Percutaneous closure of the left atrial appendage using the Amplatzer Cardiac Plug in patients with atrial fibrillation: evaluation of safety and feasibility

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Abstract

Background: Ischaemic stroke is a common complication of atrial fibrillation (AF). Cardiology societies recommend assessing the risk of ischaemic stroke and using adequate prevention in patients with AF. Currently, oral anticoagulants and antiplatelet drugs are the most commonly used methods of stroke prevention. Left atrial appendage (LAA) is thought to be the main source of thrombi in patients with AF. LAA closure procedures that have been recently introduced into the clinical practice are an alternative method of stroke prevention in patients with contraindications to oral anticoagulants or with a high risk of bleeding. Two systems of percutaneous LAA closure are currently available, the Watchman plug and the Amplatzer Cardiac Plug, but experience with these procedures is still very limited.

Aim: To provide early results regarding safety and feasibility of percutaneous LAA closure with the Amplatzer Cardiac Plug in patients with AF and multiple comorbidities resulting in a high risk of stroke and bleeding complications.

Methods: Twenty one patients with AF, at least 2 points in the CHADS2/CHA2DS2VASc score and a high risk of bleeding as assessed by the HAS-BLED score (at least 3 points) underwent percutaneous Amplatzer Cardiac Plug implantation. Patients with less than 3 points in the HAS-BLED score were also included in the study if they had contraindications to oral anticoagulants (e.g. previous haemorrhage, recurrent bleeding, epidermolysis) or suffered from recurrent ischaemic stroke despite anticoagulant treatment. The Amplatzer Cardiac Plug was implanted using the standard technique under fluoroscopic and echocardiographic guidance.

Results: Percutaneous LAA closure with the Amplatzer Cardiac Plug was performed in a group of patients with many comorbidities who had a high risk of ischaemic stroke (CHA2DS2VASc score 4.43 ± 1.4 points) as well as a high risk of bleeding (HAS-BLED score 3.0 ± 0.7 points). LAA occlusion was successfully performed in 20 (95.2%) patients. A serious periprocedural complication (cardiac tamponade requiring pericardiocentesis) occurred in 1 (4.76%) patient.

Conclusions: Successful LAA occlusion is feasible in a vast majority of patients undergoing this procedure. The rate of serious periprocedural complications is relatively low. LAA occlusion is justified in a group of patients with a high risk of ischaemic stroke and a high risk of bleeding or contraindications to oral anticoagulants.

Key words: Amplatzer Cardiac Plug, atrial fibrillation, stroke, closure of the left atrial appendage

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INTRODUCTION

Atrial fibrillation (AF) is the most common supraventricular arrhythmia occurring in 1–2% of the general population. Prevalence of this arrhythmia continues to rise and the number of patients with AF has been estimated to increase 2.5-fold (to 5.6 million in the United States) by 2050 [1].

The presence of AF is associated with a 2-fold increase in all-cause mortality. In addition, AF leads to many complications including stroke which is one of the most dangerous sequelae of AF and a major cause of mortality in this patient group [2]. Published data indicate that AF is associated with a 5-fold increase in the risk of stroke [3]. Stroke due to AF results in a nearly twice higher mortality and more severe disability due to permanent neurological deficits compared to stroke of other aetiology. It is also associated with an increased risk of recurrent stroke [4].

According to the current European Society of Cardiology guidelines, oral anticoagulant (OAC) therapy is indicated in all patients at high risk of thromboembolic complications as estimated by the CHADS2/CHA2DS2VASc score [5]. Until recently, vitamin K antagonists were mainly used for this purpose but it has been shown that with this therapy, the international normalised ratio (INR) is kept within the therapeutic range (2.0–3.0) for only about 60% of the treatment time [6–8].

In addition, both warfarin and newer oral anticoagulants (dabigatran, rivaroxaban, apixaban) increase the risk of severe bleeding complications (about 2–3% per year), and the rate of intracranial haemorrhages associated with anticoagulant therapy is about 0.1–0.5% per year, depending on the drug used [9, 10]. Thus, a continued search for new methods for stroke prevention in patients with AF seems justified.

Development of thrombi in the left atrium is a key factor in the pathogenesis of stroke related to AF. Using transoesophageal echocardiography, it has been shown that the major source of embolic material in patients with AF is the left atrial appendage (LAA) [11, 12]. It has been estimated that 90% of thrombi responsible for ischaemic strokes in these patients originate from LAA [12].

