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Effectivity of left atrial appendage occlusion with AtriClip in 155 consecutive patients – Single center study



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ABSTRACT

Objectives: Left atrial appendage (LAA) plays a crucial role in the etiopathogenesis of the stroke in patients with non-valvular atrial fibrillation. Different methods of surgical occlusion of the LAA have been associated with different levels of acute and chronic success rate. This paper presents our experience with LAA occlusion using the AtriClip.

Methods: 155 patients undergoing cardiac surgery procedures with epicardial AtriClip exclusion of the LAA were enrolled in the study. The AtriClip was placed via a sternotomy, thoracotomy or from a thoracoscopic approach. Postoperative variables such as thromboembolic events, clip stability, and endocardial leakage around the device were examined by transesophageal echocardiography (TEE) and/or computed tomography (CT). Patients were then contacted via telephone and questionnaire regarding episodes of stroke and actual anticoagulation therapy was completed.

Results: Avg. age of the study population was 66.9 years (102 males). Clip was implanted from sternotomy or thoracotomy in 77 patients and from thoracoscopy in 78 patients. The perioperative success rate of clip implantation was achieved in 98% of patients. 10 patients (6.4%) were revised for bleeding, but none of the revisions were due to clip implantation. During the hospitalization and follow-up period, consisting of 2422 patient-months, 4 of the cardiac patients experienced transitory ischemic attacks and 2 patients experienced a cerebrovascular attack.

Conclusions: Epicardial clip exclusion of the LAA appears to be a reproducible and safe surgical method with a high success rate. Our follow-up confirmed clip stability, complete occlusion of the LAA, and absence of any AF-related thromboembolic events. These results support regular usage of AtriClip during LAA closure.

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Introduction

The left atrial appendage (LAA) is the most frequent source of thromboembolism (TE) in patients with non-valvular atrial fibrillation (AF), in whom the risk of TE is five times greater than in patients without AF [1]. Thrombi in left atrium (LA) are located in 9.8% patients with non-valvular AF and despite the anticoagulation therapy, 3.4% of patients are presented with thrombus in LAA [2]. For this reason, the guidelines of the European Society of Cardiology [3] recommend the exclusion of LAA during the surgical treatment of AF. The advantage of LAA removal during the surgical treatment of AF was confirmed in several non-randomized studies [4,5] and it is also an important part of Cox-MAZE IV procedure [6,7].

LAA occlusion may also play a role in treatment option for patients with chronic AF, who are contraindicated to anticoagulation therapy. This subset of patients with warfarin usage may be as high as 14–44% of cardiac patients [8,9]. The purpose of the study was to evaluate the efficiency (no cul de sac, no flow through the clip) and safety (no revision or bleeding due to the clip implantation) of AtriClip implantation.

Material and methods

Between July 2012 and September 2016, a total of 155 patients underwent a cardiac surgery procedure with AtriClip implantation at the Cardiac Surgery Department, Hospital of České Budějovice, Czech Republic. All patients had preoperative transesophageal echocardiography (TEE) to document and confirm the absence of pre-existing LAA thrombus. The AtriClip was standardly implanted using the thoracoscopic approach, thoracotomy approach or through sternotomy during concomitant procedures.

For purposes of this study, all LAA occlusions were with the AtriClip, or the second generation – AtriClip Pro (AtriCure, West Chester, OH, USA). The implantable device is a self-closing external LAA occluder that is available in 4 sizes, from 35 mm to 50 mm. It consists of two nitinol springs joined by two titanium parallel rods covered with Dacron polyester fabric.

Our postoperative anticoagulation strategy followed the hospital protocol. After the MAZE procedure, patients are administered warfarin with a target INR range between 2 and 3. After 3 months, if the patient is in sinus rhythm, warfarin is discontinued and the patient's medication is changed to antiaggregation therapy.

Follow-up to assess LAA closure was performed by TEE and some patients from the beginning of the study had also CT examination at 1- to 3-month postoperatively. Criteria of successful LAA occlusion were defined as absence of residual stump or pouch smaller than 1 cm and no persistent flow into the LAA using Doppler echocardiography. Telephone questionnaires focused on documenting any postoperative events – TIA/CVA or intracranial/internal bleeding as well as to confirm compliance with anticoagulation/antiaggregation therapy regimen were administered.

Results

A total of 155 patients were included in this study. Patients were mainly male (65.8%) and the average age was 66.9 years. 21.9% of patients had suffered from TIA/CVA preoperatively and the average CHA₂DS₂-VASc score was 2.7 (Table 1). The majority of cases were performed off-pump – during thoracoscopic AF ablation (45.8%) or as a standalone AtriClip implantation in 4.5% of patients (Table 2).

