



Left Atrial Appendage Epicardial Clip (AtriClip): Essentials and Post-Procedure Management

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Abstract

Left atrial appendage exclusion is a viable alternative to anticoagulation for stroke risk reduction in atrial fibrillation patients. In this article we address the essentials and post-procedural management of left atrial appendage exclusion using the AtriClip. Ischemic strokes that are related to atrial fibrillation (AF) are the most devastating and the most disabling ischemic strokes due to larger emboli compared to carotid disease. Anticoagulation (AC) is the standard approach for stroke risk reduction in AF patients. Unfortunately, near 10 percent percent of AF patients who would benefit from AC (CHA2DS2-VASc score of 2 or more) have absolute contraindications for AC. A higher percentage may have relative contraindications. Moreover, among the patients who can be on AC, only sixty percent are able to maintain a therapeutic international normalized ratio (INR). This has traditionally left almost half of AF patients at a significant stroke risk without protection. The advent of newer non-vitamin K anticoagulants (NOACs) has slightly improved the problem given their improved intracranial bleeding profile, the inherent and still significant risk of bleeding from anticoagulation persists.

Introduction

Ischemic strokes that are related to atrial fibrillation (AF) are the most devastating and the most disabling ischemic strokes due to larger emboli compared to carotid disease.^[1,2] Anticoagulation (AC) is the standard approach for stroke risk reduction in AF patients. Unfortunately, near 10 percent percent of AF patients who would benefit from AC (CHA2DS2-VASc score of 2 or more) have absolute contraindications for AC.^[3,4] A higher percentage may have relative contraindications. Moreover, among the patients who can be on AC, only sixty percent are able to maintain a therapeutic international normalized ratio (INR).^[5] This has traditionally left almost half of AF patients at a significant stroke risk without protection. The advent of newer non-vitamin K anticoagulants (NOACs) has slightly improved the problem given their improved intracranial bleeding profile, the inherent and still significant risk of bleeding from anticoagulation persists.^[6]

A growing interest in the left atrial appendage (LAA) has been driven by the observation that ninety percent of thrombi in non-valvular AF and sixty percent of those in valvular AF develop in the LAA.^[7] Left atrial appendage exclusion however has been inconsistent in terms of techniques, rates of complete exclusion, and thus adoption.^[10] This led to redundant evidence regarding whether the concept of left atrial appendage occlusion offers any reduction in stroke risk for AF patients. In the past decade, the interest in the LAA

exponentially increased and a larger body of evidence has evolved in association with newer LAA occlusion devices. The validity of the concept of LAA occlusion in AF-related stroke risk reduction has been best demonstrated by the PROTECT AF trial's 45 months follow up outcomes.^[11] For the first time in a well powered study they demonstrated that LAA occlusion is non-inferior to anticoagulation in stroke risk reduction.

Feasibility of a number of devices as well as their efficacy in achieving reliable complete LAA occlusion has been demonstrated.^[11-16] Devices designed to exclude the LAA from the circulation are either applied from the outside (epicardial devices) or reside inside the appendage (endocardial devices). The most widely used endocardial device is the Watchman device, which is a percutaneously delivered polyester fabric on a nitinol frame ([Figure 1B]). The Lariat device utilizes a combined percutaneous and epicardial approach to deliver a lasso around the appendage guided by an intraluminal magnet tip ([Figure 1A]). The AtriClip is made of a two polyester-covered parallel tubes with nitinol springs ([Figure 1C]). Generally, endocardial devices are in contact with blood stream, and for that reason, the recommendation is to resume anticoagulation for 2 months after endocardial devices are implanted, making this a less attractive option for patients with absolute contraindications for AC. Also, endocardial devices do not sit as well within LAAs with abnormal morphologies; a situation better addressed by epicardial devices. Our preference is to use the AtriClip epicardial clip. In our experience, this device is easy to use and allows adjusting position of the clip after deployment as needed. Also, the AtriClip was not associated with pericarditis and/or thrombosis, which makes it in our opinion safer than the reported outcomes with the Lariat system.^[17-19] These reports however are not large enough to draw definitive conclusions.

Key Words

Atrial fibrillation, Left atrial appendage, Stroke.

