

Long-Term Survival Comparison of Mitral Valve Repair and Mitral Valve Replacement in Rheumatic Mitral Valve Disease: A Propensity Score Analysis

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Objective: Rheumatic mitral valve disease could be treated either mitral valve repair or mitral valve replacement. The present study aimed to study 5-year survival related to mitral valve surgery using propensity score matching to reduce selection bias.

Materials and Methods: Between January 2007 and December 2013, 695 patients who underwent isolated mitral valve surgery were divided into two groups and matched with propensity score. Five-year survival was analyzed to assess outcomes following mitral valve repair and mitral valve replacement.

Results: Six hundred ninety-five patients were studied. After propensity matching, 267 patients in each group of mitral valve repair and mitral valve replacement, the groups had no differences in baseline characteristics. Log rank testing demonstrated no difference in unmatched group ($p=0.49$). After propensity-matched analysis, there was difference between 5-year survival of mitral valve repair at 89.8% (95% CI 84.9 to 93.2) and at 94.6% (95% CI 90.4 to 97.0) for mitral valve replacement with $p=0.09$ and hazard ratio 1.77 (95% CI 0.87 to 3.56, $p=0.113$).

Conclusion: The authors observed non-significant lower 5-year survival rates among patients with rheumatic mitral valve diseases who underwent mitral valve repair compared to replacement. Mitral valve repair in rheumatic heart disease should remain the main selection in experienced valve centers with high quality measures.

Keywords: Rheumatic mitral valve disease; Mitral valve replacement; Mitral valve repair; Propensity score matching

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Rheumatic heart disease (RHD) is the leading cause of all valvular disease in Thailand especially in cases with mitral stenosis pathology^(1,2). Complex rheumatic mitral valve (MV) pathology involves every component of the MV, which are annulus, leaflets, and subvalvular apparatus^(3,4). MV replacement is the main treatment for rheumatic MV disease, however, the advantage of MV repair over MV replacement is the avoidance of complications related to continuing anticoagulation therapy of systemic thromboembolism⁽⁵⁾. Reoperation after MV repair is considered to affect long term survival⁽⁶⁾.

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Valve repair is regarded as an established form of treatment for mitral regurgitation due to the superior results of valve repair over replacement⁽⁷⁾. Surgeons choose to perform either mitral repair or replacement depending on their personal preference. Besides complete surgical correction of all the valvular lesions, their etiology plays an essential part in the short and long-term results⁽⁸⁾.

Likewise, mechanical valve replacement has repeatedly been shown to provide excellent durability and hemodynamic function⁽⁹⁾. When compared with tissue prosthesis, the patient is exposed to an incremental risk of thromboembolism and anti-coagulant-related complications⁽¹⁰⁾. The present study aimed to provide data regarding whether MV repair or replacement produced better outcomes for patients with rheumatic MV disease using long-term survival data with propensity score analysis to reduce the effect of treatment selection bias and potential confounders.

Materials and Methods

Subjects

Between January 2007 and December 2013,

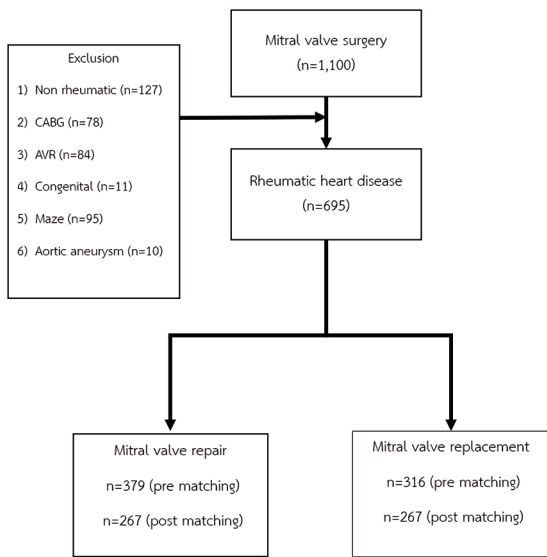


Figure 1. Patients flow chart.

1,100 patients had undergone MV surgery in Central Chest Institute of Thailand. After excluding non-rheumatic causes, 127 patients were enrolled, along with 78 combined coronary artery bypass grafting (CABG) patients, 84 combined aortic valve replacement (AVR) 84 patients, 11 combined congenital heart surgery patients, 65 combined maze procedure patients, and 10 combined aneurysmal operation patients. Six hundred ninety-five patients underwent isolated MV surgery. Patients were divided into two groups for analysis, repair with MV repair for 379 patients, and replacement with MV replacement with either mechanical valve or bioprosthesis for 316 patients (Figure 1).

