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Original Article

Gender in post-cardiac transplant patients has no effect on the occurrence of death, major cardiovascular events or development of cardiac allograft vasculopathy

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Abstract: Objectives: The effect of gender on outcome in post-cardiac transplant morbidity and mortality including the occurrence of transplant vasculopathy is not well established. The goal of this study was to evaluate adverse post-transplant outcomes based on gender with a focus on cardiac allograft vasculopathy (CAV). Methods: Using our post-transplant database at the University of Arizona, the effect of gender after heart transplantation on death, major adverse cardiac events (MACE defined as the combined occurrence of myocardial infarction, percutaneous coronary intervention, coronary bypass surgery, re-transplantation, and death) and the occurrence of CAV was evaluated retrospectively over 3 years. Results: A total of 149 patients were evaluated in our database. Over the study period after the first year post-transplantation, a total of 4,7% deaths occurred. There were no differences in death between males and females (4.3% vs 6.1%, p = ns). MACE occurred in similar degrees between males and females (7.8% vs 9.1%, p = ns). Furthermore, the occurrence of an abnormal coronary angiogram or significant intima thickening seen during intracoronary ultrasound studies was similar between the genders for every year studied. Conclusions: Gender does not effect on the occurrence of CAV at any year's post-cardiac transplantation. Furthermore, it has no effect on MACE and mortality.

Keywords: Cardiac transplantation, heart transplant, organ transplantation, gender bias mortality, major adverse cardiac events, cardiac allograft vasculopathy, transplant rejection

Introduction

Cardiac transplantation continues to serve as the gold standard in the treatment of end-stage, or Stage D, heart failure refractory to medical management [1, 5]. Prior studies have calculated a 20% 5-year survival for Stage D patients pre-transplant, often with a median survival time of 6 months [2, 3]. However, with a successful cardiac transplant, the median survival time has increased to 12.5 to 14.8 years [4]. In the last decade, the number of cardiac transplants conducted in the US has increased by 67.4% [6]. Three years post-transplantation, almost 75% of patients can conduct activities of daily living with minimal symptoms [7].

Despite the increased rates of cardiac transplantation and increased survival time post-transplant, the procedure presents significant complications in the life to follow. Complications occur in two major periods- early (days after transplant) and delayed (months/years after transplant) [8]. Early complications include primary graft dysfunction, donor immune system rejection of the transplant, and infection, particularly respiratory tract infections, due to the use of immunosuppression post-procedure [8, 9]. In addition, cardiac arrhythmias, such as atrial fibrillation within a few weeks post-transplant and long-term atrial flutter and atrial tachycardia, are common in cardiac transplant patients [9, 10]. Delayed complications of cardiac transplants include malignancies, immunosuppression, cardiac allograft vasculopathy, and chronic renal dysfunction [8, 24]. The most common malignancies seen have been squamous cell lung carcinoma and Kaposi's sarcoma [11]. Long-term negative effects have been seen for immunosuppressive efforts to decrea-

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se the likelihood of rejection, specifically with calcineurin inhibitors, corticosteroids, and tacrolimus, to name a few [12].

Cardiac allograft vasculopathy (CAV) or cardiac transplant vasculopathy is a major delayed complication of cardiac transplants that arises without significant indicators, due to an immunologic reaction of the host to the transplant [13, 14]. This is specifically initiated when the host's immune system recognizes the foreign graft and activates a variety of mechanisms, such as T-cell proliferation triggered by HLA-mismatch, or activation of CD8+ T cells against foreign MHC class I on the transplant, leading to the development of endothelial activation and vasculopathy [13, 14]. Characterized by intimal thickening, vasculopathy early after transplant can be isolated to donor-transmitted focal epicardial thickening. However, post-transplantation, it can progress distally to include diffuse atherosclerotic plaques and intimal thickening of the coronary arteries, thereby giving a poor prognosis [14, 15]. By 3 years post-transplantation, 75% of cardiac transplant recipients are diagnosed with the condition [14]. Current detection methods include angiography and intravascular ultrasound, with ultrasound being the more sensitive of the tools used [13].

