

# Left Atrial Appendage Exclusion Using the AtriClip Device: A Case Series<sup>☆</sup>



Sarah Page, BMBS<sup>a\*</sup>, Jane Hallam, MBBS<sup>a</sup>, Neelprada Pradhan, MBBS<sup>a</sup>,  
Brian Cowie, MBBS, FANZCA<sup>b</sup>, Tuong Phan, MBBS, FANZCA<sup>b</sup>,  
Desmond McGlade, MBBS, FANZCA<sup>b</sup>, Alex Rosalion, MBBS, FRACS (CTS)<sup>a</sup>,  
Andrew Newcomb, MBBS, FRACS (CTS)<sup>a</sup>,  
Michael Yii, MBBS, MS, FRACS (CTS)<sup>a</sup>

<sup>a</sup>Department of Cardiothoracic Surgery, St Vincent's Hospital, Melbourne, Vic, Australia

<sup>b</sup>Department of Anaesthesia, St Vincent's Hospital, Melbourne, Vic, Australia

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## Background

Atrial fibrillation (AF) affects 1.5–2% of the population and is associated with a five-fold increased lifetime risk of stroke [1]. The left atrial appendage (LAA) is the source of embolic strokes in up to 90% of patients with non-valvular AF with clots in the left atrium [2].

## Methods

We reviewed the clinical notes and echocardiographic findings of 20 patients who underwent open cardiac surgery in which concurrent AtriClip (Atricure Inc, Westchester, OH, USA) device insertion was attempted at our institution from July 2013 to February 2015. This was to examine the safety and efficacy of LAA exclusion with clip devices during open cardiac surgery. Indications for LAA exclusion included a history or suspicion of atrial arrhythmia, left ventricular dilatation, or a history of transient ischaemic attacks.

## Results

All 20 of the 20 participants had successful placement of the clip device (100% success rate). There were no adverse events related to the device and no perioperative mortality. There were three late deaths due to chronic obstructive pulmonary disease (COPD), leukaemia, and refractory congestive cardiac failure. No late device related complications were found on follow-up imaging in the remaining patients.

## Conclusions

The results of our study demonstrate the LAA exclusion during open cardiac surgery with the AtriClip device is safe, has a 100% success rate, and appears to be stable over time.

## Keywords

Left atrial appendage • Atrial fibrillation

## Introduction

Atrial fibrillation is the most common persistent cardiac arrhythmia, affecting 1.5–2% of the population [2,3]. The prevalence increases with age, reaching up to 15% in octogenarians [4]. Patients with non-valvular AF have a five-fold increased lifetime risk of stroke, and 17-fold risk with

valvular AF, which are often fatal or lead to significant disability [3–6].

The left atrial appendage (LAA) is a remnant of the embryonic left atrium [4,5]. It is a 2–4 cm tubular structure with a thin, fragile wall, and separated from the left atrium by an oval shaped orifice, that is on average 1.1 cm in diameter. The LAA is the source of embolic strokes in up to 90% of patients

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\*Corresponding author at: Department of Cardiothoracic Surgery, The Townsville Hospital, 100 Angus Smith Drive, Douglas, QLD 4814, Australia.

Tel.: 07 4433 1111, Email: [sm.page@bigpond.com](mailto:sm.page@bigpond.com)

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with non-valvular AF who have clots in the left atrium [2,7–11]. Studies have also implicated the LAA in the initiation and maintenance of AF [2,12]. It can be the site of triggers that induce paroxysmal AF and of re-entrant drivers in persistent AF. Furthermore, the LAA can be the source of embolic material in the absence of AF in patients with significant left ventricular dysfunction [11]. Atrial thrombi, the majority located in the LAA, have been identified in approximately 15% of patients with severely dilated cardiomyopathy in sinus rhythm.

