Left atrial appendage closure followed by 6 weeks of antithrombotic therapy: A prospective single-center experience

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BACKGROUND Currently, 2 different left atrial appendage (LAA) closure systems are available for stroke prevention in nonvalvular atrial fibrillation but comparative data are lacking.

OBJECTIVES To prospectively compare procedural data and patient outcome for 2 contemporary LAA closure systems and to investigate an alternative antithrombotic treatment regimen in high-risk patients.

METHODS Patients with nonvalvular atrial fibrillation, with high risk for stroke, and who either had contraindication or were not willing to accept oral anticoagulation were prospectively enrolled. Watchman (Boston Scientific, Natick, MA; group A) or Amplatzer Cardiac Plug (St Jude Medical, Minneapolis, MN; group B) devices were implanted. All patients received antithrombotic therapy for 6 weeks. After repeat transesophageal echocardiography, patients were switched to aspirin.

RESULTS Eighty patients were enrolled. There was no statistical difference in patient characteristics in groups A and B: CHA_2DS_2-VASC score: 4.1 ± 1.5 versus 4.5 ± 1.8; HASBLED score: 3.1 ± 1.1 versus 3.1 ± 1.1, respectively. LAA closure was achieved in 78 of 80 patients (98%) (group A: 38 of 40 [95%] vs group B: 40 of 40 [100%]). There was no difference in procedure time (group A: 48 ± 16 minutes vs group B: 47 ± 15 minutes; $P = .69$) and fluoroscopy time (group A: 6.0 ± 4.7 minutes vs group B: 7.3 ± 4.4 minutes; $P = .25$). Major complications included 1 air embolism and delayed tamponade in each group. After 6 weeks, 1 device dislodgment and 4 device-related thrombi were detected. Ninety-four percent of the patients (73 of 77) were switched to aspirin after 6 weeks. During a median follow-up of 364 days (Q1–Q3: 283–539 days), no systemic embolism occurred, but 3 patients died (heart failure: n = 2; bleeding: n = 1).

CONCLUSIONS Implantation of both LAA closure devices can be performed with high success rates in high-risk patients. Postprocedural 6 weeks antithrombotic therapy followed by aspirin therapy needs to be confirmed in a larger study.

KEYWORDS Left atrial appendage closure; Stroke; Atrial fibrillation

ABBREVIATIONS **ACP** = Amplatzer Cardiac Plug; **AF** = atrial fibrillation; **ASA** = aspirin; **DPI** = dual platelet inhibition; **LA** = left atrium/atrial; **LAA** = left atrial appendage; **NVAF** = nonvalvular atrial fibrillation; **OAC** = oral anticoagulation; **PROTECT-AF** = Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation; **TEE** = transesophageal echocardiography; **TIA** = transient ischemic attack; **VKA** = vitamin K antagonist

(Heart Rhythm 2013;10:1792–1799)

Introduction

Atrial fibrillation (AF) is the most prevalent arrhythmia associated with a 5-fold increased risk for stroke.[1] For many years, oral anticoagulation (OAC) using vitamin K antagonists (VKAs) has been the therapeutic cornerstone in stroke prevention for high-risk patients, which is nowadays defined by the $CHADS_2VA_2SC$ score.[2] However, in the real world, VKA therapy is often not tolerated, complicated by bleeding, and/or not administered for various reasons.[3] The therapeutic concept of left atrial appendage (LAA) occlusion is based on the observation that the vast majority of atrial thrombi originate from the LAA in patients with nonvalvular atrial fibrillation (NVAF).[4] Preventing blood flow into the LAA should avoid thrombus formation and hence reduce the risk of embolic stroke.[5,6] Importantly, in the updated 2012 AF guidelines, LAA occlusion has been introduced as a therapeutic concept in stroke prevention.[7] Currently, 2 different LAA occlusion devices are commercially available: Watchman (Boston Scientific, Natick, MA) and Amplatzer Cardiac Plug (ACP; St Jude Medical, Minneapolis, MN). Recently, the randomized Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation (PROTECT-AF) study confirmed the concept of sealing the LAA with the

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1547-5271/$-see front matter http://dx.doi.org/10.1016/j.hrthm.2013.08.025

Watchman device in non high-risk patients. However, in this study, all patients remained on OAC for at least 45 days and the acute implantation success rate was only approximately 90%: the implantation of the Watchman device was associated with substantial complications often linked to complex LAA anatomy.[6] Moreover, it remains unknown whether beneficial clinical effects of the Watchman device are directly transferable to the ACP system.[8,9] Therefore, we aimed (1) to compare procedural data and patient outcome for both LAA occluder devices and (2) to investigate an alternative antithrombotic treatment regimen in high-risk patients.

Methods

Patients

Between June 2010 and June 2012, patients with NVAF, with high risk for stroke, and who either had contraindication or were not willing to accept long-term OAC were prospectively enrolled in this study. All patients gave written informed consent before the procedure.