Interestingly, however, the effect of gender on post-transplantation adverse outcome is still not well established. Previous studies have examined donor-recipient gender mismatching and concluded an increased number of rejections and reduced 1-year survival post-transplant [16, 22, 23]. Concerning the influence of gender on CAV, similar analyses of donor-recipient mismatch have been analyzed, attributing a higher risk of vasculopathy occurrence in male recipients with female donors [17, 18]. Other studies have also concluded that gender mismatch overall increases the occurrence of vasculopathy, no matter the combination [19]. However, the effect of recipient gender on the development of CAV has not been thoroughly investigated. Concerning mortality and morbidity post-transplantation, previous studies fail to yield a cohesive conclusion. For instance, a 2019 study concluded no difference in survival between men and women recipients of cardiac transplants [20] and a 2002 study concluded that gender did not significantly influence outcomes of transplantation [21]. However, there remains the need for additional retrospective studies to thoroughly delineate gender's effect on morbidity and mortality to provide a baseline conclusion.

The goal of this study was to evaluate adverse post-transplant outcomes based on the gender of the recipient after transplantation with a focus on CAV. Using our post-transplant database at the University of Arizona, the effect of gender on outcome was evaluated retrospectively over a period of 3 years.

Material and methods

This study evaluated post-transplant outcomes of individuals who had completed a cardiac transplant procedure at the University of Arizona Medical Center. We included all transplant patients who have available data regarding death, the development of CAV and major adverse cardiac events (MACE which was defined as the combined occurrence of myocardial infarction (MI), percutaneous coronary intervention (PCI), coronary bypass surgery (CABG), re-transplantation, and death). An Excel sheath was created with detailed data entry. Cardiac catheterization reports and outcome data were reviewed and extracted from the chart. Death data was extracted from the Social Security death database. This study was exclusively done with the registered patients from the University of Arizona and no subjects were deliberately excluded. This study was approved by the institutional review board.

Outcome data was obtained from electronic medical records, specifically MI, PCI, CABG, minimal intimal thickening (MIT), transplant vasculopathy, transplantation, and death. Using this data, we conducted a retrospective analysis on all cardiac transplant patients from 2005-2008. Included were patients who had data about their outcome data after their transplantation including gender. Excluded were patients less than 18 years and patients with missing information about gender and outcomes.

Statistical analysis

Chi-square analysis was used to determine the relationship between gender and death in the cohort post-transplantation. To examine the effect of overall age and age at transplantation on death status, one-way ANOVA was used. The interaction of gender with MACE was evaluated

Table 1. Baseline characteristics (MACE = major adverse cardiac events)

	Male (n = 116)	Female (n = 33)
Baseline MIT>0.4	33 (28.4%)	8 (24.2%)
Abnormal baseline angiogram	12 (10.3%)	3 (9.1%)
MACE (MI/PCI/CABG/Re-Transplantation/Death)	9 (7.8%)	3 (9.1%)
Death	5 (4.3%)	2 (6.1%)

Table 2. Demographic and medication information

Age in yrs (St. Dev)	55.1 (11)
Age in yrs at transplant (St. Dev)	51.2 (11)
Left ventricular ejection fraction % (St. Dev)	56.4 (7.1)
Medications (%)	
Tacrolimus	38
Sirolimus	12
Mycophenolate	70
Cyclosporine	52
Prednisone	91

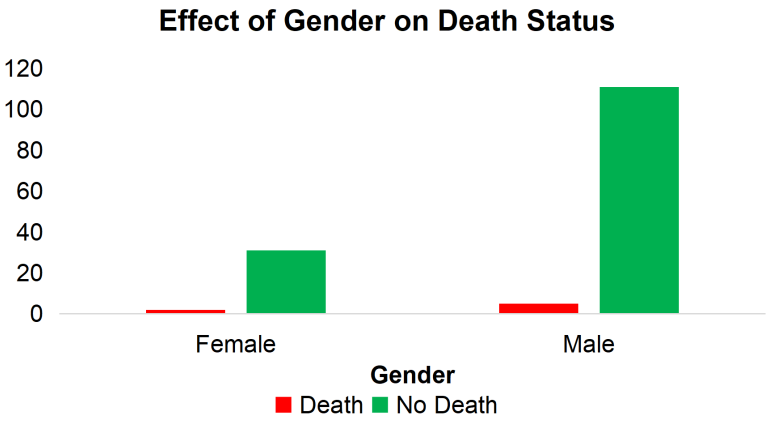

Figure 1. Gender did not have a significant effect on death status (*P* = .675).

using chi-square tests followed by the calculation of odds ratio and relative risks. The individual interactions of gender. with each of the following MIT examined at baseline and every year post-transplant, angiogram results at baseline, and yearly post-transplant were all analyzed via chi-square tests.