Ethical approval and informed consent

The present study was a therapeutic study based on a single center retrospective cohort of patients with MV surgery at the Central Chest Institute of Thailand. Because the data were obtained retrospectively and were anonymous, informed consent was exempted. The present study was approved by the Human Research Ethics Committee of Thammasat University No. 1, Faculty of Medicine (Protocol number MTU-EC-ES-0-003/59).

Surgical procedure

A median sternotomy approach and conventional ascending aorta and bicaval cannulation were used. Antegrade cold blood cardioplegia was routinely perfused every 25 minutes for myocardial protection. The techniques for these procedures were either

the classical left atriotomy or a combined superior transeptal approach. The choice of technique was surgeon-dependent for each case. MV replacement was performed with either non-chordal preservation or secondary chordal preservation, which may need PTFE Goretex to be neochordal. The choice of prosthesis used in the procedures was either a bi-leaflet mechanical valve or a bioprosthesis. Bioprosthesis was preferred for patients aged above 60, using the technique of either simple interrupted sutures or interrupted mattress suturing. Reparation techniques were used to increase openings such as commissurotomy, or to increase leaflet mobilization such as leaflet thinning. Furthermore, leaflet augmentation with autologous pericardium was used to correct subvalvular deformities such as chordal and papillary muscle splitting. Intraoperative transesophageal echocardiography was routinely used.

Outcomes

Operative mortality was defined as death within 30 days of surgery or in-hospital death. All deaths were classified as cardiac in origin unless a non-cardiac cause was diagnosed clinically or at autopsy. The end point of the study was defined as the cardiac or valve-related death excluding operative mortality.

Postoperative anticoagulant management

The repair and bioprosthetic valve replacement group of patients were administered warfarin as anticoagulation for three months postoperatively, with a target international normalized ratio (INR) of 1.8 to 2.5. Thereafter, warfarin was maintained if cardiac rhythm was atrial fibrillation. The mechanical valve replacement group patients were administered warfarin for their lifetime with target INR of 2.0 to 3.0.

Propensity scores matching methods and statistical analyses

From a preliminary study in Central Chest Institute of Thailand and Yua et al.⁽¹¹⁾, data were collected on patients who had undergone MV surgery to study the survival rate of patients with MV disease from RHD. MV replacement, either prosthetic heart valve replacement or mechanical valve was the control group which had a 5-year survival rate of 75.6%, and MV repair surgery, which had a 5-year survival rate of 85.3%. Comparison of the 5-year survival rate values between these two groups is a 2-way hypothesis test at a statistical significance value of 0.05 and a power value of 80%. The ratio

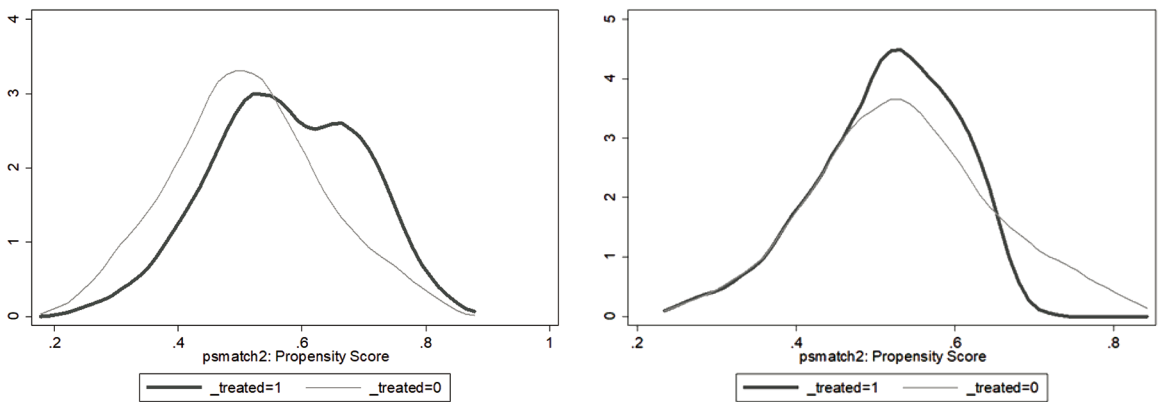


Figure 2. Histogram of distribution of propensity score: before matching (left) and after matching (right).

of patients who received MV repair to patients who received MV replacement was 0.588. The sample size calculation was done using the Stata, version 13 (StataCorp LP, College Station, TX, USA) in the category of log rank test comparing two survival rates [stpower logrank.756.853, p1(0.588)]. Therefore, according to the calculation, the number of samples in the control group or the group of patients who received surgery, there were 340 MV replacements and 240 patients who had MV repair surgery, for a total of 580 patients.

