

Valve Surgery in a Low-Volume Center in a Low- and Middle-Income Country: A Retrospective Cross-Sectional Study

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Background: Valvular heart disease (VHD) has a significant prevalence and mortality rate with surgical intervention continuing to be a cornerstone of therapy. We aim to report the outcome of patients undergoing heart valve surgery (HVS) in a low-volume center (LVC) in a low- and middle-income country (LMIC).

Methods: A cross-sectional retrospective study was conducted at the Jordan University Hospital (JUH), a tertiary teaching hospital in a developing country, between April 2014 and December 2019. Patients who underwent mitral valve replacement (MVR), aortic valve replacement (AVR), tricuspid valve replacement (TVR), double valve replacement (DVR), CABG + MVR, and CABG + AVR patients were included. Thirty-day and two-year mortalities were taken as the primary and secondary outcomes, respectively.

Results: A total number of 122 patients were included, and the mean age was 54.46 ± 14.89 years. AVR was most common (42.6%). There was no significant association between STS mortality score or Euroscore II with 30-day and 2-year mortality.

Conclusion: LVC will continue to have a role in LMICs, especially during development to HICs. Further global studies are needed to assert the safety of HVS in LVC and LMICs.

Keywords: valve surgery, low-volume center, low- and middle-income country

Introduction

The main cause of death worldwide is cardiovascular disease (CVD), which accounts for over 17.5 million deaths annually, 80% of which take place in low- and middle-income countries.¹

One of the major causes of CVD is valvular heart disease (VHD), which has a significant prevalence and mortality rate.^{2,3} VHD affects 2.5% of the adult population in the United States, with aortic and mitral valve disease accounting for most cases.⁴ For both aortic and mitral valve disease, surgical intervention continues to be a cornerstone of therapy and is associated with significant improvements in patient morbidity and mortality. However, valve surgeries are complicated, with significant perioperative morbidity and mortality.⁵

Most of the world's population reside in low- and middle-income countries (LMICs) without adequate access to cardiac surgical care. In addition, these countries are facing increased burden of CVD due to many factors such as population growth, urbanization of CVD disease, and transition from communicable to noncommunicable diseases.⁶

Despite the progress made within the field of global cardiac surgery, there is still uncertainty regarding cardiac surgical services in LMIC which are needed in up to 33% of CVD cases. Still, six billion people lack access to safe, inexpensive cardiac surgical care when it is necessary. Cardiothoracic surgery is behind non-cardiac surgical treatment in terms of importance as a component of healthcare.⁶ In LMICs, whether cardiac surgery is provided at all and at what level depends primarily on four key factors; government commitment and resource availability, primary healthcare

systems, which are frequently insufficient and fall short in their front-line role towards prophylaxis and diagnostic monitoring, socioeconomic factors that cause rheumatic heart disease (RHD) in the first place, and the highly specialized field of cardiac surgery, whose standards differ from how it is carried out in the developed world.⁷

Studies have shown better performance and lower mortality rates in high-volume centers. On the other hand, 30-day and 1-year mortality rates are higher in low-volume centers for many procedures performed, including CABG, aortic valve replacement, and mitral valve replacement.⁸⁻¹⁰ Nevertheless, most of the data published regarding this subject emerge from high-volume centers. Consequently, this raises concerns about the generalizability of their findings and the reproducibility of valve surgery in low-volume centers. Our study aims to report the outcome of patients undergoing valvular surgery in a low-volume center in a LMIC.

Methods

Study Design and Population

Retrospective data was extracted from the cardiovascular database of the Jordan University Hospital, a low-volume center. A total of 122 patients who underwent valvular heart surgery between April 2014 and December 2019 were included. We included mitral valve replacement (MVR), aortic valve replacement (AVR), tricuspid valve replacement (TVR), double valve replacement (DVR), CABG and MVR, and CABG and AVR patients. The exclusion criteria were urgent cases, age under 18 years, and CABG only surgery. Thirty-day mortality was taken as the primary outcome, which involves death within 30 post-operative days. The secondary outcome was death in 2-year follow-up. We systematically collected preoperative patient variables, surgical procedure information (including type of procedure), and postoperative clinical outcomes to calculate the STS and EuroSCORE II risk scores.^{11,12} The EuroSCORE II score included age, sex, angina symptoms, insulin-dependent diabetes mellitus, New York Heart Association functional class, peripheral artery disease, neurological or musculoskeletal dysfunction severely affecting mobility, previous cardiac surgery, chronic pulmonary disease, pulmonary artery systolic pressure, renal function with creatinine clearance, critical preoperative state, active endocarditis, left ventricular ejection fraction, recent myocardial infarction, procedure urgency and weight of the procedure. The STS score included 67 demographic and operative variables.