Among newer methods of ischaemic stroke prevention in AF, percutaneous LAA closure procedures have been introduced as a possible alternative to drug therapy. Initial clinical experience, also including some Polish centres, was gathered with the PLAATO system [13–15]. Despite promising results, however, this system was removed from the market due to commercial reasons. Two systems of percutaneous LAA closure are currently available, Watchman and Amplatzer Cardiac Plug (ACP). A randomised study (PROTECT-AF) was undertaken with the use of Watchman plug [16], while the literature data regarding ACP are limited but it is the latter method that allows immediate withdrawal of OAC therapy by complete occlusion of the LAA entry with an additional disk.

The aim of this study was to evaluate safety and feasibility of percutaneous LAA closure with ACP in patients with nonvalvular AF and multiple comorbidities resulting in a high risk of stroke and bleeding complications.

METHODS

Study group

We evaluated consecutive 21 patients aged 18 years and above with documented AF, regardless of gender. The inclusion criteria were as follows:

1. Indications for anticoagulant therapy, with ≥ 2 points in the CHADS2/CHA2DS2VASc score (congestive heart failure or left ventricular systolic dysfunction: 1 point, arterial hypertension: 1 point, age above 75 years: 2 points, diabetes: 1 point, stroke or other thromboembolic complication: 2 points, previous myocardial infarction, peripheral arterial disease or atherosclerotic plaques in the aorta: 1 point, age 65–74 years: 1 point, female gender: 1 point) [5].

2. High risk of bleeding complications as determined by the HAS-BLED score of ≥ 3 points (arterial hypertension with systolic blood pressure values of > 160 mm Hg: 1 point, renal dysfunction requiring dialysis therapy, prior renal transplantation or creatinine level ≥ 200 μmol/L: 1 point, hepatic dysfunction defined as chronic liver disease or significantly increased hepatic enzyme activity: 1 point, stroke: 1 point, previous bleeding: 1 point, labile INR values: 1 point, age > 65 years: 1 point, alcohol abuse: 1 point, drug use, e.g. antplatelet drugs or non-steroidal anti-inflammatory drugs: 1 point) [5].

3. Contraindications to OAC therapy in patients with lower HAS-BLED scores, including previous haemorrhagic stroke, recurrent clinically significant bleeding, skin necrosis.

4. Recurrent ischaemic stroke despite OAC therapy.

5. Informed patient consent obtained after an extensive discussion regarding procedural details, benefits, and potential complications.

Left atrial appendage occlusion was performed with the use of the ACP device. This device consists of two main parts: a lobe with small hooks which is the main fixing component preventing any subsequent dislocation of the device, and a proximally located disk. The purpose of the disk is to provide tight occlusion of the LAA entry (Fig. 1). The disk is connected to the lobe by a flexible waist that allows the disk to be tilted in relation to the lobe. This allows optimal adjustment of the disk to the LAA entry plane and thus providing tight occlusion. The device may be used to occlude a LAA that is at least 1 cm deep.

Amplatzer Cardiac Plug implantation procedure

The procedure of ACP implantation was preceded by intravenous administration of 500 mL of normal saline to provide nephroprotection, and 1 g of cephalazone as a measure to
prevent bacterial endocarditis. In addition, all patients who were not receiving antithrombotic therapy at the time of procedure were administered a loading dose of acetylsalicylic acid (300 mg) and clopidogrel (300 mg) at least 2 hours before the procedure. Continued acetylsalicylic acid therapy was recommended for at least 6 months, and clopidogrel therapy (75 mg/day) for 1–3 months, unless other indications for the use of these drugs were also present.

Implantation procedures were performed under general anaesthesia with transoesophageal echocardiographic and fluoroscopic guidance.

Stage I: Transseptal puncture. Transseptal puncture was performed using standard equipment including the Brockenbrough needle and a 8 F SL0 St. Jude Medical transseptal sheath. The puncture was guided by transoesophageal echocardiography and left atrial pressures and performed in the middle lower part of the septum. This puncture site is recommended for both safety reasons and the ease of reaching LAA with the guiding system. In echocardiography, the septum was imaged in two perpendicular planes, a bicaval view and an aortic short-axis view (Fig. 2). After transseptal puncture and introduction of the system to the left atrium, unfractionated heparin was administered in an initial dose of 1000 U/10 kg of body weight to increase the activated clotting time to at least 250 s.

