

# Left atrial appendage closure with the Amplatzer™ Cardiac Plug: Rationale for a higher degree of device oversizing at implantation

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## Abstract

**Background:** *In left atrial appendage (LAA) closure, the correct sizing of the implantable devices is crucial. Data on the time-dependent changes in the shape and positioning of LAA occlusion devices are missing. We analyzed the results of 33 consecutive patients after implantation of an Amplatzer™ Cardiac Plug (ACP) LAA closure device to get more information on the optimal device sizing during implantation.*

**Methods and results:** *Thirty-three consecutive patients were enrolled in this observational study. ACP implantation was guided by fluoroscopy and three dimensional transesophageal echocardiography (3-D TEE). Device sizing was based on the largest measured diameter of the intended landing zone adding 2–4 mm of device oversizing. Fluoroscopies were performed at 1 day after, and after 3 months, control 3-D TEE was performed 3 months after implantation. The stability of device positioning and shape was matched with the results of 3-D TEE. Patients' mean age was  $70.2 \pm 8$  years; mean CHA<sub>2</sub>DS<sub>2</sub>VASc score was  $3.8 \pm 1.1$ . According to the manufacture's classification, the post-implant degree of compression of the device-lobe was classified in three categories 1) undercompression "square-like shape" (1 patient); 2) optimal compression "tire-like shape" (20 patients), 3) overcompression "strawberry-like shape" (12 patients). Changes in the degree of device compression by more than one classification class occurred in 18/33 of our patients. A complete loss of device compression ("square-like shape") was observed in 9 patients. Despite the changes in device compression, a complete closure of the LAA was achieved in 32/33 patients.*

**Conclusions:** *There is a temporal change in shape and positioning of the ACP within 3 months after implantation. A late decompression of the ACP lobe was observed in 61% of our patients, leading to a complete loss in device compression in 27%. This observation may be the rationale for a higher degree of ACP oversizing during implantation. (Cardiol J 2015; 22, 2: 201–205)*

**Key words:** left atrial appendage occlusion, Amplatzer™ Cardiac Plug, device sizing, fluoroscopy

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## Introduction

Left atrial appendage (LAA) occlusion is an interventional “local” therapy for stroke prevention in patients with atrial fibrillation [1–3]. A randomized clinical trial, together with a recently published long-term follow-up data, established LAA occlusion as non-inferior to warfarin therapy in the prevention of cardioembolic episodes in patients with atrial fibrillation [4, 5]. The current European Society of Cardiology guidelines classified LAA occlusion as a class IIb therapy [6]. Assuming the great variability in LAA anatomy, the correct implantation and stable fixation of the devices may be technically challenging [7, 8]. Despite enormous efforts in preimplantation diagnosis, using angiography, multiplane transesophageal echocardiography (TEE), 3-dimensional TEE, intracardiac echocardiography, computed tomography and magnetic resonance imaging, final device placement may not be always absolutely predictable [9–11]. The assurance of the temporal stability of the initially achieved shape and placement of the LAA closure device placement might be of importance for persisting complete LAA closure. In this manuscript, our results on early and late post implant fluoroscopy to assess the temporal stability of the implanted Amplatzer™ Cardiac Plug (ACP) device were presented.

## Methods

All patients undergoing percutaneous LAA closure with the ACP device between September 2011 and January 2013 at our institution were enrolled in this prospective observation. The specifications of the implanted ACP device were published previously [3, 12]. The implantations were performed under heavy sedation and heparin therapy resulting in an activated clotting time > 300 s. The mean left atrial pressure was kept in a range > 12 mm Hg. The implantation was guided by angiography and 3-D TEE in all patients. The device was oversized by 2–4 mm in relation to the largest echocardiographic or angiographic diameter of the intended landing zone. Complete occlusion of the LAA was verified by color Doppler echocardiography prior to and immediately after release of the device. The resulting positioning of the device was verified by fluoroscopy in an optimized right anterior oblique (RAO) projection, which provides the best view on the relation of disc and lobe positioning of the implanted device. On day 1 after device implantation, the patients underwent a second fluoroscopy

