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"Effectiveness of Suture Closure of Left Atrial Appendage to Prevent Thromboemboli in Atrial Fibrillation among Patients Undergoing Bio-Prosthetic Mitral Valve Replacement"

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Abstract

Objectives: Atrial fibrillation is the most common sustained arrhythmia. Patients with atrial fibrillation have a fivefold higher risk of thrombo-embolism and stroke. Aim of current study is to assess effectiveness of intra operative suture closure of left atrial appendage in prevention of thrombo-embolism.

Methods: 400 patients underwent bio-prosthetic mitral valve replacement between 2011 and 2017. Pre-operatively, they had rheumatic mitral valve disease and atrial fibrillation with controlled heart rate. The study group included 200 cases. Intra-operatively, each one had continuous suturing of margins of the mouth of left appendage with 4/o polypropylene suture. Postoperatively, they received anticoagulants for 90 days. The control group included 200 patients. They didn`t have such suturing of appendage. They received indefinite anticoagulants. Follow up continued for 78 months and included clinical examination every 3 months and trans-esophageal echocardiography every year.

Results: Study group included 200 patients 109 (54%) females, mean age of 29 ± 2.1 years. Suturing of the margins of atrial appendage needed 4 ± 0.25 minutes to be conducted after incising the left atrium and examining the appendage. Atrial thrombi were removed from the appendage in 10patients (5%). Postoperative thrombi or thrombo-emboli weren't reported. Control group 200 patients, 101(51%) females, mean age 30 ± 1.02 years. Intra-operatively, thrombi in appendage were extracted in 8 patients (4%). Trans-esophageal echocardiography showed left appendage-thrombi in six patients (P-value 0.0001) and one case of thrombo embolism was reported.

Conclusion: Intra-operative suture closure of left atrial appendage kept patients, having atrial fibrillation, free of thrombo embolic events in contradistinction to the control group. This technique is effective and reproducible.

Keywords: Atrial fibrillation; Left atrial appendage-thrombosis; Thrombo embolism; Suture closure of left atrial appendage; Rheumatic valvular atrial fibrillation

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Introduction

Researchers reported that the incidence of Left Atrial Thrombi (LAT) was significantly higher in patients with atrial fibrillation (14%) compared with patients in sinus rhythm (1%; P<0.001). Patients with Atrial Fibrillation (AF) have a fivefold higher risk of stroke. Cerebral thrombo embolism is the number one cause of long-term disability and the third leading cause of death in patients with AF [1,2]. Unfortunately, oral anticoagulants have a narrow therapeutic window, require frequent monitoring, have significant drug-to-drug and food-to-drug interactions and carry the risk of bleeding or thrombo-embolism. It has significant side-effects, especially in the aged. In some series up to 40% (14% to 44%) of patients had relative or absolute contraindications to chronic warfarin therapy [3,4]. Cox-Maze procedures are expensive and relatively time consuming. Some patients are having contraindications to these procedures and their results are inferior in rheumatic patients. Many authors reported that Cox procedure was not widely adopted because of its complexity and invasiveness [3-5]. Patients with valvular atrial fibrillation, who have controlled

heart rate by medications, have only one problem with AF that is LAT and subsequent possible thrombo-embolism. At the time of planning for current study we did not have any facilities at our center for surgical treatment of arrhythmias. Thus, an alternative, effective low-risk therapy is required. Alternative approaches are evolving, as a possible treatment strategy for patients at risk of thrombo embolic complications originating from LAA. LAA exclusion can be easily performed by either intra operative obliteration or occlusion [5]. Aim of current study is to assess the effectiveness and reproducibility of suture closure of LAA for prevention of thrombo embolism among patients having valvular chronic AF and medically- controlled heart rate. In addition to LAA, there are multiple sources of emboli among aging population with AF such as atherosclerotic plaques of the aorta, cerebral arteries and left ventricular scars or aneurysms. That is why we selected relatively- young adult patients who were candidates for bio-prosthetic valve replacement due to rheumatic Mitral Valve (MV) disease associated with AF. Selection of bio-prosthetic MV replacement for the study group of patients can be of a little clinical value unless we are going to perform a simple technique to avoid postoperative administration of oral anticoagulants. Thus; we selected suture closure of the inner orifice of the LAA.

Methods

This Prospective randomized study has been carried out since 1st February, 2011. It was completed on 30th August 2017. Four hundred patients underwent bio-prosthetic MV replacement and completed follow up at Department of Cardio-thoracic Surgery in Suez Canal University Hospitals and Ain Shams University Hospitals, Cairo, Egypt. This study included patients with rheumatic MV disease associated with chronic AF who was candidates for bio-prosthetic MV replacement. For each patient, heart rate was medically controlled before his surgery.

Exclusion criteria

Patients with mitral and aortic valve disease, Bio-prosthetic MV replacement was not the selected option, Uncontrollable rapid AF or incomplete follow up. Also, tow perioperative deaths were excluded.