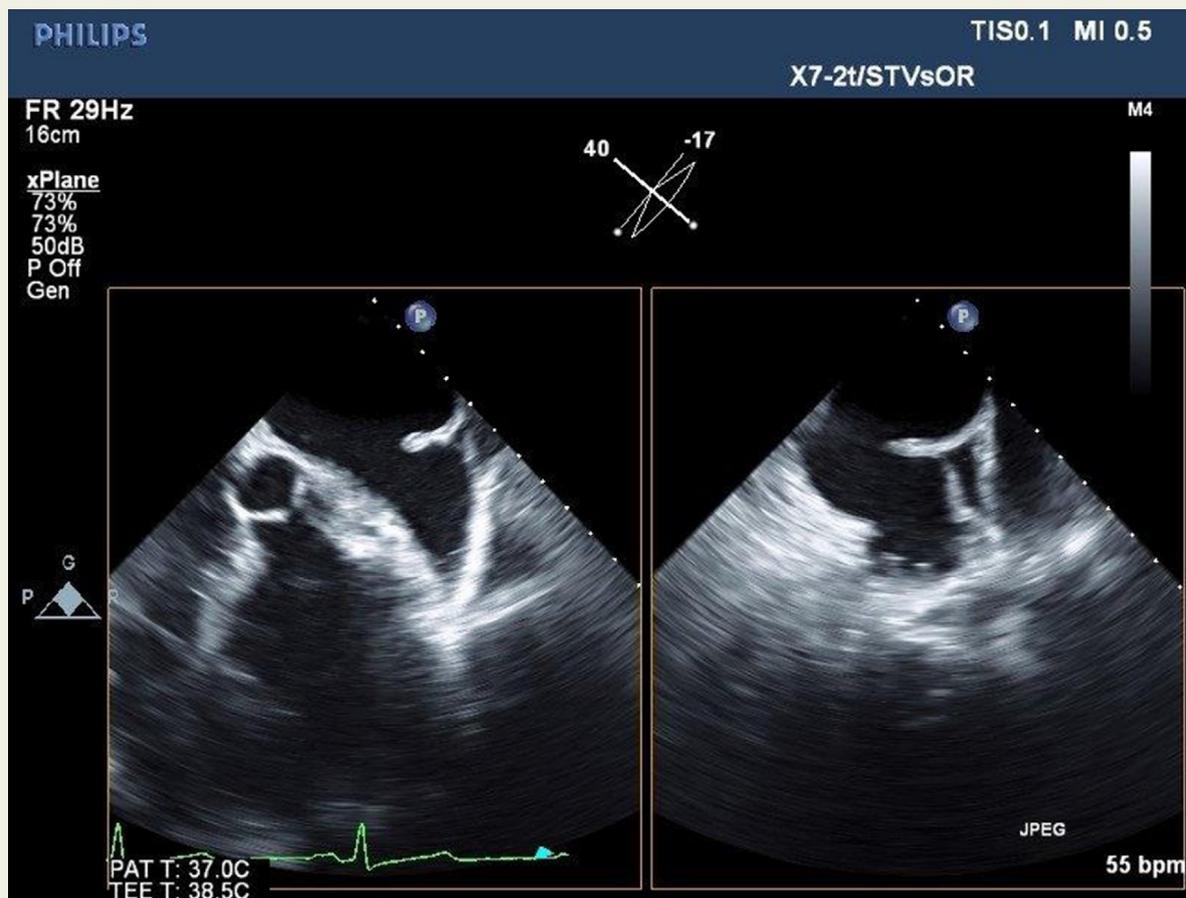
Recent guidelines recommend the CHA<sub>2</sub>DS-VASc<sub>2</sub> stratification scheme to assess stroke risk in patients with non-valvular AF [13]. One point is awarded for each risk factor, including congestive cardiac failure, hypertension, age >75 (doubled), age 65 to 74 years, diabetes mellitus, stroke/transchaemic attack (TIA)/thromboembolism (doubled), vascular disease (myocardial infarction, complex aortic plaque, peripheral arterial disease), sex category (female). A patient with a score of 2 has an adjusted stroke rate of 2.2% per year, and this increases with increasing score. Oral anticoagulant with vitamin K antagonists (VKA) or novel oral anticoagulants (NOAC) for stroke prevention is recommended for patients with a score of 2 or more.

Warfarin, the most commonly used VKA, is associated with a 67% ischaemic stroke risk reduction [4]. However, its use is limited by the narrow therapeutic index, its need for frequent monitoring and dose adjustments, interaction with foods and other medications, and bleeding risk [5,6,10]. Up to 40% of patients have a relative or absolute contraindication to chronic warfarin therapy and of eligible patients nearly 50% will cease warfarin [5,6].

Novel oral anticoagulants developed, including dabigatran, rivaroxaban, and apixaban, are also associated with bleeding risk and lack of widely available reversal agents [1,3,10]. They are cleared by the kidneys and so raise concerns for use in patients with renal impairment. Poor compliance is also an issue as they have short half-lives, with some requiring twice daily dosing, and the cost can be burdensome.