The present study was non-randomized therapeutic research, and as such, selection bias, confounding-by-indication, confounding-by-contraindication, and imbalanced prognostic determinants could potentially occur. Therefore, a propensity score matching (PSM) between the two groups before the estimation of the treatment effects was performed⁽¹²⁾. First, logistic regression was used to model the probability of being assigned to MV repair over MV replacement using the following parameters: age, gender, weight, height, the New York Heart Association (NYHA) classification, atrial fibrillation, diabetes, ejection fraction, chronic kidney disease, severity of tricuspid regurgitation, type of pathology, and surgeon. The estimated probability of the model, called the propensity score, was used for a 1:1 nearest-neighbor matching without replacement, and using a caliper 0.02 times standard deviation of propensity score⁽¹³⁾. Figure 2 shows the histogram of distribution of propensity score, which resulted in a well-balanced cohort.

Data were presented as frequencies or means with standard deviations. Comparisons of characteristics between groups were performed using the chi-square or Fisher's exact tests for categorical variables and Student's independent t-test for continuous variables.

A p-value of less than 0.05 and a standardized difference of more than 0.2 was considered significant⁽¹⁴⁾. Long term survival was calculated according to the Kaplan-Meier method. Kaplan-Meier survival analysis was completed with the log rank statistic to differentiate between the two survival curves. Cox regression analysis was used to assess the effect of MV operation on survival. Stata, version 14 (StataCorp LP, College Station, TX, USA) was used for statistical analyses.

Results

Baseline characteristics

Between January 2007 and December 2012, six hundred ninety-five patients were enrolled in the present study. Of these patients, 379 were in the MV repair group, and 316 were in the MV replacement group. Baseline clinical and echocardiographic characteristics before PSM are summarized in Table 1. There were statistical differences in gender, height, weight, body surface area, atrial fibrillation, tricuspid regurgitation, MV area, and mean MV pressure gradient between two groups at the baseline before PSM ($p < 0.05$).

Table 1 shows the 534 patients after PSM with 267 in MV repair and 267 in the replacement group. There were no significant differences except left ventricular end-diastolic diameter at 49.96 ± 6.1 mm versus 51.53 ± 5.5 mm ($p < 0.001$, SMD -0.270), tricuspid regurgitation ($p = 0.012$, SMD 0.148), effective mitral regurgitant orifice area at 15.1 ± 4.3 mm² versus 17.9 ± 5.1 mm² ($p < 0.001$, SMD -0.593), and mean MV pressure gradient at 7.9 ± 1.1 mmHg versus 8.5 ± 2.2 mmHg ($p < 0.001$, SMD -0.354). The mean of propensity scores in each group were different. The balance of propensity scores before and after matching were shown in Table 1. After matching,

