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Epicardial clip occlusion of the left atrial appendage during cardiac surgery provides optimal surgical results and long-term stability†

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Abstract

OBJECTIVES: Occlusion of the left atrial appendage (LAA) has become an integral and important part of the surgical treatment of atrial fibrillation. Different methods of surgical occlusion of the LAA have been associated with varying levels of short- and long-term success for closure. The purpose of this study was to evaluate long-term results of epicardial placement and endocardial occlusion in patients undergoing cardiac operative procedures.

METHODS: A total of 101 patients (average age 65.7 years) undergoing cardiac operative procedures with the epicardial AtriClip Exclusion System of the LAA were enrolled in the study. The AtriClip was placed via a sternotomy or a thoracotomy or from a thoracoscopic approach. Postoperative variables, such as thromboembolic events, clip stability and endocardial leakage around the device, were examined by transoesophageal echocardiography (TEE) and/or computed tomography.

RESULTS: Perioperative clip implantation was achieved in 98% of patients. TEE and/or computed tomography conducted during the follow-up period, comprising 1873 patient-months with a mean duration of 18 ± 11 months, revealed no clip migration, no leakage around the device and no clot formation near the remnant cul-de-sac. During the follow-up period, 4 of the cardiac patients experienced transitory ischaemic attacks, whereas no patient experienced a cerebrovascular attack.

CONCLUSIONS: The Epicardial AtriClip Exclusion System of the LAA appears to be a feasable and safe operative method with a high success rate. Long-term follow-up confirmed clip stability, complete occlussion of the LAA and absence of any atrial fibrilation-related thromboembolic events. These results need to be confirmed by a larger, multicentre study.

Keywords: Left atrial appendage closure • Atrial fibrillation • AtriClip

INTRODUCTION

The left atrial appendage (LAA) is the most frequent source of thromboembolism in patients with atrial fibrillation (AF), in whom the risk of thromboembolism is 5 times greater than in patients without AF [1]. For this reason, the guidelines of the European Society of Cardiology [2] recommend the exclusion of the LAA during the operative treatment of AF. The advantage of removing the LAA during the surgical treatment of AF was confirmed in several non-randomized studies [3, 4], and it is also an important part of the Cox-maze IV procedure [5].

Isolated occlusion of the LAA may also be a treatment option for patients with chronic AF who are not candidates for AF surgery and who are contraindicated for anticoagulation therapy. The subset of patients taking warfarin may be as high as 14–44% of cardiac patients [6, 7].

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MATERIALS AND METHODS

Between July 2012 and September 2015, a total of 101 patients underwent a cardiac operative procedure for AtriClip implantation at the Department of Cardiac Surgery, Hospital of České Budějovice, Czech Republic. All patients were examined with transoesophageal echocardiography (TEE) preoperatively to document and confirm the absence of a pre-exisiting LAA thrombus. The AtriClip was implanted via a thoracoscopic or a thoracotomy approach or through a sternotomy to shorten the ischaemic time on cardiopulmonary bypass or to reduce the risk of postoperative bleeding from the resected LAA in patients with fragile tissues.

For the purposes of this study, the AtriClip, or the second generation, AtriClip Pro (AtriCure, West Chester, OH, USA), was used for all LAA occlusions. The implantable device is a self-closing external LAA occluder that is available in 4 sizes from 35 mm to 50 mm. It comprises 2 nitinol springs joined by 2 titanium parallel rods covered with Dacron polyester fabric. The parallel compression planes put a symmetrical pressure of 2–8 psi over the entire contact area.

The AtriClip is attached to a deployment system, from which it is released, but only after confirmation of complete closure using TEE.

Our postoperative anticoagulation strategy followed the hospital protocol. After the maze procedure, patients are given warfarin with a target International normalized ratio range of 2 to 3. After 3 months, if the patient is in sinus rhythm, warfarin is discontinued, and the patient's medication is changed to antiaggregation therapy. After an operation just for LAA occlusion, patients are placed on anti-aggregation therapy for 1 month.

LAA closure was assessed by TEE and/or computed tomography examination at 1 to 3 months postoperatively. Using Doppler echocardiography, successful LAA occlusion was defined as the absence of a residual stump or pouch <1 cm and no persistent flow into the LAA. Telephone questionnaires were used to document any postoperative events of interest—transient ischaemic attack (TIA)/cardiovascular accident (CVA) or intracranial/internal bleeding as well as to confirm compliance with the anticoagulation/anti-aggregation regimen administered to patients.

RESULTS

A total of 101 patients were included in this prospective study. Patients were mainly men (63.4%) and the average age was 65.7 years; 20.8% of patients had TIAs/CVAs preoperatively, and the average CHA_2DS_2-VASc score was 2.5 (Table 1). The majority of cases were performed off pump during thoracoscopic AF ablation or as an AtriClip implant-only procedure (Table 2). The implantation process for the AtriClip was identical for off-pump and on-pump procedures. The implants were all done on a filled beating heart under the guidance of TEE.

