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Přehledový článek | Review

Percutaneous exclusion of the left atrial appendage in prevention of systemic embolism

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ABSTRACT

Left atrial appendage is the most frequent place of blood clot formation in heart cavities. The thrombus formation increases a risk of a systemic embolism especially in patients with a permanent atrial fibrillation. The standard preventive treatment is the oral anticoagulation therapy. Another possible treatment is an exclusion of a left atrial appendage. We present current overview of risks and benefits of surgical and percutaneous elimination of a left atrial appendage. We present the first experience with AMPLATZER Cardiac Plug system in an elimination of a left atrial appendage. We concluded that an exclusion of left atrial appendage could become a useful possibility of prevention of systemic embolization in patients with an atrial fibrillation, but is not still an alternative therapy for anticoagulation therapy at present.

SOUHRN

Levá srdeční síň je místo, kde dochází nejčastěji k formování trombu u nemocných s fibrilací síní. Systémová embolizace je pak u těchto nemocných závažnou zdravotní komplikací. V prevenci systémové embolizace u nemocných s fibrilací síní se nejčastěji používá perorální antikoagulační léčba. Další možností pak je eliminace ouška levé síně. V článku je podán přehled současných možností chirurgické a katetrizační eliminace ouška levé síně. Jsou prezentovány první praktické zkušenosti s použitím systému AMPLATZER Cardiac Plug při katetrizačním uzavírání ouška levé síně.
Závěr: Dosavadní data a zkušenosti ukazují, že katetrizační uzavření ouška levé síně je dobrou možností prevence systémové embolizace u pacientů s fibrilací síní. Zatím však není alternativou k zavedené perorální antikoagulační léčbě.

Introduction

Systemic embolism, especially cerebral embolism, is a very serious health problem. Approximately 15–20% of ischemic strokes are caused by an atrial fibrillation (AF) according to the literature. AF occurs in 3–5% of people older than 65 years with a 5% risk of stroke per year. The risk increases up to 30% per year in octogenarians or elderly [1–4]. The most frequent location of a thrombus is a left atrial appendage (LAA). In people with a permanent AF

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combined with the rheumatic valve disease, LAA is a region of formation of thrombus in about 57% of cases and in about 90% in cases of non-rheumatic AF [4,5]. The oral anticoagulation therapy (AT) is nowadays a standard treatment diminishing the risk of ischemic stroke. Hart's meta-analysis shows that AT decreases the risk of ischemic stroke by about 64%, while the antiplatelet therapy only by about 22% [6–9]. However, a significant group of high risk people with a permanent AF is contraindicated to AT and in some other cases AT is unsatisfactory and insufficient [10].

The location of LAA has led to the idea that the risk of stroke in patients with AF operated for a valve heart disease could be reduced by eliminating LAA. Although a surgical elimination of LAA has been made since late 1940's, there is still a lack of data about benefits and effectiveness of this procedure. The standard techniques of the LAA elimination are the excision, ligation, suture or stapler. In accordance with published studies, the LAA elimination is not always successful. The range of successful complete elimination fluctuates between 0–73%, regarding a type of procedure [11–15]. It is evident that in a standard clinical practice a success of LAA is influenced either by a type, quality or accuracy of procedure.

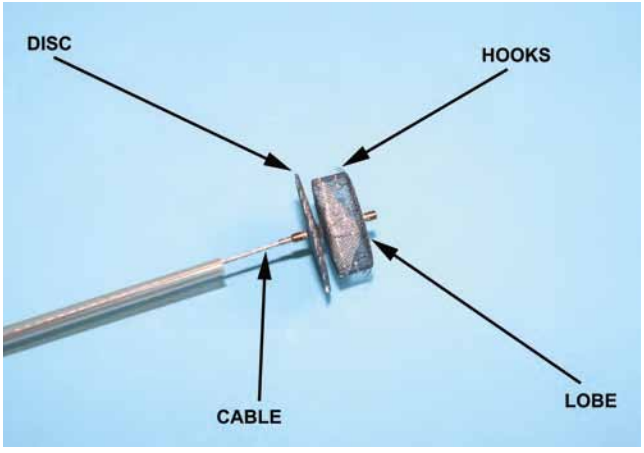

Fig. 1 – AMPLATZER Cardiac Plug.

