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Original Article

Percutaneous occlusion of the left atrial appendage with AMPLATZER® Cardiac Plug for the prevention of thromboembolic events in chronic atrial fibrillation

Francisco Chamié*, Enio Guérios, Valério Fuks, Angélica Bösiger, Marcio Carvalho, João Otávio de Queiroz Araujo

Hospital Federal dos Servidores do Estado, Rio de Janeiro, RJ, Brazil

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ABSTRACT

Background: Atrial fibrillation (AF) increases the risk of thromboembolic events caused by emboli originating in the left atrial appendage (LAA). Mechanical methods for LAA occlusion have been developed as an alternative to oral anticoagulation. The aim of this study was to present an initial experience with the AMPLATZER® Cardiac Plug.
Methods: Patients with permanent or paroxysmal AF and with contraindications or complications of oral anticoagulation were included. Patients with LAA anatomy and measures compatible with the occluder, and without thrombi, were selected through transesophageal echocardiography.
Results: A total of 14 procedures were performed in 13 patients (5M:8F), with mean age of 66.7 years. Significant bleeding and previous strokes were found in 69.2% and 53.8%, respectively. AF was permanent in 84.6% and paroxysmal in the remainder. The mean diameters of the ostium and the landing zone were 23.9 mm and 20.8 mm, respectively. Bilobulated LAA was observed in 76.9%. Procedures were possible in all cases. Sixteen devices were used in 13 patients, a ratio of 1.2:1, and only one patient required a second device for LAA occlusion. The mean follow-up was 12.2 months. All LAA remain closed, with no residual defect to date. There was only one late death, unrelated to the procedure.
Conclusions: LAA occlusion using the AMPLATZER® Cardiac Plug device was shown to be safe and effective in this small series of patients. The initial results are encouraging and indicate the transcatheter closure of the LAA as an alternative to oral anticoagulation therapy in selected patients.

Oclusão percutânea do apêndice atrial esquerdo com AMPLATZER® Cardiac Plug para prevenção de fenômenos tromboembólicos na fibrilação atrial crônica

Palavras-chave:
Tromboembolia
Acidente vascular cerebral
Fibrilação atrial

RESUMO

Introdução: A fibrilação atrial (FA) aumenta o risco de eventos tromboembólicos por êmbolos originados em apêndice atrial esquerdo (AAE). Métodos mecânicos para a oclusão do AAE foram desenvolvidos como alternativa à anticoagulação oral. O objetivo deste trabalho foi apresentar uma experiência inicial com o AMPLATZER® Cardiac Plug.
Métodos: Incluímos pacientes com FA permanente ou paroxística, que apresentavam contraindicações ou complicações derivadas da anticoagulação oral. Pacientes com anatomia e medidas do AAE compatíveis com o oclusor, e sem trombos foram selecionados por meio de ecocardiograma transesofágico.
Resultados: Foram realizados 14 procedimentos em 13 pacientes (5M:8F), com média de idade de 66,7 anos. Sangramento significativo e acidentes vasculares cerebrais prévios foram encontrados em 69,2% e em 53,8%, respectivamente. A FA era permanente em 84,6% e paroxística no restante da amostra. Os diâmetros médio do óstio e da zona alvo mediram 23,9 mm e 20,8 mm, respectivamente. AAE bilobulados foram observados em 76,9%. Os procedimentos foram possíveis em todos os casos. Dezesseis dispositivos foram usados em 13 pacientes, numa razão de 1,2:1, e apenas 1 paciente precisou de um segundo dispositivo para oclusão do AAE. O tempo médio de acompanhamento foi de 12,2 meses. Todos os AAE permanecem fechados e sem defeito residual até o momento. Houve apenas um óbito tardio não relacionado ao procedimento.

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* Corresponding author: Rua Real Grandeza, 108, salas 223-224, Botafogo, CEP: 22281-034, Rio de Janeiro, RJ, Brazil.
E-mail: fchamie@pobox.com (F. Chamié).
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Conclusões: A oclusão do AAE com o dispositivo de AMPLATZER® Cardiac Plug mostrou ser segura e eficaz nesta pequena série de pacientes. Os resultados iniciais são encorajadores e apontam para o fechamento transcateter do AAE como alternativa para a anticoagulação oral em pacientes selecionados.