The study group

Two hundred patients had rheumatic valvular AF. Preoperatively, heart rate was controlled by medications given for each patient. Intra-operatively, Patients having mitral valve surgery receive general anesthesia. Incision can be made vertically through the sternum down to the level of the 4th rib (minimally invasive MV. replacement). After the heart is exposed, canulae are placed to start cardiopulmonary bypass. An incision is made in the left atrium to expose the left atrial cavity and explore the LAA. All patients included in the study group had continuous suturing of inner margins of LAA. We used 4/o propylene suture material giving a very smooth regular suture line. Each time we started the suturing with an inverted ligature then, continued through the endocardium and sub-endocardial layers to the end of the orifice (horizontal sutures). These horizontal sutures were intended to be away from the circumflex coronary artery lying on the outer surface of the root of the appendage. The suture material is durable and strong enough to withstand intra-atrial pressures. The MV was then replaced with a bio- prosthetic valve. The left atrium was then closed and the patient weaned from cardiopulmonary bypass. After surgery patients were taken to an Intensive Care Unit (ICU).

The control group

Included two hundred patients. Each patient had the same surgical steps except for suturing of inner margins of the LAA (there is no exclusion of the LAA). According to the guide lines, each patient had oral anticoagulants during the first three months after surgery. The control group continued anticoagulant therapy. Seventy eight months follow up included clinical examination every 3 months and Trans-Esophageal Echocardiography (TEE) every year.

Statistical analysis

Sample size was estimated according to certain equations. Randomization was done by keeping every second patient into the control group. Patients were arranged according to their hospital number. Normally distributed continuous data were expressed as mean ± SD. Abnormally distributed data were expressed as median and range. Outcome percentages were expressed as the percentage. Categorical data were expressed as absolute numbers and proportions. Freedom from LAT and thrombo-embolic complications was calculated and analyzed. Clinical profiles were compared using the Fisher exact test (a statistical significance test). All data analyses were performed with the SPSS system for statistics (SPSS 11.0 for Windows, SPSS, Inc.; Chicago, IL) TEE for our group of patients was carried out along with other patients from out-patient clinic and was interpreted along with other patients' reports (double blind test).

Results

The study group included two hundred patients 91 males (46%) and 109 females (54%), age ranged between 16and 36 y. and mean age of 29 ± 2.1 years (Table 1). Suturing of inner margins of LAA took 4 ± 0.25 min to be conducted after incising the left atrium and exploring the LAA. Thrombi in left atrial appendage were removed from the appendage in 10 patients (5%). Mean cross clamp time was 55 ± 7 min. Perioperative mortality was one patient (0.5%) due to respiratory failure. Mean Hospital stay was 5 ± 2.2 days. Postoperative embolic manifestations were not reported in any case during follow up. Postoperative TEE did not detect any suspicious martial neither in the appendage nor on left atrial wall. No one case of disruption of suture line along the mouth of LAA has been reported. Control group included 99 males (49%) and 101 females (51%), age ranged between 17 and 41 years mean age 30 ± 1.02 years. Intra-operatively, we found left atrial thrombi in 8 patients (4%). Mean cross clamp time was 53 ± 9 min. Mean hospital stay was 5 ± 3.5 days. Perioperative mortality was one patient (0.5%) after extensive brain stem infarction. Postoperatively, all patients continued oral anticoagulants. Transesophageal echocardiography proved left atrial thrombi in 4 females and two males (3%). Seventy one months after surgery, an additional case of thrombo embolism was reported with prosthetic valve free of thrombi but there was a large LAT. Thus, there were not any postoperative thrombotic or thrombo-embolic events among the study group whereas there were 3.5% incidence of thrombi and thrombo-embolic events among the control group (P value 0.0001). Also, intra operative left atrial thrombi were found among the study

Table 1: General characters.

Features	Study group	Control group	Significance
Number of patients	200	200	P value=0.231
Range of age	16 to 36 years	17 and 41 years	P value=0.31
Mean age	29 ± 2.1 years	30 ± 1.02 years	P value=0.512
Gender	Male 91 (46%)	Males 99 (49%)	P value=0.121
	Female 109 (54%)	Females 101 (51%)	

Statistically significant results= P value<0.005, Insignificant results= P value>0.005

Table 2: Results.