Most recently, some less invasive thoracoscopic techniques have been invented and introduced into a clinical practice. The LAA elimination is performed solely, or together with the MAZE ablation of AF. The data are limited also in case of this procedure [16–20].

The last possibility of the LAA elimination is the percutaneous closure via a transseptal puncture. The combined transseptal and transpericardial accesses are also tested – Lariat Suture Delivery Device (SentreHEART, Inc.; Palo Alto, Calif).

Percutaneous closure of a left atrial appendage

First experiences with the percutaneous closure of LAA were released shortly after 2000 – the first dedicated system was percutaneous left atrial appendage occlusion (PLAATO) [21,22]. Meier published first experiences with the LAA closure by Amplatzer ASD Occluder in 2003 [23]. There are currently two dedicated systems on the market – WATCHMAN (Atritech Inc., Plymouth, Minnesota) and AMPLATZER Cardiac Plug (Amplatzer Cardiac Plug AGA Medical Corporation, a part of St. Jude Medical, Inc.; St. Paul, Minneapolis). The AMPLATZER Cardiac Plug system (Fig. 1) is used at our department, therefore a short description of the procedure with this device follows.

Transoesophageal echocardiography (TEE) is an important first step in patients screened for the LAA closure. It is necessary to measure the size, shape, and position of LAA in some distinct projections (Fig. 2A, 2B). The anatomic variability of LAA is vast. The TEE examination is also required immediately before the implantation of the device in order to avoid casual thrombus in LAA. The routine and safe transseptal puncture is crucial in the LAA closure process (Fig. 3A, 3B). A stiff guiding wire is placed through a transseptal catheter into a left atrium (LA), the most optimally into a left pulmonary vein. Using this guiding wire, a 8–13F sheath is inserted into LA and then into LAA (Fig. 4). LAA angiography in some distinct projections is suitable as well (Fig. 5). The AMPLATZER Cardiac Plug is made from Nitinol mesh and consists of

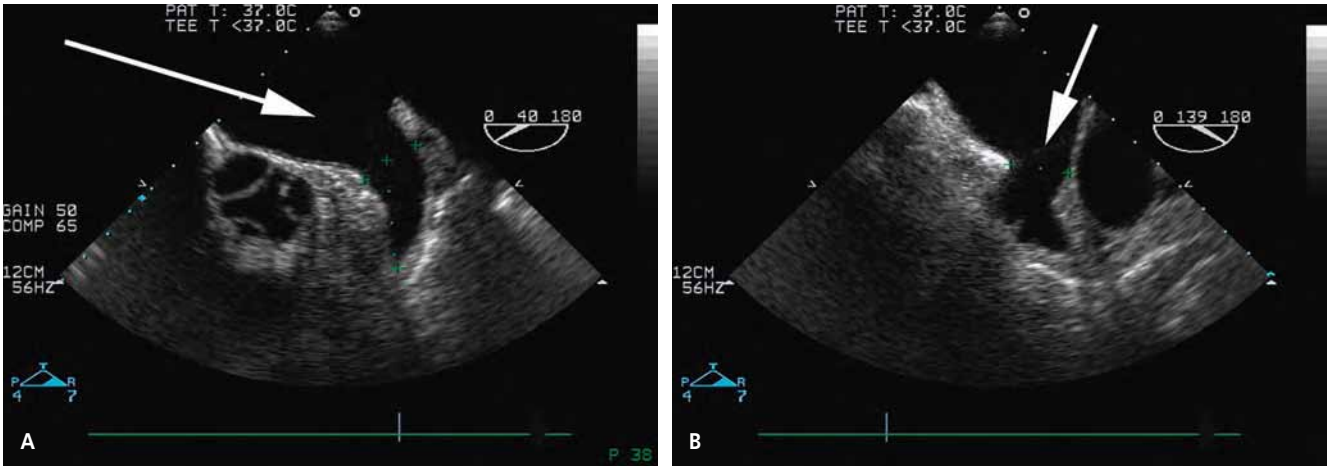

Fig. 2 – (A, B) TEE picture and the LAA – measurement.

