

Impact of Sex on Cardiac Remodelling and Long-Term Outcomes Following Mitral Valve Replacement

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Abstract

Background: Differences in cardiac remodeling after mitral valve (MV) surgery between the sexes is poorly understood. Inferior outcomes for females undergoing MV surgery compared to males have been suggested in the literature, although causative factors behind this discrepancy have not been identified. **Materials and Methods:** In this propensity-matched, retrospective, single-center study, we sought to identify the impact that sex may have on cardiac remodeling and long-term outcomes to better inform clinical decision making in MV surgical intervention. Outcomes were compared between males and females undergoing MV replacement (MVR) between 2004 and 2018. The primary outcome was cardiac remodeling 1 year postoperatively. Secondary outcomes included mortality, stroke, myocardial infarction (MI), reoperation of the MV, and rehospitalization. **Results:** 314 males and 314 females were included after propensity matching. Males demonstrated a significant degree of improved left ventricular remodeling while females did not, and females showed a significant degree of left atrial remodeling while males did not. Mortality rates were relatively equivalent between the two groups, although males were more likely to develop sepsis and require rehospitalization due to MI. **Conclusions:** There has been little research exploring the differences in cardiac remodeling between the sexes after MVR. The results of this study have suggested that MVR is equally safe for both sexes and has demonstrated a difference in the heart's ability to remodel after MVR. The significance of this difference has the potential to result in largely different clinical outcomes for males and females. Further study is necessary to fully elucidate this relationship.

Introduction

The prevalence of valvular heart disease (VHD) is estimated to be 2.5% in developed nations and increases with age, occurring in 14.0% and 12.6% of males and females over the age of 75, respectively [1,2]. Mitral valve disease (MVD) is the most common valvular lesion, with at least moderate mitral regurgitation (MR) occurring in 1.7% of all individuals and 9.3% of those over the age of 75 [2]. The only definitive treatment for MVD is surgical repair or replacement with a mechanical or bioprosthetic valve. Consideration for MV surgical intervention depends on the expected outcomes associated with various preoperative and intraoperative factors and sex is a factor that has been demonstrated to influence these factors [8, 14]. Preoperatively, females are referred later in the disease process with generally higher rates of comorbidities [11-15]. Intraoperatively, there is an increased likelihood of MVR over repair for females compared to males [12, 13, 15] and an increased likelihood of concomitant procedures [13, 14]. Postoperatively, studies have demonstrated inferior outcomes for females as compared to males in MV surgery, with up to a 2.5x increased mortality for females aged 40-59 [11, 12, 18, 19]. While it is well known that the heart remodels after MV surgery, there is little evidence on the impact of sex on cardiac remodeling post MV surgery.

Cardiac remodeling is an integral part of valvular and other cardiac diseases. Changes to hemodynamics, chamber pressure, metabolism, inflammation, and a multitude of other mechanisms can lead to remodeling of the cardiac chambers. In the context of MV disease, cardiac remodeling most often includes left atrial (LA) and left ventricular (LV) dilation as well as an increased LV ejection fraction (LVEF). The consequences of

cardiac remodeling include development of arrhythmias and heart failure [20, 21]. It is therefore imperative to understand the factors influencing cardiac remodeling after MV surgery as reversal of pathological remodeling may impact an individual's recovery and long-term prognosis.

Although higher rates of comorbidities and delayed surgical referral may explain the inequity in MV surgery outcomes between males and females, there have been no factors definitively identified as having a causal effect. The current literature seeking to identify the impact of sex and surgical approach on postoperative cardiac remodeling and outcomes is insufficient. Consequently, identical guidelines are used to treat both sexes while females continue to suffer inferior postoperative outcomes. Current trends in medicine seek to personalize treatments for individual patients. In order to minimize the disease burden and optimize quality of life, treatment in MVD should also be tailored to an individual's specific presentation. In this propensity-matched retrospective study, we look to identify variations in postoperative cardiac remodeling and outcomes between males and females who have undergone MVR to better inform the clinical decision-making process for patients requiring surgical MVR.

Materials and Methods

Patient data were collected from a database that included surgical intervention, preoperative comorbidities, as well as postoperative complications and outcomes. 2,912 patients who had undergone either a MV repair or replacement from 2004-2018 at the Mazankowski Heart Institute, University of Alberta Hospital were included in the database. Follow up information and outcomes from all post-operative assessments performed at the University of Alberta Hospital were also included. Approval for this study was obtained from the local research ethics board. Individual waiver for consent was granted by the local research ethics board.