Data Analysis

Counts and percentages were used to present categorical variables while mean and standard deviation were used to interpret continuous variables. Chi-square test was used to identify the factors associated with patients' mortality. *T*-test and correlation coefficients were used to assess the factors associated with patient's STS scores as appropriate. Any test with a *P*-value <0.05 was considered statistically significant. IBM SPSS v.26 was used to conduct the analysis.

Ethics

This study was approved by Jordan University Hospital Institutional Review Board, and all procedures performed were in accordance with the ethical standards of the institutional and national research committee and the principles of the World Medical Association Declaration of Helsinki. The requirement for informed consent was waived because this study was retrospective, conformed to standards for minimal risk research and did not affect patient safety or clinical care. To protect patient confidentiality, personal identifiers were removed from spreadsheets used for data analyses and all reports.

Results

Characteristics of the Included Patients

The total number of the patients who underwent valve replacement surgery from 2014 to 2019 was 124. Two patients were excluded from the analysis due to insufficient data in their medical records resulting in 122 patients included in the analysis. The percentage of females in the included patients was 57.4% and the mean age was 54.46 ± 14.89 . Most of the patients had hypertension (54.1%) and 31.1% of the cohort had diabetes. Triple vessel disease existed in 1.6% of the patients and 5.7% of the patients had >70.0% Left Anterior Descending (LAD)

stenosis [Table 1](#). Furthermore, 36.9% of the patients had aortic stenosis and 37.7% of the patients had mitral a. The frequencies of severe aortic, mitral, and tricuspid regurgitation were 8.2%, 16.4% and 0.8%, respectively. Additionally, the most frequent valve disease etiology was degenerative valve (33.6%) [Table 2](#). Atrial fibrillation existed in 16.4% of the included patients whereas 24.6% of the patients were current smokers. Most of the patients underwent cardiac intervention previously (55.7%) [Table 3](#). All surgeries were elective in status and only 1.6% of the patients received intra-aortic balloon pump. Most of the patients underwent aortic valve replacement

Table 1 Comorbidities of Participants

Variable	Response	Frequency (n = 122)	Percentage (%)
Sex	Male	52	42.6
	Female	70	57.4
Hypertension	Yes	66	54.1
Diabetes	Yes	38	31.1
Peripheral Arterial Disease	Yes	4	3.3
Cancer within the last 5 years	Yes	3	2.5
Stroke	Yes	7	5.7
Heart Failure	Yes	12	9.8
Sleep Apnea	Yes	9	7.4
Dialysis	Yes	1	0.8
Liver Disease	Yes	4	3.3
Respiratory Diseases	Yes	7	5.7
Pulmonary Hypertension	Yes	5	4.1
Triple Vessel Disease	Yes	2	1.6
LAD Stenosis	60–70%	15	12.3
	>70%	7	5.7

Abbreviation: LAD, Left anterior descending artery.

Table 2 Valve Pathology

Variable	Response	Frequency (n = 122)	Percentage (%)
Aortic Stenosis	Yes	45	36.9
Mitral Stenosis	Yes	46	37.7
Aortic Regurgitation	Yes	10	8.2
Mitral Regurgitation	Yes	20	16.4
Tricuspid Regurgitation	Yes	1	0.8

(Continued)

Table 2 (Continued).

Variable	Response	Frequency (n = 122)	Percentage (%)
Valve Disease Etiology	Bicuspid	3	2.5
	Congenital	1	0.8
	Calcified	35	28.7
	Degenerative	41	33.6
	Rheumatic	37	30.3
	HOCM	3	2.5
	Primary Aortic Disease, Atherosclerotic Aneurysm	2	1.6
Reoperation Status	First Surgery	117	95.9
	Reoperation	5	4.1

Abbreviation: HOCM, Hypertrophic obstructive cardiomyopathy.

Table 3 Cardiovascular Characteristics of Participants

Variable	Response	Frequency (n = 122)	Percentage (%)
Syncope	Yes	5	4.1
NYHA Classification	Class 2	6	4.9
	Class 3	12	9.8
History of Endocarditis	Yes	3	2.5
Active Endocarditis	Yes	2	1.6
Alcohol Use	Yes	1	0.8
Tobacco Use	Never	75	61.5
	Former	17	13.9
	Current	30	24.6
Previous Cardiac Interventions	Yes	68	55.7
	No	54	44.3
Medications	Beta Blocker	80	65.6
	Angiotensin Converting Enzyme Inhibitor/Angiotensin Receptor Blockers	80	65.6
	Insulin	4	3.3
	Steroids	4	3.3
Presentation	Myocardial Infarction/Angina	2	1.6
	Cardiogenic Shock	1	0.8

(Continued)

Table 3 (Continued).

