International Surgery Journal
Kothari A et al. Int Surg J. 2023 Sep;10(9):1490-1495
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20232641

Original Research Article

Aortic valve replacement using interrupted pledgeted non everting suture technique versus simple suture technique in small aortic annulus, does it influence patient prosthetic mismatch

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Received: 08 July 2023
Revised: 08 August 2023
Accepted: 16 August 2023

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ABSTRACT

Background: This study aims at comparing post-op outcome and incidence of patient prosthetic mismatch (PPM) post aortic valve replacement (AVR) using pledgeted versus simple suture technique in isolated aortic stenosis patients with small aortic annulus undergoing AVR with 18-21 mm mechanical bi-leaflet valve in Indian population.
Methods: A retrospective study, conducted in KEM Hospital, Mumbai in patients who underwent AVR between January 2015 to December 2018. Pre-operative data and 1-year post-op hemodynamic data of patients undergoing AVR using interrupted non everting pledgeted and interrupted simple suture technique were compared.
Results: 68 patients were selected for study after applying exclusion criteria (pledgeted 44, simple 24). Both groups were comparable in terms of age (p=0.46), sex (p=0.41), and valve pathologies. Incidence of severe PPM was higher in pledgeted group in patients with valve size 18-19 mm (p=0.20) but similar in valve size 20-21 mm group (p=0.30). Patients with severe and moderate PPM had poor post-operative LV function.
Conclusions: PPM is a common and alterable entity. Severe PPM is responsible for adverse hemodynamic function and congestive heart failure among patients with small sized aortic valve implantation (18-21 mm). Use of simple suture technique had a slight benefit over pledgeted technique in reducing incidence of severe PPM (not statistically significant) and better recuperation during short term follow up.

Keywords: Small aortic root, PPM, Simple suture technique, Pledgeted suture technique

INTRODUCTION

Aortic stenosis in Western countries is commonly seen above age of 60 years, caused by degenerative etiology in majority. In Indian population, it usually presents before 60 years of age with senile degeneration being the most common cause for isolated aortic stenosis (65.6%) while rheumatic etiology is seen in 2.9% cases only.[1] A significant difference is present between aortic dimensions in Indian and Western population with aortic valve diameter being smaller than standard values in Indian population in majority of BSA ranges.[2] Hence, particularly for Indian population surgeons come in contact with small aortic root more often in cases of isolated aortic stenosis.

Prosthesis-patient mismatch (PPM) was first described in 1978 by Rahimtoola.[3] It is encountered when effective orifice area (EOA) of the prosthetic valve implanted is very small in relation to body surface area (BSA). PPM leads to poor hemodynamic function, decreased regression of left ventricular hypertrophy, less freedom from late cardiac events and mortality. Most accurate parameter to characterize PPM is indexed effective orifice area (IEOA), calculated as EOA of prosthesis divided by patient's BSA. IEOA less than 0.65 cm^2/m^2 is classified as severe PPM

whereas values between 0.65–0.85 cm^2/m^2 being classified as moderate PPM.[4] New generation mechanical valves can be implanted in supra annular position, which can offer maximum achievable EOA and hence PPM can be avoided. Not only geometry and characteristics of prosthetic valve including stent design and sewing ring are important but also the suturing technique has impact on PPM. Conventional suturing techniques for AVR includes interrupted everting or non-everting pledget suturing. Using the pledget suture, due to additional material in the outflow tract it reduces the effective outflow diameter which results in high transvalvular gradients post-surgery in patients with small aortic root.

Earlier studies performed by Tabata et al observed that non-everting mattress sutures with pledget can impair the hemodynamic function of the bioprosthesis 19 or 21 mm valve, contributing to the transvalvular gradient and predisposing to pannus formation.[5] Another study by Ugur et al concluded that no significant difference is seen with type of suture placement and EOA.[6] Kim et al compared interrupted pledget mattress, interrupted non-pledget mattress, and "figure-of-eight" non-pledget suture techniques, implanting both mechanical and bioprosthetic stented valves and concluded that no difference in in-hospital mortalities or cardiac adverse events in each suture group whereas non-pledgeted suture had significantly lower moderate and severe PPM rates in patients with small aortic annulus (18-21 mm).[7]

The present study aims at comparing post-operative outcome, incidence of PPM and early mortality post AVR using interrupted pledgeted non everting suture technique with interrupted simple suture technique in isolated aortic stenosis patients with small aortic annulus undergoing AVR with 18-21 mm mechanical bi-leaflet valve in Indian population.

METHODS

Inclusion criteria

This was a retrospective analysis, conducted in cardiac surgery department of KEM Hospital Parel, Mumbai in patients who underwent AVR with mechanical bi-leaflet prosthetic valve for isolated severe aortic stenosis in time period of January 2015 to December 2018.