The periprocedural success rate, which was defined as complete LAA occlusion with no persistent flow into the LAA, as determined using Doppler echocardiography and a residual stump <1 cm, was achieved in 98% of the patients. Two patients who did not meet these criteria had residual stumps of 18 mm and 15 mm (Table 3). Procedures for both patients were completed thoracoscopically, and the 2 cases were among the first 10 cases performed by the surgeon. These failures could be attributed to the learning curve associated with the procedure.

Table 1: Preoperative characterictics

Variables	*n* = 101
Male, *n* (%)	64 (63.4)
Average age (years)	65.7 ± 6.6
Diabetes mellitus, *n* (%)	23 (22.8)
Hypertension, *n* (%)	71 (70.3)
Renal insuficiency, *n* (%)	16 (15.8)
TIA/CVA preoperatively, *n* (%)	21 (20.8)
Peripheral vascular disease, *n* (%)	3 (3.0)
COPD, *n* (%)	31 (30.7)
Paroxysmal AF, *n* (%)	16 (15.8)
Persistent AF, *n* (%)	80 (79.2)
Atrial flutter, *n* (%)	5 (5)
LVEF	59.3 ± 8.0
Average CHA_2DS_2-VASc score	2.5 ± 1.3

TIA: transient ischaemic attack; CVA: cerebrovascular event; COPD: chronic obstructive pulmonary disease; AF: atrial fibrillation; LVEF: left ventricular ejection fraction.

During the postoperative, in-hospital recovery period, 6.9% patients underwent revision for bleeding. None of these were associated with the AtriClip implantation procedure, and all of these patients had undergone on-pump procedures (Table 4). One patient had bleeding from the distal anastomosis of a venous graft; 1 from the proximal anastomosis of a venous graft; and 1 from an aortic suture after aortic valve replacement. In 4 patients, the source of postoperative bleeding was not found but was probably caused by diluted coagulopathy. During postoperative hospitalization and recovery, no patient had a TIA and 1 patient had a CVA that resulted in death. This patient was a 73-year-old woman with a CHA_2DS_2-VASc score of 5 undergoing a coronary artery bypass graft plus closure of a patent foramen and concomitant AtriClip implantation. TEE in the intensive care unit did not show a thrombus in the left atrium or on the endocardial side of the closed LAA.

The hospital mortality rate was 7.9%. All of the 8 deaths occured in the on-pump group and correlated with the group of patients with high preoperative EuroSCOREs (average 13.2). All of the 8 patients died of systemic inflammatory response syndrome with multiorgan failure during their stay in the intensive care unit on Day 2, 2, 10, 13, 21, 21, 22 and 60, respectively. During the follow-up period, 1 patient died of pneumonia in a regional hospital 6 months after the operation.

Table 2: Perioperative characteristics

Variables	*n* = 101
CABG, *n* (%)	9 (8.9)
Valve procedure, *n* (%)	22 (21.8)
Combined procedure, *n* (%)	6 (5.9)
Thoracoscopic AF ablation + AtriClip, *n* (%)	57 (56.4)
AtriClip as a single procedure, *n* (%)	7 (6.9)

CABG: coronary artery bypass grafting; AF: atrial fibrillation.

Table 3: Periprocedural success rate

Variables	*n* = 101
Complete LAA occlusion, *n* (%)	99 (98.0)
LAA leak, *n* (%)	0 (0)
LAA residual stump >1 cm, *n* (%)	2 (1.9)

LAA: left atrial appendage.

Table 4: Postoperative characteristics

Variables	*n* = 101
Revision for bleeding, *n* (%)	7 (6.9)
TIA, *n* (%)	0 (0)
CVA, *n* (%)	1 (1)
ICU stay (days)	4.0 ± 3.9
Hospital stay (days)	11.2 ± 5.7

TIA: transient ischaemic attack; CVA: cerebrovascular accident; ICU: intensive care unit.

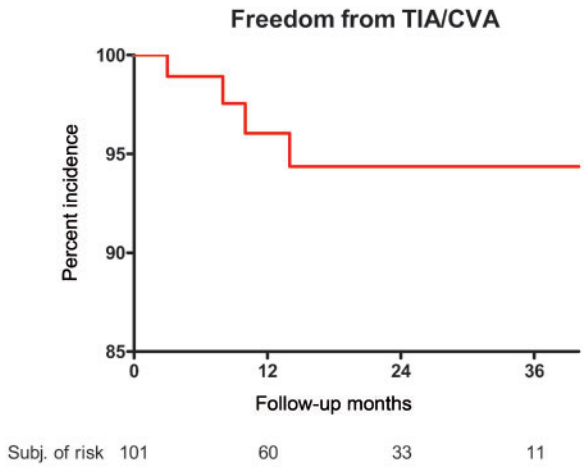

Figure 1: The incidence of TIAs/CVAs during the follow-up period. TIAs: transient ischaemic attacks; CVAs: cardiovascular accidents.

