Rev Esp Cardiol. 2013;66(2):90–97

Original article

Immediate and One-year Results in 35 Consecutive Patients After Closure of Left Atrial Appendage With the Amplatzer Cardiac Plug

José R. López-Mínguez,* Javier Eldoayen-Gragera, Reyes González-Fernández, Concepción Fernández-Vegas, María E. Fuentes-Cañamero, Victoria Millán-Nuñez, Juan M. Nogales-Asensio, Ana Martínez-Naharro, Sara Sánchez-Giralt, Manuel Doblado-Calatrava, and Antonio Merchán-Herrera

Sección de Hemodinámica y Cardiología Intervencionista, Servicio de Cardiología, Hospital Universitario Infanta Cristina de Badajoz, Badajoz, Spain

Article history:
Received 6 March 2012
Accepted 28 April 2012
Available online 29 August 2012

Keywords:
Left atrial appendage
Amplatzer occluder
Atrial fibrillation
Non-fluoroscopic electroanatomic mapping
X-ray computerized tomography
Magnetic resonance imaging

ABSTRACT

Introduction and objectives: Left atrial appendage closure can be an attractive option for patients with nonvalvular atrial fibrillation and a contraindication to oral anticoagulants, provided that satisfactory results can be achieved during implantation and follow-up.

Methods: Thirty-five consecutive patients, not eligible for randomized trials with oral anticoagulants, had an Amplatzer occlusion device implanted under general anesthesia. After the first 5 patients, 3-dimensional imaging was incorporated. The results of the implantation and the follow-up were analyzed over a 1-year period.

Results: The mean age was 74.65 (7.61) years, with a $CHADS_2$ score of 2.41 (1.53) and a CHA_2DS_2-VASc score of 3.17 (1.60). Implantation failed in 1 patient and 5 needed a change in the selected plug size. There were no cardiac complications during the implantation or hospital stay. There was 1 vascular complication (arteriovenous fistula). Transesophageal echocardiography monitoring was performed at 24 h, 1, 3, 6, and 12 months and we found 5 thrombi which were resolved with heparin. In the follow-up period of 21.14 (10.09) months, 3 patients aged>80 years died, none of them due to heart problems, and one transient ischemic stroke without further consequences.

Conclusions: Left atrial appendage closure by an experienced operator can be a treatment option with few complications and with efficient results at>1 year in reducing thromboembolic and hemorrhagic complications, even in very high-risk groups.

Resultados inmediatos y a más de un año en 35 pacientes consecutivos a los que se realiza cierre de orejuela izquierda con el dispositivo Amplatzer Cardiac Plug

Palabras clave:
Orejuela izquierda
Dispositivo oclusor
Fibrilación auricular
Cartografía electroanatómica no fluoroscópica
Tomografía computarizada
Resonancia magnética

RESUMEN

Introducción y objetivos: El cierre del apéndice auricular izquierdo puede ser una opción terapéutica atractiva para pacientes con fibrilación auricular no valvular y contraindicación para tomar anticoagulantes orales, siempre que se obtengan buenos resultados durante la implantación y en el seguimiento.

Métodos: Se analizó a 35 pacientes consecutivos y no elegibles para los estudios aleatorizados con anticoagulantes orales a los que se implantó el dispositivo oclusor Amplatzer. Tras los primeros 5 casos, se incorporó una técnica de imagen 3D. Se analizaron los resultados de la implantación y de seguimiento durante 1 año.

Resultados: La media de edad era 74,65 ± 7,61 años, con un $CHADS_2$ de 2,41 ± 1,53 y un CHA_2DS_2-VASc de 3,17 ± 1,60. No se pudo implantar el dispositivo en 1 caso y en 5 fue necesario cambiar la medida seleccionada. No hubo ninguna complicación cardiaca durante la implantación ni durante la estancia hospitalaria. Hubo una complicación vascular (fístula arteriovenosa). Se realizó seguimiento con ecocardiografía transesofágica a las 24 h y tras 1, 3, 6 y 12 meses; se documentaron 5 trombos, que se resolvieron con heparina. En el seguimiento de 21,14 ± 10,09 meses, hubo 3 muertes de pacientes mayores de 80 años, ninguna de ellas cardiológica, y un accidente isquémico transitorio sin secuelas.

Conclusiones: El cierre del apéndice auricular izquierdo por un operador con cierta experiencia puede ser una opción terapéutica con pocas complicaciones y con resultados a más de 1 año eficaces en la reducción de complicaciones tromboembólicas y hemorrágicas, incluso en poblaciones de muy alto riesgo.

SEE RELATED ARTICLE:
http://dx.doi.org/10.1016/j.rec.2012.09.011, Rev Esp Cardiol. 2013;66:79–82.

* Corresponding author: Servicio de Cardiología, Hospital Universitario Infanta Cristina de Badajoz, Avda. Elvas s/n, 06006 Badajoz, Spain.
E-mail address: lopez-minguez@hotmail.com (J.R. López-Mínguez).