Data Source

The APPROACH (Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease) database, electronic health records, and discharge abstract databases were utilized in order to collect the relevant pre and postoperative information. The APPROACH database contains comprehensive clinical information from patients undergoing coronary angiography in Alberta. The details of this clinical database and its use have been described previously [28].

Study Cohort

This study included patients with severe MV disease that underwent MVR at the University of Alberta Hospital between January 1, 2004, and December 31, 2018 (Figure 1). Exclusion criteria included repair of the MV or if data was incomplete (n=1673), if they were in a critical preoperative state (n=24) (need for intra-aortic balloon pump, acute renal failure requiring dialysis, respiratory failure requiring ventilation), or if there was a preoperative diagnosis of endocarditis (n=96). A total of 1072 patients were included consisting of 476 males and 596 females (Figure 1). After propensity matching, 314 males and 314 females were included. Patients were followed for a maximum of 16 years with a median follow-up of 8.4 years.

Outcomes

The primary outcome was cardiac remodeling within 1 year postoperatively. Functional, anatomical, and hemodynamic assessments included preoperative and postoperative LVEF, LV internal dimension in diastole (LVIDd), LA size (mm), LA volume index (ml/m²), MV area (MVA) (cm²), and MV peak and mean gradients. Secondary outcomes include mortality at any time postoperatively, postoperative stroke, myocardial infarction (MI), reoperation of the MV, and rehospitalization. Both during admission and following discharge for the index procedure, outcome data were collected and identified based on admitting diagnosis for any readmission. MI was defined as the primary diagnosis of ST-segment elevation MI (STEMI) or non-STEMI for readmission any time during the follow-up period. Stroke was defined as the primary diagnosis at readmission at any point during the follow-up period. Reoperation of the MV was defined as MVR, surgical repair, or repair of complications originating from the index procedure. New-onset AF was defined as AF

arising after the index procedure with no prior history of AF. Residual MR included moderate or severe MR within 1 year postoperatively.

Statistical analysis

Continuous variables and categorical variables were summarized as mean \pm standard deviation (SD) and count (percent) respectively. The Society of Thoracic Surgery (STS) Risk Score for each patient was calculated using the online STS calculator [29]. Propensity score matching techniques were used to control for the difference in the baseline covariates. The propensity score was estimated using a multivariable logistic regression model with biological sex as the dependent variable and the baseline characteristics as covariates including age, BMI, pulmonary disease, cerebrovascular disease, renal disease, current smoker, past smoker, hypertension, dyslipidemia, liver disease, gastrointestinal disease, malignancy, peripheral vascular disease, diabetes mellitus, congestive heart failure, prior MI, prior percutaneous coronary intervention (PCI), prior coronary artery bypass grafting (CABG), prior AF/flutter, implant type, pump time, cross-clamp time, STS score and LVEF. Greedy matching techniques without replacement and a caliper width equal to 0.2 of the standard deviation of the logit of the propensity score were applied to match male patients 1:1 to female patients. Standardized mean difference was used to evaluate the balance before and after matching. A standardized difference of 0.1 or less was deemed to be the ideal balance.

The paired t-test was used to compare the pre- and post-operative echocardiographic measurements and the absolute changes in LV size, LA size, and LA volume index between male and female patients. Cox proportional hazards regression models and the Fine & Gray model [30] were implemented to determine the hazard ratios of sex difference on the primary and non-fatal secondary outcomes. McNemar test was performed to compare the postoperative complications by sex. The survival curve was plotted for all-cause mortality at longest follow-up using Kaplan-Meier methods. The interaction between sex and implant type for all-cause mortality at longest follow-up was tested by adding implant type and an interaction term of sex and implant type into the Cox model. Reverse Kaplan-Meier methods were used to estimate the median follow-up time. Statistical analyses were executed using the SAS 9.4. (SAS Institute, Cary NC). A p-value <0.05 was deemed of statistical significance. All statistical tests were two-sided.

Results

Baseline Demographics

The original database included 2,912 consecutive patients who had undergone MV surgery at the University of Alberta between January 1, 2004, and December 31, 2018 (Figure 1). 1,239 patients underwent an MVR and met the inclusion criteria. Baseline demographic data before and after propensity matching are summarized in Tables 1 & 2 respectively. Prior to propensity matching, males were found to be older than females, more likely to have renal disease, peripheral vascular disease, a prior MI, prior CABG, an LVEF $<30\%$, and a higher STS risk score (Table 1). After propensity score matching, there were no significant differences in preoperative or intraoperative characteristics between females and males (Table 2).