Exclusion criteria

Exclusion criteria were as follows: concomitant mitral valve, tricuspid valve surgery, concomitant coronary artery bypass grafting surgery, concomitant root enlargement procedures, and patients below 18 years of age were excluded.

Sample size

68 patients undergone for elective cardiac surgery after applying exclusion criteria.

The sample size is selected based on the time duration of the study and average cases per year of AVR. So, we have selected 60 as the minimum sample size based on previous year's record of patient who had undergone AVR.

After local ethical committee approval, patient's baseline data were collected from medical records. Patients were divided into two groups, one with AVR using interrupted non everting pledgeted mattress suture technique (44) and other using simple interrupted suture technique (24). Follow-up clinical information was received from mailed questionnaires, review of medical records, or death certificates and telephonic interviews with the patients or their local physicians.

Patient demographics, characteristics, echocardiography findings and operative notes were reviewed. Echocardiography findings evaluated were EOA (cm^2), LV systolic function, gradient across the aortic valve in pre and post-operative period. Follow up Echocardiography data was analyzed at 1-year post surgery. IEOA was calculated and compared to classify PPM after surgery. We also took in consideration post-operative recovery, early mortality, LV remodeling, occurrence of cardiac adverse events, and other adversities like paravalvular leak, bleeding requiring re-exploration, arrythmias, AKI, respiratory and CNS complications.

AVR were performed with standard technique by midline sternotomy. It was performed by various surgeons without favoring any particular suturing technique. Intraoperative TEE was routinely used. Native valve was excised, calcification debrided. In pledgeted group, Ethibond 2-0 17 mm pledgeted suture was used with pledget placement on LV side. Similarly, in simple suture group Ethibond 2-0 17mm sutures were being used with supra annular implantation in both groups.

For statistical analysis, continuous variables were expressed as mean±standard deviation or median (interquartile range), as necessary. Categorical variables were expressed as absolute number (percentage). Comparisons of proportions were performed using the χ^2 test or Fisher's exact test, as appropriate. Group comparison for continuous variables was tested with the student's unpaired t test.

RESULTS

A total of 230 aortic valve replacement cases were operated in time period of January 2015 to December 2018, out of which only 134 cases underwent valve replacement with 18-21 mm size bi-leaflet prosthetic valves. The study population calculated after applying exclusion criteria came to be of 76 cases out of which 8 patients were lost to follow up. The study group were divided into two groups based on suture technique used (pledgeted 44, simple 24).

Both groups were comparable in terms of age, sex, and valve pathologies (degenerative, rheumatic, bicuspid valve) similar pre-operative characteristics including heart failure (LVEF <40%), NYHA class, trans aortic gradients, and presence of hypertension were observed in both the groups (Table 1).

CPB and cross clamp time were similar in both the groups (Table 2). All types of prosthetic bi-leaflet mechanical valves were used and evenly distributed in both the groups.

Post operatively mean IEOA were comparable in both the groups. Only 1 mortality was observed in pledgeted group which was due to non-cardiac cause. 1 case of paravalvular leak was seen in both groups, which was mild and did not require re-exploration and managed conservatively with regular follow up. Incidence of various complications are listed below in (Table 3).

Incidence of severe PPM was higher in pledgeted group in patients with small aortic annulus (valve size 18-19 mm) but was not significant (p=0.20) whereas incidence of severe PPM was similar in valve size 20-21 mm group (p=0.30). Moderate PPM rates were similar in both the groups (Table 4 and Figure 1).

Similar post-operative recovery and LV function were seen in both the groups (pledgeted and simple). Patients with severe and moderate PPM had poor post-operative LV function as compared to group with no hemodynamically significant PPM. Post-operative gradients were higher in severe PPM group as compared to moderate and no PPM groups which was statistically significant (p<0.01) (Table 5).

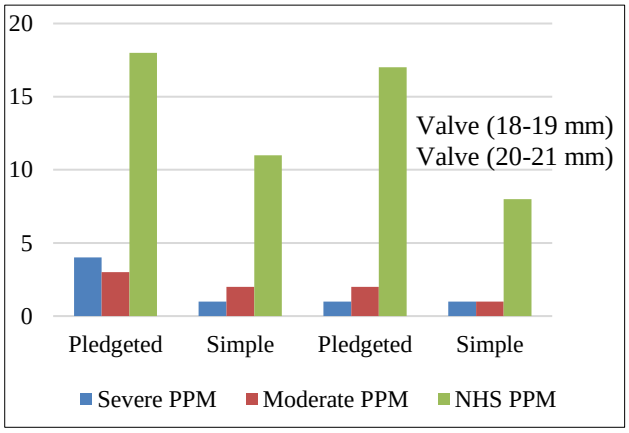

Figure 1: PPM Incidence with valve sizes and suture technique.