Table 1. Characteristics of mitral valve surgery patient

Variables	Before matching				After matching			
	MV repair (n=379)	MV replacement (n=316)	p-value	Std. diff.	MV repair (n=267)	MV replacement (n=267)	p-value	Std. diff.
Age (years); mean±SD	51.2±15	52.07±11.9	0.404	0.065	51.4±11.7	52.49±14.5	0.273	-0.083
Female; n (%)	195 (51.5)	180 (57.0)	<0.001	-0.111	152 (56.9)	146 (54.7)	0.663	0.045
Height (cm); mean±SD	161.52±8.6	159.72±8.5	0.006	-0.210	160.28±8.6	159.67±8.2	0.342	0.073
Weight; mean±SD	58.18±11.8	55.35±12.4	0.002	-0.233	56.51±12.3	55.71±11.4	0.378	0.068
Body surface area (cm ²); mean±SD	1.61±0.2	1.56±0.2	0.001	-0.230	1.58±0.2	1.57±0.2	0.512	0.100
Atrial fibrillation; n (%)	40 (10.6)	59 (18.7)	0.016	0.231	39 (14.6)	34 (12.7)	0.615	0.054
NYHA classification; n (%)			0.064	0.116			0.064	0.064
NYHA I	67 (17.7)	60 (19.0)			53 (19.9)	57 (21.3)		
NYHA II	188 (49.6)	134 (42.4)			106 (39.7)	116 (43.4)		
NYHA III	91 (24.0)	76 (24.1)			75 (28.1)	59 (22.1)		
NYHA IV	33 (8.7)	46 (14.6)			33 (12.4)	35 (13.1)		
LVEDD (mm); mean±SD	51.61±5.4	49.68±6.1	<0.001	0.334	49.96±6.1	51.53±5.5	<0.001	-0.270
LVEDS (mm); mean±SD	32.72±5	31.99±5	0.056	0.144	31.91±5.1	32.45±4.9	0.158	-0.109
EF (%); mean±SD	58.47±12.5	57.07±12.5	0.142	-0.113	57.78±12.4	58.79±12.8	0.292	-0.080
Dyslipidemia; n (%)	77 (20.3)	71 (22.5)	0.056	0.052	62 (23.2)	61 (22.8)	1.000	0.009
Hypertension; n (%)	80 (21.1)	69 (21.8)	0.228	0.018	51 (19.1)	56 (21.0)	0.666	0.047
Chronic renal disease; n (%)	36 (9.5)	17 (5.4)	0.113	-0.157	11 (4.1)	16 (6.0)	0.430	0.086
Diabetes; n (%)			0.677	-0.066			0.677	0.015
Oral therapy	25 (6.6)	16 (5.1)			17 (6.4)	15 (5.6)		
Insulin	2 (0.5)	2 (0.6)			2 (0.7)	1 (0.4)		
Tricuspid pressure gradient (mmHg); mean±SD	38.76±14.2	40.93±19.4	0.090	0.127	41.35±20.2	39.98±13.4	0.303	0.080
Tricuspid regurgitation; n (%)			0.012	0.173			0.012	0.148
No	202 (53.3)	132 (41.8)			96 (36.0)	113 (42.3)		
1+	161 (42.5)	169 (53.5)			161 (60.3)	142 (53.2)		
2+	9 (2.4)	12 (3.8)			7 (2.6)	10 (3.7)		
3+	6 (1.6)	3 (0.9)			3 (1.1)	2 (0.7)		
4+	1 (0.3)	0 (0.0)			0 (0.0)	0 (0.0)		
Effective regurgitant orifice area by 2D (mm ²); mean±SD	15.2±3.7	18.1±5.3	<0.001	-0.66	15.1±4.3	17.9±5.1	<0.001	-0.593
Mean MV pressure gradient (mmHg); mean±SD	7.3±6.8	12.9±1.1	<0.001	-1.103	7.9±1.1	8.5±2.2	<0.001	-0.354
Propensity score; mean±SD	0.57±0.1	0.51±0.1	<0.001	-0.518	0.51±0.1	0.53±0.2	0.14	0.126

MV=mitral valve; SD=standard deviation; NYHA=New York Heart Association; LVEDD=left ventricular end diastolic diameter; LVEDS=left ventricular end systolic diameter; EF=ejection fraction

no difference of propensity score was shown with 0.51±0.1 in MV repair group and 0.53±0.2 in MV replacement group (p=0.14, SMD 0.126).

Table 2 presents the intraoperative and postoperative data. There were no differences in bypass time and cross-clamp time between the repair group and the replacement group before and after PSM. After matching, differences were observed in postoperative norepinephrine usage at 3% versus 9% (p=0.005, SMD 0.254), in the rates of late death at 15.4% versus 8.6% (p=0.023), and late reoperation at 4.9% versus 1.5% (p=0.046).

The overall 5-year survival rate was 91.6% (95% CI 88.9 to 93.7). The survival rate up to five years following RHD-related MV repair was 90.7% (95% CI 86.8 to 93.6) and replacement 92.8% (95%

CI 88.6 to 95.5). Kaplan-Meier curves comparing survival rates in MV repair and MV replacement are shown in Figure 3. Log rank testing demonstrated no difference in the unmatched group (p=0.49). After propensity-matched analysis, there was a non-significant difference between survival to 5 years of MV repair at 89.8% (95% CI 84.9 to 93.2) and at 94.5% (95% CI 90.4 to 97.0) in MV replacement with p=0.09 and hazard ratio 1.77 (95% CI 0.87 to 3.56, p=0.113) as shown in Table 3.

