Early-Term Hemodynamic Performance And Clinical Results of 19-mm st. Jude Medical Regent Valve In Patients With Small Aortic Annulus Undergoing Dual Valve Replacement: A Retrospective Study

Dong Wei
Shandong University
Shijie Zhang
Shandong University
Xianfeng Cheng
Shandong University
Junjie Huang
Shandong Provincial Hospital affiliated to Shandong First Medical University
Shanghao Cheng
Shandong University
Yan Yun
Qilu Hospital of Shandong University
Diming Zhao
Shandong University
Jinzhang Li
Capital Medical University
Zezhong Wu
Shandong University
Yanwu Liu
Shandong University
Hechen Shen
Shandong University
Huibo Ma
Qingdao University
Haizhou Zhang
Shandong University
Zhengjun Wang
Shandong University
Chengwei Zou
Shandong University

Xiaochun Ma (mxcmxc2008@163.com)
Shandong University https://orcid.org/0000-0003-1055-4691

Research article

Keywords: Dual Valve Replacement, Small Aortic Annulus, 19-mm St. Jude Medical, Regent Valve, Prosthesis Patient Mismatch

Posted Date: October 11th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-958944/v1

Early-term Hemodynamic Performance and Clinical Results of 19-mm st. Jude Medical Regent Valve in Patients with Small Aortic Annulus Undergoing Dual Valve Replacement: a retrospective study

Dong Wei[1,7†], Shijie Zhang[1,2†], Xianfeng Cheng[1,3†], Junjie Huang[2†], Shanghao Chen[1,2], Yan Yun[4], Diming Zhao[1,2], Jinzhang Li[5], Zezhong Wu[1,2], Yanwu Liu[1,2], Hechen Shen[1,2], Huibo Ma[6], Haizhou Zhang[1,2], Zhengjun Wang[1,2*], Chengwei Zou[1,2*], Xiaochun Ma[1,2*]

[1]Department of Cardiovascular Surgery, Shandong Provincial Hospital, Cheeloo College of Medicine, Shandong University, Jinan, China

[2]Department of Cardiovascular Surgery, Shandong Provincial Hospital affiliated to Shandong First Medical University, Jinan, China

[3]Department of Cardiovascular Surgery, Weifang People's Hospital, Weifang, China.

[4]Department of Radiology, Qilu Hospital of Shandong University, Jinan, China

[5]Department of Physiology and Pathophysiology, School of Basic Medical Sciences, Capital Medical University, Beijing, China

[6]Qingdao University Medical College, Qingdao University, Qingdao, China

[7]Department of Cardiovascular Surgery, Qilu Hospital of Shandong University, Jinan, China

*** Correspondence:**

Xiaochun Ma mxcmxc2008@163.com

Chengwei Zou zouchengwei@sdu.edu.cn

Zhengjun Wang zhjwang512@163.com

†These authors have contributed equally to this work and share first authorship.

Keywords: Dual Valve Replacement, Small Aortic Annulus, 19-mm St. Jude Medical Regent Valve, Prosthesis Patient Mismatch

Abstract

Background

The prosthesis selection in patients with small aortic annulus undergoing aortic valve replacement (AVR) has always been a challenge, especially in dual valve replacement (DVR, combined aortic and mitral valve replacement). The present study aimed to analyze early-term hemodynamic parameters of 19-mm St. Jude Medical Regent (SJMR19) valve in patients with small aortic annulus undergoing DVR.

Methods

Between January 2015 to December 2020, 54 patients with small aortic annulus who underwent DVR were divided into two groups: SJMR19 valve group (n=30) and 21-mm mechanical (M21) valve group (n=24). The perioperative and early-term hemodynamic data were collected and analyzed.

Results

A significant difference in terms of maximum transaortic flow velocity (Vav max), maximum transaortic pressure gradient (PGav max), left ventricular mass index (LVMi) and left ventricular mass (LVM) was observed postoperatively in both groups. The postoperative left ventricular ejection fraction (LVEF) was significantly higher while the

LVM and LVMi was evidently decreased in the SJMR19 group, compared with the M21 group. In order to confirm the influencing factors on postoperative LVEF, a multiple linear regression analysis model was established by including all candidate variables and the implanted valve type was identified in the multivariate analysis as an independent predictor for postoperative LVEF.

Conclusions

The postoperative cardiac function and hemodynamic parameters was improved both in the SJMR19 and M21 groups. The postoperative LVEF, LVM and LVMi were better in the SJMR19 group compared with those of the M21 group. And the implanted valve type might possess the predictive value of postoperative LVEF in patients with small aortic annulus undergoing DVR.

Introduction

Multivalvular heart disease seriously threatens the public health and combined mitral and aortic valve pathology appears most frequently[1]. Lee and his colleagues summarized the baseline characteristics and outcomes of 623,039 patients included in the Society of Thoracic Surgeons (STS) database undergoing valve surgeries between 1993 and 2007, among whom 57.8% received combined aortic and mitral valve surgeries[2]. Replacing the diseased valves with appropriate prostheses aim at restoring the hemodynamic stability and improving the clinical symptoms[3]. Despite remarkable advancements in valve surgery in recent decades, the prosthesis selection in patients with small aortic annulus (SAA) undergoing aortic valve replacement (AVR) has been constantly challenging for the cardiovascular surgeons worldwide[4]. The challenge is even more serious in dual valve replacement (DVR, combined aortic and mitral valve replacement) for patients with SAA[1-3, 5-7]. The challenge mainly lies in the occurrence of prosthesis patient mismatch

(PPM) following AVR in patients with small aortic root due to the effective orifice area (EOA) of inserted prosthetic valve insufficient in relation to body mass index (BMI). The main hemodynamic consequence of PPM is to generate transvalvular gradients higher than expected through normally functioning prosthetic valves that has been associated with worse hemodynamics and poorer long-term prognosis[8-10].