The 2017 guidelines for the management of AF provided a Class IIA recommendation that surgical management of the LAA may be considered in patients with AF undergoing cardiac surgery with level C evidence [14].

The LAA can be excised by amputating stapling devices or scissors [8,10,15]. It can also be excluded by suturing, with a running suture, purse string suture or external ligation, or by stapling. However, surgical ligation of the LAA is frequently



**Figure 1** LAA prior to device deployed on TOE.

Abbreviations: LAA, left atrial appendage; TOE, transoesophageal echocardiograph.

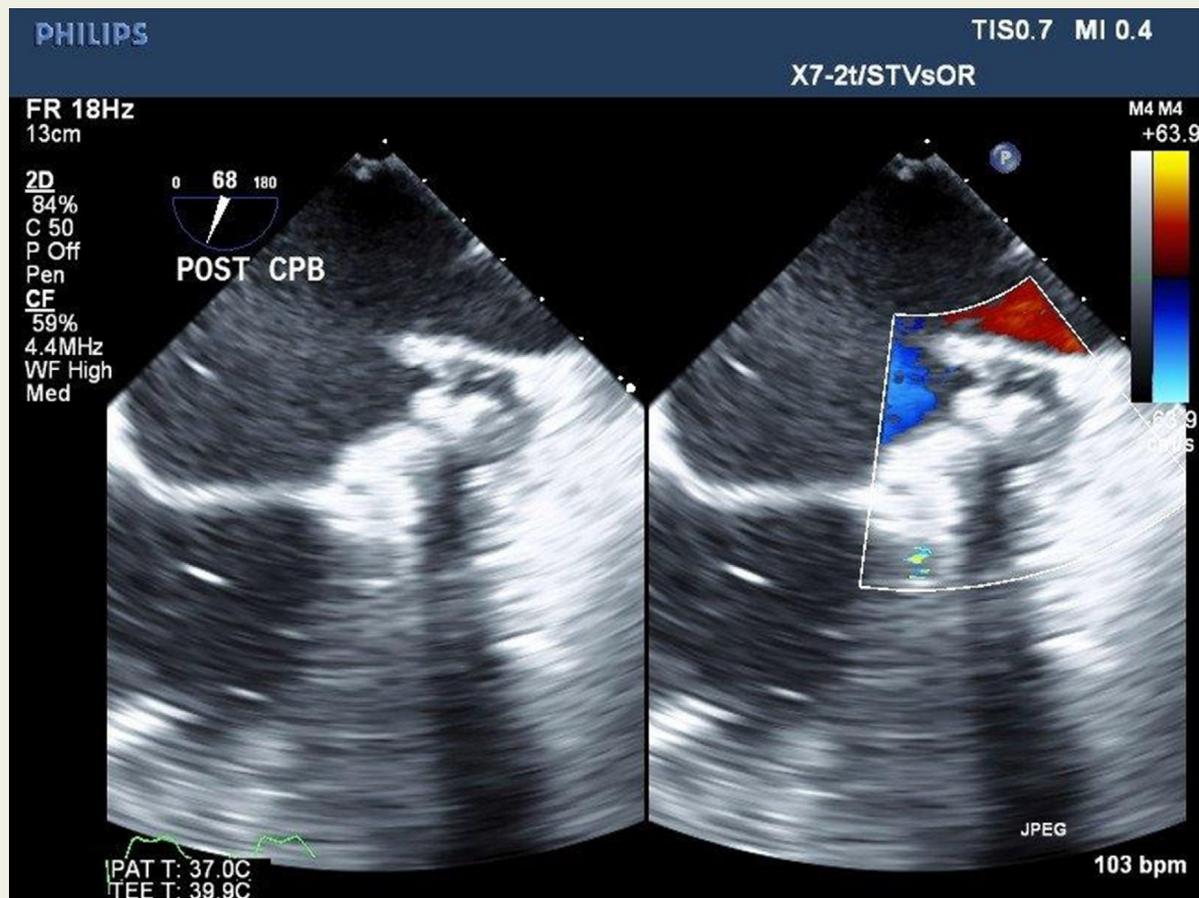
incomplete with persistent flow demonstrated on transoesophageal echocardiography or remaining LAA stumps greater than 1 cm in maximum length after closure [2,6,8]. A study comparing methods of LAA closure found surgical closure of the LAA was incomplete in nearly 60% of cases [8]. Surgical excision of the LAA had the greatest success rate (73%) over suture exclusion (23%), and stapler exclusion (0%). In partially closed LAAs with persistent flow identified, the prevalence of LAA thrombus was as high as 67% in stapler exclusion and 46% in suture exclusion [6,8]. Concerns remain regarding the risk of atrial tears and increased postoperative bleeding in surgical LAA occlusion, and the functional impact on haemodynamics [10,11]. The LAA contributes around 30% of total atrial natriuretic peptide and a reduction in this may contribute to heart failure and fluid retention.