Stage II. Following transseptal puncture, the sheath was introduced into LAA using a guidewire. Angiography was performed with manual contrast agent administration in at least two perpendicular planes (right and left anterior oblique views). Based on these images, LAA anatomy was determined and the largest LAA dimension was measured (Fig. 3). Independent from the angiographic evaluation, LAA entry dimension...
was also evaluated at this stage in multiple planes by transoesophageal echocardiography (Fig. 4). The size of an implanted ACP device was chosen depending on the maximum measured LAA neck width: for LAA neck sizes up to 22 mm, an ACP device oversized by 2 mm was used, and a device oversized by 4 mm was used for LAA neck sizes above 22 mm. After LAA angiography, the transseptal sheath was replaced with the ACP introduction system which was placed in LAA.

Stage III: The ACP system was prepared and introduced into LAA using the sheath. The tip of the introduction system was placed at mid-depth of the appendage. Then, an appropriately sized ACP device was introduced under fluoroscopic and echocardiographic guidance (2-chamber view) to allow expansion of the ACP lobe perpendicularly to the LAA long axis. When the position of the ACP lobe and its stability were confirmed, the introduction system was removed, releasing the ACP disk (Figs. 5A, B).

Stage IV. Before the introduction system was released, an appropriate position of the ACP device in the LAA neck entry was evaluated, along with the effectiveness of LAA occlusion (Figs. 6, 7). Postprocedural evaluation of the ACP device position included its stability and appropriate location in relation to the mitral valve and the left circumflex coronary artery. In addition, the pericardium was checked for any effusion during the procedure.

A successful LAA closure was defined as no flow distal to the ACP disk or trace flow between the disk and the lobe by angiographic and echocardiographic evaluation. During ho-
spitalisation, echocardiography to check for any pericardial effusion was repeated twice, first within several hours after the procedure and then before hospital discharge.

Evaluation of ACP implantation safety included the following adverse events: death, cardiac tamponade, pericardial effusion requiring follow-up and prolonged hospitalisation, stroke, device embolisation, device dyslocation, and coronary artery air embolism.

**RESULTS**

The study group included 14 men and 7 women. Mean patient age was 71 years, and one third of patients were above 75 years of age. The study population included patients at increased risk of both thromboembolic and bleeding complications, with the mean CHA2DS2VASc score of 4.43 points, and the mean HAS-BLED score of 3 points (Table 1).

Table 2 shows comorbidities in the study group. A majority of the study group were patients with low left ventricular ejection fraction and chronic heart failure — 9 patients, including 6 patients with a cardiac resynchronisation therapy defibrillator (CRT-D) device, and 3 patients with an implantable cardioverter-defibrillator (ICD). In addition to these patients, an ICD or CRT-D had also been implanted in 2 subjects, including for primary prevention of a sudden cardiac death in 1 patient, and for secondary prevention of a sudden cardiac death in 1 patient with hypertrophic cardiomyopathy.

The mean LAA neck diameter by transoesophageal echocardiography was 20.3 ± 4.2 mm (min. 14 mm, max. 28 mm). Similarly, the mean LAA neck diameter as measured by LAA angiography was 20.7 ± 3.8 mm (min. 14 mm, max. 28 mm). The implanted ACP device size ranged from 16 mm to 30 mm (Table 3).

Successful LAA closure was obtained in 20 (95.2%) patients. In 1 patient, optimal effect of the procedure was not possible due to anatomical reasons (an additional LAA lobe precluding tight occlusion of the appendage). In 90% of successful procedures (18 patients), LAA closure was possible with the initially chosen device size. In 2 patients, the device size had to be changed (for a smaller sized device in 1 patient, and a larger sized device in the other patient).

Total procedure duration, fluoroscopy time, and the amount of contrast agent administered are shown in Table 4. A serious periprocedural complication occurred in 1 (4.76%) patient who had cardiac tamponade requiring pericardiocentesis. This adverse event likely occurred to left atrial wall damage during withdrawal of the ACP introduction system. In addition, clinically and haemodynamically insignificant pericardial effusion that required no intervention was noted in 2 (9.5%) patients (Table 5). Other types of periprocedural complications reported in the literature, including stroke, ACP dislocation, ACP thrombosis, and coronary artery air embo-

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**Table 1. Characteristics of the study group**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [years]</td>
<td>71.19 ± 9.4</td>
</tr>
<tr>
<td>Age &gt; 75 years</td>
<td>7 (33.3%)</td>
</tr>
<tr>
<td>Female gender</td>
<td>7 (33.3%)</td>
</tr>
<tr>
<td>Number of points in the CHA2DS2VASc score:</td>
<td>4.43 ± 1.4</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>2 (8.33%)</td>
</tr>
<tr>
<td>3</td>
<td>3 (12.5%)</td>
</tr>
<tr>
<td>4</td>
<td>6 (25%)</td>
</tr>
<tr>
<td>≥ 5</td>
<td>10 (41.67%)</td>
</tr>
<tr>
<td>Number of points in the HAS-BLED score:</td>
<td>3 ± 0.7</td>
</tr>
<tr>
<td>2</td>
<td>5 (20.83%)</td>
</tr>
<tr>
<td>3</td>
<td>11 (45.83%)</td>
</tr>
<tr>
<td>4</td>
<td>5 (20.83%)</td>
</tr>
</tbody>
</table>