Some studies have reported acceptable results of aortic root enlargement (ARE) among young and middle-aged patients with SAA[5, 6, 11], whereas the outcomes remain controversial in elderly patients due to an elevated surgical risk. Additionally, stentless valves have been reported previously to lower the postoperative residual trans-aortic valve pressure[12-14], which has also been limited due to high technical requirements and undetermined long-term durability[4, 15-17]. Currently bileaflet mechanical heart valve is still the most implanted aortic prosthesis. The 19-mm St. Jude Medical Regent mechanical aortic (SJMR19) valve is a canonical bileaflet supra-annular stented mechanical aortic valve which has proven to achieve a better EOA and hemodynamic performance[18]. However, relevant evidence is scarce regarding the early-term hemodynamic and clinical outcomes of (SJMR19) valve in patients with SAA undergoing the DVR.

The aim of the present study was to report the early-term hemodynamic and clinical results of the DVR with a SJMR19 versus 21mm mechanical (M21) valve in patients with SAA.

Materials and methods

2.1 Patient selection and grouping

This single-center retrospective cohort study was approved by the Ethics Committee of Shandong Provincial Hospital affiliated to Shandong First Medical University. The written informed consents were waived because it was a retrospective study. This study was conducted according to the Good Clinical Practice (GCP) and principles of the Declaration of Helsinki. 54 patients were successively enrolled in our study from January 2015 to December 2020. The subjects recruited were the ones who satisfied the following criteria: (A) older than 60 years; (B) undergoing DVR (combined aortic and mitral valve replacement) with prosthetic mechanical valves (for aortic position: SJMR-19 versus 21-mm mechanical valve); (C)aortic annulus diameter<23mm. The subjects were removed if the exclusion criteria were met: (a) whose perioperative and follow-up data were insufficient; (b) who underwent bioprosthetic valve replacement or re-do surgeries; (c) lost to follow-up; (d) complicated with coronary atherosclerotic disease and other peripheral vascular diseases. All necessary clinical data of included subjects were comprehensively collected during the interval from admission, discharge to follow-up. All operations of DVR were performed by one surgical team. All patients were categorized into two subgroups according to the implanted prosthetic aortic mechanical valves. 30 patients (SJMR19 group) underwent AVR with SJMR19 whereas 24 cases (M21 group) underwent AVR with 21mm mechanical (M21) valve.

2.2 Surgical procedures

The operation was performed under general anesthesia with endotracheal intubation through a median sternotomy incision. For cardiopulmonary bypass (CPB), arterial cannulation was routinely positioned in the ascending aorta; venous cannulation was normally through the superior and inferior vena cava. For myocardial protection, cold blood cardioplegia was perfused into left and right coronary arteries or a retrograde perfusion was through coronary sinus. After excising the diseased valves and measuring the dimensions of valve annulus, the appropriate artificial aortic valves were chosen. The dual valve replacement was performed under mild or moderate hypothermic. The patients were transferred to the surgery cardiac intensive care unit following the procedures.

2.3 Echocardiography

Echocardiographic assessment was performed using the PHILIPS iE33 color Doppler ultrasonography. The M-mode, two-dimensional, continuous pulsed-wave as well as color Doppler were applied with the standard views assessed comprehensively. The maximum transaortic flow velocity (Vav max), maximum transaortic pressure gradient (PGav max), maximum transtricuspid flow velocity (Vtv max), maximum transtricuspid pressure gradient (PGtv max), left ventricular mass index (LVMi), left ventricular mass (LVM) and pulmonary arterial systolic blood pressure were measured or calculated according to the recommendation of the American Society of Echocardiography. Left ventricular ejection fraction (LVEF) was calculated using the modified Simpson rule method.

2.4 Anticoagulation and Follow-up

The patients were administrated with warfarin sodium tablets after operation. International normalized ratio (INR) was used to monitor the anticoagulation intensity and stabilized at the level between 1.8 and 2.5. Echocardiographic assessment was routinely performed 7 days postoperatively. All patients were closely followed-up for echocardiography in the outpatient department 1, 3 and 6 months after discharge from inpatient care.

2.5 Statistical analysis

SPSS Statistics 25.0 software was used for statistical analysis. If normally distributed, continuous variables were expressed as the mean ± standard deviation (SD); if not, were expressed as the median (interquartile deviation). Categorical variables were present as the frequency (n) and percentage (%). In order to analyse the continuous variables, the Student's t test was used when the variables conform to the normal distribution. Otherwise, if the skew distribution was met, the non-parametric Mann-Whitney U test was applied. For categorical variables, chi-square test or Fisher's exact test was selected. Binary logistic regression analysis was applied for multivariate analyses. To establish a multivariate predictive model, possible candidate variables, such as gender, age, BMI, aortic cross-clamp time, operation time, hypertension, preoperative LVEF and the implanted valve type were selected for stepwise analysis. A two-sided p valve less than 0.05 was considered statistically significant.

Results

3.1 Patient characteristics

3.1.1 Inclusion of patients

85 patients were consecutively recruited in the study from January 2015 to December 2020, shown in Fig. 1. 11 patients were excluded from the study due to the presence of coronary atherosclerotic disease (n=9) and other peripheral vascular diseases (n=2); 20 patients excluded for undergoing the bioprosthetic valve replacement (n=18) or re-do surgeries (n=2).

