnosed on surveillance TEE. In fact, the annual stroke rate due to DRT is only 0.3% per 100 patient years according to data from the PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic PROTECtion in Patients With Atrial Fibrillation) clinical trial and Continued Access Registry. Furthermore, while the annual risk of stroke was 1.1% in the EWOLUTION (Registry on WATCHMAN Outcomes in Real-Life
Utilization) trial, there was only one case of DRT identified in these patients.

Several risk factors were identified as predictors of developing DRT, such as antiplatelet/anticoagulation regimen, device size, and atrial fibrillation burden.\textsuperscript{16} Although most cases of DRT in the PROTECT AF trial occurred in patients receiving DAPT, more recent studies failed to demonstrate association with drug regimen post implant.\textsuperscript{19,20} However, early discontinuation of anticoagulation or antiplatelet therapy seems to play a role in the development of DRT.\textsuperscript{18} It has been reported that lack of endothelialization of the device might occur up to 13 months post implant, but this was not associated with DRT.\textsuperscript{21}

DRT is typically managed by restarting or prolonging anticoagulation, and the outcomes are usually favorable. In the EWOLUTION trial, thrombus resolution was noted in all patients who had a follow-up TEE regardless of whether their medications were adjusted based on the TEE findings.\textsuperscript{19}

CONCLUSION

The data available thus far indicate that the rate of DRT and DRT-related stroke is small. However, it is important to identify as it may have an impact on the duration of anticoagulant or antiplatelet therapy. Although several risk factors have been identified to predict development of DRT, it is unclear which patients are at increased risk for embolization. At this time, it might be reasonable to prolong anticoagulation in high-risk patients for 3 months after their surveillance TEE and ensure that all patients are eventually transitioned to lifelong mono antiplatelet therapy when there is no evidence of DRT or peridevice leak.

Conflict of Interest Disclosure:
The authors have completed and submitted the Methodist DeBakey Cardiovascular Journal Conflict of Interest Statement and none were reported.

Keywords:
atrial fibrillation, device-related thrombus, WATCHMAN

REFERENCES