A number of devices for percutaneous closure of the LAA have been designed, including the Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATOO), WATCHMAN, and Amplatzer devices [6]. However, the percutaneous approach is associated with high procedure failure rates and serious procedure and device related adverse events including air embolism, postoperative bleeding, cardiac perforation, pericardial effusion, device migration and sepsis [3,6,9,10,15].

Occlusion of the LAA during open cardiac surgery with external clips placed near the base of the LAA may be a safe and effective method to reduce the risk of embolic strokes in at risk patients.

## Methods

This study reviewed the first 20 patients that underwent cardiac surgery via median sternotomy at our institution in which concurrent LAA closure with the AtriClip device was attempted. Ethics approval and informed consent from participants or their next of kin was obtained. Indications for LAA exclusion included a history or suspicion of atrial arrhythmia, left ventricular dilatation, or a history of transient ischaemic attacks. The clips were inserted at any point after sternotomy. The AtriClip Standard device deployment option with a head articulation, 6 cm stiff shaft and a plunger system was used in each case. The clips comprise parallel titanium crossbars covered in woven polyester fabric, and were available in four sizes (35, 40, 45 and 50 mm). The efficacy of LAA exclusion was assessed at operation with transoesophageal echocardiography. Success was defined as the absence of flow and less than 1 cm maximum length of residual stump remaining in the LAA [8] [Figures 1 and 2].



**Figure 2** LAA after device deployed on TOE.  
Abbreviations: LAA, left atrial appendage; TOE, transoesophageal echocardiograph.

**Table 1** Participants and follow-up.

	Number	Reason
Attempted	20/20	
Surgical follow-up		
- Attended	19/20	1 lost to follow-up
- Median time of f/up	73 days	
- Range of time of f/up	39–281 days	
Post op TTE		
- Attended	17/20	1 lost to follow-up,
- Median time of f/up	375 days	1 unable to attend,
- Range of time of f/up	74–615 days	1 late death
Phone follow-up		
- Participated	19/20	1 lost to follow-up
- Median time of f/up	538.5 days	
- Range of time of f/up	330–892 days	

Abbreviations: TTE, transthoracic echocardiogram.

Postoperative transthoracic echocardiograms were examined to exclude long-term complications. Operation reports, discharge summaries, and follow-up letters were reviewed. Information was also obtained from the patient's local medical officer, the patient, or next of kin to further assess long-term safety. All statistical analysis was performed using Microsoft Excel.

AtriClip insertion was attempted and completed in all 20 of the patients [Table 1]. One participant was lost to follow-up. Two participants were not available for a postoperative transthoracic echocardiogram, one due to unrelated medical complications, and the other due to a late death from COPD. The participant's family and local medical officer were able to confirm that he had not had a stroke following his surgery. There were two participants who had late deaths, however they both attended their postoperative clinical review and transthoracic echocardiogram, and their families and local medical officers were able to confirm that they had not had a stroke following their surgeries.

The median time to the most recent postoperative clinical review by a cardiothoracic surgeon or cardiologist was 73 days. Participants then had a postoperative transthoracic echocardiogram. The median time until this review was 375 days. Local medical officers and participants were also contacted to further assess safety. The median time until this phone call was 538.5 days.

