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Mitral Para-valvular leakage following usage of non-pledgeted compared to Teflon-pledgeted sutures

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***Abstract*---**Background: Despite a wide variety of mitral prosthesis suturing, pledgeted annular sutures are preferred to lower the incidence of para-valvular leakage (PVL). However, there is limited evidence in the literature on the effect of non-plegeted sutures on such serious complication. Objective: The purpose of this study was to determine the safety and practicality of employing non-pledgeted sutures for Mitral valve replacement (MVR), especially regarding postoperative PVL. Patients and methods: Data on 100 patients with MVR were gathered from Cairo University Hospitals. Cases were split into two groups: group 1 underwent surgery using non-pledgeted horizontal sutures where in group 2 we used Teflon-pledgeted sutures. Preoperative, operative, and postoperative factors including follow-up echocardiographic examination one year following discharge, were compared between the two groups. Results: Both groups had similar preoperative characteristics, with group 1 including 49 patients compared to 51 patients in group 2. Data showed significantly shorter cross clamping (AXC) time in group 1 (p value < 0.05), intraoperative TEE has never observed para-prosthetic leakage in both groups, there was no significant difference regarding both mean ICU and hospital stay. we found no significant difference in the number of cases

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presenting with IE nor PVL in both groups (p value > 0.05). Conclusion: With no increase in the risk of PVL, a non-pledgeted suture approach provides an equal alternative to the conventional use of pledgets during MVR.

***Keywords*---**Mitral valve replacement, Non-pledgeted sutures, Aortic cross clamp time and para-valvular leakage.

Introduction

The term "paravalvular leakage" (PVL) refers to improper connection between the valve annulus and sewing ring (1, 2). PVL in mitral position affects 6% to 15% of cases underwent MVR. The resultant Para-prosthetic regurgitation and hemolytic anemia can be severe mandating intervention (2,3). Mitral position, Senile tissue friability, Annular calcification and infection are known anatomical risk factors for PVL (4,5). While continuous suturing technique in mitral position, mechanical prosthesis and has been shown to increase the risk of PVL in the mitral location, the use of non-pledged sutures is still debatable (6,7). We aimed to assess whether the use of the horizontal non-pledgeted mitral prosthesis suturing technique is as safe as usage of Teflon-pledgeted technique.

Patients And Metods

This randomized prospective study included 100 patients who underwent isolated surgical MVR and were involved in two suturing techniques: horizontal non-pledged technique and Teflon-pledged technique. It was conducted in the department of cardio-thoracic surgery, Faculty of Medicine, Cairo University, from January 2018 to December 2020, with the goal of assessing the risk of mitral PVL incidence following surgical MVR using non-pledged suturing technique. Significant PVL is defined as para-prosthetic regurgitation that caused congestive heart failure, significant hemolysis clinically or occupying more than one third of the sewing ring as detected during follow up trans-thoracic echocardiographic examination. Operative mortality and morbidity including PVL were defined as those that occurred within 30 days after the operation.

Inclusion criteria: Patients with isolated MVR.
Exclusion criteria: patients below age of 18 or above 60, severe mitral annular calcification, MVR for infective causes, other valvular or coronary lesions, aortic valve and/or root surgeries, LV EF< 35%, Major adverse cardiac and cerebrovascular events and cases with congenital collagen disorder.

One hundred consecutive patients meeting the above criteria were entered into the study. The patients were randomly assigned to one of two groups: group 1, a horizontal non-pledgeted sutures were used, comprised 49 patients: and group 2, a Teflon-pledgeted sutures were used, comprised 51 patients. All patients in both groups underwent the same anesthetic and preparative surgical techniques. All patients underwent routine preoperative investigation including electrocardiogram, Chest X-ray, hemoglobin, urea, electrolyte, serum creatine, and echocardiography with intraoperative trans-esophageal echocardiography and

post operative trans-thoracic echocardiographic follow up studies at 6 and 12 months-duration after surgery.

Ethical approval

An approval of the study was obtained from Cairo University academic and ethical committee. Every patient's parent signed an informed written consent for acceptance of the operation. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Preoperative Surgical technique

Transesophageal echocardiography was conducted after a median sternotomy to examine the diseased mitral valve and suspected other abnormalities in the heart or ascending aorta. Following the establishment of cardiopulmonary bypass through Aorto-bicaval cannulation, the aorta was cross-clamped, and the heart was arrested using cold blood-based cardioplegic solution into the aortic root, in all cases, MVR were carried out through left atriotomy approach.
To expose the mitral valve, a wide incision was made in the left atrium parallel to the interatrial groove and to preserve the ventriculo-annular continuity, the anterior mitral leaflet was removed while the posterior leaflet and chordae were spared. The mitral annulus was correctly measured to pick the suitable sized prosthesis.