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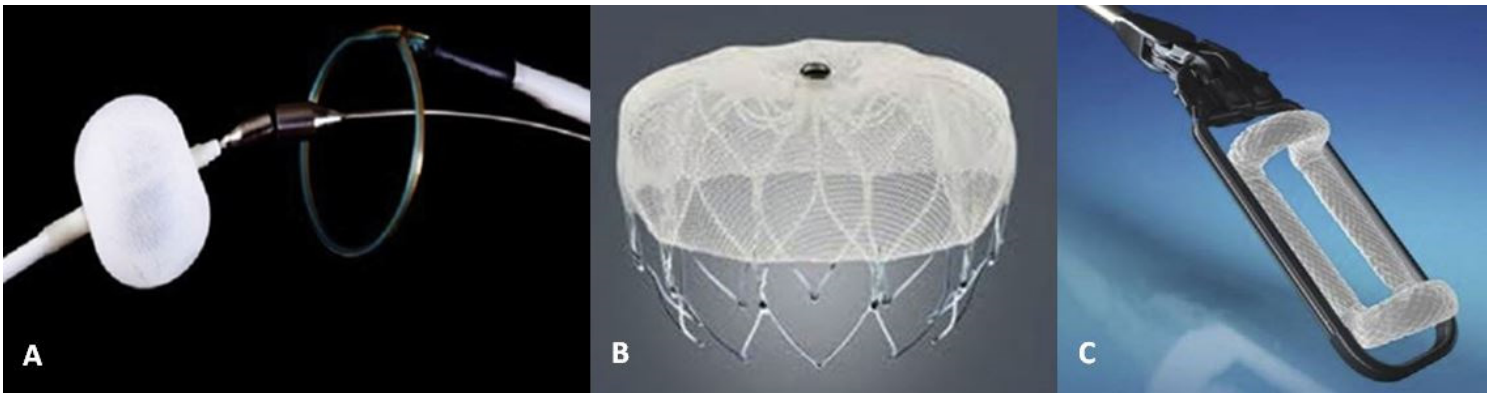


Figure 1: **A: the Lariat system. B: the Watchman device. C: the AtriClip**

In this article, we outline our experience using the AtriClip and our recommendations for its use and management after the procedure. Although no societal guidelines exist to date, our recommendations are in agreement with other reports from high-volume centers publishing their experiences with the AtriClip.

The AtriClip

This LAA occlusion device is made of two parallel titanium tubes with elastic nitinol springs covered by knit braided polyester. The delivery allows for application on a beating heart, as well as allows redeployment in case of initial suboptimal placement. It has shown excellent results regarding feasibility and near 100 percent occlusion rates documented by CT scan and TEE, leading to its approval by the CE and the FDA.^[12,13]

Indications and Application

Closure of the LAA is indicated for any patient with atrial fibrillation (paroxysmal or chronic) undergoing a cardiac surgery or

an ablation procedure. For patients not undergoing cardiac surgery, LAA exclusion is indicated if anticoagulation is not tolerated, not preferred by patient or failing to achieve adequate protection. In this case, absolute contraindications to AC or abnormal LAA morphology both favor the AtriClip over a percutaneous endocardial device. For patients undergoing an ablation, isolated thorascopic LAEE is part of the procedure, and our preference is the use of the AtriClip in this situation. Our algorithm for application of the AtriClip in patients not undergoing cardiac surgery is outlined in [Figure 2].

The AtriClip is applied epicardially with no foreign body contact to bloodstream. The clip is applied to the base of the appendage, and the process is not affected by atypical LAA morphologies. It can be applied with concomitant cardiac operations as well as in isolated thorascopic procedures. With either, intra-operative transesophageal echocardiography (TEE) is necessary to ensure absence of a LAA thrombus prior to application, as well as to confirm the absence of residual flow or a significant stump after clip application. In cases with concomitant cardiac surgery, our preference is to apply the clip after initiation of cardiopulmonary bypass but before cardioplegic arrest. In the isolated thorascopic procedures, the appendage is approached via the left chest while using a double lumen endotracheal tube. The patient is supine with a bump under the left hemithorax and with the left arm positioned above the head. This position allows for groin access and makes conversion to a sternotomy accessible, if needed.^[20]

Post-Procedural Concerns and Management

Whether done thorascopically or with concomitant cardiac procedure, occlusion of the LAA using the AtriClip is a fairly simple procedure with a low morbidity profile, provided that the patient can tolerate single lung ventilation. Post-procedure management should address the infrequent adverse events as well as decisions regarding anticoagulation and routine follow up imaging. The prevalence of post-procedural adverse events is primarily driven from single center experience reports, and their respective management is based on experts' opinion from centers of large AtriClip experiences. Adverse events include pericardial effusions with or without pericarditis, tachyarrhythmias and respiratory dysfunction mostly related to atelectasis.