3.1.2 Basic characteristics of SJMR19 group compared with those of M21 group

In the SJMR19 group, 13.3% were male patients and the mean age was 58.87±6.04 years whereas in the M21 group, 39.1% were male and the mean age was 56.58±5.72 years. 10.0% had hypertension and 6.7% were with type 2 diabetes in the SJMR19 group whereas 20.8% and 4.2% were complicated with hypertension and type 2 diabetes respectively in the M21 group. 63.3% were with atrial fibrillation or atrial flutter (Af or AF) and 50.0% with pulmonary artery hypertension (PAH) in the SJMR19 group and 62.5% and 50.0% were complicated with Af or AF and pulmonary arterial systolic pressure (PASP) respectively in the M21 group. And the body surface area (BSA) was similar in both groups. The detailed information of two groups were summarized in table I.

3.2 Comparison of group SJMR19 and group M21

3.2.1 Comparison of preoperative echocardiographic data between the SJMR19 and M21 group

In terms of preoperative echocardiographic data, two groups were comparable and the SJMR19 group carried an aortic annulus with a similar mean size compared with the M21 group (2.15±0.19cm vs 2.27±0.20cm, P=0.668). The detailed data of two groups were presented in table II.

3.2.2 Comparison of time of operation and hospitalization between the SJMR19 and M21 group

There were no statistically significant differences between two groups regarding the operation time (263.73±44.09min vs 260.52±41.30min, P=0.794), aortic cross-clamp time (109.00±22.38min vs 110.96±26.84min, P=0.771), CPB duration (145.40±28.22min vs 146.92±30.67min, P=0.851), length of ICU stay (3.10±1.24d vs 3.48±1.44d, P=0.323) and duration of hospitalization (21.57±6.71d vs 24.65±11.96d, P=0.238) (table III). None of these patients received mechanical assistance from extracorporeal membrane oxygenation (ECMO) and intra-aortic ballon pump (IABP).

3.2.3 Improved postoperative cardiac function and hemodynamics in the SJMR19 and M21 group

In the SJMR19 group, the postoperative levels of LVEF were significantly enhanced versus the preoperative values (57.40±4.01% vs 59.4±2.43%, P=0.007). The PGav max declined from 50.41±28.47mmHg to 22.23±5.30mmHg (P<0.001) and the Vav max decreased from 339.24±106.95cm/s to 234.47±27.18cm/s (P<0.001). The remaining echocardiographic parameters all improved compared with the preoperative values including the LVM (201.82±59.10g vs 146.82±36.54g, P<0.001), LVMi (119.12±33.10g/m^2 vs 86.35±18.15g/m^2, P<0.001), Vtv max (316.57±56.65cm/s vs 248.83±37.56cm/s, P<0.001), PASP (30.29±6.48mmHg vs 48.21±15.65mmHg, P<0.001) (table IV).

However, there was no significant increase in the postoperative levels of LVEF versus the preoperative values (54.83±6.13% vs 55.75 ± 5.14%, P=0577) in the M21 group. The PGav max reduced from 46.80±26.82mmHg to 23.88±8.00mmHg (P<0.001) and the Vav max decreased from 326.54±101.96cm/s to 240.92±42.56cm/s (P<0.001). Consistently, the remaining parameters improved postoperatively including the LVM (218.50±78.01g vs 171.35±52.25g, P<0.001), LVMi (127.22±46.00g/m^2 vs 99.34±27.80g/m^2, P<0.001), Vtv max (317.59±56.33cm/s vs 229.44±53.99cm/s, P<0.001), PASP (47.50±16.36mmHg vs 27.31±8.99mmHg, P<0.001) (table V).

3.2.4 Comparison of postoperative cardiac function and hemodynamics between the SJMR19 and M21 group

For patients in the SJMR19 group, the postoperative LVEF was significantly elevated and LVM and LVMi were evidently reduced, compared with patients in the M21 group

(LVEF: 59.40±2.43% vs. 55.75±5.14%, P=0.001; LVM:146.82±36.54g vs 171.35±52.25g, P=0.048; LVMi: 86.35±18.15g/m vs. 99.34±27.80g/m, P=0.044) (Fig. 2). Whereas the remaining parameters including the Vmv max (166.89±44.16cm/s vs 175.05±29.85cm/s, P=0.823), PGmv max (11.89±4.59mmHg vs 12.57±4.14mmHg, P=0.842), Vav max (234.47±27.18cm/s vs 240.92±42.56cm/s, P=0.502), Vtv max (248.83±37.56cm/s vs 229.44±53.99cm/s, P=0.184), PGtv max (25.21±6.47mmHg vs 21.88±8.59mmHg, P=0.151), PASP (30.29±6.48mmHg vs 27.31±8.99mmHg, P=0.205) show no significant difference between two groups (table VI).

3.3 Predictive model for postoperative LVEF incorporating LMR

Multivariate linear analysis of postoperative LVEF was carried out by including all candidate variables and the implanted valve type was identified in the multivariate analysis as an independent predictor for postoperative LVEF (p=0.003) (table VII).