Variable	Response	Frequency (n = 122)	Percentage (%)
Intravenous Inotropes	Yes	11	9
Post-operative resuscitation within 24 hours of the procedure	Yes	2	1.6
Syncope	Yes	14	11.5

Abbreviation: NYHA, New York Heart Association.

surgery (42.6%) followed by mitral valve surgery (35.2%) [Table 4](#). The mean of the ejection fraction and creatinine level before the surgery were $48.80\% \pm 7.64\%$ and 0.81 ± 0.65 , respectively. Of the included patients, 3.3% died within 30 days of the surgery and 4.1% of them died within 2 years of it. The mean risk of mortality STS and Euroscore II were 1.8 ± 1.21 and 1.7 ± 1.71 , respectively [Table 5](#).

Table 4 Surgical Characteristics of Participants

Variable	Response	Frequency (n = 122)	Percentage (%)
Status of Surgery	Elective	122	100
Intra-aortic Balloon Pump	Yes	2	1.6
History of Cardiac Arrest	Yes	9	7.4
History of Myocardial Infarction	Yes	66	54.1
Operation	Mitral	43	35.2
	Aortic	52	42.6
	Tricuspid	1	0.9
	Mitral and Tricuspid	5	4.1
	Aortic and Tricuspid	5	4.1
	Mitral and Aortic	16	13.1
Valve Type	Mechanical:	70	57.4
	Mitral	45	36.9
	Aortic	25	20.5
	Tissue:	32	26.2
	Mitral	11	9
	Tricuspid	1	0.8
	Aortic	20	16.4
	Repair:	19	15.6
	Mitral	10	8.2
Tricuspid	9	7.4	
Minimally Invasive	Mitral	10	8.2
Sternotomy		112	91.8

(Continued)

Table 4 (Continued).

Variable	Response	Frequency (n = 122)	Percentage (%)
Mortality 30 days	Yes	4	3.3
	No	118	96.7
Mortality 2 years	Yes	5	4.1
	No	117	95.9

Table 5 Demographic Characteristics of Participants

Variable	Mean	SD	Range
Age (years)	54.46	14.89	19–80
Weight (kg)	78.23	13.75	45–115
Height (cm)	165.30	7.74	148–190
Hematocrit	29.53	13.31	7.07–52
WBC	8.27	2.95	3.51–30
Platelet Count	232.17	81.59	70.2–513
Level Creatinine	0.81	0.65	0.29–7.21
Ejection Fraction	48.80%	7.64%	20% - 60%
Risk of Mortality STS	1.8	1.21	0.37–7.34
Euro Score 2	1.7	1.71	0.5–13.04

Factors Associated with 30-Day Mortality and 2-Year Mortality

Regarding the factors associated with 30-day mortality, cancer within the last 5 years was significantly associated with 30-day mortality (P-value=0.012) as the patients who had cancer had significantly higher 30-day mortality rate than their counterparts. Furthermore, patients who had respiratory diseases and poor mobility and had significantly higher 30-day mortality rate (P-value=0.001, P-value<0.001). Patients who were on insulin therapy and Angiotensin Converting Enzyme Inhibitor/Angiotensin Receptor Blockers had significantly lower 30-day mortality rate (P-value=0.011, P-value=0.038). Patients who presented with cardiogenic shock or needed Intra-aortic Balloon Pump had significantly higher 30-day mortality (P-value<0.001, P-value=0.001). The analysis of the factors associated with 2-year mortality demonstrated that patients who had atrial flutter, third-degree heart block and second-degree heart block had significantly higher 2-year mortality (P-value<0.001). Patients on beta-blockers had significantly lower 2-year mortality rate than their counterparts (P-value=0.048). Additionally, higher age, platelet count and creatinine level were associated with significantly higher 2-year mortality. Additionally, lower ejection fraction was significantly associated with 2-year mortality (P-value=0.046). Moreover, there was no significant association between STS mortality score or Euroscore II with 30-day and 2-year mortality [Table 6](#).

Table 6 Factors Associated with Patients' Mortality

P-value		
Variable	30-Day Mortality	2-Year Mortality
Sex	0.886	0.212
Hypertension	0.886	0.491
Diabetes	0.185	0.134
Peripheral Arterial Disease	0.666	0.911
Cancer within the last 5 years	0.012*	0.933
Stroke	0.562	0.846
Heart Failure	0.469	0.587
Sleep Apnea	0.296	0.803
Dialysis	0.831	0.978
Liver Disease	0.666	0.911
Respiratory Diseases	0.001*	0.846
Pulmonary Hypertension	0.628	0.889
Triple Vessel Disease	0.762	0.955
LAD Stenosis	0.824	0.364
Aortic Stenosis	1.000	1.000
Mitral Stenosis	0.758	0.719
Aortic Insufficiency	0.522	0.919
Mitral Insufficiency	0.313	0.695
Tricuspid Insufficiency	0.481	0.828
AV Disease Etiology	0.084	0.201
Reoperation Status	0.628	0.889
Atrial Fibrillation	0.297	0.580
Atrial Flutter	0.762	0.001*
Third Degree Heart Block	0.831	0.000*
Second Degree Heart Block	0.831	0.000*
Sick Sinus	0.666	0.911
Poor Mobility	0.000*	0.978
Syncope	1.000	1.000
NYHA Classification	1.00	0.596
History of Endocarditis	0.710	0.933
Active Endocarditis	0.831	0.978
Alcohol Use	0.831	0.978

(Continued)

Table 6 (Continued).