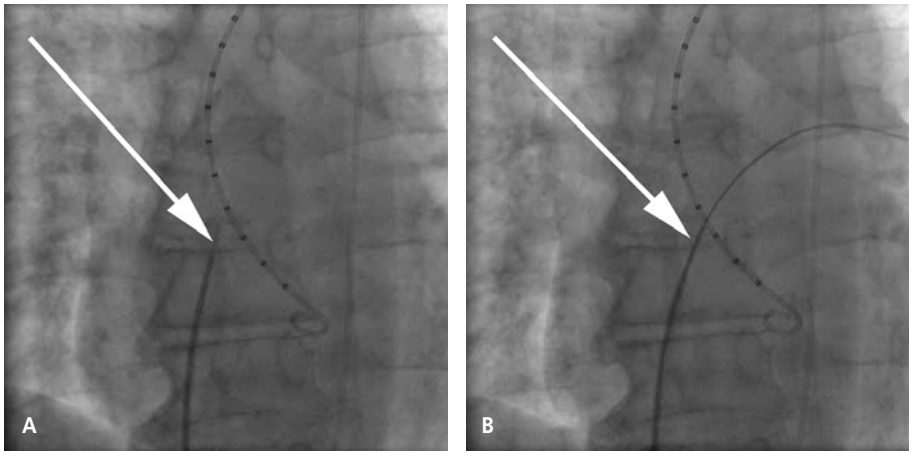

Fig. 3 – (A, B) Transseptal puncture.

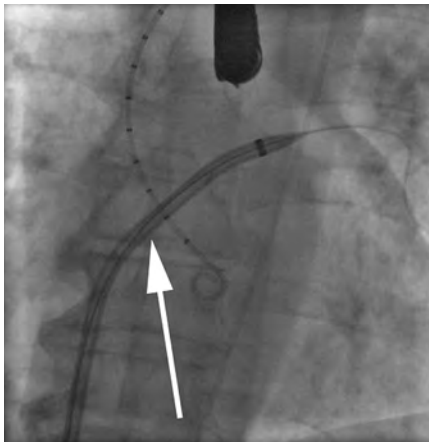

Fig. 4 – Access of the sheath through the atrial septum into the LA.

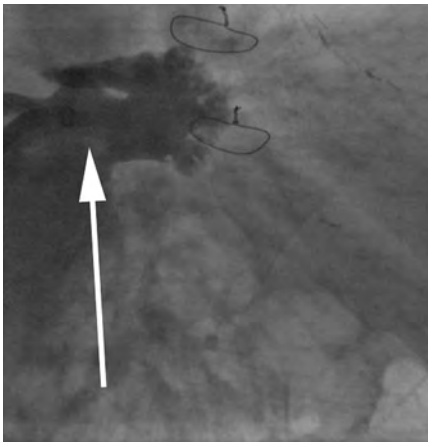

Fig. 5 – Angiography of the LAA.

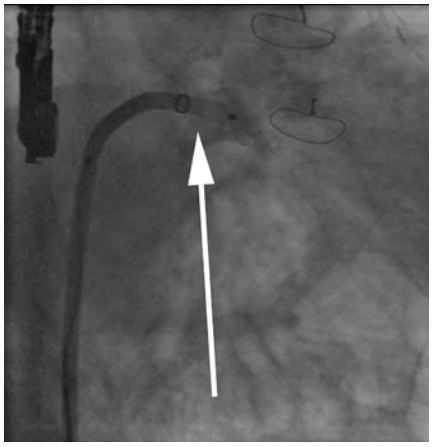

Fig. 6 – The device before its withdrawal from the sheath.

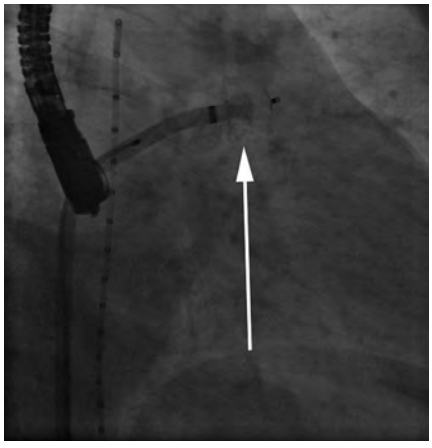

Fig. 7 – The lobe in the LAA.