using the same optimized RAO projection. All patients received a dual antiplatelet therapy i.e. aspirin and clopidogrel for 3 months. All patients underwent repeat TEE and fluoroscopy 3 months later, as described above. All fluoroscopies obtained during implantation, after 1 day and after 12 weeks were analyzed, comparing disc-placement, lobe-placement, lobe compression, and the distance between device disc and lobe over time. Examples of typical findings of position and shape of the ACP device are given in Figures 1 and 2.

The study was approved by the local ethical committee and all patients gave their written informed consent.

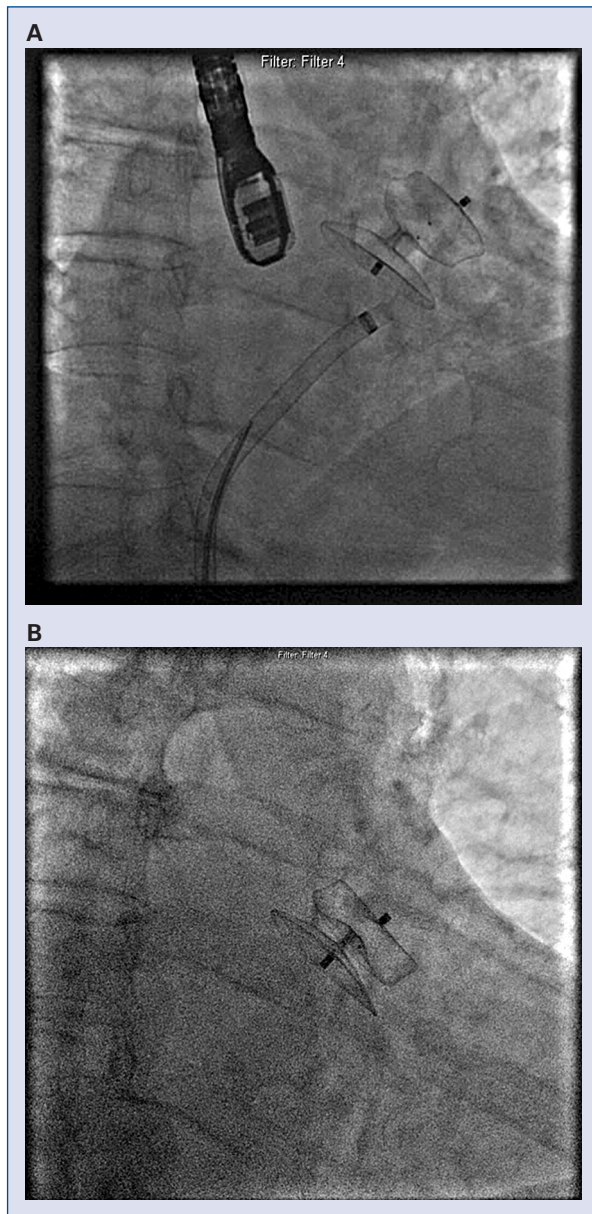
## Results

Thirty-five consecutive patients (20 female, 15 male; mean age  $70.2 \pm 8.5$  years) were enrolled in this observational study. ACP implantation was successful in 33 patients. In 1 patient, implantation was impossible due to an extremely small and angulated LAA, and 1 patient was excluded from the analysis due to device embolization. Seventeen patients showed permanent atrial fibrillation, while 16 patients exhibited paroxysmal/persistent atrial fibrillation. The mean CHA<sub>2</sub>D<sub>2</sub>VASc score was  $3.8 \pm 1.1$ . The majority of our patients had at least one contraindication to oral anticoagulation. The diameter of the implanted ACP devices was: 18 mm (n = 2); 20 mm (n = 7); 22 mm (n = 3); 24 mm (n = 7); 26 mm (n = 9); 28 mm (n = 4); 30 mm (n = 1).