Discussion

The most serious sequela of rheumatic fever involves the subsequent development of RHD. Namely, its involvement of the MV can lead to mitral regurgitation and/or stenosis. Where surgery

Table 2. Intraoperative and postoperative data

	Before matching				After matching			
	MV repair (n=379)	MV replacement (n=316)	p-value	Std. diff.	MV repair (n=267)	MV replacement (n=267)	p-value	Std. diff.
Pathology; n (%)			<0.001	-0.304			<0.001	1.246
Regurgitation	312 (82.3)	60 (19.0)			200 (74.9)	59 (22.1)		
Stenosis	36 (9.5)	163 (51.6)			36 (13.5)	121 (45.3)		
Mixed	31 (8.2)	93 (29.4)			31 (11.6)	87 (32.6)		
Type of prosthesis; n (%)			<0.001	-4.023			<0.001	2.284
Biological	0 (0.0)	89 (28.2)			0 (0.0)	74 (27.7)		
Mechanical	0 (0.0)	227 (71.8)			0 (0.0)	193 (72.3)		
Ring	379 (100)	0 (0.0)			267 (100)	0 (0.0)		
Prosthesis size (mm); mean±SD	30.61±2.8	31.22±2.8	0.004	0.217	31.25±2.8	30.8±2.8	0.035	0.162
Cross clamp time (hours); mean±SD	0.97±0.5	0.98±0.5	0.793	0.023	0.99±0.6	1.02±0.5	0.480	-0.055
Cardiopulmonary bypass time (hours); mean±SD	1.35±0.5	1.37±0.6	0.632	0.027	1.36±0.6	1.39±0.5	0.480	-0.047
Postoperative norepinephrine usage; n (%)	17 (4.5)	27 (8.5)	0.028	0.165	8 (3.0)	24 (9.0)	0.005	0.254
Postoperative stay (days); mean±SD	11.7±7.9	11.83±7.5	0.825	0.017	11.77±7.8	11.98±8.6	0.736	-0.026
In hospital death; n (%)	7 (1.8)	9 (2.8)	0.616	0.066	7 (2.6)	7 (2.6)	1.000	0.000
Late death; n (%)	48 (12.7)	32 (10.1)	0.551	-0.080	41 (15.4)	23 (8.6)	0.023	0.209
Late reoperation; n (%)	19 (5.0)	5 (1.6)	0.011	-0.193	13 (4.9)	4 (1.5)	0.046	-0.193
F/U time (month); mean±SD	49.68±31.8	44.78±32.5	0.046	-0.152	45.7±32.3	48.59±33	0.245	-0.089

MV=mitral valve; SD=standard deviation

Table 3. Survival of patients in mitral valve repair and replacement before and after propensity score matching

Postoperative	Before matching			After matching		
	Repair [95% CI]	Replacement [95% CI]	p-value	Repair [95% CI]	Replacement [95% CI]	p-value
12 months	96.4% [93.8 to 98.0]	97.8% [95.3 to 99.0]	0.4916	96.1% [92.6 to 98.0]	98.3% [95.6 to 99.4]	0.0862
24 months	93.5% [90.3 to 95.7]	95.2% [91.7 to 97.3]		91.9% [87.5 to 94.8]	96.3% [92.7 to 98.1]	
36 months	92.1% [88.6 to 94.6]	92.8% [88.6 to 95.5]		90.4% [85.6 to 93.6]	94.6% [90.4 to 97.0]	
48 months	91.3% [87.6 to 94.0]	92.8% [88.6 to 95.5]		89.8% [84.9 to 93.2]	94.6% [90.4 to 97.0]	
60 months	90.7% [86.8 to 93.6]	92.8% [88.6 to 95.5]		89.8% [84.9 to 93.2]	94.6% [90.4 to 97.0]	