Discussion

Aortic prosthetic valve replacement could effectively reduce the left ventricular afterload and reverse the cardiac hypertrophy. The standard aortic valve replacement has proven to improve both the survival and symptoms of patients. Since Rahimtoola and his colleagues[19] proposed its concept several decades ago, this phenomenon of PPM following valve replacement has been intensively investigated. In patients with PPM, symptomatic improvement is compromised and worse hemodynamic data has also been associated with PPM following AVR. More importantly, mismatch is negatively correlated with the regression of LV hypertrophy, as well as long-term survival[20-22]. Tasca et al. [23] has concluded that the decrease of left ventricular mass would be to varying degrees achievable regardless of PPM, if the effective orifice areas index (EOAI) of replaced prosthetic valves increased postoperatively. And the better the EOAI is, the more the remodeling of LV is reversed following operations. Thanks to the new generation of artificial valves with better EOA, the incidence of moderate and severe PPM has markedly declined in recent years. The SJMR19 valve has been uniformly accepted as a feasible option in patients with SAA[18]. However, the evidence of early-term hemodynamic performance and clinical results is still scarce in patients with SAA undergoing DVR with SJMR19 valve. In this study, the postoperative cardiac function and hemodynamics were evaluated by echocardiography in both the SJMR19 and M21 groups and a significant improvement in terms of LVM, LVMi, Vav max and PGav max was observed in both groups. Of note, the postoperative LVEF was significantly higher while the LVM and LVMi was evidently decreased in the SJMR19 group, compared with the M21 group. In order to confirm the influencing factors on postoperative LVEF, a multiple linear regression analysis model was established by including all candidate variables and the implanted valve type was identified in the multivariate analysis as an independent predictor for postoperative LVEF.

The optimal surgical approach for those patients with SAA remains debated. And several surgical strategies such as ARE, supra-annular stented prosthetic valves, stentless bioprostheses, and sutureless and rapid-deployment bioprostheses have been proposed to improve the postoperative hemodynamics and outcomes[4]. In recent decades, transcatheter aortic valve replacement (TAVR) has burgeoned as a plausible alternative for surgical AVR in patients with high, moderate and even low surgical risk[24, 25]. In particular, its excellent hemodynamic results have gained adequate attention among patients with SAA[4, 26]. The procedures of ARE have not been widely performed due to the increased complexity of the procedures as well as prolonged cardiopulmonary bypass and aortic cross-clamp time[20, 27, 28]. And several studies have observed an elevated operative mortality among the patients undergoing ARE[20, 29, 30]. Besides, stentless and sutureless bioprostheses are not commercially available in China and relevant evidence in SAA is still limited in Chinese population. Although the number of TAVR annually performed in China has rapidly increased in recent decades, the high medical expense indeed confines its clinical popularity in China. Thus to date the SJMR valve has consistently been a reasonable choice for AVR as well as DVR, in patients with SAA.

Special attention should be paid to interpret the results in this study. First, the retrospective design might trigger potential bias and it was also a single-center study. Second, the sample size was relatively small. Third, the mid- to long-term outcomes were missing in this study.

Conclusion

For patients with SAA undergoing DVR, early-term hemodynamic performance and clinical results were acceptable with SJMR19. The postoperative cardiac function was improved both in the SJMR19 and M21 groups. The postoperative LVEF, LVM and LVMi were better in the SJMR19 group compared with the patients in the M21 group. And the implanted valve type was identified in the multivariate analysis as an independent predictor for postoperative LVEF.

Abbreviations

AVR: Aortic valve replacement; DVR: Dual valve replacement; SJMR19:19-mm St. Jude Medical Regent; M21:21-mm mechanical; Vav max: Maximum transaortic flow velocity; PGav max: Maximum transaortic pressure gradient; LVMi: Left ventricular mass index; LVM: Left ventricular mass; LVEF: Left ventricular ejection fraction; STS: Society of Thoracic Surgeons; SAA: Small aortic annulus; EOA: Effective orifice area; EOAI:

Effective Orifice Areas index; BMI: Body mass index; PPM: Prosthesis patient mismatch; ARE: Aortic root enlargement; GCP: Good Clinical Practice; CPB: Cardiopulmonary bypass; Vtv max: Maximum transtricuspid flow velocity; PGtv max: Maximum transtricuspid pressure gradient; INR: International normalized ratio; SD: Mean ± standard deviation; Af: Atrial fibrillation; AF: Atrial flutter; PAH: Pulmonary artery hypertension; BSA: Body surface area; ICU: Intensive Care Unit; ECMO: Extracorporeal membrane oxygenation; IABP: Intra-aortic ballon pump; TAVR: Transcatheter aortic valve replacement; NYHA: New York Heart Association; MS: Mitral stenosis; MI: Mitral insufficiency; AS: Aortic stenosis; AI: Aortic insufficiency; TI: Tricuspid insufficiency; AV: Aortic Valve.

Ethics approval and consent to participate

This single-center retrospective cohort study was approved by the Ethics Committee of Shandong Provincial Hospital and the written informed consent was waived due to the retrospective design.

Consent for publication

Consents for publication were obtained from all individuals involved in our study.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This manuscript was supported by the National Natural Science Foundation of China (81800255) and Natural Science Foundation of Shandong Province (ZR2019MH025, ZR2018BH002).

Author Contributions

Dong Wei, Shijie Zhang, Xianfeng Cheng and Junjie Huang have given substantial contributions to the conception or the design of the manuscript, Shanghao Chen, Yan Yun, Diming Zhao and Jinzhang Li to acquisition, analysis and interpretation of the data. All authors have participated to drafting the manuscript, Xiaochun Ma, Zhengjun Wang and Chengwei Zou revised it critically. All authors read and approved the final version of the manuscript.