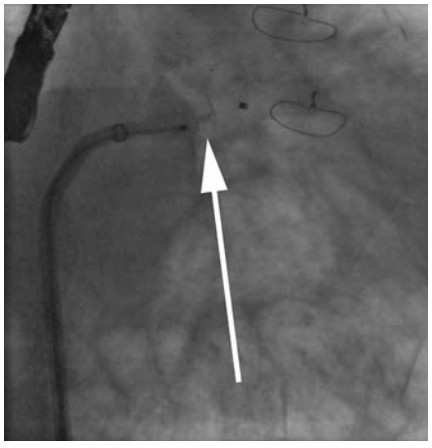

Fig. 8 – The device completely released in the LAA with cable.

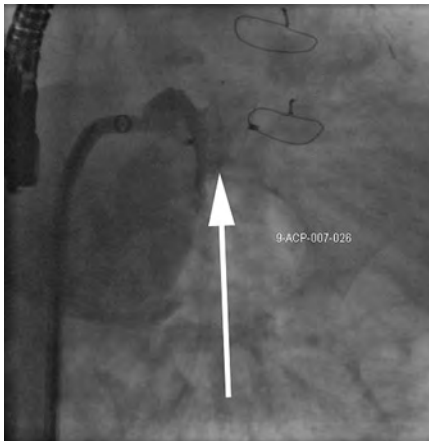

Fig. 9 – The released device, the angiographic control of the position.

two parts. The first part is the lobe with small hooks that is placed into a cavity of LAA, fixing the device inside. The second part is the disk that closes a LAA orifice. The device is introduced by a cable, as similarly as with other Amplatzer devices (Fig. 1). After thorough assurance of its position and stability, the cable is unscrewed and the plug is released. Before releasing, reposition or withdrawal of the device is possible. Positioning and stability verification of the plug is performed by TEE with a parallel angiographic control (Fig. 6–10).

The procedure in our department is performed in an analgosedation, another alternative is a general anesthesia. Heparin (100 U/kg) is given during the procedure. No patient died due to periprocedural complications. One

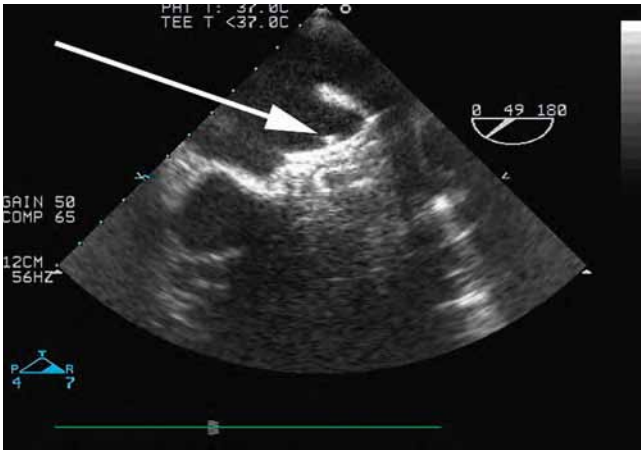

Fig. 10 – The released device, TEE control of the position.

patient had an acute cardiac tamponade with necessity of surgical revision. The surgeon found the contusion and hematoma on the boundary between the upper left pulmonary vein and the LAA. The contusion was caused by the edge of sheath, which passed through the septum only with heavy resistance. The sheath then held onto the wall of LA after removing the wire. However, the surgeon found no leak or bleeding. No other serious complications occurred in our patients.

The dual antiplatelet therapy (aspirin 100 mg + clopidogrel 1× 75 mg/day) is used over the next three months following the procedure and then aspirin (100 mg) after that 3-month period. We have no mortality in follow-up period of 3–20 months. A small flat thrombus was verified on the plug's disk in one patient, who prematurely quitted the dual antiplatelet treatment without our approval. Two patients have trivial leaks. No systemic embolism has occurred in any our patient. Furthermore, no patient used warfarin.