**Table 2. Comorbidities in the study group**

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Number (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease</td>
<td>14 (66.7%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>14 (66.7%)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>6 (28.6%)</td>
</tr>
<tr>
<td>History of stroke/TIA</td>
<td>8 (38.1%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>6 (28.5%)</td>
</tr>
<tr>
<td>History of bleeding or predisposition to bleeding (e.g., peptic ulcer disease)</td>
<td>11 (52.4%)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>9 (42.8%)</td>
</tr>
<tr>
<td>Implanted device:</td>
<td></td>
</tr>
<tr>
<td>Pacemaker</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>ICD</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>CRT-D</td>
<td>7 (33.3%)</td>
</tr>
</tbody>
</table>

CRT-D — cardiac resynchronisation therapy-defibrillator; ICD — implantable cardioverter-defibrillator; TIA — transient ischaemic attack.
Percutaneous closure of the left atrial appendage using the Amplatzer Cardiac Plug in patients with AF

DISCUSSION

Despite several years of experience with different percutaneous LAA closure systems, this form of stroke prevention in patients with nonvalvular AF has not become widely adopted. Unresolved issues include lack of data on optimal patient selection, risk of periprocedural complications, and a possibility of incomplete LAA closure. Residual LAA flow after implantation of the Watchman plug is a common phenomenon found in 32% of patients, although it has not been shown to increase the rate of thromboembolic complications [17]. In contrast, the ACP device uses an additional disk occluding LAA entry and thus potentially allows a higher rate of complete closure. However, this system has been the most recent one to be introduced clinically and thus its safety and effectiveness still require evaluation.

The only prospective, randomised, multicentre study that evaluated the effectiveness and safety of LAA closure was the Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF) trial. This study evaluated the effectiveness and safety of LAA closure using the Watchman device as compared to warfarin therapy. The study included 707 patients, with 463 of them randomised to implantation of a Watchman plug. It was shown that the effectiveness of stroke prevention using the Watchman device is noninferior to warfarin therapy, but with a significantly lower risk of bleeding complications [16]. However, the combined safety endpoint that included both bleeding complications and periprocedural complications occurred significantly more commonly among patients in the Watchman plug implantation group than in the warfarin group (7.4 vs. 4.4 per 100 patient-years). In the intervention group, the most common safety endpoint was cardiac tamponade requiring percutaneous or surgical drainage (4.8% patients). Other safety endpoints included periprocedural strokes (1.1%) and implant embolisation (0.6%). Overall, major complications occurred in 6% of patients undergoing invasive treatment in the PROTECT AF study.

Our results on ACP implantation may be compared with only two other ACP registries: a European registry that included 143 patients and an even smaller, two-center Asia-Pacific experience registry including 20 patients [18, 19]. In the first of these registries, successful LAA closure was obtained in 96% of cases, and in the other in 19 of 20 patients (95%). In our study group, ACP deployment resulted in successful LAA closure in 20 of 21 patients (95.2%). These results are in agreement with the literature data and indicate that these procedures may be performed with a relatively high success rate.

When evaluating percutaneous LAA closure using ACP, a factor of equal importance to its effectiveness is the analysis of procedural safety. Data on the rate and type of complications occurring with this type of procedure are crucial for determining the criteria of patient selection for ACP implantation. In our opinion, decisions regarding patient selection for this treatment should be ultimately based on both the estimated risk of stroke and bleeding complications and the risk of periprocedural complications. Unfortunately, heterogeneity regarding stroke and bleeding risk in various registries and studies precludes direct comparisons, both in regard to ACP implantation outcomes in particular studies and in terms of comparing ACP implantation safety with that of the Watchman plug.

Park et al. [18] in an analysis of patients undergoing LAA closure using ACP who were included in the European regi-
Our study population included much more sicker patients, as evidenced by a high mean CHA2DS2VASc score of 4.43 ± 1.4 points. In addition, these patients were characterised by not only a high stroke risk but also a high bleeding risk, with the HAS-BLED score of ≥ 3 points (or lower HAS-BLED risk but with contraindications to OAC such as previous central nervous system bleeding or skin necrosis). Beside stroke and bleeding risk, a much higher comorbidity burden in our study population is also evidenced by a large proportion of patients with heart failure and an implanted defibrillator (either CRT-D or ICD; 11 patients). Despite this, the rate of major complications in our study population was rather low.

