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Incidence, Characteristics, and Clinical Course of Device-Related Thrombus After Watchman Left Atrial Appendage Occlusion Device Implantation in Atrial Fibrillation Patients

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ABSTRACT

OBJECTIVES This study investigated characteristics and clinical impact of device-related thrombus formation after Watchman device implantation in atrial fibrillation (AF) patients.

BACKGROUND Left atrial appendage occlusion using the Watchman device is an effective alternative to anticoagulation for stroke prevention in AF patients. However, device-related thrombus formation remains an important concern after Watchman implantation.

METHODS From 2006 to 2014, 119 consecutive AF patients underwent Watchman implantation. Transesophageal echocardiographic (TEE) follow-up was scheduled at 45 days, at 6 months, and at 12 months after the procedure. The incidence, characteristics, and clinical course of device-related thrombus formation detected by TEE were assessed.

RESULTS Follow-up TEE identified thrombus formation on the Watchman device in 4 patients (3.4%). The prevalence of chronic AF was 100% in patients with thrombus, which was higher than that for patients without thrombus (40.0%). Deployed device size was numerically larger in patients with thrombus (29.3 ± 3.8 mm vs. 25.7 ± 3.2 mm, respectively). All patients with thrombus discontinued any of the anticoagulant/antiplatelet therapy which was required under the study protocol. After restarting or continuing warfarin and aspirin therapy, complete resolution of the thrombus was achieved in all patients at subsequent follow-up TEE. Warfarin therapy was discontinued within 6 months for all cases, and there was no thrombus recurrence. The mean follow-up duration was 1,456 ± 546 days, with no death, stroke, or systemic embolization events in patients with thrombus.

CONCLUSIONS AF burden, device size, and anticoagulant/antiplatelet regimens can be associated with device-related thrombus after Watchman device implantation. Short-term warfarin therapy was effective, and the clinical outcomes were favorable. (J Am Coll Cardiol EP 2017;■:■–■) © 2017 by the American College of Cardiology Foundation. Published by Elsevier. All rights reserved.

Embolic stroke is a serious and often debilitating complication of atrial fibrillation (AF). Oral anticoagulation using warfarin therapy has long been the gold standard for the prevention of embolic stroke (1). The left atrial appendage (LAA) is the primary source (>90%) of thromboembolism in nonvalvular AF (2,3). Percutaneous occlusion of the LAA has emerged as a device-based treatment alternative to long-term anticoagulation therapy in the prevention of AF-associated stroke. The PROTECT-AF

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

LAA = left atrial appendage

SEC = spontaneous echocardiographic contrast

TEE = transesophageal echocardiography

(Watchman Left Atrial Appendage System for Embolic Protection in Patients With AF) trial demonstrated the efficacy of the Watchman device (Boston Scientific, Marlborough, Massachusetts) to prevent stroke, systemic embolism, and cardiovascular death, compared to warfarin therapy (4,5). In the United States, the Watchman device is the only LAA occlusion device approved by the U.S. Food and Drug Administration.

Residual peri-device leakage and unexpected device-related thrombus after implantation of the Watchman device are important clinical concerns. A previous study reported that residual leakage was not associated with risk for thromboembolism (6). There have been some reports of device-related thrombus formation associated with the Watchman device (7–9); however, patient characteristics and clinical implications of the device-related thrombus are still unknown. In this study, the incidence, characteristics, and clinical courses of left atrial thrombus associated with the Watchman device were investigated.

METHODS

STUDY POPULATION. This study population included 119 consecutive AF patients who underwent Watchman implantation from June 2006 to March 2014 at our institution. All patients received the Watchman device as participants in the PROTECT-AF clinical trial (n = 10), the CAP (Continued Access Protocol) registry (n = 61), the PREVAIL (Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy) clinical trial (n = 22), or the CAP 2 Registry (n = 26). Inclusion and exclusion criteria of the PROTECT AF and PREVAIL trials have been described previously (4,10). The Watchman device was successfully deployed in all patients. All data for this study were collected from an established interventional cardiology laboratory database approved by the Cedars-Sinai Medical Center Institutional Review Board.

ECHOCARDIOGRAPHIC ANALYSIS. Transthoracic and transesophageal echocardiography (TEE) was performed prior to Watchman device implantation to calculate left ventricular ejection fraction and exclude patients with intracardiac thrombus. Baseline LAA flow velocity was measured, and spontaneous echocardiographic contrast (SEC) was graded by a score of 0+ (none) to 3+ (severe) (11). The severity of mitral regurgitation was also evaluated according to previous reports (12).

WATCHMAN DEVICE IMPLANTATION. The Watchman device implantation was performed as previously described (4). The procedure was performed with the patient under general anesthesia. Intravenous heparin was given as a bolus dose to achieve an activated clotting time of >250 s in all patients. The TEE and an LAA angiogram were used to determine optimal device size (there are 5 sizes ranging from 21 to 33 mm in maximum diameter). All patients were placed on warfarin (international normalized ratio: 2 to 3) and aspirin (81 to 325 mg daily) therapy and discharged the next day.

FOLLOW-UP PROTOCOL. After the procedure, clinical and TEE follow-up were scheduled at 45 days, at 6 months, and at 12 months during the first year, as dictated by the trial protocol (5). In patients within the CAP or CAP-2 registry, follow-up TEE at 6 months was not planned. Thrombus formation and residual leakage into the LAA were evaluated during each follow-up TEE. Device-related thrombus was defined as thrombus formation attached to the Watchman device.

Warfarin therapy was discontinued if the TEE at 45 days showed complete closure of the LAA, no residual peri-device flow (jet >5 mm in width), or no device-related thrombus. After warfarin treatment was stopped, aspirin therapy was continued and daily clopidogrel (75 mg) was started until the 6-month follow-up was completed. After that point, only aspirin therapy was continued indefinitely. Patients who deviated from the above-described prescribed anticoagulation and antiplatelet regimen were defined as off-protocol patients. When the device-related thrombus is detected, warfarin and aspirin therapy is maintained, and follow-up TEE is scheduled for 3 or 6 months after the detection of thrombus. After the first year, clinical follow-up was scheduled semiannually by clinic visit or telephone interview. Clinical events included death, stroke, and systemic embolism.

STATISTICAL ANALYSIS. Data are mean ± SD for continuous variables. Categorical variables are numbers with relative percentages. The SPSS statistical software version 20 (IBM Corp., Armonk, New York) was used for all statistical calculations.

RESULTS

Follow-up TEE was performed in 117 patients (98.3%) at 45 days, 66 patients (55.4%) at 6 months, and 101 patients (84.9%) at 12 months. Follow-up TEE identified thrombus attached to the Watchman device (device-related thrombus) in 4 patients (3.4%),