CI=confidence interval

Compare Before and After Matching

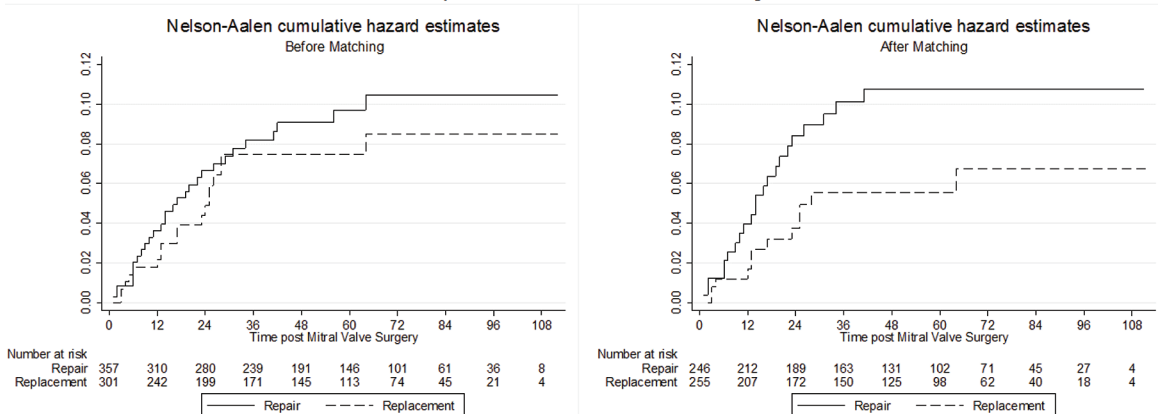


Figure 3. Cumulative incidence of mortality in propensity score-matched patients: before matching (left) and after matching (right).

is indicated, MV replacement is usually necessary although in some cases, MV repair is possible⁽⁶⁾.

The present study showed comparative long-term outcome of MV surgery in rheumatic MV diseases. MV replacement and MV repair have their own advantages and disadvantages^(7,8). Therefore, PSM analysis was utilized in an attempt to remove selection bias to show the survival effect of the type of MV surgery⁽¹²⁾.

Rheumatic MV pathology is complex, and every component can be affected. MV repair has advantages of allowing the patient to avoid long term anticoagulant medication, which increases the risk of bleeding. However, the risk of reoperation is a major disadvantage affecting long term survival.

After removing selection bias with PSM analysis, baseline demographic data between both groups did not show significant differences except postoperative norepinephrine usage, mean MV pressure gradient. This could be explained by the unmeasured bias, which is a disadvantage of PSM analysis. The 5-year survival study of MV surgery for rheumatic MV disease demonstrated comparably no statistically significant differences in overall cardiac mortality ($p=0.08$) and adjusted hazard ratio ($p=0.512$) consistent to the previous study^(6,15,16).

Data⁽¹⁵⁾ suggests that MV repair is associated with mortality and survival benefit along with greater freedom from thromboembolic with some compromise in durability. In young patients with rheumatic valve disease, mitral valvuloplasty is an excellent alternative to valve replacement with penicillin prophylaxis postoperatively^(17,18). Factors associated with successful repair consisted of age less than 60 years, ring size to body surface area greater than 19.0, and the absence of residual MR at the end of surgery⁽⁴⁾.

Despite the evidence of superior outcomes of MV repair, Russel et al. demonstrated no difference in long-term survival following MV repair in Australia with the increased risk of surgical re-operation in valve repair using percutaneous balloon valvulotomy for a non-invasive approach⁽¹⁹⁾. There was no difference in late cardiac death, reoperation, and all valve-related complications in rheumatic mitral surgery. In this large prospective cohort study, they have demonstrated that adjusted long-term survival following rheumatic MV repair surgery in Australia is no different to replacement and no different to non-RHD. Interpretation of valve surgery outcomes requires careful consideration of patient factors that may also influence survival⁽²⁰⁾. Studies investigating

case load and MV repair have specifically suggested the development of centers of excellence for MV repair⁽²¹⁾, with minimum standards suggested for such centers⁽²²⁾. However, it should be emphasized that long-term survival would be attributed to the type of procedures. The authors survival rates and this lack of difference in survival rates and outcomes between the different surgical techniques were found to be in line with earlier studies of MV repair and replacement for RHD related and non-RHD related valve disease^(8,23-27).

Conclusion

Based on the present study, there was no difference in 5-year survival rates between MV repair and replacement in rheumatic-related valve disease. The authors support the current guidelines, which recommend considering the repair of rheumatic valve disease only in experienced centers when a durable and successful repair is likely or when the advisability of long-term anticoagulation management is questionable.

What is already known on this topic?

Rheumatic MV disease is the most common valvular heart disease in Thailand. Both MV repair and replacement are preferred treatments, but no study has been conducted to determine the effectiveness and long-term outcomes of MV repair in comparison with MV replacement.

What does this study add?

This study is the first to compare MV repair with MV replacement in the treatment of complex rheumatic MV disease in Thailand. The authors identified a higher rate of reoperation in the MV repair group. However, the 5-year survival outcome did not show a significant difference between MV repair and replacement.

Conflicts of interest

The authors declare no conflict of interest.

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