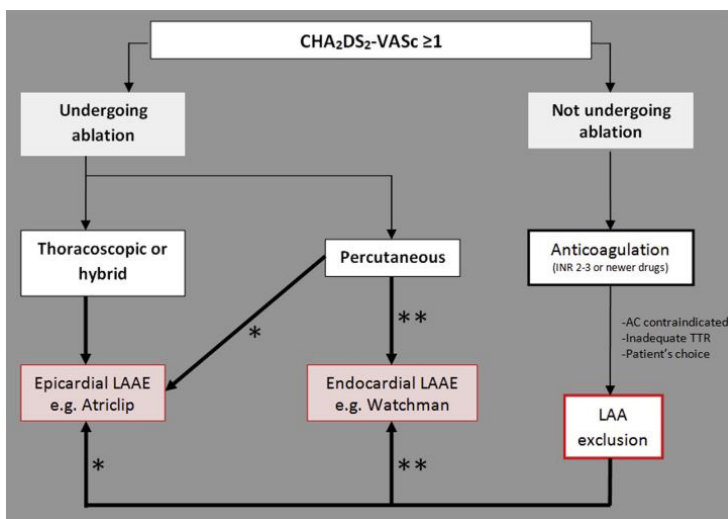


Figure 2: **Our algorithm for patients with atrial fibrillation not undergoing cardiac surgery.**

*Preferred, with contraindications to anticoagulation or unfavorable left atrial appendage morphology. **Preferred with nonsurgical candidates and those with previous cardiac or left thoracic surgery. CHA2DS2-VASc, congestive heart failure, hypertension, age >75 and diabetes. Adapted with permission from Bedeir K, Holmes DR, Cox JL, Ramlawi B. Left atrial appendage exclusion: An alternative to anticoagulation in non-valvular atrial fibrillation. *The Journal of Thoracic and Cardiovascular Surgery* 2017;153:1097-1105. mellitus, previous history of stroke or transient ischemic attack, vascular disease, age 65-74 years, and female sex category; AC, anticoagulation, TTR, time in therapeutic range, LAA, left atrial appendage; LAEE, left atrial appendage exclusion. -105.

Table 1: Anticipated post-procedural adverse events.

Adverse event	Etiology	Management
Pericardial effusion	- Volume overload, partly related to sudden decrease in ANP	- Prevention: 1) empiric 7 day course of furosemide, 2) delayed removal of chest tubes after open surgery
	- Pericarditis (rare after Atriclip)	- Treatment if occurs (~1%): 1) Course of oral steroids with quick taper, 2) diuresis, 3) if symptomatic or hemodynamic impact, drainage.
Tachyarrhythmias	- Non specific to Atriclip, although volume overload due to decrease ANP may be related	- Avoid volume overload - Standard treatment of RVR with beta blockade, amiodarone and DCCV if needed.
Respiratory dysfunction	- Usually with isolated thoracoscopic LAAE in patients with borderline FEV1.	- Judicious pain control, minimize narcotics as able. - Diuresis
	- Usually related to atelectasis	- Early ambulation, chest physical therapy.

ANP: Atrial natriuretic peptide, RVR: rapid ventricular response, DCCV: direct current cardioversion, LAAE: left atrial appendage exclusion, FEV1: forced expiratory volume/1second

Adverse Events

Pericardial effusions, can occur after Atriclip application. Although initial European and US reports of feasibility and safety reported no pericardial effusions in one hundred and four patients, subsequent experiences however did reveal an occurrence of pericardial effusions in approximately one percent of patients, that is rarely of clinical consequences.^[12,13] Other epicardial devices reported a pericardial effusion rate of ten to fifteen percent.^[18,19]

Accumulation of fluid in the pericardial sac is difficult to predict, and is usually related to volume overload, pericarditis, or both. While volume overload is universal in on-pump concomitant cardiac surgery, it is less so with isolated thoracoscopic Atriclip application with judicious peri-operative fluid management. Theoretically however, effective exclusion of the LAA may accentuate volume overload by sudden withdrawal of serum atrial natriuretic peptide (ANP) levels, which is primarily secreted from the atrial appendages. Beside volume overload, pericarditis may be another cause of pericardial effusions, although less common. In canine models, the Atriclip has been shown to be completely inert and to produce minimal to no reaction to the tissues in contact.^[21] Despite that, post pericardiotomy pericarditis can still occur after Atriclip application, with unclear direct relationship to the clip itself.