Results

Demographics

A total of 149 patients (33 female, 116 male) who underwent a cardiac transplant were evaluated in this study, with an age range of 24 to 77 years (mean age = 55.1 +/- 11.9 years), and mean age at transplant being 51.2 +/- 11.8 years. **Tables 1** and **2** provide all baseline characteristics and demographic information.

Effect of gender on mortality

We found no effect of gender on the occurrence of deathin post-cardiac transplant patients. The interaction between gender and death was first evaluated. Pearson Chi-Square tests revealed no significant interaction between gender and death X2(1, N = 149) = .176, P = .675. The relative risk of gender on death was 1.406 (CI = .286-6.920) while the relative risk of gender on no death was .982 (CI = .893-1.079). The total odds ratio for gender (F/M) producing death was .698 (CI = .129-3.774) (**Figure 1**). As noted, the mean age of all individuals at the time of our study was 55.14 (+/- 11.9) years, and the mean age at the time of transplantation was 51.44 (+/- 11.8) years. In the "no death" group, the mean age was 54.99 (+/- 11.8) years while the age at transplantation was 51.44 (+/- 11.6) years. For the seven death cases, the mean age at transplantation was 46.86 (+/- 14.55) years. One-way ANOVA results indicated no significant difference between overall age and death status (F1,141 = 3.479, P = .064, η2 = .024) or between age at the time of transplantation and death status (F1,147 = 1.014, P = .316, η2 = .007).

Effect of gender on MACE (defined as the combined occurrence of myocardial infarction, percutaneous coronary intervention, coronary bypass surgery, re-transplantation, and death)

There was no significant relationship between gender and occurrence of any MACE post-trans-

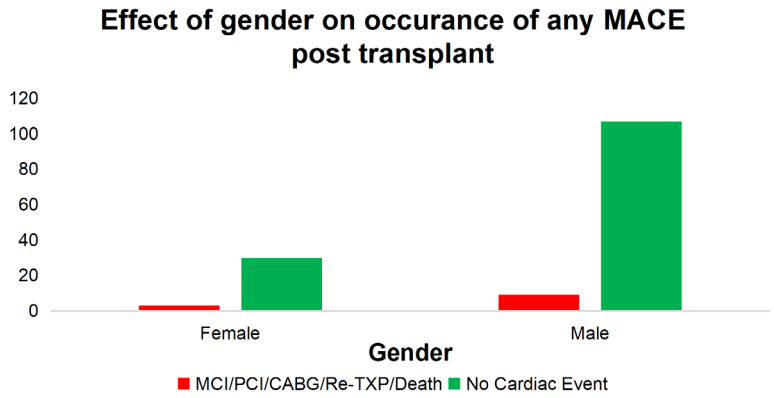

Figure 2. Gender had no significant effect on the occurrence of a MACE post-transplant (*P* = .522).

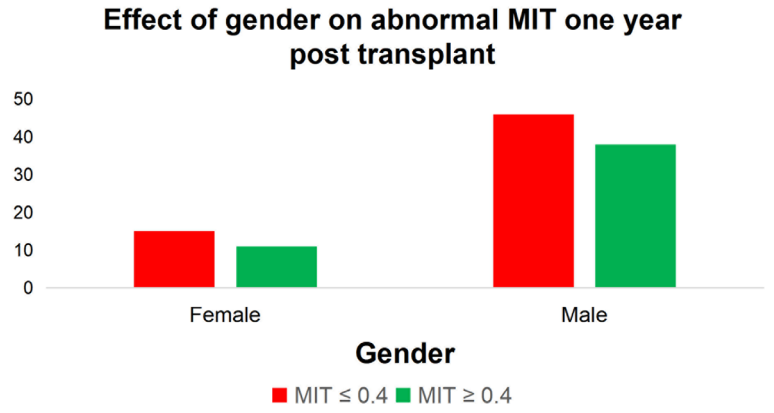

Figure 3. There was no significant effect of gender on the occurrence of allograft vasculopathy one year post-transplant (*P* = .793).