Periprocedural success rate was defined as complete LAA occlusion with no persistent flow into the LAA using Doppler echocardiography and residual stump smaller than 1 cm. The periprocedural success was achieved in 98% of the patients. Three patients who did not meet this criterion had residual stumps of 18 mm, 15 mm and 14 mm (Table 3). These patients were operated thoracoscopically and the two cases were among the series of first ten cases. These failures could be attributed to the learning curve of the procedure.

Table 1 – Preoperative characteristics.

Variables	No. = 155
Male	102 (65.8%)
Mean age	66.9 ± 6.9
Diabetes mellitus	39 (25.2%)
Hypertension	117 (75.5%)
Renal insufficiency	20 (12.9%)
TIA/CVA preoperatively	34 (21.9%)
Peripheral vascular disease	10 (6.5%)
COPD	40 (25.8%)
Paroxysmal AF	35 (22.6%)
Persistent AF	111 (71.6%)
Atrial flutter	9 (5.8%)
LVEF	59.6 ± 7.0
Mean CHA ₂ DS ₂ -VASc score	2.7 ± 1.5

TIA, transitory ischemic attack; CVA, cerebrovascular event; COPD, chronic obstructive pulmonary disease; AF, atrial fibrillation; LVEF, left ventricle ejection fraction.

Table 2 – Perioperative characteristics.

Variables	No. = 155
CABG	32 (20.6%)
Valve procedure	39 (25.2%)
Combined procedure	6 (3.9%)
Thoracoscopic AF ablation + AtriClip	71 (45.8%)
AtriClip as a lone procedure	7 (4.5%)
CABG, coronary artery bypass grafting.	

Table 3 – Periprocedural success rate.

Variables	No. = 155
Complete LAA occlusion	152 (98.0%)
LAA leak	0 (0%)
LAA residual stump >1 cm	3 (1.9%)
LAA, left atrial appendage.	

Table 4 – Postoperative characteristics.

Variables	No. = 155
Revision for bleeding	10 (6.4%)
TIA	0 (0%)
CVA	1 (0.6%)
ICU stay (days)	4.1 ± 3.8
Hospital stay (days)	12.1 ± 5.2
TIA, transitory ischemic attack; CVA, cerebrovascular event.	

During ICU stay, 10 patients (6.4%) underwent revision for bleeding. None of these were associated with the AtriClip implantation procedure and all these patients had undergone on-pump procedures (Table 4). One of the patients had bleeding from the distal anastomosis of a venous graft, one from the proximal anastomosis of a venous graft and another one of the patients from an aortic suture after aortic valve replacement. In seven patients the source of postoperative bleeding was not found but was probably caused by diluted coagulopathy. During postoperative hospitalization and recovery, one patient experienced a CVA that resulted in death. This patient was a 73-year-old woman with CHA₂DS₂-VAsC score of 5 undergoing a CABG plus closure of a patent foramen and concomitant AtriClip implantation. TEE in the ICU did not show a thrombus in the left atrium or on the endocardial side of the closed LAA.

Hospital mortality was 8.4%. All of the 13 deaths occurred in the on-pump group and correlated with the group of patients with high preoperative EuroSCORE (avg. 11.8).

During the long term follow-up, 4 transitory ischemic attacks were reported (Fig. 1). From the available medical records (TEE or CT), there were no thrombi in the left atrium or on the endocardial side of the closed LAA in these patients. There was not seen any clip migration or structural deterioration of the clip as well. In our group of patients, there was one CVA in patient 1 month after discontinuation of NOAC in the time period of 1 year after thoracoscopic ablation procedure. Follow-up time consisted of 3904 patient-months and mean duration time of follow-up 25.2 ± 13.4 months (Table 5).

Table 5 – Patients' follow-up.

Variables	No. = 142
TIA	4 (2.8%)
CVA	1 (0.7%)
Antiaggregation usage	62 (43.7%)
Warfarin usage	55 (38.7%)
NOAC usage	20 (14.1%)
LMWH usage	5 (3.5%)
TIA, transitory ischemic attack; CVA, cerebrovascular event; NOAC, novel oral anticoagulants; LMWH, low molecular weight heparin.	