Group allocation

Two groups were formed according to the device type used: group A: Watchman device; group B: ACP device. Before the procedure, all patients were prospectively allocated to 1 treatment group in a nonrandomized 1:1 fashion before LAA imaging (Figure 1). Group allocation was therefore independent of underlying LAA anatomy.

Procedure and transseptal puncture

All procedures were performed under conscious sedation by using boluses of midazolam and a continuous infusion of propofol (1%). A transesophageal echocardiography (TEE) probe was introduced to rule out intracardiac/LAA thrombus. All procedures were performed by 2 experienced cardiac electrophysiology physicians (K.R.J.C. and B.S.). After a single transseptal puncture by using the modified Brockenbrough technique under TEE control, one 8-F sheath (SL1, St Jude Medical) was positioned within the left atrium (LA). Thereafter, a single heparin bolus (80–100 IE/kg of body weight) was administered. The transseptal sheath was exchanged with the device delivery sheath (14-F Watchman and 10–13-F ACP) and continuously flushed with heparinized saline (20 mL/h). LAA dimensions were determined from selective LAA angiograms in standard angulations (right anterior oblique 30/25 caudal and right anterior oblique 30/15 cranial) and TEE measurements (45°, 90°, and 135°). The appropriate device size was chosen according to the manufacturer's recommendations.

LAA closure devices

Group A: Watchman device

Both systems have been described in detail elsewhere.[6,9,10] In brief, the Watchman LAA closure device consists of a self-expanding nitinol frame structure with fixation barbs and a permeable polyester fabric that covers the surface of the device facing the LA. The device is available in 5 sizes, ranging from 21 to 33 mm (with a step size of 3 mm), and the device that is approximately 20% larger than the diameter of the LAA landing zone is chosen to ensure stable anchoring.

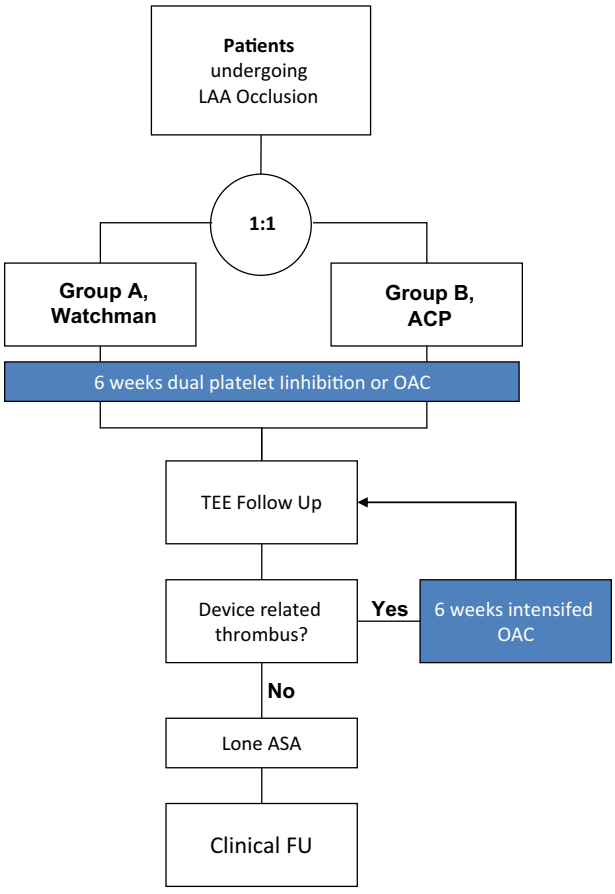

Figure 1 Flowchart of prospective patient allocation to each treatment group and mode of postprocedural care. ACP = Amplatzer Cardiac Plug; ASA = aspirin; FU = follow-up; LAA = left atrial appendage; OAC = oral anticoagulation; TEE = transesophageal echocardiography.

Group B: ACP device

The ACP device consists of a delivery catheter and an implantable, self-expanding device constructed from a nitinol mesh and a polyester patch. The device consists of a lobe and a disc joined by a central pin. The lobe carries stabilizing hooks to ensure retention, and the disc seals the outer part of the LAA orifice. The ACP lobe ranges between 16 and 30 mm (with a step size of 2 mm). The diameter of the disc is 4 or 6 mm larger than the lobe for the 16–22 mm or 24–30 mm devices, respectively. The lobe size should be 20% larger than the narrowest diameter of the LAA body to ensure sufficient lobe fixation.

Device implantation

After device deployment, sufficient anchoring was confirmed by pulling and releasing the delivery catheter under fluoroscopic and TEE surveillance. If the device position or anchoring was unsatisfactory, the device was either repositioned or a different device size was considered more suitable. If the initially attempted device type could not be implanted (residual flow >5 mm; shoulder >7 mm), switch to the other device was allowed in a second procedure.