Mitral valve prosthesis (MVP) suturing technique

Passing from atrial to ventricular side, 13 to 15 stitches were placed. In group 1, we used non-pledgeted Ethibond in horizontal mattress fashion while in group 2, we used Teflon-pledgeted Ethibond vertical sutures. After securing MVP position and function, the left atrial incision was closed using non-absorbable polypropylene sutures, and a vent catheter was inserted into the left ventricle for deairing then aorta was de-clamped and Transesophageal echocardiography was performed to confirm appropriate deairing as well as to evaluate the prosthesis competency and the existence of a PVL. Eventually, the patient is weaned from cardiopulmonary bypass, pacing wires and drainage tubes were implanted, and the incision was closed layer by layer as is customary in surgery.

Statistical analysis

Continuous data were expressed as mean and standard deviation or median with the interquartile range and categorical data as percentages. All reported P values are two-sided, and P values of ≤ 0.05 were considered statistically significant. All statistical analyses were performed with SPSS version 22.0 (SPSS, Inc., Chicago, IL, USA). All statistical analyses were done with the help of a departmental statistician.

Results

Group 1 (non-pledgeted suturing) comprised 49 patients (26 females), mean age was 36.78 years, Group 2 (pledgeted suturing) comprised 51 patients (30 females), mean age was 40.09 years. There was no significant difference in preoperative characteristics between both groups regarding age, gender, comorbidities, and dominance of the mitral lesion as shown in table (1). Both cross-clamp time (AXC) and bypass time for group 1 were significantly shorter than in the other group (p value <0.0001). Other postoperative outcomes including reopening for bleeding, Mechanical Ventilation (MV) time, ICU stay and hospital stay were not significantly different between the 2 groups.

According to 1-year echocardiographic data, the incidence of substantial PVL was somewhat greater in group 1 (6.1% vs 1.96%) than in group 2, although the difference was statistically insignificant.

Table (1): Comparing characteristics of the two patient groups undergoing MVR surgery, group 1 with non-pledgeted sutures, group 2 with Teflon-pledgeted sutures

	Group 1(N =49), Mean ± SD, or Number (%)	Group 2	P value
Age	36.78 ± 11.33	40.09 ± 9.77	0.12
Female gender	26 (53.06%)	30 (58.88%)	0.45
Hypertension	4 (8.16%)	6 (11.76)	0.55
Diabetes mellitus	2 (4.08%)	4 (7.84%)	0.43
Atrial fibrillation	2 (4.08%)	3 (5.88%)	0.68
New York Heart Association class (on admission) I–II III–IV	 10 (20.41%) 39 (79.59%)	 13 (23.53%) 137 (74.51%)	 0.64 0.92
Dominance of mitral disease Mitral stenosis Mitral regurgitation	 32 (65.31%) 17 (34.69%)	 28 (54.90%) 23 (45.09%)	 0.66 0.46
AXC time (minutes)	57.8 ± 0.3	61.6 ± 0.5	**<0.0001**
Bypass time (minutes)	84.7 ± 0.6	89.5 ± 0.8	**<0.0001**
Reopening for bleeding	2 (4.06%)	3 (5.88%)	0.68
MV time (hours)	11.47 ± 4.45	11.22 ± 4.54	0.78
ICU stay (days)	1.27 ± 0.56	1.33 ± 0.65	0.62
Hospital stay (days)	7.3 ± 0.4	7.4 ± 0.8	0.43
Significant PVL	3 (6.1%)	1 (1.96%)	0.29

Discussion

Inadequate sealing between the prosthetic valve's outer surface and the surrounding tissue causes paravalvular leak (PVL), which permits blood to regurgitate similarly to valvular regurgitation. Thus, most surgeons choose Teflon-pledged suturing techniques, particularly in the mitral location where PVL complications have been found to occur more frequently (8). Our study suggested that the non-pledgeted suture technique may be utilized as safely as the traditional pledgeted suture technique, with clinically comparable outcomes in the term of significant PVL.

Reviews reported by LaPar et al. (9), Tabata et al. (10) and Chan et al. (6) showed no significant statistical difference in incidence of PVL following Aortic valve replacement using non-pledgeted sutures compared to Teflon-pledgeted sutures. Vlessis et al. (11) in 1997 demonstrated shorter ACX and CPB times on using non-pledgeted sutures for AVR. These results cope well with that published by LaPar et al. (9) and Tabata et al. (10). We found that, lack of need for pledget-orientation and positioning on using non-pledgeted suturing besides clarity of view of the next stitch allowed for faster suturing and significantly shorter ACX time and CPB time (P value < 0.0001). In contrary, Kim et al. (12) found that, the two techniques showed no statistically significant differences in the aortic cross-clamp time and cardiopulmonary bypass time.

4% of cases we operated in this study suffered significant PVL within 1 year of follow up. This is similar to results cited in studies conducted by Cappelli et al. (13), Ozan Gürsoy et al. (14) and Gürsoy et al. (15). Although incidence of PVL was higher among patients with non-pledgeted technique (6.1%) than in the pledgeted technique group (1.96%), it was statistically insignificant. This is comparable to results showed by Kim et al. (12) and Dziubek et al. (16).

Conclusion

We propose that the nonpledged horizontal mattress suture approach may be utilized as safely as the usual pledged suture technique during MVR, with no substantial increase in PVL. More research is needed to see if these clinical results can be replicated in a larger, prospectively followed patient cohort.

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