Post-operative cardiac adverse events and other adversities were also similar between the two groups and did not depend on the type of suture technique (Table 6).

Table 1: Pre-operative data.

Patient characteristics	Pledgeted (n=44) (%)	Simple (n=24) (%)	P value
Age	62.11±1.86	61.47±1.95	0.19
Male	30 (68.2)	17 (70.8)	0.41
BSA (m^2)	1.48±0.14	1.44±0.15	0.28
NYHA class III or IV	16 (36.4)	9 (37.5)	0.46
Preoperative LVEF <40%	9 (20.5)	7 (29.2)	0.21
Hypertension	24 (54.5)	12 (50)	0.36
Aortic valve area (mean)	0.78±0.19	0.81±0.21	0.55
Aortic valve gradient (peak)	82.26±33.33	79.38±31.65	0.73
Aortic valve gradient (mean)	53.47±16.56	49.14±14.77	0.29
Valve pathology			
Degenerative	39 (88.6)	20 (83.3)	0.30
Rheumatic	2 (4.5)	2 (8.3)	0.277
Bicuspid	3 (6.8)	2 (8.3)	0.453

Table 2: Intra-operative findings.

Patient variables	Pledgeted (%)	Simple (%)	P value
CC time (min)	66.28±26.55	68.19±23.88	0.72
CPB time (min)	99.16±32.49	101.34±34.50	0.75
Valve implanted			
18, 19 mm	24 (54.5%)	14 (58.3%)	0.38
20, 21 mm	20 (45.5%)	10 (41.7%)	0.38
Average sutures used (median)	12	16	0.002

Table 3: Post-operative results at 1 year follow up.

Variables	Pledgeted (%)	Simple (%)	P value
Mean EOA (cm^2)	1.65±0.91	1.68±1.23	0.91
Mean IEOA (cm^2/m^2)	1.01±0.26	1.07±0.35	0.43
Severe PPM	5 (11.4)	2(8.3)	0.46
Moderate PPM	5 (11.4)	3 (12.5)	0.45
LVEF <40%	6 (13.6)	4 (16.7)	0.36
Prosthetic-valve gradient (mean)	16.66±4.22	15.57±3.89	0.30
Early mortality (<1 month)	1 (2.3)	0	<0.0001
Paravalvular leak	1 (2.3)	1 (4.2)	0.33
Bleeding requiring re-exploration	2 (4.5)	3 (12.5)	0.11
Arrythmias	3 (6.8)	3 (12.5)	0.22
Respiratory pathology	5 (11.4)	3 (12.5)	0.45
AKI	3 (6.8)	4 (16.7)	0.10
CNS events	2 (4.5)	1 (4.2)	0.48

Table 4: PPM incidence with valve sizes and suture technique.

Valve size	Pledgeted (%)	Simple (%)	P value
Valve 18-19 mm			
Severe PPM	4 (16.7)	1 (7.1)	0.20
Moderate PPM	3 (12.5)	2 (14.3)	0.44
NHS PPM	17 (70.8)	11 (78.6)	0.40
Valve 20-21 mm			
Severe PPM	1 (5)	1 (10)	0.30
Moderate PPM	2 (10)	1 (10)	0.50
NHS PPM	17 (85)	8 (80)	0.36

Table 5: Post-operative outcome in relation to PPM at 1 year follow up.

Factors	Severe PPM	Moderate PPM	NHS PPM	P value
LVEF <40%	2 (28.6%)	1 (12.5%)	6 (11.3%)	0.19
Prosthetic valve gradient (mean)	23.46±7.32	18.66±4.55	14.78±3.68	<0.01

Table 6: Relation of post-operative complications to pre-operative and intra-operative characteristics.