Surgical Detail

Intraoperative differences before propensity matching included males having a longer time spent on cardiopulmonary bypass and a longer time with a cross-clamp placed (Table 1). These differences were not present after propensity matching. There were no significant differences in the types of valve replacements used with 79.8% of males and 77.2% of females receiving tissue valves (Table 1).

Cardiac Remodelling

Postoperative cardiac remodeling data are summarized in Tables 3 and 4. Both groups showed a significant reduction in peak and mean MV gradients with males having an initial peak MV gradient of 18.5 ± 10.2 mmHg and a postoperative gradient of 15.1 ± 6.4 mmHg ($p=0.006$). Females had an initial MV peak gradient of 20.7 ± 9.4 mmHg to 16 ± 5.8 mmHg postoperatively ($p<0.001$). Males began with a mean MV gradient from 8.6 ± 6.8 mmHg preoperatively to 5.7 ± 2.9 mmHg postoperatively ($p=0.001$), and females had an initial mean

gradient of 9.2 ± 5.1 mmHg and a postoperative mean gradient of 5.7 ± 2.8 mmHg ($p < 0.001$). Both groups were found to have an increase in MVA after MVR with males having an initial MVA of 1.5 ± 0.8 cm² and a post replacement area of 1.8 ± 0.9 cm² ($p < 0.001$), and females with an initial MVA of 1.3 ± 0.6 cm² and a postoperative MVA of 1.8 ± 0.9 cm² ($p < 0.001$). Only males demonstrated significantly improved LV remodeling with an initial LVIDd of 54.7 ± 8.9 mm and a postoperative LVIDd of 51.1 ± 10.2 mm ($p < 0.001$). Initial LVIDd in females was 47.8 ± 7.4 mm, and postoperatively it was 47.2 ± 7.7 mm ($p = 0.251$). Males also showed a significant reduction in LVEF with an initial LVEF of $51.9\% \pm 10.6\%$ and a postoperative LVEF of $49.2\% \pm 11.9\%$ ($p = 0.003$). Females did not demonstrate the same reduction with an initial LVEF of $53.3\% \pm 10.6\%$ and a postoperative LVEF of $53.8\% \pm 11.5\%$ ($p = 0.929$). In contrast, it was only females that demonstrated significantly improved LA remodeling. Males had an initial LA volume index of 60 ± 35.7 ml/m² and a postoperative LA volume index of 60 ± 28.8 ml/m² ($p = 0.077$), while females began with a LA volume index from 57.9 ± 24 ml/m² preoperatively to 55.6 ± 20.8 ml/m² postoperatively ($p = 0.011$). Females were also the only group to show a significant reduction in LA diameter. Males had an initial LA diameter of 5.4 ± 1.2 cm and a postoperative diameter of 5.3 ± 1.2 cm ($p = 0.09$). Females began with an LA diameter of 5.3 ± 1.1 cm and post MV replacement had an LA diameter of 5 ± 0.9 cm ($p = 0.037$). There were no significant differences in the absolute anatomical changes between males and females (Table 4).

Peri-operative Outcomes and Post-MVR Survival

Secondary outcomes for these patients after propensity matching are summarized in tables 5 and 6. There were no significant differences in mortality during the at 30 days, 1 year, or at longest follow-up. Although at all time points after 1 year, males had a numerically higher mortality rate than females (figure 2, table 5). At the median follow up time of 8.4 years, there were 107 deaths in the male group (57.5%) and 99 deaths in the female group (50.9%) [adjusted hazard ratio (HR): 1.19; 95% confidence interval (CI): 0.9-1.56; $p = 0.22$]. Males were more likely to experience an MI during the follow-up period with 20 MIs recorded (8.9%) and 10 MIs recorded for the female group (5.5%) [HR: 2.16; 95% CI: 1.02-4.59; $p = 0.045$]. Males were also more likely to develop sepsis postoperatively. 28 males (8.9%) and 11 females (3.5%) developed sepsis postoperatively ($p = 0.005$). There were no significant differences in the incidence of heart failure, readmission for stroke, reoperation of the MV, residual MR, new-onset AF, pacemaker insertion rates, or acute kidney injury postoperatively.