During the long-term follow-up period, 4 transitory ischaemic attacks were reported (Fig. 1). The first patient was on sinus rhythm and anti-aggregation therapy and had a CHA_2DS_2-VASc score of 4. The second and third patients had AF and were taking warfarin; each had a CHA_2DS_2-VASc score of 1. The fourth patient was in normal sinus rhythm and taking a novel anticoagulant (rivaroxaban), with a CHA_2DS_2-VASc score of 4. From the available medical records (TEE or computed tomography), there were no findings of thrombus in the left atrium or on the endocardial side of the closed LAA in these 4 patients. In the second patient, there was a newly diagnosed steal syndrome of the right vertebral artery, which could be a cause of the TIA. In our group of patients, there was no CVA during the follow-up period, which comprised 1873 patient-months and a mean follow-up period of 18.5 ± 11.3 months (Table 5).

Table 5: Patient follow-up

Variables	*n* = 92
TIA, *n* (%)	4 (4.3)
CVA, *n* (%)	0 (0)
Anti-aggregation usage, *n* (%)	21 (22.8)
Warfarin usage, *n* (%)	33 (35.9)
NOAC usage, *n* (%)	11 (12.0)
LMWH usage, *n* (%)	4 (4.3)
No AA/AC therapy, *n* (%)	23 (25)

TIA: transitory ischaemic attack; CVA: cerebrovascular accident; NOAC: novel oral anticoagulants; LMWH: low-molecular-weight heparin; AA: anti-aggregation; AC: anticoagulation.

DISCUSSION

Different LAA occlusion techniques are routinely used during cardiac operative procedures. The most common techniques are ligation, resection, suture closure and stapler resection. Kanderian *et al.* [8] compared the success rates of different operative methods used in a real-world practice. A group of 137 patients underwent LAA excision, suture closure or stapler resection. The criteria for complete LAA occlusion were lack of communication (flow) between the LAA and LA and no residual LAA stump >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 a mitral valve operation with concomitant LAA ligation. Incomplete ligation was found in 36% of patients, with echo contrast or thrombus in LAA in half of them [9]. Gillinov *et al.* [10] described a group of 222 patients with LAA excision using a mechanical stapler. They reported the need for additional stitches in 10% of patients and periprocedural CVAs in 2%. The success rate of these surgical techniques varies widely (0–73%), necessitating the development of safer, more effective options for LAA occlusion.

The safety, efficacy and relatively short AtriClip implantation time were previously described in European and US trials [11, 12]. Both studies showed good results with high success rates of LAA occlusion and no periprocedural complications related to the AtriClip device during short-term follow-up. It must be mentioned that both studies included only patients treated with a sternotomy approach. Starck *et al.* [13] demonstrated complete electrical isolation of the LAA using the AtriClip. LAA methods that include both electrical and mechanical isolation of the LAA may provide a clinical advantage over approaches that may only have a single mode of isolation.

Besides the surgical methods of LAA occlusion, different types of catheter devices are available in clinical practice. The Watchman LAA occlusion device (Boston Scientific, Marlborough, MA, USA) is perhaps the most frequently implanted and clinically tested device of the percutaneous closure devices commercially available. Experience and trials (such as PROTECT-AF, PREVAIL) suggest that the 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 the appropriate anatomy. The PROTECT-AF study included 463 patients in the interventional group, of whom only 349 were successes at 45 days after implantation and 355 at 6 months after implantation (due to spontaneous closure of residual leaks during the follow-up period). Implantation was considered successful also if residual peri-device flow (endoleak) existed, but the jet width was <5 mm. In the subgroup of patients (349) who had successful implants, the primary efficacy event rate (stroke, cardiovascular or unexplained death and systemic embolization) was 1.9/100 patients/year, and the primary safety endpoint (excessive bleeding, periprocedural complication—pericardial effusion, device embolization, procedural-related stroke) was 1.5/100 patients/year in the interventional group of patients. However, the primary safety end-point was 7.4/100 patients/year if the entire group of patients randomized to treatment was included in the analysis [14].

Incomplete occlusion has a clinical impact on a patient's future health status. Garcia-Fernandez *et al.* retrospectively assessed 205 patients after a mitral valve operation with appendage ligation performed in 58 patients. A higher risk of stroke was noted in patients with incomplete or undone LAA ligation. Multivariate analysis also identified a higher risk in patients with incomplete LAA ligation, which is associated with a higher risk of stroke than leaving the appendage intact [15]. Cullen *et al.* [16] found an association between LAA patency after surgical occlusion and thrombus formation in cases in which TEE was done before cardioversion for postoperative AF within 30 days of cardiac surgery. Thrombus occurred in 47% of patients with a patent LAA vs 17% of patients with an absent or non-patent LAA after surgical intervention.