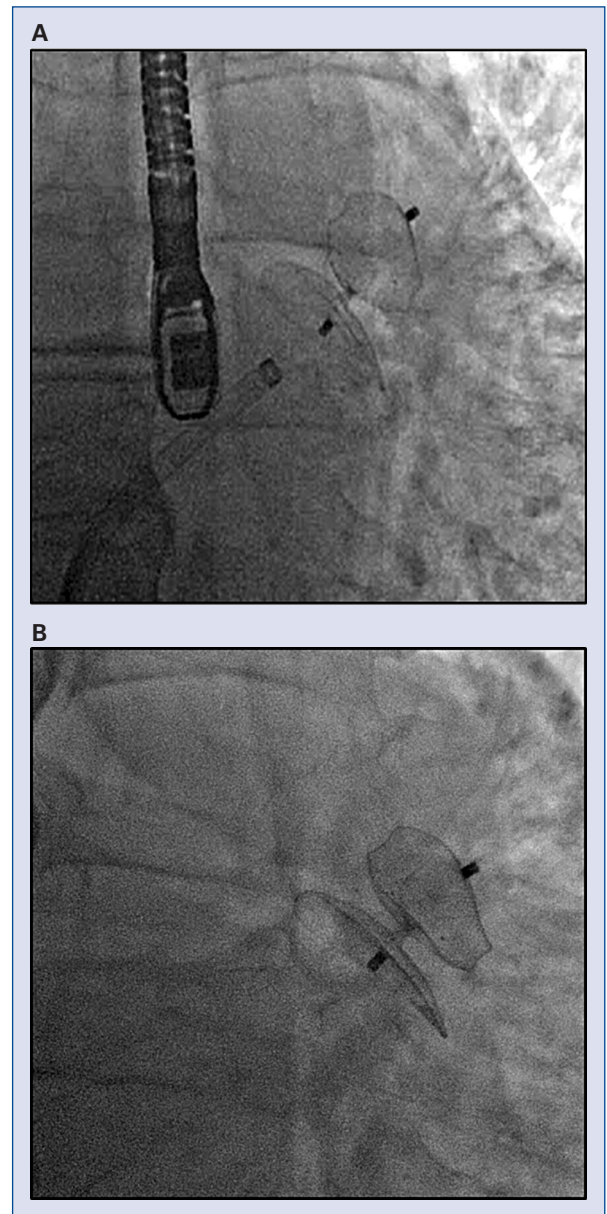
Regarding the classification of device-lobe compression, in 12 patients a “strawberry-like” overcompression of the ACP was achieved, in 20 patients an optimal compression (“tire-like”), and in 1 patient an undercompression (“square-like”), respectively [13]. A complete LAA-closure was achieved in all patients verified by 3-D TEE.

At fluoroscopy at day 1, 29 of 33 patients showed stable device placement compared to implantation. In 4 patients, an early change in device positioning was observed due to a too deep implantation of the ACP. Due to the tension of the “dish-like shaped” device disc, deployment and minimal dislocation of the lobe of the device occurred. In 1 patient with an early change in device positioning, an incomplete adaption of the disc in the area of the ridge to the left upper pulmonary vein could be detected by follow-up 3-D TEE (minor leak < 3 mm).

At 3-month follow-up fluoroscopy changes in the degree in compression of the device lobe —



**Figure 1.** This example of a 72-year-old male patient implanted with a 26 mm device demonstrates the nearly complete loss of the device lobe compression during follow-up. The degree of initial lobe compression during implantation is adequate (“tire-like”) (A). Lobe decompression leads to narrowing of device lobe and disc (“square-like”) (B).