Conclusions

In this study, we looked to identify the impact of sex on remodeling and outcomes post MVR. After propensity matching and isolating for surgical approach, our results demonstrate significant cardiac remodeling postoperatively for both sexes. Interestingly the cardiac remodeling was inconsistent between the two groups. Males showed significantly improved remodeling of the LV while females had significant remodeling of the LA. A study by Goldstein et al randomized 251 patients to either MV repair or replacement and followed the patients for 2 years. Both MV repair and replacement groups demonstrated significant remodeling of the LV end-systolic volume index within the first year postoperatively [22]. Ebd Alaziz & Ibrahim similarly followed 20 males and 25 females who had undergone MVR for chronic MR. These patients demonstrated a reduction in LVEF from $61.09 \pm 7.6\%$ to $59.67 \pm 6.56\%$, in LA size from 5.55 ± 0.88 cm to 4 ± 0.54 cm, and LV end-systolic diameter from 4.06 ± 0.65 cm to 3.45 ± 0.51 cm at 1-year postoperatively [23]. Even so, no studies have compared the differences in remodeling between sexes with a large number of propensity-matched patients and our results demonstrate a difference in the heart's ability to remodel after MVR. Males demonstrated a significant reduction in LV size and LVEF, while females did not. Females demonstrated a significant reduction in LA size and volume, while males did not. This distinction in cardiac remodeling demonstrates variability in cardiac adaptation after MV surgery. The significance of this difference has the potential to result in variable clinical outcomes for males and females, including long-term freedom from heart failure and mortality. Further study is necessary to fully elucidate this relationship.

In contrast to previous literature, our results demonstrated that after propensity matching and isolating for surgical approach females and males have similar rates of morbidity and mortality post MVR, and when there were significant differences between the sexes males had inferior outcomes. Vassileva et al performed a study

including 47,602 patients undergoing isolated MV surgery and divided patients by sex and surgical approach [12]. This study found the MV repair rate for males was 44.0% and 31.9% for females, with remaining patients receiving MVR. Higher operative and in-hospital mortality rates were identified for females. Women demonstrated a higher mortality rate than men with 8.2% and 9.3% for males and females respectively. Even after adjustment for differences in baseline characteristics and admission status, the mortality rate for females undergoing MVR was still increased compared to their male counterparts [12]. Song et al demonstrated similar results with their study of 24,977 patients from The STS National Database who underwent isolated MV repair or replacement [18]. Females were shown to have significantly increased rates of morbidity and mortality with the largest difference being in the 40-59 year age group with approximately 2.5x the rates of mortality in females as compared to males, this survival disadvantage diminished with aging [18]. As there were multiple potential causes of these discrepancies in prior literature, we sought to identify whether sex alone impacts the outcomes post-MV surgery by matching patients based on comorbidities and isolating for surgical approach. We found no significant difference in mortality between males and females following MVR. Our results demonstrated that when males and females were matched for preoperative comorbidities and surgical approaches, males had inferior postoperative with an increased likelihood of developing sepsis and requiring rehospitalization due to MI postoperatively than females.

Our results have demonstrated significant variations in cardiac remodeling between males and females post MVR. Both males and females demonstrated significant changes in MVA as well as peak and mean gradients, although chamber remodeling was distinctly different between the sexes. Males demonstrated a significant reduction in LV diameter and LVEF while females did not show these changes. In contrast, females showed a significant reduction in LA diameter and volume while males did not. This difference in chamber remodeling demonstrates variability in the heart's ability to adapt after MV surgery. The significance of this difference is unknown but has the potential to result in different clinical outcomes between the sexes, including long-term freedom from symptoms of heart failure and rates of mortality. Further study of this discrepancy is necessary to fully elucidate this relationship.