Regardless of the etiology, we recommend initial prevention using a short course of empiric diuresis. Our practice is to administer forty mg of oral furosemide daily for the first seven postoperative days. For clip application with concomitant cardiac surgery, we commonly keep the mediastinal drains in for an extra 24 hours beyond our usual practice. In approximately one percent of patients, effusions may develop despite the preventive measures taken. In this case, a short course of oral methylprednisolone with a quick taper is recommended. Most cases resolve with a short course of steroids and diuresis and produce no clinical symptoms. In the very rare incidence of a significantly large effusion with symptoms or echocardiographic evidence of impaired right sided filling, a pericardial window should be done.

Atrial tachyarrhythmias are common after cardiac surgery, and the

specific role of the AtriClip is difficult to delineate. In our experience, this has not been an additional problem in patients with an AtriClip added to their concomitant cardiac operation. Rapid ventricular response in these patients may be attributed to a number of non-clip related postoperative factors including myocardial excitability, systemic inflammatory response as well as volume and electrolyte abnormalities. All these factors tend to normalize in the early post-operative period. Our approach to managing tachyarrhythmias with rapid ventricular response is standard. We use amiodarone for rate control and possible cardioversion, and with potential electrical cardioversion if clinically indicated.

Respiratory dysfunction manifested by hypoxia following thoracoscopic AtriClip application is usually related to atelectasis after single lung ventilation and is addressed in the standard approach. Adequate pain control without respiratory suppression is crucial, together with early ambulation, respiratory toilet, physical therapy and avoidance of volume overload. Common adverse events are summarized in [Table 1]. Other post-operative events are usually non-clip specific and are managed in their respective standard fashion with no specific managements related to the clip.

Decisions after the procedure

Decisions regarding anticoagulation and imaging (postoperative and routine follow up) should be made and are usually tailored to patient and procedural characteristics. Regarding anticoagulation the decision is often straight forward, given that a contraindication to anticoagulation is commonly the reason why these patients were referred for LAA exclusion. For patients without contraindications to anticoagulation, the decision is less straight forward. The Zurich group published their three and half year follow up for 36 patients receiving the AtriClip.^[22] The mean CHA2DS2-VASc score was 3.7 and only three patients were continued on anticoagulation. There was one transient ischemic attack (TIA) during the follow up period of 1284 patient-days and there were no strokes observed. The same group reports a reduction in stroke rate in 291 patients with a mean CHA2DS2-VASc score was 3.1, who received the AtriClip with concomitant surgery. Patients that did not receive anticoagulation after LAA exclusion had a stroke incidence of 0.5 per 100 patient years (compared to an expected stroke rate of four strokes per 100 patient years). Also, the 45 months follow-up data from the PROTECT AF trial demonstrate the efficacy of LAA exclusion in preventing strokes in patients not on anticoagulation.^[11] Based on the above evidence, there is an expert consensus that anticoagulation is not needed after AtriClip application. Aspirin is usually started post-operative day one and continues indefinitely.

Routine imaging post-operatively or during follow up is not cost effective. Ailawadi et al^[1] imaged sixty one patients undergoing LAA AtriClip application at three months post-operative using computerized tomography angiography (CTA), or TEE when contrast agents were contraindicated. All patients with confirmed intra-operative complete LAA occlusion had no flow at follow up. Out of three patients that had incomplete LAA exclusion seen intra-operatively, two patients had no flow into the LAA at three months, and only one patient had persistent flow. Emmert et al^[7] performed a CTA on thirty two patients at one, two and three years follow up.

All patients had a completely occluded LAA, with no residual flow or stump more than one centimeter. There were no left atrial thrombi noted. Kurfurst et al^[23] followed up 101 patients undergoing AtriClip application (the majority through a thoracoscopic approach) for a mean of eighteen months. Patients underwent either a CTA or a TEE and all the patients showed stable clips without residual flow or significant stump, and no left atrial thrombus. Based on the above evidence, we do not obtain follow up imaging when intra-operative TEE confirms satisfactory occlusion of the LAA at its base.

Disclosure

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Conclusion

Exclusion of the LAA is a concept with growing evidence and increasing adoption. The AtriClip is the most commonly used epicardial device with one hundred thousand units sold worldwide before May 2017. Application process is simple, short and safe with minimal adverse events related to the device itself. Potential adverse events are minor and with rare clinical consequences. The evidence is sufficient to justify no routine follow up imaging if intraoperative placement is satisfactory. Evidence regarding anticoagulation management postoperative is less robust and extrapolated from data utilizing other LAA exclusion devices. Further well-powered long-term evidence is needed to confidently guide anticoagulation management in patients receiving the AtriClip but have no contraindications to anticoagulation.

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