Discussion

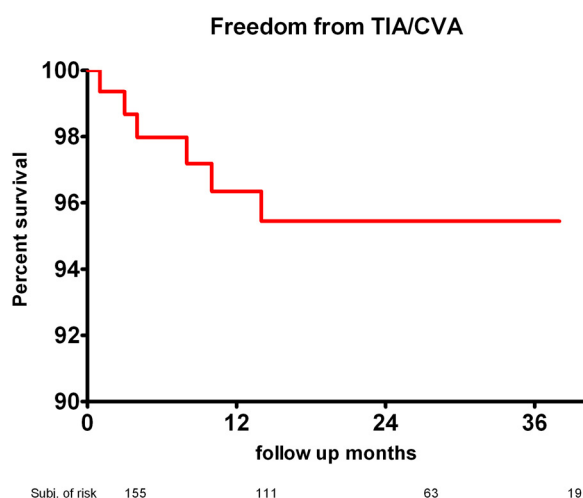
Different techniques of surgical LAA occlusion are used during cardiac surgery procedures. The most common techniques are ligation, resection, endocardial suture closure and stapler resection. In a paper from Kanderian et al. [10] a success rate of different surgical methods in was compared. A group of 137 patients underwent LAA excision, suture closure or stapler resection. The criterion for complete LAA occlusion was lack of communication (flow) between the LAA and LA and no residual LAA stump greater than 1 cm. Only 73% of resections, 23% of suture closures and 0% of stapler resections met these criteria. Katz et al. examined 50 patients after mitral valve surgery with concomitant LAA ligation. Incomplete ligation was found in 36% of patients with echo contrast or thrombus in LAA in half of them [11]. Gillinov et al. [12] described a group of 222 patients with LAA excision using a stapler. In their paper, the need for acute additional stitches was described in 10% of patients.

Incomplete occlusion has negative clinical impact on a patients' future health status. In a paper of Garcia-Fernandez et al. authors assessed 205 patients after mitral valve surgery with appendage ligation performed in 58 patients. In patients with incomplete or undone LAA ligation was described higher stroke risk. After multivariate analysis they identified a higher risk in patients with incomplete LAA ligation, which has a higher stroke risk than leaving the appendage intact [13].

LAA patency after surgical occlusion was associated with thrombus formation in a paper of Cullen et al. [14], where transesophageal echocardiography was done before cardioversion within 30 days of cardiac surgery. Thrombus occurred in 47% of patients with a patent LAA versus 17% of patients with an absent or non-patent LAA after surgical intervention.

The safety, efficacy of AtriClip implantation time was previously described in European and US trials [15,16]. Both studies have shown good results with high success rates of LAA occlusion and no periprocedural complications related to the AtriClip device during follow-up. Both studies included only patients treated with a sternotomy approach. In a paper of Starck et al. [17], they demonstrated complete electrical isolation of the LAA using the AtriClip, what could be beneficial during surgical ablation of atrial fibrillation.

Beside the surgical methods of LAA occlusion, different types of catheter devices are available in clinical practice. The Watchman LAA occlusion device from Boston Scientific is

**Fig. 1 – Freedom from TIA/CVA during follow-up period.**

perhaps the most frequently implanted and clinically tested device of the percutaneous closure devices commercially available. Experience and trials (such as PROTECT-AF, PRE-VAIL) suggest that Watchman is not inferior to permanent anticoagulation in thromboembolic event prevention and is associated with less frequent bleeding complications than permanent anticoagulation. However, percutaneous devices are associated with a clinically significant rate of serious periprocedural complications and are suitable for only a well-defined group of patients with suitable anatomy. Implantation was considered as successful also if residual peri-device flow (endoleak) existed but the jet width was below 5 mm, what could be prothrombogenic issue in patients' future life. In the interventional group was described high rate of periprocedural complications [18].

Other less frequently used devices for percutaneous LAA occlusion are Amplatzer [19] or Lariat using hybrid, percutaneous and epicardial approach for ligation of LAA [20].

There are still some controversies about the type of AF and the risk of stroke. Several randomized and observational studies had documented a similar risk of thromboembolic events in patients with paroxysmal and persistent AF [21–24]. In contrast, other studies have shown that the risk of thromboembolism is lower in anticoagulated patients with paroxysmal AF than in those with persistent AF [25,26]. All of these results should be adjusted to the risk profile of patients which is expressed, for example, by CHA₂DS₂-VASC score.

We also have to comment on the patients with insufficient perioperative implantation in our study. In two patients the AtriClip was positioned distally due to non-ideal anatomy (appendage with more than one part – “cauliflower anatomy”). The third patient (9th patient) had a residual pouch of 18 mm, with no evidence of a thrombus formation. All of the patients, as well as all the remaining patients, had complete appendage occlusion distally from the positioned AtriClip without any leak, confirmed by TEE or CT scan. The implantation of the AtriClip is now routinely performed under TEE guidance, which will probably exclude situations with insufficient positioning resulting with a residual stump of the LAA, as previously described [27]. We have to comment on the limitations of the study. It is a single center observational study without any control group. The reason is that the occlusion of the LAA is an important part of the MAZE procedure and all surgeons have followed this protocol.

Conclusion

In our study the AtriClip implantation was associated with no periprocedural complications and no thrombus formation on the endocardial side of occluded LAA. The AtriClip represents an effective and safe tool for occlusion of the LAA during on-pump or off-pump AF surgery.

Conflict of interest

None of the authors have a conflict of interest regarding this paper.

Ethical statement

Authors state that the research was conducted according to ethical standards.

Informed consent

All patients had signed up informed consent.

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