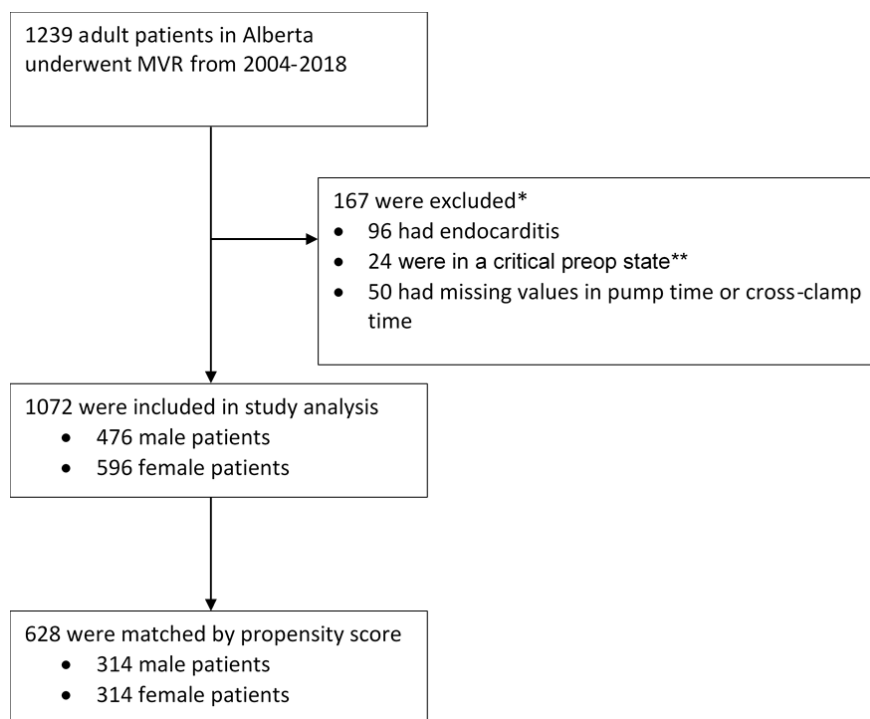
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Figure 1. Study Population Flowchart



* Some overlap existed; therefore, the numbers breakdown did not add up to the total.

**Need for intra-aortic balloon pump, respiratory failure requiring vent, cardiogenic shock.

Table 1. Baseline characteristics of patients that underwent MVR before matching(N=1072)

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Values are No. (%) or mean \pm SD

Table 2. Baseline characteristics of patients that underwent MVR after matching(N=628)

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Table 3. Hemodynamic, Functional, and Anatomical Changes Before and After MVR(N=628)

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Table 4. Absolute anatomical changes before and after MVR(n=628).

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ECHO median follow-up time: 4 months.

Table 5. Secondary outcomes post MVR (Comparing male to female patients) (N=628).

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*The rates in brackets are estimates from Kaplan-Meier Curve.

Table 6. Post-operative complications post MVR (N=628).

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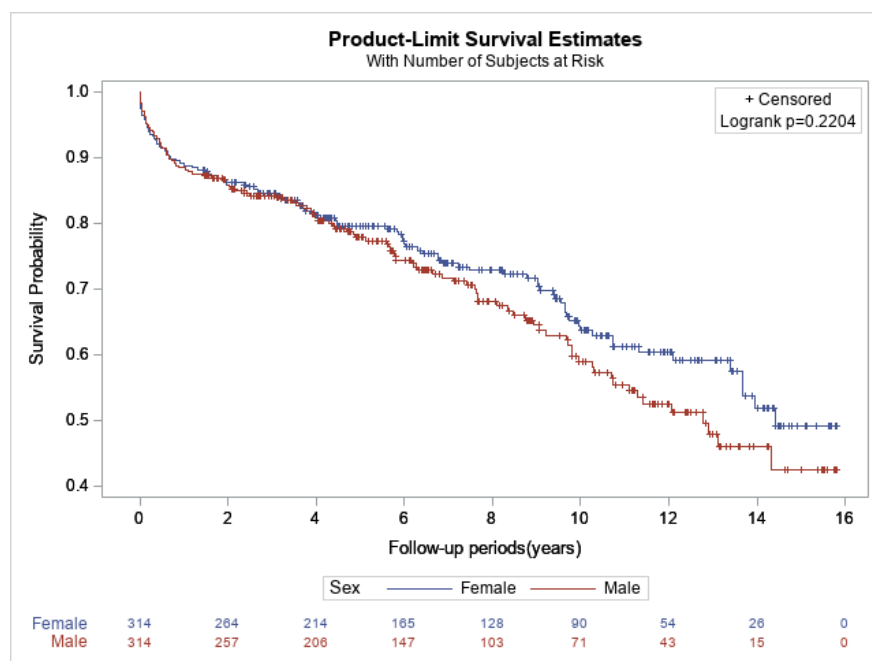


Figure 2. Kaplan Meier curve for all-cause mortality at longest available follow-up.