Discussion

While considering the LAA exclusion, we should keep in mind that the LAA is a region prone to thrombus formation in some patients. However, the LAA has some important physiological functions. It has a crucial positive role in a systolic function of LA, improves a filling of a left ventricle and thereby influences cardiac output. It has a buffer function in liquid volume and pressure in a LAA. LAA elimination increases both size and mean pressure in LA. LAA distention helps to induce a diuresis. It has a certain role in a sensation of thirst. A LAA is hormonally active, producing an atrial and probably a brain natriuretic peptide [24].

The percutaneous closure of LAA is a tough procedure – it is essential to manage routinely the transseptal puncture and the implantation takes place in a very thin-wall cavity of LA and LAA (0.4–1.5 mm). The procedure might be connected with couple of complications (e.g. tamponade, device embolization, a periprocedual stroke, air embolism), another problem could be a residual leak or thrombus formation on a device. Sievert [21] states that he had one tamponade in a group of first 15 patients with PLAATO system. Ostmayer [25] states 97.3% primary success in a group of 111 patients with PLAATO. One patient died during the hospitalization. The pericardial effusion was verified in four patients, two of them had tamponade. Hemothorax was documented in one patient. Stroke occurred in 2.2% patients of the group. Six months after the procedure, the LAA was totally occluded in 98% of the patients. Sick [26] published first experience with the WATCHMAN system in a group of 66 patients. The LAA was totally occluded in 93% of patients 45 days after the procedure. Two patients had device embolization, two had tamponade, one had air embolization and one patient's occluder was damaged. Billowing thrombus was verified in four cases (successfully treated by the anticoagulation therapy), transient ischemic attack (TIA) in two cases. Park [27] describes first experience with the AMPLATZER Cardiac Plug system. It was successful in 96% in a group of 143. Serious complications occurred in 10 cases (7%): periprocedural stroke (3×), device embolization (2×), tamponade (5×).

PROTECT AF study [28,29] is the only randomized study up to date. This study was drafted as a study of non-inferiority of the percutaneous closure of LAA by the WATCHMAN system against the standard AT by warfarin. 707 patients with atrial fibrillation and risk of stroke ($CHADS_2 \geq 1$) were randomized in the rate of 2 : 1 (WATCHMAN 463 : 244 warfarin). The mean follow-up was 18 months. The combined end-point (either stroke, cardiovascular death or systemic embolism) was detected in 3% of patients in WATCHMAN group and 4.9% in warfarin group. Non-inferiority of invasive procedure was therefore proved.

From the primary safety end-point (device embolization, tamponade, brain bleeding, gastrointestinal tract bleeding with a necessity of using ≥ 2 transfusions), brain bleeding occurrence was significantly higher in the warfarin group (2.5% vs. 0.2%) and also other types of bleeding were higher (4.2% vs. 3.5%). Serious complications in the WATCHMAN group were experienced in 12.3% of patients (tamponade 4.8%, periprocedural stroke 1.1% and device embolization 0.6%). The overall frequency of ischemic stroke was higher in the WATCHMAN group (3% vs. 2%) due to periprocedural stroke. Reddy extended the assessment of the study of about 460 patients from the WATCHMAN registry and evaluated separately the data from the second part of the PROTECT AF study. Significant decrease in complications was documented [30].

Conclusions

1. The percutaneous closure of LAA is an acceptable and useful possibility of prevention of systemic embolization in patients with an atrial fibrillation.
2. The procedure cannot be considered as an alternative to the AT. Only those contraindicated to the AT or people with serious complications of AT should be indicated to the percutaneous closure. Although the PROTECT AF study proved non-inferiority elimination of the LAA by the WATCHMAN system, incidence of periprocedural complications was quite disturbing. More data are needed.
3. Because of the possibility of serious periprocedural complications, this procedure should only be

performed at departments with routine experience with the transseptal puncture and the percutaneous interventions in a LA.

4. In general, the elimination of LAA should be carefully considered and undertaken only in patients with evident dysfunction of the LAA. It should not be performed in a patient with a real possibility of sinus rhythm restoration.

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