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Device-Related Thrombosis After Percutaneous Left Atrial Appendage Occlusion for Atrial Fibrillation

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ABSTRACT

BACKGROUND Transcatheter left atrial appendage (LAA) occlusion is an alternative strategy for stroke prevention in patients with atrial fibrillation (AF).

OBJECTIVES This study sought to determine the incidence, predictors, and prognosis of thrombus formation on devices in patients with AF who were treated with LAA closure.

METHODS The study retrospectively analyzed data from patients treated with 2 LAA closure devices seen in 8 centers in France from February 2012 to January 2017.

RESULTS A total of 469 consecutive patients with AF underwent LAA closure (272 Watchman devices [Atritech, Boston Scientific, Natick, Massachusetts] and 197 Amplatzer devices [St. Jude Medical, Minneapolis, Minnesota]). Mean follow-up was 13 ± 13 months, during which 339 (72.3%) patients underwent LAA imaging at least once. There were 98 major adverse events (26 thrombi on devices, 19 ischemic strokes, 2 transient ischemic attacks, 18 major hemorrhages, 33 deaths) recorded in 89 patients. The incidence of device-related thrombus in patients with LAA imaging was 7.2% per year. Older age (hazard ratio [HR]: 1.07 per 1-year increase; 95% confidence interval [CI]: 1.01 to 1.14; p = 0.02) and history of stroke (HR: 3.68; 95% CI: 1.17 to 11.62; p = 0.03) were predictors of thrombus formation on the devices, whereas dual antiplatelet therapy (HR: 0.10; 95% CI: 0.01 to 0.76; p = 0.03) and oral anticoagulation at discharge (HR: 0.26; 95% CI: 0.09 to 0.77; p = 0.02) were protective factors. Thrombus on the device (HR: 4.39; 95% CI: 1.05 to 18.43; p = 0.04) and vascular disease (HR: 5.03; 95% CI: 1.39 to 18.23; p = 0.01) were independent predictors of ischemic strokes and transient ischemic attacks during follow-up.

CONCLUSIONS Thrombus formation on the device is not uncommon in patients with AF who are treated by LAA closure. Such events are strongly associated with a higher risk of ischemic stroke during follow-up. (REgistry on Real-Life EXperience With Left Atrial Appendage Occlusion [RELEXAO]; NCT03279406) (J Am Coll Cardiol 2018;71:1528–36)

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Percutaneous left atrial appendage (LAA) occlusion is an alternative to lifelong oral anticoagulation (OAC) for stroke prevention in patients with nonvalvular atrial fibrillation (AF) and with contraindications to OAC (1). The 2 most commonly used LAA closure systems are the Watchman nitinol cage device (Atritech, Boston Scientific, Natick, Massachusetts) and the Amplatzer LAA occluder device (St. Jude Medical, Minneapolis, Minnesota), which consists of a nitinol cylinder connected to a disk to form a nitinol plug. The main evidence supporting the noninferiority of LAA occlusion versus warfarin comes from the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) (2,3) and PREVAIL (Watchman LAA Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy) (4) randomized trials using the nitinol cage device. The safety and feasibility of its use were assessed in the CAP (Continued Access to PROTECT AF) (5) and EWOLUTION (Registry on WATCHMAN Outcomes in Real-Life Utilization; NCT01972282) registries (6). Data from large observational studies also support the safety, efficacy, and feasibility of LAA occlusion with the nitinol plug device (7–11).

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Thrombus formation on the device is a possible finding during follow-up after LAA closure. Most studies report an incidence of device-associated thrombus close to 3% to 6%, although a higher rate was reported in a small study (12). The clinical significance of thrombus formation on the device is poorly known, and whether it is associated with more frequent occurrence of ischemic strokes is debated (10,13,14). Moreover, consensus on appropriate antithrombotic regimens after LAA closure remains an issue. The aim of this study was to evaluate, in daily practice, clinical outcomes in patients using the 2 main LAA closure systems, differences in antithrombotic management at discharge from hospital, and the incidence, predictors, and prognosis of thrombus formation on the device after LAA occlusion.

METHODS

STUDY DESIGN AND STUDY GROUP. In this retrospective cohort study, we centralized and analyzed data from all patients with AF who were treated with LAA closure in 8 French cardiology departments from February 2012 to January 2017. These centers acquired their data prospectively and then agreed to contribute to this pooled analysis. Subjects eligible for LAA closure, according to appropriate local and European guidelines (1,15), were recruited from the general population in each institution, with a multidisciplinary decision taken in all centers. All physicians who performed device insertion procedures attended a thorough training and certification program to ensure an appropriate level of expertise and to minimize risk to patients.

STUDY ASSESSMENTS AND OUTCOMES. Patient follow-up was conducted according to each institution's standard practice, and antithrombotic management was decided for each patient on an individual basis. A clinical visit between 1 and 3 months post-procedure and follow-up visits at 6, 12, and 24 months were generally performed. LAA imaging to detect thrombus on the device and peridevice leaks was performed by 2-dimensional transesophageal echocardiography (TEE) or a computed tomography (CT) scan done between 1 and 3 months after LAA closure, and then generally at 12 months, following a consensus proposed by the French Society of Cardiology (15). A committee of 3 investigators (B.P., P.D., J.C.D.) evaluated all TEE and CT scans in which a thrombus was identified, and consensus for diagnosis was obtained in case of disagreement.

Reporting on adverse events in this study used as its basis the monitoring that was done until the end of the follow-up period. Death, cardiovascular death, ischemic stroke, and transient ischemic attack (TIA) definitions were established according to Valve Academic Research Consortium criteria (16). A Bleeding Academic Research Consortium type 3 or more hemorrhage was considered a major hemorrhage (17). A device-related thrombus was defined as the detection of a thrombus adherent to the luminal (left atrial) side of the device by TEE or CT scan. Major adverse events were defined as all-cause death, ischemic strokes or TIAs, major hemorrhages, and device-related thrombus occurring during follow-up.

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation
CT = computed tomography
DAPT = dual antiplatelet therapy
LAA = left atrial appendage
OAC = oral anticoagulation
TEE = transesophageal echography
TIA = transient ischemic attack

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