**Figure 2.** This example of a 76-year-old male patient implanted with a 28 mm device shows the degree in device lobe decompression which occurred in the majority of our patients. The lobe compression during implantation could be classified as overcompressed (“strawberry-like”) (A). During follow-up the decompression of the lobe leads to a lower degree in lobe compression (“tire-like”) (B).

more than one class — were observed in 18 of 32 patients. These changes uniformly consist of an increase in the diameter and decompression of the lobe of the ACP. In 9 of the 12 patients with device overcompression, a change from a “strawberry-like shape” into a “tire-like shape” was observed. In 9 of the 20 patients with a “tire-like shape” a change into a “square-like shape” with a complete loss of device

compression was observed (Fig. 1). An example of moderate decompression of the ACP lobe is given in Figure 2. No changes in device decompression, more than one class were observed in 14 patients. As a consequence of the decompression of the device lobe, a narrowing between lobe and the disc of the device occurred (Fig. 1). Despite these changes in late

device position, there was not a single case of late occurrence of a peri-device leak. Device embolization after successful implantation was not observed.

## Discussion

The main finding of our observational study was that during follow-up, there was a variable degree in loss of device lobe compression in 18/33 patients. In 9 of these patients, there was a complete loss of compression of the device lobe (from “tire-like shape” to “square-like shape”) [13]. However, despite the relevant changes in device compression, there was only 1 case of a peri-device leak.

To the best of our knowledge, the presented study is the first report on the phenomenon of temporal decompression of a LAA occluding device. During implantation the devices were oversized by 2–4 mm in relation to the largest diameter of the intended “landing zone“. This approach in device selection is comparable to other studies on LAA occlusion using the ACP device [12, 13]. A specific amount of device oversizing is also used for implantation of the Watchman™ LAA occlusion device [1, 4]. There are no data linking device oversizing to specific procedure related complications, mainly pericardial effusions [13].

Incomplete LAA closures after implantation of a percutaneous closure device are reported for all devices [1–5, 13–15]. Sick and coworkers reported a 7% early peri-device flow in 75 Watchman™ patients [1]. In the PROTECT AF trial, Holmes et al. [4] reported a prolonged warfarin use due to a significant peri-device flow in 14% of their study patients at 45 days after implantation. In a more recent paper of the PROTECT AF investigators, a detailed analysis of this problem was presented. The investigators revealed a rate of any peri-device flow after Watchman™ implantation of 41% to 32%, after 1 month and 1 year; respectively [5]. Bai et al. [15] found an incidence of peri-device leaks in up to 35% in a series of 58 consecutive patients 1 year after Watchman™ implantation. In this study, the leaks were more likely to become bigger and also new gaps occurred. In ACP implantation series, incomplete LAA closure was reported in the range of 4% to 21% of moderate to severe leaks [12, 13]. Despite the fact that we demonstrated relevant changes in the compression of the implanted ACP devices a peri-device leak was found only in 1 patient. In our study, we analyzed the shape of the implanted ACP 3 months after implantation. The observed device decompression might be

a late phenomenon and may occur after fixing the device due to complete endothelialization of the device disc. However, earlier occurrence of device decompression, prior to complete endothelialization, may lead to device dislocation and may cause peri-device leaks. This may explain the observation by Freixa et al. [15] that a lower degree of ACP compression was linked to the occurrence of late peri-device leaks. In several implantation series with Plaato™, Watchman™ and Amplatzer™ devices, there was no association between the presence of residual peri-device flow and the occurrence of thromboembolic events [1, 2, 13, 14]. To our opinion, these results must be interpreted with caution due to the small sample size, low event rates and insufficient statistical power of these sub-analyses. Therefore, the benign character of residual peri-device leaks after percutaneous LAA occlusion is not proven and complete closure of the LAA should be attempted.

## Conclusions

In the majority of our patients, there was a variable loss in device lobe compression of the implanted ACP. In connection with other presented clinical data we would like to support the strategy of a higher degree in device oversizing during ACP implantation.

**Conflict of interest:** None declared

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