Patient characteristics	Post-operative complications (%)	P value
LVEF		
<40 (10)	3 (30)	0.26
>40 (58)	12 (20.7)	
Age		
>60 (54)	18 (33.3)	0.16
<60 (14)	3 (21.4)	
NYHA class		
III/IV (25)	6 (24)	0.38
<III (43)	9 (20.9)	
CPB time		
>120 (13)	4 (30.8)	0.20
<120 (55)	11 (20)	

DISCUSSION

Bi-leaflet mechanical valves can be implanted in complete supra annular position, that gives a larger diameter than intra annular implantation and results in decreased flow obstruction but exact benefit of supra annular implantation is debatable.[8] In a randomized trial, Guenzinger et al compared results of 2 different mechanical valves, and concluded that there is no improvement of hemodynamic performance with supra annular implantation over intra-supra annular implantation technique.[9]

Hemodynamics may also vary with suturing technique. With use of standard interrupted non everting pledgeted technique, pledget may partly obstruct LVOT. A mm reduction of geometric orifice area of implanted valve on each side may result in 30% decrease in annular size.[10] Pledget may also be responsible for pannus formation and increased transvalvular gradients over time as suggested by Tabata et al and Petracek et al.[5,11] Increased trans-aortic gradients in patients with small aortic annulus are particularly susceptible for development of PPM.[11]

Many studies previously have shown increased operative mortality in AVR, when associated with moderate or severe PPM.[12-18] However we did not observe any early mortality in our study. A significant association between

PPM severity and long-term risk of congestive heart failure as shown by Milano et al, Pibarot et al and Ruel et al was in agreement with our findings.[12,18,19] It can be explained as due to high trans aortic gradients in cases of severe or moderate PPM, there is less decrease in LV hypertrophy post- surgery and low LVEF subsequently. PPM also results in poor symptom reduction and stagnant coronary flow reserves.[20] PPM is also accounted for increased complications post AVR especially neurological events as stated by Nozohoor et al but in our study, we did not observe such association which can be compared to study by Vaquero et al.[21,22]

Various benefits and shortcomings of different suture techniques have been mentioned in literature, pledgeted mattress suture technique is associated with less incidence of paravalvular leak compared to simple suture technique.[23] Englberker et al also compared pledgeted suture technique with other suture techniques and observed a lesser incidence of paravalvular leak with pledgeted technique but in our study, we did not observe any difference, which was consistent with study findings of Tabata et al.[5,24] Only 1 case of mild paravalvular leak was seen in each group and resolved with time. Similarly, simple suture technique diminishes the risk of thrombosis and embolism.[25-28] Other advantages of simple suture technique have been described.[25,26]

Simple suture technique offers a larger prosthesis-annular ratio and is associated with larger EOA and less incidence of PPM independent of the prosthesis size.[5] On basis of our observations, simple suture technique had a slight advantage over pledgeted non everting suture technique in reducing severe PPM for valve sizes 18, 19 mm (p=0.20) whereas incidence of severe PPM was equivocal in valve sizes 20, 21 mm and hence is not dependent on suture technique. Overall, in our study suture technique does not significantly affect PPM in supra annular implantation of mechanical bi-leaflet prosthetic valve, and results were comparable to Ugur et al.[6]

We additionally also observed incidence of post-operative complications in relation to adverse pre-operative patient characteristics and CPB time. It was conceived that they were risk factors for increased post-operative events both cardiac and non-cardiac (p values not significant). Proper pre-operative evaluation and stabilization of these patients before surgery should be done to avoid these complications and CPB time should be kept low as possible required to conduct safe surgery for them.

Limitations

It was a retrospective non randomized observational study and AVR was performed by different surgeons. In our center, most AVR are performed using interrupted non pledgeted horizontal mattress suturing technique hence sample size was less. Only 1 year follow up data was analyzed, hence long-term hemodynamic performance and mortality was not evaluated with different suture techniques.

AVR in patients with small aortic root should be performed taking necessary precautions, using appropriate valve design and intra-operative techniques to achieve maximum IEOA to avoid PPM.[29] Suture technique should be tailored to individual patient's need and surgeon's experience as no technique is superior to other.

CONCLUSION

PPM is a common and alterable entity. Severe PPM is responsible for adverse hemodynamic function and congestive heart failure among patients with small sized aortic valve implantation (18-21 mm). Incidence of PPM is decreasing with availability of newer generation mechanical bi-leaflet valves with ability to be implanted in complete supra annular position with pertinent suture technique. Still if PPM is suspected other methods can be used to avoid it, including root enlargement procedures or use of stentless bio prosthesis which profess to have high EOA, depending on availability, feasibility, cost and surgical risk to benefit ratio. The present study inferred that use of interrupted simple suture technique had a slight benefit over interrupted non everting pledgeted technique in reducing incidence of severe PPM (not statistically significant) and better recuperation in patients with small sized mechanical prosthetic aortic valve implantation (18-19 mm) during short term follow up.

ACKNOWLEDGEMENTS

Authors would like to thank all the patients who willingly participated in the study and the concerned hospital for support in implementing a multidepartment approach.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kothari A, Jadhav UE. Aortic valve replacement using interrupted pledgeted non everting suture technique versus simple suture technique in small aortic annulus, does it influence patient prosthetic mismatch. Int Surg J 2023;10:1490-5.