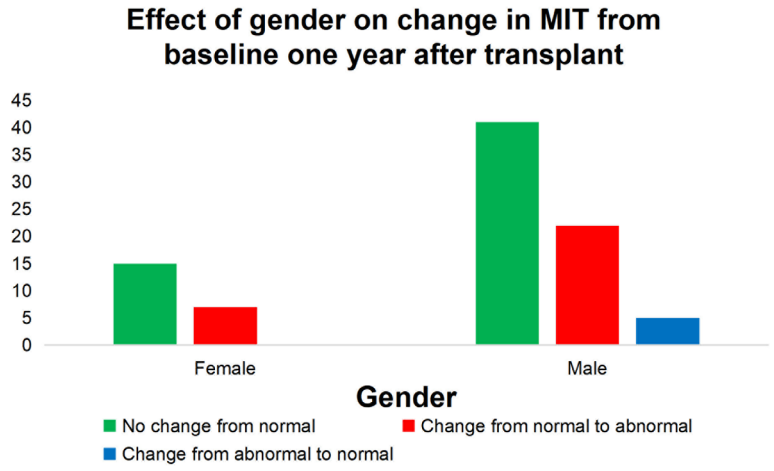

Figure 4. Gender did not significantly impact any change in MIT from baseline values one year after cardiac transplant (*P* = .571).

plantation (P = .522), with an odds ratio of 1.172 (CI: .336-4.082) of experiencing MI, PCI, CABG, re-transplantation, or death (**Figure 2**).

Effect of gender on MIT or abnormal angiogram results as a surrogate for CAV

All cardiac transplant patients would undergo routine left heart catheterization one year post-transplantation and yearly thereafter in the first few years unless indicated sooner based on the cath lab finding or symptoms. Chi-square tests evaluating the effect of gender on a baseline MIT>0.4 mm results showed no significant relationship [X2(1, N = 149) = .228, P = .633]. The OR for gender and MIT>0.4 mm was calculated as 1.242 (CI: 509-3.033). Chi-square tests between gender and MIT>0.4 mm after one year of transplantation yielded no significant results [X2(1, N = 110) = .069, P = .793] with an OR of 1.126 (CI: .463-2.740) (**Figure 3**). When evaluating whether gender was associated with at least one MIT≥0.5 mm, chi-square results yielded insignificant results [X2(1, N = 149) = 1.805, P = .179].

Chi-square tests evaluating the interaction of gender with either no change in MIT from normal baseline, a change from normal to abnormal, a change from abnormal to normal, or no change from abnormal IVUS result (>0.5 mm) revealed no relationship between gender and any change in result [X2(3, N = 110) = 2.006, P = .571] (**Figure 4**). When examining any change from normal to abnormal MIT in three years, there was no significant relationship with gender as well [X2(1, N = 110) = 1.083, P = .354] (**Figure 5**).

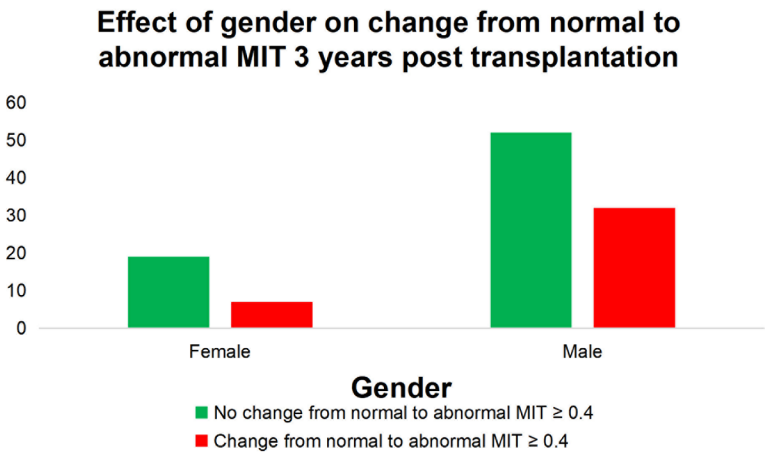

Figure 5. Gender did not have a significant impact on the development of allograft vasculopathy, as measured by change in MIT, in patients three years post cardiac transplantation.