Acknowledgments

None.

References

[1] Unger P, Clavel MA, Lindman BR, Mathieu P, Pibarot P. Pathophysiology and management of multivalvular disease. Nat Rev Cardiol. 2016;13:429-40.

[2] Lee R, Li S, Rankin JS, O'Brien SM, Gammie JS, Peterson ED, et al. Fifteen-year outcome trends for valve surgery in North America. Ann Thorac Surg. 2011;91:677-84; discussion p 84.

[3] Wojakowski W, Baumgartner H. The Year in Cardiology 2018: Valvular Heart Disease. Eur Heart J. 2019;40:414-21.

[4] Freitas-Ferraz AB, Tirado-Conte G, Dagenais F, Ruel M, Al-Atassi T, Dumont E, et al. Aortic Stenosis and Small Aortic Annulus. Circulation. 2019;139:2685-702.

[5] Okuyama H, Hashimoto K, Kurosawa H, Tanaka K, Sakamoto Y, Shiratori K. Midterm results of Manouguian double valve replacement: comparison with standard double valve replacement. J Thorac Cardiovasc Surg. 2005;129:869-74.

[6] Zhong Q, Xiao Y, Chen J, Ma R. Strategy of aortic root enlargement in patients undergoing aortic and mitral valve replacement. Ann Thorac Surg. 2010;90:782-7.

[7] Mubarak Y, Abdel Jawad AAR. Aortic Root Enlargement in patients with small aortic annulus undergoing double valve replacement. Is it justified? A retrospective Comparative cohort study. Heart Surg Forum. 2021;24.

[8] Medalion B, Lytle BW, McCarthy PM, Stewart RW, Arheart KL, Arnold JH, et al. Aortic valve replacement for octogenarians: are small valves bad? Ann Thorac Surg. 1998;66:699-705; discussion -6.

[9] Sawant D, Singh AK, Feng WC, Bert AA, Rotenberg F. Nineteen-millimeter aortic St. Jude Medical heart valve prosthesis: up to sixteen years' follow-up. Ann Thorac Surg. 1997;63:964-70.

[10] Kratz JM, Sade RM, Crawford FA, Jr., Crumbley AJ, 3rd, Stroud MR. The risk of small St. Jude aortic valve prostheses. Ann Thorac Surg. 1994;57:1114-8; discussion 8-9.

[11] Prakash S, Agarwal S, Dutta N, Satsangi DK. A comparative study of surgical treatment of small aortic root with or without aortic root enlargement using a single prosthesis type. J Cardiovasc Med (Hagerstown). 2010;11:836-42.

[12] David TE, Puschmann R, Ivanov J, Bos J, Armstrong S, Feindel CM, et al. Aortic valve replacement with stentless and stented porcine valves: a case-match study. J Thorac Cardiovasc Surg. 1998;116:236-41.

[13] David TE. Aortic valve replacement with stentless porcine bioprostheses. J Card Surg. 1998;13:344-51.

[14] Van Nooten G, Caes F, François K, Van Belleghem Y, Taeymans Y. Stentless or stented aortic valve implants in elderly patients? Eur J Cardiothorac Surg. 1999;15:31-6.

[15] Luciani GB, Casali G, Auriemma S, Santini F, Mazzucco A. Survival after stentless and stented xenograft aortic valve replacement: a concurrent, controlled trial. Ann Thorac Surg. 2002;74:1443-9.

[16] Lopez S, Mathieu P, Pibarot P, Mohammadi S, Dagenais F, Voisine P, et al. Does the use of stentless aortic valves in a subcoronary position prevent patient-prosthesis mismatch for small aortic annulus? J Card Surg. 2008;23:331-5.

[17] Pavoni D, Badano LP, Ius F, Mazzaro E, Frassani R, Gelsomino S, et al. Limited long-term durability of the Cryolife O'Brien stentless porcine xenograft valve. Circulation. 2007;116:I307-13.

[18] Bach DS, Sakwa MP, Goldbach M, Petracek MR, Emery RW, Mohr FW. Hemodynamics and early clinical performance of the St. Jude Medical Regent mechanical aortic valve. Ann Thorac Surg. 2002;74:2003-9; discussion 9.

[19] Rahimtoola SH. The problem of valve prosthesis-patient mismatch. Circulation. 1978;58:20-4.

[20] Head SJ, Mokhles MM, Osnabrugge RL, Pibarot P, Mack MJ, Takkenberg JJ, et al. The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years. Eur Heart J. 2012;33:1518-29.

[21] Fallon JM, DeSimone JP, Brennan JM, O'Brien S, Thibault DP, DiScipio AW, et al. The Incidence and Consequence of Prosthesis-Patient Mismatch After Surgical Aortic Valve Replacement. Ann Thorac Surg. 2018;106:14-22.

[22] Tasca G, Brunelli F, Cirillo M, DallaTomba M, Mhagna Z, Troise G, et al. Impact of valve prosthesis-patient mismatch on left ventricular mass regression following aortic valve replacement. Ann Thorac Surg. 2005;79:505-10.

[23] Tasca G, Mhagna Z, Perotti S, Centurini PB, Sabatini T, Amaducci A, et al. Impact of prosthesis-patient mismatch on cardiac events and midterm mortality after aortic valve replacement in patients with pure aortic stenosis. Circulation. 2006;113:570-6.

[24] Rahhab Z, El Faquir N, Tchetche D, Delgado V, Kodali S, Mara Vollema E, et al. Expanding the indications for transcatheter aortic valve implantation. Nature reviews Cardiology. 2020;17:75-84.

