Successful Percutaneous Closure of Left Atrial Appendage with Periprocedural Hemorrhage Stopped by the Implanted Device

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Abstract
Atrial fibrillation (AF) is the most common arrhythmia and affects 1% of the population. It is associated with the need for oral anticoagulation therapy for stroke prevention. Based on the fact that more than 90% of stroke causing thrombus has its origin within the left atrial appendage (LAA) [1], nonpharmacological approaches such as isolation of LAA from the blood circulation were proposed. However, this invasive way of stroke prevention has its own risk related to the device and procedure.

Keywords: Atrial Fibrillation; Left Atrial Appendage Closure; Pericardial Effusion

Abbreviations: AF: Atrial Fibrillation; NVAF: Non-Valvular Atrial Fibrillation; LAA: Left Atrial Appendage; LAAC: Left Atrial Appendage Closure; NYHA: New York Heart Association; TTE: Transthoracic Echocardiography; TEE: Transesophageal Echocardiography; INR: International Normalized Ratio; UFH: Unfractionated Heparin; RV: Right Ventricle; ACT: Activated Clotting Time

Introduction
Atrial fibrillation (AF) is the most common cardiac arrhythmia affecting 1% of the population and is associated with fourfold to fivefold increase in the risk of ischemic stroke, regardless of etiology [2-5]. In recent years the left atrial appendage (LAA) has received significant medical evidence for its role in generating stroke-causing blood clots in patients with non-valvular atrial fibrillation (NVAF). Left atrial appendage closure (LAAC) with percutaneously implanted occluder in the LAA has been shown to be non-inferior to warfarin in the prevention of ischemic stroke in patients with NVAF [5]. This way of stroke prevention may be considered in patients with high bleeding risk, who have a history of serious bleeding complication and because of which have absolute contraindication to oral anticoagulation (OAC) therapy. The Watchman device (Boston Scientific Corp., Marlborough, MA, USA) was the first of its kind alternative to OAC therapy and its safety and effectiveness was demonstrated in randomized, clinical trials [6-8]. Nonetheless, the LAAC procedure is associated with complications related to the device, such as pericardial effusion, device embolization, and device-related thrombus formation [6-9].

Case Report
A 61-year-old man with paroxysmal NVAF and several comorbidities including hypertension, coronary artery disease, heart failure in NYHA class II and hyperlipidemia was admitted to the hospital for the assessment of indications and feasibility of the percutaneous LAAC. Both thromboembolic and bleeding risk were high as demonstrated by the CHA2DS2-VASc and HAS-BLED scores, with 3 points of each. Furthermore patient had an absolute contraindication to OAC therapy due to reported inability to maintain the international normalized ratio (INR) within the therapeutic range, and due to the repeated history of severe gastrointestinal bleeding during vitamin OAC therapy. In order to the qualification to the procedure the transesophageal echocardiography (TEE) was performed to assess the anatomy of LAA: depth, shape and width.
of the orifice. Evaluation of the interatrial septum (IAS) before its puncture and exclusion of the presence of thrombi inside the LAA were also performed during TEE.

Based on the patient’s history, high bleeding and thromboembolic risk and good LAA morphology for the procedure the patient was qualified for the percutaneous LAAC. The procedure was performed under general anesthesia with TEE and fluoroscopic guidance. After trans septal puncture un fractionated heparin (UFH) was administrated to continue the procedure with prolonged activated clotting time (ACT) to at least 250 s. Following the sheath introduction to the LAA, angiographic projections were made to assess the shape of LAA. Based on acquired angiographic planes and TEE visualization, the 24 mm Watchman device has been chosen. During the procedure of positioning the device, fluid appeared in the pericardial sac, what was observed on TEE (Figure 1).

In fluoroscopy it was evident that contrast is getting through the LAA to pericardium, thus the injury to the LAA wall was confirmed (Figure 2). In TEE the pericardial effusion was enlarging during the procedure up to 16 mm behind the right ventricle (RV). At this moment the heart rate kept stable on the level of 60 beats per minute, but the drop of systolic blood pressure to 60 mmHg was observed. Because of the patient’s hemodynamic instability, the intravenous adrenaline and saline infusion was started. The next day thoracic echocardiography (TTE) has shown that the level of fluid maintains stable, with no increase in its amount and there was no compression on heart’s cavities. With this TTE result it was safe to initiate the dual antiplatelet therapy to avoid the thrombus formation on the device. Repeated TTE assessments revealed decreasing amount of the fluid in pericardial sac to 4 mm in the ninth day after LAAC procedure. Six weeks later the follow-up TEE and TTE were performed and neither fluid in pericardial sac, nor thrombus on the device was present.

### Discussion

Pericardial effusion is one of the serious adverse events related to the LAAC procedure and constituted the majority of complications. The PROTECT AF trial was the first randomized trial assessing the efficacy and safety of Watchman device [6]. The study revealed that pericardial effusion requiring surgical intervention or pericardiocentesis appeared in 1.6% and 2.4% of cases, respectively. Procedure-related pericardial effusion with tamponade was relatively frequent but not fatal [10]. The other randomized trial, that let the device get into the daily clinical practice, was PREVAIL trial. The adverse events related to the procedure was significantly lower than in PROTECT AF trial and occurred in 4.2% of the cases in Watchman arm [8]. Pericardial effusions that required to be managed with surgical intervention decreased from 1.6% to 0.4%, while those required pericardiocentesis decreased from 2.4% to 1.5% [8]. The EWOLUTION registry was created to collect real-life data regarding LAAC procedure and more than thousand patients were included. The overall rate of complications during 7 days after procedure was 2.8%, which is lower than in any previous conducted trial or registry [11].

Pericardial effusion appeared only in 5 cases including only one cardiac tamponade. Comparing the data previously revealed from the PROTECT AF trial and CAP (Continued Access PROTECT AF Registry) study and PREVAIL trial showed learning curve demonstrated improved implant profile in experienced and new operators [8,10]. The safety profile of EWOLUTION registry was also favorable in comparison to previous results. Pericardial effusion appears to be a serious complication, usually requiring management with catheter or surgical drainage. Nevertheless, patients that could be managed conservatively had no long-lasting consequences and no associated deaths have been reported after pericardial effusion in clinical trials, as well as in single center reports [12]. Our case proves that successful implantation of the device effectively eliminates LAA from the blood circulation and can prevent pericardial effusion during LAAC, which results in avoiding tamponade and the need of further interventions.

### Conclusion

The safety profile of the LAAC procedures improved during last few years, even in high risk patients with several co-morbidities. The improvement in device deployment techniques and increased operator’s experience decreased procedure related complications.
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