CONCLUSIONS

Based on our experience, successful LAA occlusion using the ACP device is feasible in most patients with multiple comorbidities and a high risk of stroke and bleeding complications. The rate of serious periprocedural complications related to ACP implantation has been relatively low among these patients. Taking into account potential complications, patient selection for this procedure should be based on careful evaluation of benefits of the invasive prevention approach, including the risk of stroke and bleeding complications when alternative strategies are used.

Conflict of interest: none declared

References


Percutaneous closure of the left atrial appendage using the Amplatzer Cardiac Plug in patients with AF


Przezskórne zamknięcie uszka lewego przedsionka za pomocą Amplatzer Cardiac Plug u chorych z migotaniem przedsionków: ocena skuteczności i bezpieczeństwa zabiegu

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Streszczenie

Wstęp: Udar mózgu jest częstym powikłaniem migotania przedsionków (AF). Towarzystwa kardiologiczne zalecają ocenę ryzyka udaru mózgu i włączenie odpowiedniej profilaktyki u chorych z AF. Najczęściej profilaktyka ta opiera się na stosowaniu leków przeciwpłytkowych lub doustnych leków przeciwkrzepliwych (OAC). U osób z przeciwwskazaniami do stosowania OAC lub wysokim ryzykiem powikłań krwotocznych nowym, alternatywnym sposobem profilaktyki udaru mózgu są rozwijane metody przeszkołnego zamknięcia uszka lewego przedsionka, będącego głównym źródłem sercowopochodnego materiału zakrzepowo-zatorowego w AF. Obecnie zastosowanie kliniczne mają zatyczki typu Watchman i Amplatzer Cardiac Plug (ACP), ale w dalszym ciągu doświadczenia z ich użyciem są bardzo ograniczone.

Cel: Celem niniejszej pracy jest ocena skuteczności i bezpieczeństwa zabiegu profilaktycznego zamknięcia uszka lewego przedsionka metodą przeszkołną z zastosowaniem ACP na podstawie wczesnych doświadczeń własnych w grupie osób z licznymi chorobami współwystępującymi, o wysokim ryzyku udaru mózgu w przebiegu niezastawkowego AF oraz o podwyższonym ryzyku krwawienia.

Metody: Do badania włączono 21 wyselekcjonowanych pacjentów mających co najmniej 2 punkty w skali ryzyka udaru mózgu CHADS2 lub CHA2DS2VASc oraz wysokie ryzyko powikłań krwotocznyczych nowym, alternatywnym sposobem profilaktyki udaru mózgu są rozwijane metody przeszkołnego zamknięcia uszka lewego przedsionka, będącego głównym źródłem sercowopochodnego materiału zakrzepowo-zatorowego w AF. Obecnie zastosowanie kliniczne mają zatyczki typu Watchman i Amplatzer Cardiac Plug (ACP), ale w dalszym ciągu doświadczenia z ich użyciem są bardzo ograniczone.

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Wyniki: Zabiegi implantacji ACP wykonano w grupie chorych bardzo obciążonych współistniejącymi chorobami, u których stwierdzano zarówno wysokie ryzyko udaru mózgu (CHA2DS2VASc 4,43 ± 1,4 pkt), jak i powikłań krwotocznyczych (HAS-BLED = 3,0 ± 0,7 pkt). Skuteczne zamknięcie uszka lewego przedsionka uzyskano u 20 (95,2%) pacjentów. Poważne powikłania okolożabiegowe stwierdzono u 1 (4,76%) osoby. Była to tamponada serca wymagająca perikardiocentezy.

Wnioski: Skuteczne zamknięcie uszka lewego przedsionków można uzyskać u większości pacjentów poddawanych procedurze wszczepienia ACP. Częstość powikłań okolożabiegowych związanych z implantacją ACP w grupie pacjentów z licznymi chorobami współwystępującymi, o wysokim ryzyku udaru mózgu i powikłań krwotocznyczych, jest względnie niska. Dlatego też stosowanie ACP można uznać za racjonalną metodę postępowania w profilaktyce udaru mózgu w tej grupie chorych.

Słowa kluczowe: Amplatzer Cardiac Plug, migotanie przedsionków, udar mózgu, zamknięcie uszka lewego przedsionka

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