## Results

The mean age of the participants was 72.4 years, ranging from 52 to 83, and 75% were male [Table 2]. Eleven patients had a history or suspicion of an atrial arrhythmia; nine of which had AF, one had atrial flutter, and one a suspicion of an atrial arrhythmia. Of these 11 participants, all had a CHA<sub>2</sub>DS<sub>2</sub>-VASc score greater than two. Of the nine patients

**Table 2** Participant demographics.

Patient Variable	Total (N = 20)	%
Age (y)		
- Mean	72.4	
- Range	51–83	
Sex		
- Male	15	75%
History or suspicion of atrial arrhythmia	11	55%
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score >2	11	55%
Age >75 years	9	45%
Age >65 years + Hypertension	11	55%
New York Heart Association		
- Class I	4	20%
- Class II	7	35%
- Class III	4	20%
- Class IV	5	25%
Pre-CPB LVEF%		
- Median	50%	
- Range	17–60%	
Oral anticoagulation post operatively	4	20%
Surgery Category		
- Urgent	2	10%
- Semi-urgent	3	15%
- Elective	15	75%
Procedure		
- CABG	14	70%
- Mitral valve repair	1	5%
- Mitral valve replacement	1	5%
- Aortic valve replacement	8	40%
- Maze	3	15%
- Pulmonary Vein Isolation	3	15%
- Other	12	60%

Abbreviations: CPB, cardiopulmonary bypass; LVEF, left ventricular ejection fraction; CABG, coronary artery bypass graft.

in sinus rhythm, eight had left ventricular dilatation, and one had a history of likely TIA. Nine participants were greater than 75 years of age, and 11 were greater than 65 years of age with co-morbid hypertension. The median preoperative left ventricular ejection fraction was 50%, ranging from 17 to 60%.

Four participants were on oral anticoagulation postoperatively. Three participants were taking warfarin, two of which were planned to cease after surgical follow-up, and one to continue for management of a pulmonary embolus. One participant was taking rivaroxaban postoperatively for management of a pulmonary embolus.

There were two urgent cases, three semi-elective, and 15 elective cases. Fourteen participants had coronary artery bypass grafting, one had a mitral valve repair, one had a mitral valve replacement, eight had aortic valve replacements, three had Maze procedures and three had pulmonary vein isolation.

**Table 3** Patient outcomes.

Patient Variable	Total (N = 20)	%	Reason
Successful clip placement	20	100%	
Clip placement related haemorrhage	0	0%	
Post procedural haemorrhage	0	0%	
Device related serious adverse events	0	0%	
Clip placement related serious adverse events	0	0%	
Stroke	0	0%	
Late deaths	3	15%	1 COPD 1 leukaemia 1 congestive cardiac failure

Abbreviation: Chronic obstructive pulmonary disease

There was a 100% procedural success rate as confirmed by transoesophageal echocardiography during the surgery [Table 3]. None of the participants required multiple attempts to deploy the device. There were no device related serious adverse events or clip placement related serious adverse events. There were no clip placement related haemorrhages or post-procedural haemorrhages. Importantly, none of the participants had clinical evidence of stroke following their surgery. There were three late deaths, one due to refractory cardiac failure, one due to COPD and one due to leukaemia.

## Discussion

The safety and efficacy of LAA closure by surgical and percutaneous techniques for longitudinal thromboembolic morbidity prevention is a topic of much interest.

Salzberg *et al.* (2008) monitored seven adult baboons that underwent off-pump AtriClip device insertion, and at 130 days from insertion, direct inspection demonstrated stable device location, persistent LAA exclusion, and complete LAA fibrosis [17].

We reviewed the first 20 patients at our institution to have LAA occlusion with the AtriClip device. All participants had successful LAA occlusion with the AtriClip device confirmed by intraoperative transoesophageal echocardiography. None of the participants required multiple attempts at device deployment. Importantly, there were no immediate or late procedure or device related complications discovered during their postoperative inpatient stay, surgeon review, postoperative transthoracic echocardiogram, or phone follow-up.

Our findings are consistent with a similar previous study, EXCLUDE, which demonstrated a greater than 95% success

rate with no adverse events related to device insertion [2,5,12]. The LAAOS (Left Atrial Appendage Occlusion Study) III has been recruiting for a randomised control trial of LAA occlusion or no LAA occlusion in patients undergoing open cardiac surgery to follow participants for 4 years [16], the results of which may further assist in drawing conclusions regarding a stroke risk benefit with the AtriClip device. In our case series, at the time of data collection, none of the participants had clinical evidence of stroke following device insertion.

## Conclusion

Our case series suggests that LAA exclusion during open cardiac surgery with the AtriClip device may be a safe and effective procedure. All participants who met the inclusion criteria had the AtriClip device deployed successfully, without significant procedure or device related adverse events. At the time of data collection, none of the participants had clinical evidence of stroke following device insertion.

## Disclaimer

Mr Yui is a consultant for AtriCure Inc.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.hlc.2017.12.006>.

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