We also have to comment on the patients with insufficient perioperative implantation in our study. In one patient, the AtriClip was positioned distally due to non-ideal anatomy (appendage with more than one part—'cauliflower anatomy') as well as to our limited experience (11th patient). The second patient (9th patient) had a residual pouch of 18 mm, with no evidence of thrombus formation. Both these patients, as well as all of the remaining patients, had complete appendage occlusion distally from the positioned AtriClip without any leak, confirmed by TEE or computed tomography scan. The AtriClip is now routinely implanted under TEE guidance, which will probably exclude situations with insufficient positioning resulting in a residual stump of the LAA, as previously described [17].

CONCLUSION

In our study, the AtriClip implant was not associated with any bleeding complications, and there was no thrombus formation on the endocardial side of occluded LAA. The AtriClip device represents an effective, safe additional tool for occlusion of the LAA during on-pump or off-pump operations. The AtriClip device is suitable for implantation from different procedural approaches—sternotomy, thoracotomy or thoracoscopy.

Conflict of interest: none declared.

REFERENCES

[1] Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg 1996;61:755–9.
[2] Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH *et al*. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. Eur Heart J 2012;33:2719–47.
[3] Cox JL, Ad N, Palazzo T. Impact of the maze procedure on the stroke rate in patients with atrial fibrillation. J Thorac Cardiovasc Surg 1999;118:833–40.
[4] Johnson WJ, Ganjoo AK, Stone CD. The left atrial appendage: our most lethal human attachment: surgical implication. Eur J Cardiothorac Surg 2000;17:718–22.
[5] Weimar T, Bailey MS, Watanabe Y, Marin D, Maniar HS, Schuessler RB *et al*. The Cox-maze IV procedure for lone atrial fibrillation: a single center experience in 100 consecutive patients. J Interv Card Electrophysiol 2011;21:47–54.
[6] Brown MT, Bussel JK. Medication adherence: who cares? Mayo Clinic Proc 2011;86:304–14.
[7] Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A *et al*. Dabigatran vs. Warfarin in patients with atrial fibrillation. N Engl J Med 2009;361:1139–51.
[8] Kanderian AS, Gillinov AM, Pettersson G, Blackstone E, Klein AL. Success of surgical left atrial appendage closure. JACC 2008;52:924–9.
[9] Katz ES, Tsiamtsiouris T, Applebaum RM. Surgical left atrial appendage ligation is frequently incomplete: a transesophageal echocardiographic study. J Am Coll Cardiol 2000;36:468–71.
[10] Gillinov MA, Pettersson G, Cosgrove DM III. Stapled exciton of the left atrial appendage. J Thorac Cardiovasc Surg 2005;129:679–80.
[11] Salzberg SP, Plass A, Emmert MY, Desboilles L, Alkadhi H, Grunenfelder J *et al*. Left atrial appendage clip occlusion: early clinical results. J Thorac Cadiovasc Surg 2010;139:1269–74.
[12] Ailawadi G, Gerdisch MW, Harvey RL, Hooker RL, Damiano RJ Jr, Salamon T *et al*. Exclusion of the left atrial appendage with a novel device: early results of a multicenter study. J Thorac Cadiovasc Surg 2011;142:1002–9.e1.
[13] Starck CT, Steffel J, Emmert MY, Plass A, Mahapatra S, Falk V *et al*. Epicardial left atrial appendage clip occlusion also provides the electrical isolation of the left atrial appendage. Interact CardioVasc Thorac Surg 2012;15:416–9.
[14] Ostermayer SH, Reisman M, Kramer PH, Matthews RV, Gray WA, Block PC *et al*. Percutaneous left atrial appendage transcatheter occlusion (PLAATO) to prevent stroke in high-risk patients with non-rheumatic atrial fibrillation: results from the international multi-center feasibility trials. J Am Coll Cardiol 2005;46:9–14.
[15] Garcia-Fernandez MA, Perez-David E, Quiles J, Peralta J, Garcia-Rojas I, Bermejo J *et al*. Role of left atrial appendage obliteration in patients with mitral valve prosthesis. J Am Coll Cardiol 2003:42:1253–8.
[16] Cullen MW, Stulak JM, Li Z, Powell BR, White RD, Ammash NM *et al*. Left atrial appendage patency at cardioversion after surgical left atrial appendage intervention. Ann Thorac Surg 2015;101:675–81.
[17] Mokráček A, Kurfirst V, Bulava A, Haniš J, Tesařík R, Pešl L. Thoracoscopic occlusion of the left atrial appendage. Innovations 2015;10:179–82.