Features	Study group	Control group	Significance
Number of cases	200	200	
Preoperative rheumatic mitral valve lesion	Tight stenosis : 77	89	Insignificant P value=0.198
	Stenosis & regurgitation: 105	101	
	Severe regurgitation: 18 cases	10 cases	
Preoperative rhythm	Atrial fibrillation for a median period of 10 y.	Atrial fibrillation for a median period of 9.3 y	Insignificant P value:0.63
Preoperative heart rate	Controlled by drugs	controlled by drugs	Insignificant
Intraoperative thrombi	10 cases (5 %)	8 cases (4 %)	Insignificant P=0.641
Mean cross clamp time	55 ± 7 minutes	53 ± 9 minutes	Insignificant P= 0.847
Mean duration of suturing of LAA inner margins	4 ± 0.25 minutes	No suturing was done	---
Mean hospital stay	5 ± 2.2 days	5 ± 3.5 days	P= 0.658
Perioperative mortality	0ne case`0.5 %	One patient 0.5%,	---
	Excluded	Excluded from the study	
Postoperative thrombi by TEE during follow up	No one case 0%	In 4 females and 2 males and one case of thrombo-embolic events (3.5%)	P value= 0.0001 Significant
Total intra-operative old thrombi in LAA versus postoperative recent thrombi	Pre-operative (old): 5%	Pre-operative(old): 4 %	P value=0.0001 Significant
	Postoperative(recent): 0%	Postoperative(recent):4.5%	
	(Old thrombi were formed while patients were receiving anticoagulants)	(Both were formed while patients were receiving anticoagulants)	

Statistically significant results = P value<0.005, Insignificant results= P value>0.005

group in 5% (10 from 200 cases) and among the control group in 4% (8 from 200 cases) formed while the patients were receiving oral anticoagulants. On the other side, no one patient had any thrombusor thrombo-emboli events among the study group postoperatively (P value=0.0001). Sinus rhythm was noticed for a mean period of 29 ± 3.5 hr postoperatively followed by AF among all patients (Table 1).

Discussion

AF is the most common clinically important cardiac arrhythmia; occurring in approximately 0.4% to 1% of the general population and increasing with age (level of Evidence is satisfactory) [5-7]. AF is a complex type of arrhythmia that is still not thoroughly understood in many patients [8]. LAA is a finger-like extension originating from the main body of the left atrium. It is a potential site for the development of thrombi. Appendage dysfunction is an independent predictor of thrombo-embolism [9]. In non-valvular AF, over 90% of stroke-causing clots that come from the heart are formed in the left atrial appendage (level of Evidence is satisfactory). Among the factors related to the presence of thrombi in the LAA are its dilation and decrease in contractility with the ensuing blood stasis little attention has been paid to the right atrial appendage (RAA) [10]. This is probably due to its location, which makes it difficult to visualize with monoplane transducers, while it is almost impossible to assess with Trans thoracic echocardiography. In the RAA, the prevalence of thrombi and their embolic complications are much lower than in the LAA [11-13]. Contractile dysfunction of the LAA causes blood stasis in its cavity and favors the presence of thrombi. Subramaniam and his colleagues (2006) found the incidence of the RAA thrombus formation much lower in patients with mitral stenos is and AF than in LAA. The contractile dysfunction of the left atrial appendage is more than that occurring in the right atrial appendage (level of Evidence is probable) [5,14]. The interest in evaluation of significance of LAA closure stems from the observation that among individuals in whom left atrial thrombus can be visualized, 90% are located in the LAA (12-14). Strokes associated with AF are severer than those with non-atrial fibrillation strokes (Level of Evidence is possible) [15,16]. Current study highlights several important issues. LAA exclusion is associated with reduced short and relatively long-term stroke rates among patients who did not receive oral anticoagulants after the first 3 months postoperatively (Table 2). This is in accordance with many research works [17-20]. The device termed PLAATO (percutaneous LAA trans-catheter occlusion) was the first LAA occlusion device. The ULTRASEAL LAA device is a percutaneous, trans-catheter device intended to prevent thrombus embolization from the LAA in patients who have non-valvular AF. Other devices exist to occlude the LAA from the inside of the heart. Surgical exclusion can be done by Thoracoscopic clipping or banding from outside the appendage is becoming possible. Exclusion from inside by suturing of inner margins of the appendage provided a satisfactory rate of success, as in this study. The American College of Cardiology/American Heart Association guidelines for the management of patients with atrial fibrillation also include LAA exclusion from systemic circulation whenever possible during cardiac surgery and reduction of left atrial size in patients at risk of developing postoperative AF [21]. However, ESC/EACTS (European Society of Cardiology/European Association of cardiothoracic Surgery) guidelines on the management of valvular heart disease of 2012, indicated that, no evidence supports the systematic surgical closure of the LAA, unless as part of AF ablation surgery [1,21]. Before current study, patients with MV disease and AF were unlikely to receive abio-prosthetic mitral valve replacement as long as they are going to receive postoperative oral anticoagulants. Our approach kept them not in need for anticoagulants except during the 1st three months post-operatively. Consequently, each patient among the study group achieved his goal by having a bio-prosthetic valve. MV replacement and exclusion of cavity of the LAA both minimized the risk of blood stasis and reduced or eliminated risk of LAT and thrombo-embolism to a satisfactory level. In spite of the fat that heart rate in AF was only medically controlled, patients neither had thrombo-embolic events, nor had they received regular anti coagulants. With a satisfactory level of evidence, we can report

that if complete LAA occlusion can safely take place in patients experiencing AF, it should be performed.

Conclusion

Suture closure of LAA intra-operatively among this group of patients kept them free of any thrombo embolic events without administration of anticoagulants. It is a reproducible approach.

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