[25] Salinas P, Moreno R, Lopez-Sendon JL. Transcatheter aortic valve implantation: Current status and future perspectives. World J Cardiol. 2011;3:177-85.

[26] Kalavrouziotis D, Rodés-Cabau J, Bagur R, Doyle D, De Larochellière R, Pibarot P, et al. Transcatheter aortic valve implantation in patients with severe aortic stenosis and small aortic annulus. Journal of the American College of Cardiology. 2011;58:1016-24.

[27] Rocha RV, Manlhiot C, Feindel CM, Yau TM, Mueller B, David TE, et al. Surgical Enlargement of the Aortic Root Does Not Increase the Operative Risk of Aortic Valve Replacement. Circulation. 2018;137:1585-94.

[28] Yu W, Tam DY, Rocha RV, Makhdoum A, Ouzounian M, Fremes SE. Aortic Root Enlargement Is Safe and Reduces the Incidence of Patient-Prosthesis Mismatch: A Meta-analysis of Early and Late Outcomes. The Canadian journal of cardiology. 2019;35:782-90.

[29] Dhareshwar J, Sundt TM, Dearani JA, Schaff HV, Cook DJ, Orszulak TA. Aortic root enlargement: what are the operative risks? The Journal of thoracic and cardiovascular surgery. 2007;134:916-24.

[30] Ghoneim A, Bouhout I, Demers P, Mazine A, Francispillai M, El-Hamamsy I, et al. Management of small aortic annulus in the era of sutureless valves: A comparative study among different biological options. The Journal of thoracic and cardiovascular surgery. 2016;152:1019-28.

Figures

Figure 1. Flow chart of participants inclusion and exclusion.

Figure 1 depicts the process of participants inclusion and exclusion.

Figure 2. Comparison of postoperative echocardiographic data between the two groups.

Figure. 2 shows the comparison of postoperative echocardiographic data between the two groups. a. For the patients in the SJMR19 group, the postoperative LVEF was significantly elevated , compared with the patients in the M21 group (P=0.001); b. LVM were evidently reduced(P=0.048); c. LVMi were also evidently reduced (P=0.044). Abbreviations: SJMR19: 19mm St. Jude Medical Regent valve; M21: 21-mm mechanical (M21) valve; LVEF: Left ventricular ejection fraction; LVM: Left ventricular mass; LVMi: Left ventricular mass index.

Tables

Table I.— Basic characteristics of SJMR19 group compared with M21 group.

Variables	SJMR19 group (n=30)	M21 group (n=24)	p value
Male	4 (13.3%)	9 (39.1%)	0.039
Age	66.87±6.04	66.58±5.72	0.163

NYHA grade	3±0.37	3±0.59	＞0.999
Height (cm)	159.03±5.93	161.79±8.50	0.167
Weigh (kg)	59.13±9.84	60.336±11.41	0.680
BSA (m^2)	1.69±0.14	1.73±0.18	0.477
BMI (kg/ m^2)	23.33±3.31	22.93±3.15	0.651
Diabetes	2 (6.7%)	1 (4.2%)	0.690
Hypertension	3 (10.0%)	5 (20.8%)	0.362
Af/AF	19 (63.3%)	15 (62.5%)	0.950
PAH	15 (50.0%)	12 (50.0%)	1.000
Valvular disease status			
MS	7 (23.3%)	11 (45.8%)	0.081
MI	7 (23.3%)	7 (29.1%)	0.627
MS with MI	16 (53.3%)	5 (20.8%)	0.015
AS	1 (3.3%)	4 (16.7%)	0.093
AI	4 (13.3%)	3 (12.5%)	0.928
AS with AI	25 (83.3%)	17 (70.8%)	0.272
TI	16 (53.3%)	7 (29.2%)	0.074

Abbreviations: NYHA: New York Heart Association; BSA: Body surface area; BMI: Body mass index; Af: Atrial fibrillation; AF: Atrial flutter; PAH: Pulmonary artery hypertension; MS: Mitral stenosis; MI: Mitral insufficiency; AS: Aortic stenosis; AI: Aortic insufficiency; TI: Tricuspid insufficiency

Table II. — Comparison of preoperative echocardiographic data between the two groups.

Variables	SJMR19 group (n=30)	M21 group (n=24)	p value
LVEF (%)	57.00±4.01	54.83±6.13	0.124
EOA mv	1.35±0.55	1.15±0.75	0.264
EOAI mv	0.80±0.33	0.67±0.44	0.215
AV annulus (cm)	2.15±0.19	2.27±0.20	0.668
Vav max (cm/s)	339.24±106.95	326.54±101.96	0.662
PGav max (mmHg)	50.41±28.47	46.8±26.82	0.639
LVM (g)	201.82±59.10	218.5±78.01	0.375
LVMi (g/m^2)	119.12±33.11	127.22±46.06	0.456
Vtv max (cm/s)	316.57±56.65	317.59±56.33	0.950
PGtv max (mmHg)	41.36±14.57	41.74±15.05	0.928
PASP (mmHg)	48.21±15.65	47.5±16.36	0.876

Abbreviations: LVEF: Left ventricular ejection fraction; EOA: Effective Orifice Areas; EOAI: Effective Orifice Areas index; AV: Aortic Valve; Vav max: Maximum transaortic flow velocity; PGav max: Maximum transaortic Pressure Gradient; LVM: Left ventricular mass; LVMi: Left ventricular mass index; Vtv max: Maximum transtricuspid flow velocity; PGtv max: Maximum transtricuspid Pressure Gradient; PASP: Pulmonary arterial systolic pressure.

