Postapproval Community Hospital Experience in the United States with Left Atrial Appendage Closure Device (Watchman)

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Background: To review the procedural safety and postimplantation complications of Watchman device implanted at 2 community hospitals for primary prevention of systemic embolization in patients with nonvalvular atrial fibrillation (NVAF) who were not candidates for long-term oral anticoagulation (OAC). *Methods:* This was a retrospective case series of 48 patients carried out in 2 community hospitals in the United States. Patients with NVAF who had a CHADS2 higher than 2 or CHADS2VASc2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack [TIA] or thromboembolism, vascular disease, age 65-74 years, and female gender) score of 3 or higher and were not candidates for long-term OAC. These patients were selected for implantation of Watchman device. They were followed up at 45 days, 6 months, 9 months, and 12 months after implantation of Watchman device to assess for complications involving the device and to determine if anticoagulation could be discontinued at the 45 days follow-up. They were monitored for any systemic thromboembolism while off anticoagulation. *Results:* The success rate of device implantation was 98% (48 of 49). Only a single patient could not get Watchman implantation because of unfavorable left atrial appendage anatomy. Access-related and device implantation-related complications were zero (0%). At 45 days follow-up and end of follow-up duration, the rate of thrombus formation on the Watchman device was 4% (2 of 48). One patient had TIA after warfarin discontinuation. *Conclusion:* With improved procedural technique and well-trained operators, Watchman implantation is feasible in a community hospital also. **Key Words:** Nonvalvular atrial fibrillation—left atrial appendage closure device—Watchman device—stroke prevention—community hospital.

Background

Atrial fibrillation (AF) is the most common cardiac arrhythmia with estimated number of individuals in 2010 being 33.5 million worldwide.[1] In the United States, the estimated prevalence of AF is about 3.03 million, with projected prevalence by 2050 to be around 7.56 million.[2] One of the most devastating complications of AF is stroke. AF increases the risk of stroke 5-fold; this risk is not homogeneous and changes cumulatively with the presence of stroke risk factors. In some patients, stroke can be the first manifestation of the AF. About 30% cryptogenic strokes have silent AF.[3]

Since 2010, 4 new medications have been approved by U.S. Food and Drug Administration (US-FDA) for stroke prevention in patients with nonvalvular AF (NVAF). These drugs are dabigatran, rivaroxaban, apixaban, and edoxaban. In spite of the significant advancement in the pharmacological therapy, around 32% of patients who have indications for anticoagulation therapy based on CHADS2 and CHA2DS2VASc (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack [TIA] or thromboembolism, vascular

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disease, age 65-74 years, and female gender) score do not receive anticoagulation.[4]

In March 2015, left atrial appendage closure (LAAC) device (Watchman, Boston Scientific Corporation Corporate Headquarters, One Boston Scientific Place, Natick, Massachusetts.) was approved by the US-FDA for stroke prevention in patients with NVAF as an alternative to oral anticoagulation (OAC) therapy.[5] LAAC device was approved for patients with CHADS2 higher than or equal to 2 or CHA2DS2VASc score of 3 or higher who are not eligible to take long-term OACs. Approval was based on the results of 2 trials: The PROTECT-AF (Watchman Left trial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) and PREVAIL (Prospective Randomized Evaluation of the Watchman LAA Closure Device in Patients with Atrial Fibrillation Versus Long Term Warfarin Therapy). PROTECT-AF trial demonstrated the noninferiority of Watchman device to warfarin for the primary composite endpoint of stroke, systemic embolism, or cardiovascular death,[6] whereas PREVAIL trial primarily addressed the safety of the device implantation.[7] After 3.8 years of follow-up of PROTECT-AF patients, percutaneous left atrial appendage (LAA) closure met criteria for both noninferiority and superiority for preventing the combined outcome of stroke, systemic embolism, and cardiovascular death, as well as superiority for cardiovascular mortality and all-cause mortality.[6] Recently, reports about implant success and safety of LAAC with Watchman device have been published to emphasize the reduction in periprocedural complications and greater net clinical benefit of this procedure. Most of these implantations have been performed in the larger centers in the United States and Europe.[8]

We report real-world postapproval experience with Watchman in 2 community hospitals in the United States. These procedures were performed by operators who were not involved in the Watchman clinical trials. This retrospective study highlights the feasibility of Watchman implantation even in community hospital settings.

Objective

The objective of this study was to review the procedural safety and postimplantation complications of LAAC device (Watchman) implanted at 2 community hospitals for primary prevention of systemic embolization in patients with NVAF who were not candidates for long-term OACs. We attempted to find the success rate of device implantation, procedure related complications, and complications during follow-up, warfarin discontinuation, and device leak at 45 days.

Methods

This was a retrospective case series of 48 patients carried out in 2 community hospitals in the United States. The subjects are patients with NVAF who had a CHADS2 higher than 2 or CHADS2VASc2 score of 3 or higher and were not candidates for long-term OAC. These patients were selected for implantation of Watchman device. As recommended by Centers for Medicare & Medicaid, approval by a physician not involved in the patient's direct care was sought for every patient selected for Watchman insertion. This case series included patients admitted between October 2015 and April 2017. Transesophageal echocardiogram was done as preprocedure imaging in all the patients within 3 weeks before Watchman insertion. All patients underwent Watchman implantation at 2 different community hospitals in Pennsylvania. Both the hospitals had 2 different teams but had the same primary operator. There was no prior experience in implantation of Watchman device except the standard extensive training received by the primary operator and ancillary staff. A cohort of 48 patients were followed-up at 45 days, 6 months, 9 months, and 12 months after implantation of Watchman device to assess for any complication involving the device and to determine OAC discontinuation at the 45-day follow-up. These patients were monitored for any systemic thromboembolism while off OAC. All the patients are enrolled in the long-term LAA occlusion registry. The 2 community hospitals have capacity of 196 and 151 beds, respectively. There is a multidisciplinary team including electrophysiologists, noninvasive cardiologists, cardiothoracic surgeons, and ancillary staff.

Device Specification/Implantation/Follow-Up

The Watchman device (Boston Scientific, Inc., Natick, MA) was implanted in a hybrid electrophysiology (EP) suite, which has a scope to be converted to an open operating room in case of an emergency. Immediate access to a cardiothoracic surgeon was available all times in case of any acute periprocedural complications. Watchman device is a self-expanding medical titanium device which is available in 5 different sizes to fit into various dimensions of LAA.[5] A permeable polyester fabric covers the left atrial surface and anchors fixated to the LAA minimizing the chances of embolization. As per the US-FDA recommendations, all 48 patients were started on aspirin 81 mg once daily and warfarin for first 45 days after procedure. TEE was performed at 45 days and warfarin was discontinued if there was less than 5-mm leak or no leak and if there was no evidence of clot on the device. Patients were treated with aspirin and clopidogrel 75 mg daily for 6 months, at which time clopidogrel was discontinued and aspirin was continued indefinitely. Every patient in the cohort was contacted at the end of follow-up period and seen in the office of the primary cardiologist.

Results

Between October 2015 and April 2017, a total of 48 (1 nonimplanted) patients (average age 79.60 years, range: