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INNOVATION

Novel technique of left atrial appendage occlusion—a pilot study

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Abstract
A clot in the left atrial appendage (LAA) is an important cause of cardio-embolic stroke. Concomitant occlusion of the LAA during cardiac surgery is found to have reduced postoperative stroke. A study was designed to observe the results of LAA occlusion in 17 patients undergoing coronary artery bypass graft surgery (CABG) and aortic valve replacement (AVR). The LAA was occluded epicardially with a SIRONIX 60-mm linear noncutting stapler (Healthium Medtech Pvt limited, Peenya, Bengaluru). The effectiveness of occlusion was confirmed by trans-esophageal echocardiography and at 2 years of follow-up with trans-thoracic echocardiography. There was no re-canalization of the LAA, and the patients remained in sinus rhythm. Concomitant LAA occlusion with a linear stapler during cardiac surgery is a safe, feasible, and reproducible option.

Keywords Left atrial appendage (LAA) · Coronary artery bypass surgery (CABG) · Aortic valve replacement (AVR) · Cardio-embolic stroke · Atrial fibrillation (AF)

Introduction

Occlusion of the left atrial appendage (LAA) as an adjunct procedure in patients undergoing cardiac surgery with atrial fibrillation (AF) is shown to reduce ischemic stroke rates (4.3%) when compared to those of the non–occluded group (7.0%) [1]. Surgical LAA occlusion can be achieved with various approaches and occluding devices. The use of AtriClip™ (AtriCure, USA) device has increased owing to the successful occlusion of the LAA without any procedural complications [2]. We used a linear surgical stapler being used for bronchial stapling and vascular stapling to achieve LAA occlusion from outside. Our study with this novel technique shows the feasibility, safety, and effectiveness of the surgical stapler as an occluding device.

Methods and methodology

A prospective non-randomized study of 17 consecutive patients was designed to observe the results of LAA occlusion; these patients were undergoing aortic valve replacement (AVR) or coronary artery bypass grafting (CABG) at our institute. Ethical clearance was obtained for the study after demonstration of its effectiveness in a homograft and subsequently using it in a patient undergoing mitral valve surgery. Informed consent was taken prior to surgery. From November 2019 to March 2020, consecutive patients meeting the inclusion criteria of age above 60 years and patients proposed to undergo CABG or AVR were enrolled in the study. Patients for CABG had their clopidogrel tablet stopped for a minimum of 3 days, but continued on aspirin tablet. All study patients were done off pump for CABG with a midline sternotomy with left internal mammary artery (LIMA) to left anterior descending artery (LAD) graft, and the rest of the coronary targets were bypassed with reversed saphenous vein grafts. During off-pump CABG, we used a Starfish positioner to gain access to the LAA base. Midline sternotomy for AVR, St. Thomas II cardioplegia, and LAA base was stapled on an arrested heart after replacing the valve and closure of the aorta. The base of the LAA was measured with a silk thread, the measurement was confirmed with a Vernier caliper, and the stapler size was chosen. A SIRONIX 60-mm linear noncutting stapler (Healthium Medtech Pvt. Limited, Peenya, Bengaluru) was used to occlude the LAA from outside after completion of the procedure (Figs. 1 and 2). The effectiveness of the occlusion was confirmed by trans-esophageal echocardiography (TEE) on the table and trans-thoracic echocardiography (TTE) at discharge. The patients were followed up at 6 months, 1 year, and 2 years. Data was collected and entered into an Excel sheet and summarized in Table 1.

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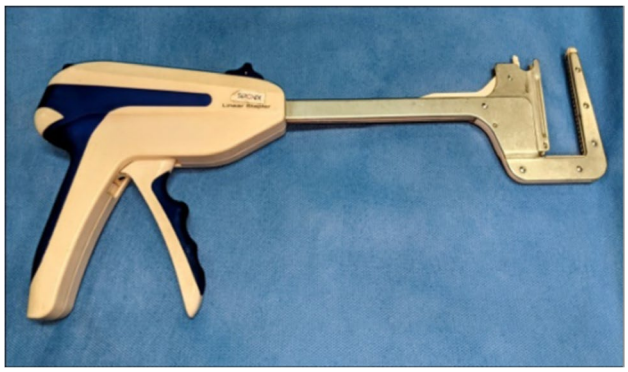


Fig. 1 Sironix stapler gun

Table 1 Demographics

Criteria	Observed values
Age range (mean)	60–75 (66.9 years)
60–69 years	10
70 years and above	7
Male vs female	88% vs 12%
No. of patients with DM2	12
No. of patients with HTN	9
Average Euro score 2	1.16%
Significant carotid lesion	0
Peripheral vascular disease	1
Preoperative AF	0

Results

Among the 17 elderly patients in sinus rhythm, the LAA was successfully occluded in all patients. There were no complications related to usage of the stapler on table and immediate postoperative period, i.e., LAA tear and impingement of the left circumflex artery. In one of the patients, two staplers were used as incomplete occlusion was demonstrated upon TEE intraoperatively owing to the large curved base of the LAA. Different morphology in LAA base was observed in all patients. Measurements, prior to stapling, we observed a mean of 34.52 mm, with the minimum being 29 mm and the maximum being 42 mm. The bleeding trend as depicted in Chart 1, we had a mean hemorrhage of 216.5 ml, with the minimum being 90 ml and the maximum being 600 ml. In the immediate postoperative period, 3 patients had transient AF in the CABG subset which reverted back once amiodarone infusion was administered. One patient had multi-organ dysfunction and succumbed at postoperative day 10. At follow-up of 6 months, 1 year, and 2 years, there was no re-canalization noted on trans-thoracic echocardiogram. Patients under follow-up remained in sinus rhythm at 2 years with no major cardiovascular event.

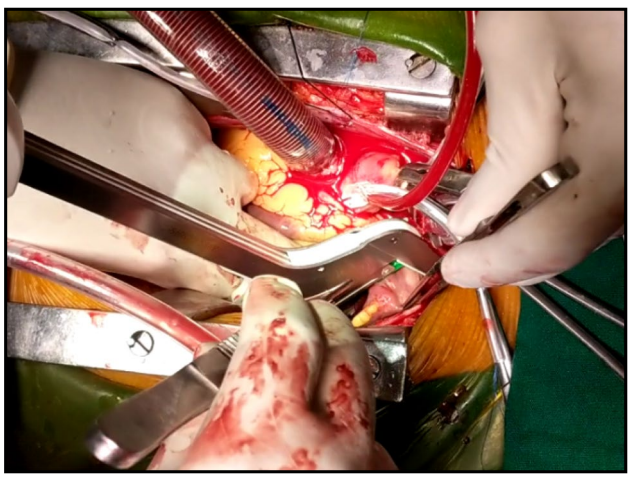


Fig. 2 Stapler being deployed on LAA

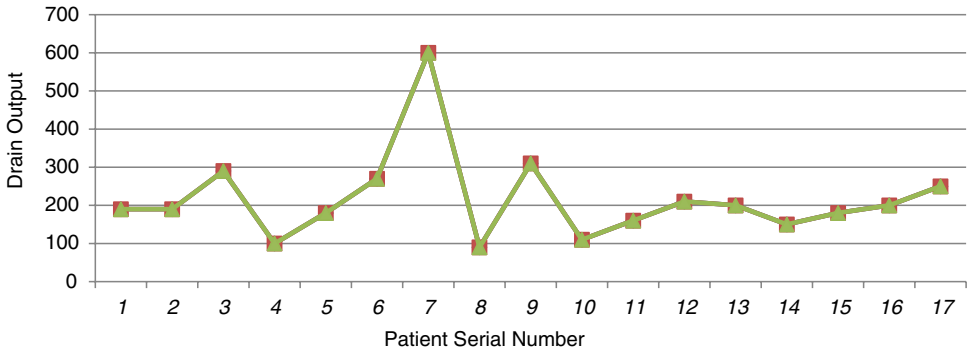
Discussion

The incidence of postoperative new-onset AF in cardiac surgery patients is around 35% [3, 4]. The source of emboli in nonvalvular AF was the LAA in 91% of the time [2, 3]. Noncompliance to medications, higher costs, and bleeding complications suggest alternative methods to exclude the LAA [4]. Current guidelines suggest there might be a benefit to exclude the LAA to prevent future stroke as a concomitant procedure during open heart surgery (class IIb and level of evidence B) [5, 6]. The guidelines also suggest LAA occlusion is not a replacement for discontinuation of anticoagulation [5, 6].

Exclusion of LAA can be achieved from the endocardial or epicardial surface, during cardiac surgery or epicardially through a thoracoscopic approach or endocardially with occluding devices using the percutaneous approach. Meta-analysis of various surgical LAA occlusion methods revealed 55–60% success rates [7]. Failure rates were initially high in the early decade, but with advancement in surgical technique and devices, satisfactory occlusion rates are reported.

Internal exclusion of LAA has been the gold standard in occlusion and practiced by many cardiac surgeons during mitral valve procedures. The cut-and-sew method of excluding the LAA during open heart surgery leaves no residual stump or chance for re-canalization. In instances where the left atrium is not opened, epicardial suture occlusion is being practiced. Tearing of the LAA during epicardial suture ligation, inclusion of the left circumflex artery in the suture, incomplete occlusion with a large LAA base are fearful complications. Percutaneous LAA exclusion has the inherent

Chart 1 Day 1 bleeding trend



drawback of leaving a foreign body in the circulatory system, which has the potential to form a thrombus and cause systemic embolization. Patients are at risk until there is complete endothelization of the implant, not to forget residual leaks.

Epicardial implantation of an AtriClip™, being performed minimally invasively or through a thoracotomy approach, has shown occlusion rates reaching 100% in recent times [2]. Our technique using the linear surgical stapler is different from the use of the AtriClip as it applies titanium clips across the epicardial surface of the LAA and seals the endocardium together leaving no scope for re-canalization. The noncutting nature of the stapler alleviates the fear of massive hemorrhage. The shoulder of the stapler prevents the inclusion of the left circumflex artery.

Most of our case subset underwent off-pump CABG, and all of the patients were in sinus rhythm. Paroxysmal AF can occur postoperatively. At 2 years of follow-up of CABG patients, none had AF or stroke. This subset may benefit from LAA occlusion without the need for anticoagulation.

Conclusion

This technique of the LAA with staplers is feasible, safe, and reproducible, and its effectiveness lasts for at least 2 years.

Author contribution Dr. P. S. Seetharama Bhat—design, implementation of the idea.

Dr. Chandra Sena M.—data collection, write-up of the manuscript, follow-up of the patients.

Dr. Rajesh Deshamukh—introduced the SIRONIX stapler while designing an occlusion device.

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Code availability Not applicable.

Declarations

Ethics approval SJICR/EC/2019/017 dated 29.03.2019.

Consent to participate Yes.

Consent for publication Yes.

Conflict of interest Nil.

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