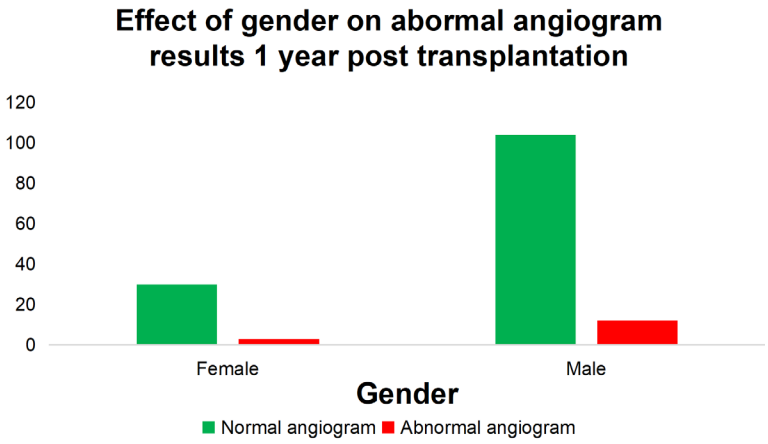

Figure 6. Gender did not have a significant impact on the occurrence of an abnormal angiogram one year post transplantation (*P* = .833).

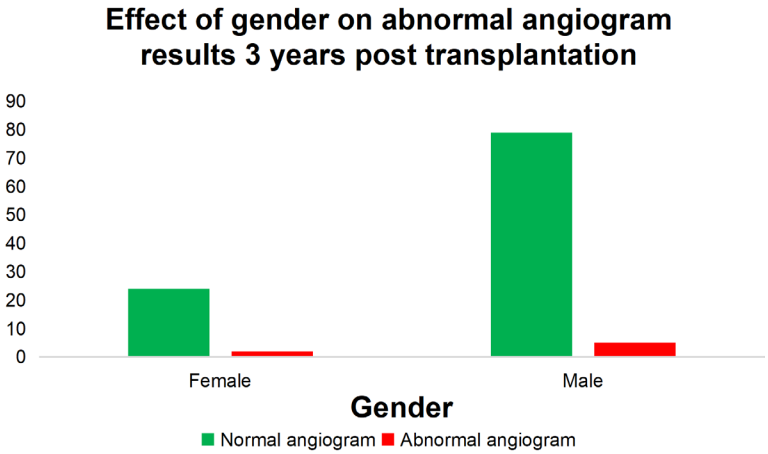

Figure 7. Gender did not have a significant impact on the occurrence of an abnormal angiogram three years post transplantation (*P* = .751).

When looking at the occurrence of an abnormal angiogram one year after transplantation, there was no significant difference in the percentage of males versus females with abnormal angiogram results (9.1% of females vs. 10.3% of males; X2(1, N = 149) = .045, P = .833) (**Figure 6**). In addition, the odds ratio of gender with an abnormal one-year angiogram is .879 (CI: .263-2.931). Upon a two-year follow-up angiogram, there was no significant difference between genders (X2(1, N = 110) = 1.621, P = .203). At three years post-transplant, there was no difference in genders in the occurrence of an abnormal angiogram result (X2(1, N = 110) = .101, P = .751) (**Figure 7**). There was no significant relationship between gender and an abnormal baseline angiogram or MIT>0.4 (45.5% of females vs. 47.4% of males; X2(1, N = 149) = .040, P = .842]. The odds ratio was .959 (CI: .630-1.459). One year post-transplant, gender did not have a significant effect on the occurrence of an abnormal angiogram or MIT>0.4 (X2(1, N = 110) = .520, P = .471) (**Figure 8**).

Discussion

This study evaluated the effect of gender (female vs male) on the occurrence of death, MACE, and vasculopathy post-cardiac transplant. Retrospectively analyzing 149 cardiac transplant patients from 2005 to 2008 at the University of Arizona Medical Center, we can conclude that gender does not have any significant impact on death, MACE, or CAV. The percentage of deaths post-transplant was not signif-

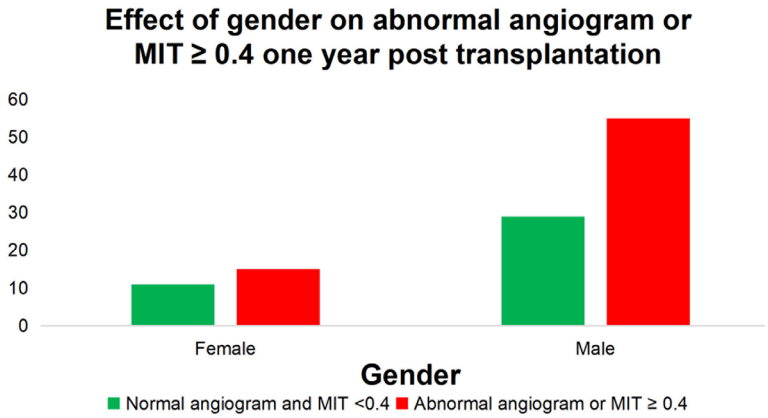

Figure 8. One-year post-transplant, gender did not have a significant effect on occurrence of abnormal angiogram or MIT ≥ 0.4 (P = .471).

