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Periprocedural Intracardiac Echocardiography for Left Atrial Appendage Closure

A Dual-Center Experience

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ABSTRACT

OBJECTIVES This dual-center study sought to demonstrate the utility and safety of intracardiac echocardiography (ICE) in providing adequate imaging guidance as an alternative to transesophageal echocardiography (TEE) during Amplatzer Cardiac Plug device implantation.

BACKGROUND Over 90% of intracardiac thrombi in atrial fibrillation originate from the left atrial appendage (LAA). Patients with contraindications to anticoagulation are potential candidates for LAA percutaneous occlusion. TEE is typically used to guide implantation.

METHODS ICE-guided percutaneous LAA closure was performed in 121 patients to evaluate the following tasks typically achieved by TEE: assessment of the LAA dimension for device sizing; guidance of transseptal puncture; verification of the delivery sheath position; confirmation of location and stability of the device before and after release and continuous monitoring to detect procedural complications. In 51 consecutive patients, we compared the measurements obtained by ICE and fluoroscopy to choose the size of the device.

RESULTS The device was successfully implanted in 117 patients, yielding a technical success rate of 96.7%. Procedural success was achieved in 113 cases (93.4%). Four major adverse events (3 cardiac tamponades and 1 in-hospital transient ischemic attack) occurred. There was significant correlation in the measurements for device sizing assessed by angiography and ICE ($r = 0.94$, $p < 0.0001$).

CONCLUSIONS ICE imaging was able to perform the tasks typically provided by TEE during implantation of the Amplatzer Cardiac Plug device for LAA occlusion. Therefore, we provide evidence that the use of ICE offered accurate measurements of LAA dimension in order to select the correct device sizes. (J Am Coll Cardiol Intv 2014;7:1036–44)

Stroke is the third cause of mortality in Western countries and the first cause of serious disability and morbidity (1). Patients with atrial fibrillation (AF) have an increased risk for stroke (2), ranging from 2% to >10% per year, depending on additional risk factors (3). As a result, AF is responsible for 15% to 20% of all ischemic strokes (4). The majority of ischemic strokes associated with AF are secondary to thromboembolism arising from the left atrial appendage (LAA). In a review of 23 studies in which the LAA was examined by autopsy, transesophageal echocardiography (TEE), or direct intraoperative inspection, intracardiac thrombus was identified in 17% of cases of nonvalvular AF, of which 91% were located in the LAA (5).

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The efficacy of chronic anticoagulation therapy to prevent ischemic strokes in AF is well established (6), and current guidelines recommend an oral anticoagulation (OAC) regimen to prevent thromboembolism to all AF patients at risk of stroke (7,8). Management of warfarin, the most commonly administered OAC drug, is complicated by a narrow therapeutic window, the need for frequent monitoring, significant drug-to-drug interactions, and the increased risk of bleeding, which limit the use of warfarin for a substantial portion of these patients. Despite the introduction of novel OAC drugs, developed to overcome these disadvantages (9–11), a considerable number of AF patients do not receive OAC due to their bleeding risk or other contraindications. For these patients, the option of LAA occlusion by percutaneous implantation of an occlusive device has shown encouraging results as an alternative to OAC therapy (12,13).

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The use of imaging techniques is of great relevance throughout all phases of the implantation procedure for LAA occlusion, specifically helping in the choice of the size of the device and in reducing the complication rate, which is still critical in the preliminary experience (13). The use of general anesthesia, typically required by TEE, can be avoided by application of intracardiac echocardiography (ICE). As previously reported by MacDonald et al. (14), this technique, used in LAA evaluation and closure for the first time by the investigators without TEE, reduced procedure time and can be performed safely under local anesthesia.

We present our dual-center experience regarding the utility and safety of ICE-guided percutaneous LAA occlusion as an alternative to implantation under TEE guidance.

METHODS

Between January 1, 2009 and April 30, 2013, all consecutive patients undergoing LAA transcatheter occlusion procedure at the Ospedale del Cuore, Fondazione G. Monasterio in Massa, and at the Azienda Ospedaliera Universitaria of Careggi in Florence were enrolled in this study. Patients scheduled for percutaneous LAA occlusion had a history of nonrheumatic AF (chronic, paroxysmal, or persistent), a high stroke risk, and absolute contraindications to OAC. Contraindications to OAC that led to LAAC were extremely different in our population of 121 patients. In 42% of cases, patients had histories of major bleeding (47% of these were on OAC), mostly spontaneous or OAC-related intracranial bleedings. In 26.4% of cases, patients had histories of minor bleeding (56% of these were on OAC), mostly gastrointestinal bleedings. Also, in 9.1% of cases, there were histories of repeated thromboembolic events on warfarin. For the remaining cases, there were further contraindications to OAC, such as 2 cases of cerebral aneurysm, hematological disorders, carcinomas, high HAS-BLED (Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile INRs, Elderly, Drugs or alcohol) scores, as well as others.

ABBREVIATIONS AND ACRONYMS

ACP = Amplatzer Cardiac Plug
AF = atrial fibrillation
CS = coronary sinus
ICE = intracardiac echocardiography
LAA = left atrial appendage
LAAC = LAA Closure
OAC = oral anticoagulant(s)
RA = right atrium
TEE = transesophageal echocardiography

CHARACTERISTICS OF THE OCCLUSION DEVICE. All patients underwent TEE examination from 2 to 5 days before the procedure to exclude the presence of thrombus in the LAA and to assess the LAA anatomy, ostium and landing zone diameters, and length. In all cases, we were able to verify that the length of the LAA was ≥10 mm in order to correctly deploy the device with sufficient space. Patients were implanted with the Amplatzer Cardiac Plug (ACP) device or Amplatzer Cardiac Plug II (Amulet) (St. Jude Medical, Plymouth, Minnesota).

The ACP device is designed for immediate occlusion of the LAA and consists of a distal lobe and a proximal disk connected by an articulating waist (**Figure 1**). It is a self-expanding device made of a nitinol mesh and 2 patches of polyester sewn into both the lobe and the disk. The lobe of the device has 6 stabilizing wires that help to anchor the device in the LAA. The device is available in sizes between 16 and 30 mm (2-mm size increments, lobe size), and the proximal disk is 4 to 6 mm larger than the lobe. The lobe has a fixed length of 6.5 mm irrespective of device size. The ACP device is recommended to be oversized by about 2 to 3 mm with respect to the LAA dimensions. The device has a wide positional adaptability due to the connecting waist, which allows the disk of the system to self-orient from the lobe and completely occlude the ostium of the LAA.

The Amulet lobe has 12 stabilizing wires for the 16- and 18-mm devices, 16 stabilizing wires for the 20- to 25-mm devices, and 20 stabilizing wires for the 28- and 34-mm devices. Stabilizing wires help to anchor the device in the LAA. The device is available in sizes between 16 and 34 mm (2-mm size increments lobe size, for the 16- to 22-mm devices and 3-mm increments, lobe size, for the 22- to 34-mm devices). The proximal disk is 6 to 7 mm larger than the lobe. The lobe length is 6.5 mm for the 16- to 22-mm devices and 10 mm for the 25- to 34-mm devices. The Amulet device is recommended to be oversized by about 2 to 3 mm with respect to the LAA dimensions (**Figure 1**).