Introduction

Atrial fibrillation (AF) of non-valvular origin is one of the most common type of arrhythmia, affecting 1 to 2% of the overall adult population.[1] It is present in up to 14% of patients older than 65 years and its incidence doubles every decade.[2] Being associated with a high risk of cardioembolic events, particularly stroke, AF accounts for approximately 15% of all ischemic strokes.[3] The risk of stroke in patients with AF increases up to five times when compared to patients in sinus rhythm.[4]

The prevention of embolic phenomena of AF is traditionally achieved through the continued use of oral anticoagulants (OAC). The most often used OAC are vitamin K antagonists, which are effective, reducing the incidence of stroke in up to 60% and death in up to 25% of patients that remain within the therapeutic range.[5] The continued use of these drugs brings several difficulties and inconveniences to patients, resulting in a large number of untreated individuals. The main problems reported are the risk of bleeding or previous episodes of significant bleeding in individuals with predisposing conditions; extreme frailty; the low rate of adherence to treatment; harmful drug interactions; the oscillation of therapeutic levels of the drug; and unwanted side effects.[6-9]

The knowledge that more than 90% of emboli in AF originate from thrombi in the left atrial appendage (LAA) led to the development of options for mechanical obliteration of this structure as an alternative therapy to OAC to prevent cerebral thromboembolic phenomena.[10-12]

In this article, the authors report their initial experience with LAA occlusion in a single center, using the first dedicated prosthesis developed for this purpose and approved for clinical use in Brazil.

Methods

Records of all patients referred for percutaneous closure of the LAA in the Interventional Cardiology Department of Structural and Congenital Defects of Hospital Federal dos Servidores do Estado in the city of Rio de Janeiro (RJ) were retrospectively analyzed.

Patients with permanent or paroxysmal AF and who had contraindications or complications caused by the continued use of OAC were selected. Selection for the procedure was attained by transesophageal echocardiography (TEE), which included patients whose atrial appendages had anatomical characteristics and diameters compatible with the standard occluder used in this service (12.6 mm to 28.5 mm)[13] and who did not have thrombi inside the LAA.

The prosthesis used was the AMPLATZER® Cardiac Plug (ACP, AGA Medical Corp., Minneapolis, USA), which is a self-expanding device made of nitinol, lined with polyester fabric. It consists of a cylindrical lobe available in diameters of 16 to 30 mm, with 2-mm increments, which corresponds to the nominal size of the prosthesis. Attached to it by a flexible connector pin is a disc; the disc is 4 mm larger than the lobe in 16 to 22-mm prostheses, and 6 mm larger in 24 to 30-mm prostheses.

To increase the safety of the procedure and reduce the risk of device displacement, six pairs of thin stabilizing hooks are fastened to the lobe, identified by radiopaque markers, which help to secure the lobe to the LAA body in the landing zone (Fig. 1).

All procedures were performed under general anesthesia and tracheal intubation, after a minimum fasting period of 8 hours, under fluoroscopic and transesophageal echocardiography guidance in the interventional cardiology laboratory.

Unfractionated heparin was administered at doses of 5,000 to 10,000 IU after obtaining transseptal access. Supplemental doses of 2,500 to 5,000 IU were administered every 30 minutes when the procedures lasted longer than 1 hour. Antimicrobial prophylaxis with 2 g of intravenous cefazolin was routinely administered. The patients were submitted to right and left heart catheterization through femoral vein puncture. Left atrial access was obtained by transseptal puncture with the standard technique using a Brockenbrough needle.

With the aid of a calibrated 5 F pigtail catheter, the LAA was catheterized and injections were performed in the right anterior oblique (RAO) view, with cranial and caudal angulation, to determine the anatomic type and to obtain measures of the ostium and the landing zone of the occluder device's lobe. The measures and anatomy were compared with those obtained with the TEE, with the largest measurements utilized to select the prosthesis to be implanted (Fig. 2).

The pigtail catheter was removed and replaced by a long guide wire (260 cm) with a curved tip (J), rigid or super rigid, inside the LAA. Over it, a long, double-curve AGA sheath was introduced, with a diameter compatible with the chosen occluder. The sheath was positioned as coaxially as possible to the LAA axis and the position was assessed using manual contrast injections, through the hemostatic valve. The chosen device was introduced through the sheath, previously loaded in the delivery system, whose lobe diameter was 2 to 4 mm larger than the largest measure obtained from the implantation landing zone. The device lobe was ideally

Figure 1. Occluder details. Note the disc at the bottom of the picture and, above it, the lobe, in which six pairs of locking hooks are displayed.