1885-5857/$ – see front matter
http://dx.doi.org/10.1016/j.rec.2012.04.017

Abbreviations

ACP: Amplatzer Cardiac Plug
AF: atrial fibrillation
CT: computed tomography
LAA: left atrial appendage
MRI: magnetic resonance imaging
OAC: oral anticoagulants

INTRODUCTION

Nonvalvular atrial fibrillation (AF) is a frequent arrhythmia whose incidence increases with age, with rates greater than 10% in patients aged>80 years.[1,2]

Apart from hemodynamic repercussions, the importance of AF lies in the fact that it is responsible for more than 20% of ischemic ictus,[3] AF being the cause of ischemic ictus with the greatest impact.[1,3]Until now oral anticoagulants (OAC) have been the main tool used to reduce cardioembolic incidents.[4] However, due to the associated risk of hemorrhage they cannot be used in one third of patients.[5,6] Although the development of new OACs (dabigatran, rivaroxaban, apixaban) has reduced some of the limitations of the original OACs (such as warfarin), especially by reducing intracranial hemorrhage and avoiding international normalized ratio monitoring, the percentage of major (2.15%-3.6% year) and minor hemorrhages (15%-20% year) has not changed significantly.[7–9]

The emergence of occlusion devices for the left appendage or left atrium appendage (LAA)[10–12] presented a new treatment option for patients with contraindications to OACs, or with high risk of bleeding due to a high HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) score,[13] with similar results to OACs.[11] It would be interesting to know the results of cohorts of patients who could not be included in the latest randomized studies of new OACs or PROTECT AF (Randomized Prospective Trial of Percutaneous LAA Closure vs Warfarin for Stroke Prevention in AF), since those patients have a higher overall risk of thromboembolic complications and hemorrhage both during the intervention and during the follow-up period.

The aim of our study was to present the results of our first 35 patients who had an occlusion device (Amplatzer Cardiac Plug [ACP], St Jude Medical Minnesota, United States) implanted, both during the intervention and during a 1-year follow-up period.

METHODS

Thirty-five patients recruited between March 2009 and November 2011 underwent LAA closure with an ACP device. The following conditions were required for inclusion: severe hemorrhage during treatment with acenocoumarol, a disease or previous clinical event that contraindicated the use of OAC, the repeated impossibility of monitoring the international normalized ratio, with instructions to suspend acenocoumarol by a hematologist. The study's protocol was accepted by the ethics committee for clinical research of our hospital and all patients provided informed consent. The aim of the study was to analyze the initial results of the safety of the technique for ACP implantation. We also analyzed the patients' long-term clinical course, including the development of embolic or hemorrhagic events, the formation of thrombi in the device and their outcome, and the long-term effectiveness of LAA closure or reduction of any residual initial shunt.

Transesophageal echocardiography (TEE) was performed in each patient 24-48 h before the intervention to rule out the presence of thrombus in the LAA. After the first 5 patients, we performed a magnetic resonance imaging (MRI) scan in 10 patients and a computed tomography (CT) scan in the last 20 patients some days prior to the intervention. One hour before, a broad spectrum antibiotic (cephalosporin) was administered. The procedure was carried out under general anesthetic. We administered 100 U/kg of heparin after transseptal puncture. Transseptal access to the left atrium was through the right femoral vein; then we performed selective angiography of the LAA with a volume similar to that of a left coronary artery and, in general, in right anterior oblique (RAO) (20-30) caudal (15-25) and also in cranial RAO (15-20) views. The standard method to correct amplification was a radiopaque ball in the plane of the midaxillary line. Measurements were taken with TEE during the intervention in 2 planes. The anatomy of the appendage anatomy was studied with a probe in the midesophageal position by means of a 0°-135° scan to obtain the minor (between 45°-70°) and major ostial diameters (approximately 135°). These measurements were usually performed in the ostium, above the corresponding point of the circumflex artery, and 5 mm-10 mm deeper, taking into account variations in the shape and direction of the axis of some appendages.

Intraoperative TEE also allowed for the position of the device release sheath after transseptal puncture to be evaluated, the correct position of the device in the appendage to be confirmed, and the correct exclusion of the appendage before its release to be checked using the Doppler-colour display. A 3-dimensional (3D) echocardiogram was used in the final 14 patients to confirm the sealing of the margins of the ostium, to ensure that the device could not have affected adjacent anatomical structures, such as the implantation of the mitral valve or the upper left pulmonary vein, and to confirm the absence complications such as a pericardial effusion.

We performed MRI studies with a Signa 1.5-T model General Electric scanner. The slices were obtained without respiratory motion through a sequence of magnetic resonance angiography with fast gradients (to achieve the best spatial resolution) and in different planes (sagittal, coronal and transversal). Cardiac CT imaging was carried out using a 64-slice scanner (General Electric Light Speed VCT Healthcare Inc.; Milwaukee, WI, United States).

To improve the images taken by the radiology department, and in the absence of specific software, we considered the possibility of exporting these images without processing them through a CARTO software system (CartoMerge™ Image Integration Module, Biosense Webster, Inc.). By means of a 3D reconstruction process of the heart and segmentation, a 3D image of the left atrium and the LAA and the pulmonary veins was achieved, allowing for detailed internal and external analysis and for very precise measurement of distances in any direction in the area. This method has been validated in previously published studies.[14,15]

The TEE and angiography measurements were compared with the measurements obtained by CARTO-CT/MRI, with special attention to the major axis, which was usually the superoinferior (SI) axis. If the measurements differed in the size of the ACP which would correspond to the range (according to the table of equivalent measurements/size for the device provided by the company), then both the TEE and the angiography were performed again, paying special attention to the ostium and the implantation-anchorage area (landing zone), approximately 1 cm within the ostium and from the inferior angle, precisely at the upper level of the circumflex artery. If the measurements did not match after a new evaluation, the consistency of the measurements and the quality of the images were checked, giving most weight to the 3D measurement of the CARTO-CT/MRI on the major axis (Fig. 1).