Table III. — Comparison of duration of operation and hospitalization between the two groups.

Variables	SJMR19 group (n=30)	M21 group (n=24)	p value

Operation time (min)	263.73±44.09	260.52±41.30	0.794
Aortic cross-clamp time (min)	109.00±22.38	110.96±26.84	0.771
CPB duration (min)	145.40±28.22	146.92±30.67	0.851
Length of ICU stay (d)	3.10±1.24	3.48±1.44	0.323
Duration of hospitalization (d)	21.57±6.71	24.65±11.96	0.238

Abbreviations: CPB: Cardiopulmonary Bypass; ICU: Intensive Care Unit

Table IV. — The preoperative and postoperative echocardiographic data in SJMR19 group.

Variables	SJMR19 group		p value
	Preoperative	Postoperative	
LVEF (%)	57.40±4.01	59.40±2.43	0.007
Vav max (cm/s)	339.24±106.95	234.47±27.18	<0.001
PGav max (mmHg)	50.41±28.47	22.23±5.30	<0.001
LVM (g)	201.82±59.10	146.82±36.54	<0.001
LVMi (g/m^2)	119.12±33.10	86.35±18.15	<0.001
Vtv max (cm/s)	316.57±56.65	248.83±37.56	<0.001
PGtv max (mmHg)	41.36±14.57	25.21±6.47	<0.001
PASP (mmHg)	48.21±15.65	30.29±6.48	<0.001

Abbreviations: LVEF: Left Ventricular Ejection Fraction; Vav max: Maximum transaortic flow velocity; PGav max: Maximum transaortic Pressure Gradient; LVM: Left ventricular mass; LVMi: Left ventricular mass index; Vtv max: Maximum transtricuspid flow velocity; PGtv max: Maximum transtricuspid Pressure Gradient; PASP: Pulmonary arterial systolic pressure.

Table V. — The preoperative and postoperative echocardiographic data in M21 group.

Variables	M21 group		p value
	Preoperative	Postoperative	
LVEF (%)	54.83±6.13	55.75±5.14	0.577
Vav max (cm/s)	326.54±101.96	240.92±42.56	<0.001
PGav max (mmHg)	46.80±26.82	23.88±8.00	<0.001
LVM (g)	218.50±78.01	171.35±52.25	0.018
LVMi (g/m^2)	127.22±46.00	99.34±27.80	0.015
Vtv max (cm/s)	317.59±56.33	229.44±53.99	<0.001
PGtv max (mmHg)	41.74±15.05	21.88±8.59	<0.001
PASP (mmHg)	47.50±16.36	27.31±8.99	<0.001

Abbreviations: LVEF: Left Ventricular Ejection Fraction; Vav max: Maximum transaortic flow velocity; PGav max: Maximum transaortic Pressure Gradient; LVM: Left ventricular mass; LVMi: Left ventricular mass index; Vtv max: Maximum transtricuspid flow velocity; PGtv max: Maximum transtricuspid Pressure Gradient; PASP: Pulmonary arterial systolic pressure.

Table VI. — Comparison of postoperative echocardiographic data between the two groups.

Variables	SJMR19 group (n=30)	M21 group (n=24)	p value
LVEF (%)	59.40±2.43	55.75±5.14	0.001
Vmv max (cm/s)	166.89±44.16	175.05±29.85	0.823
PGmv max (mmHg)	11.89±4.59	12.57±4.14	0.842
Vav max (cm/s)	234.47±27.18	240.92±42.56	0.502
PGav max (mmHg)	22.23±5.30	23.88±8.05	0.372

LVM (g)	146.82±36.54	171.35±52.25	0.048
LVMi (g/m²)	86.35±18.15	99.34±27.80	0.044
Vtv max (cm/s)	248.83±37.56	229.44±53.99	0.184
PGtv max (mmHg)	25.21±6.47	21.88±8.59	0.151
PAH (mmHg)	30.29±6.48	27.31±8.99	0.205

Abbreviations: LVEF: Left ventricular ejection fraction; Vmv max: Maximum transmitral flow velocity; PGmv max: Maximum transmitral Pressure Gradient; Vav max: Maximum transaortic flow velocity; PGav max: Maximum transaortic Pressure Gradient; LVM: Left ventricular mass; LVMi: Left ventricular mass index; Vtv max: Maximum transtricuspid flow velocity; PGtv max: Maximum transtricuspid Pressure Gradient; PAH: Pulmonary arterial hypertension.

Table VII. — Standardized and non-standardized partial regression coefficients

The independent variables	Partial regression coefficient	Standard error	Standardized partial regression coefficient	T	P
Constant	60.447	8.005		7.551	0.000
Preoperative LVEF	0.204	0.101	0.242	2.019	0.050
Aortic valve type	-3.066	0.955	-0.348	-3.210	0.003

Abbreviations: LVEF: Left Ventricular Ejection Fraction.