icantly different between females and males (P = .675). In addition, when evaluating the occurrence of any cardiac event post-transplant, there was no significant difference between the percentage of males and females affected as well. CAV was evaluated based on any occurrence of abnormal MIT or angiogram results, and like the previously mentioned variables, gender had no significant effect on the results.

These results are in stark contrast with previous studies evaluating gender-specific outcomes in cardiac transplants. For instance, Weiss et al. in 2009 concluded that female cardiac transplants, irrespective of the sex of their donor, had lower survival rates when compared to men [30]. In 2013, Kaczmarek et al. published a retrospective analysis of 67,855 cardiac transplants which concluded the highest survival in male recipients of male donor hearts [22]. However, our results contrast these prior studies by providing evidence of no significant difference in mortality, occurrence of MACE, or CAV between males and females. In addition, Khush et al. in 2023 concluded that the female gender was associated with a lower risk of developing CAV while our results indicate no significant effect of gender on MIT changes post-transplant [26].

However, recently published analyses of gender concerning cardiac procedures and transplantation agree with our findings. For instance, when evaluating the impact of gender on the mid-term prognosis of CABG patients, Jang et al. concluded that sex did not influence the risk of death from MI in the population [24]. In addition, single-center and multicenter studies evaluating gender equality in heart transplantation produced results consistent with our findings: recipient gender or donor gender did not significantly affect post-transplant mortality or overall outcomes [21, 25, 26, 28]. Furthermore, when evaluating the survival outcomes of 34,198 heart transplant recipients, Moayedi et al. found no significant difference in survival between men and women after transplantation [20]. Similarly, Hickey et al. in 2016 concluded that despite men being more likely to have co-morbidities such as diabetes, hypertension, and dyslipidemia, there was no significant difference in mortality between the two genders post-transplantation [27]. Additionally, Garcia-Cosio et al. in 2021 also evaluated the outcomes of heart transplant recipients using the Spanish Heart Transplant Registry and similar 1-year survival post-transplant between men and women [29]. Interestingly, these results can be applied to generalized organ transplantation. A 2021 study evaluating recipient sex's impact on transplant outcomes highlighted that recipient sex by itself does not impact graft survival, but when taken into consideration with age, does significantly impact outcomes [30]. Moreover, in a 2022 retrospective study of kidney transplants to compare graft survival based on recipient sex, there was no significant relationship between recipient gender and graft survival [31].

Thus, this study contributes to the growing evidence that recipient gender in cardiac transplant does not have any significant effect on mortality, or cardiac events, such as PCI, MI, re-transplantation, CABG, or vasculopathies. However, the study does come with its limitations. For instance, we are only examining 3 years of data (2005-2008) at a single center. This affects overall generalization attempts, given that the data pool is limited. In addition, our subjects had a wide age range (24 to 77), which poses the possibility of the natural course of aging as a confounding variable. Further studies should evaluate aging as a continuous variable and its impact on gender-related out-

comes. In addition, increased numbers of female recipients must be included for a more equitable analysis. However, given that women only account for 25% of the heart transplant waitlist, our study has very precisely matched this (33 females out of 149 individuals; 22%), supporting its accurate representation of the cardiac transplant patient database nationally [32, 33]. Based on our data, we view gender not as a risk factor for worse outcomes post-heart transplantation. Therefore, any decision to perform heart transplantation should not consider gender as a risk factor. Furthermore, any effort should be made to improve gender disparity in heart transplantation.

Limitations

Our data came from a single-center study, limiting our results to our state population. This retrospective study needs confirmation in randomized prospective trials. Furthermore, it was conducted over three years, limiting our results to short-term outcomes.

Conclusions

Gender does not affect the occurrence of post-transplant CAV at any year post-cardiac transplantation up to 3 years. Furthermore, it has no effect on MACE and mortality.

Disclosure of conflict of interest

None.

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