Figures

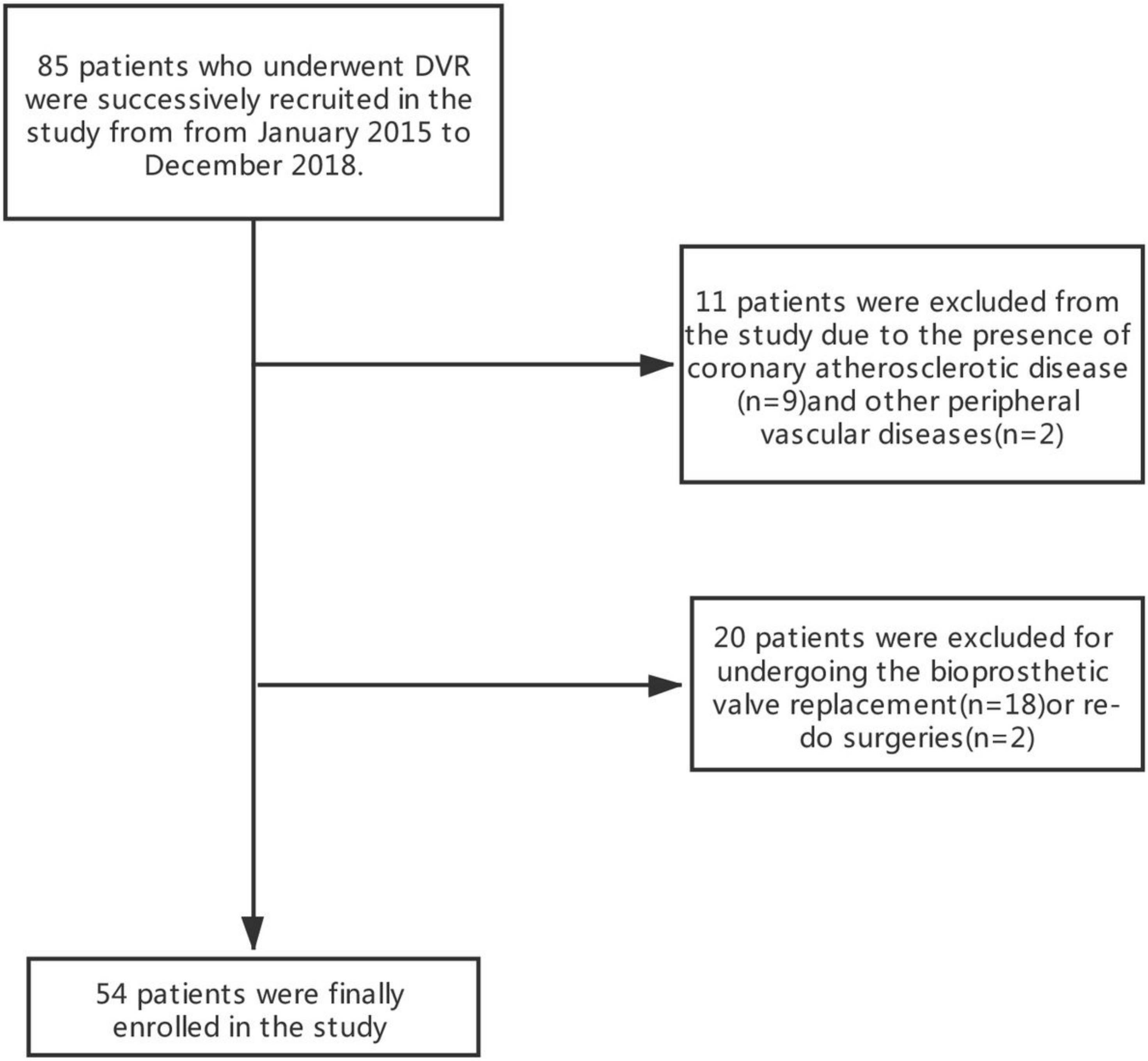

Figure 1

Flow chart of participants inclusion and exclusion.

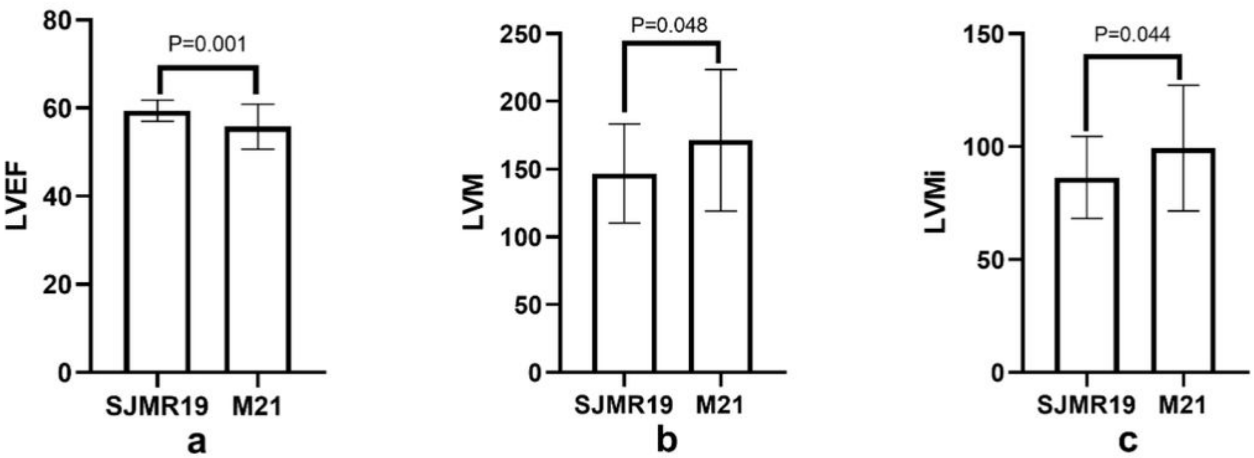

Figure 2

Comparison of postoperative echocardiographic data between the two groups.