P-value			
Variable		30-Day Mortality	2-Year Mortality
Tobacco Use		0.668	0.687
Previous Cardiac Interventions		0.321	0.272
Medications	Beta Blocker	0.586	0.048*
	Angiotensin Converting Enzyme Inhibitor/Angiotensin Receptor Blockers	0.011*	0.795
	Insulin	0.038*	0.911
	Steroids	0.666	0.911
Presentation	Myocardial Infarction/Angina	0.762	0.955
	Cardiogenic Shock	0.000*	0.978
Intravenous Inotropes		0.412	0.761
Resuscitation within 24 hours of the procedure		0.001*	0.955
Status of Surgery		0.831	0.978
Intra-aortic Balloon Pump		0.001*	0.995
Syncope		0.628	0.889
History of Cardiac Arrest		1.000	1.000
History of Myocardial Infarction		1.000	1.000
Operation		0.202	0.332
Valve Type		0.634	0.766
Age (years)		0.428	0.000*
Weight (kg)		0.762	0.929
Height (cm)		0.842	1.000
Hematocrit		0.954	0.689
WBC		0.260	0.190
Platelet Count		0.861	0.031*
Level Creatinine		0.358	0.002*
Ejection Fraction		1.000	0.046*
STS Mortality Score		0.370	0.773
Euro Score		0.163	0.553

Note: *Indicates statistically significant variables, with $p < 0.05$.

Discussion

Most of the world's population live in LMICs, with delayed and even limited access to cardiac surgery service contrary to the needs and availability for this service in high-income countries (HICs). Approximately one-third of people with CVD in LMICs will probably need surgery, but more than 90% of them have no access.^{1,13,14} Jordan is Classified as an upper-

middle income country, part of LMIC, by the World Bank. Only 55% of Jordan's population are insured through both public and private insurance.^{15,16} The total health expenditures are equivalent to 7.5% of the GDP,¹⁷ which is relatively high when compared to LMICs (5.8%) but still low compared to HIC (11.8%).^{1,18} This low GDP makes the relative cost of cardiac surgery in LMICs high in comparison with HIC, in spite of the low crude cost of these surgeries in LMICs.¹

Another problem that LMICs face is the availability of well-trained healthcare providers, and multi-discipline teams.⁷ A study of the adult cardiac surgeons registered in CTSNET records showed the presence of 11.12 surgeons per million people in North America, which constitute around 33% of total surgeons worldwide. In comparison, sub-Saharan Africa had 0.12 surgeons per million people (1.05% of total).¹ In this study, Jordan has 1.7 adult cardiac surgeons per million. The number of cardiac surgeons registered in the Jordanian Association of Cardiac Surgeons and living in Jordan, whether practicing or not, is 4 per million people, which is still low compared to LMICs.

In this low-volume center retrospective study conducted in an LMIC, the median age was 54.5 years, a lot younger than in developed countries, ranging from 64 years in Euro Heart Survey on Valvular Heart Disease¹⁹ and 68 in the German Valve registry.²⁰ However, it is similar to numbers from Jordan and other LMICs.^{21–23} This is explained by the younger population of Jordan where approximately 35% of the population is younger than 15 years, and only 3.7% is older than 65 years.¹⁵ This will probably change in the future as people above 60 will constitute around 16% of the population in 2050,²⁴ which will further increase the demands on cardiac surgery services.

We report a 30-day mortality rate of 3.3% and 2-year mortality rate of 4.1%. Most studies found in the literature are those of high-volume centers in HIC demonstrating excellent performance and lower mortality rates. On the other hand, higher mortality rates are usually reported in low-volume centers, including valve replacement.^{8,9} Usually, these represent high volume of single valve surgery, whereas when we look at the national registries or combined valves surgery, such as our cohort, we find comparable results.²⁵ The mortality rate in Germany varies from 3.6 for aortic valve replacement to 12.4 in aortic and mitral valve procedures.²⁶ Other studies reported 30-day postoperative mortality of 6.7% and equally distributed among the two cohorts²⁷ and an in-hospital mortality of 7.6% that is higher for female patients who had undergone concomitant CABG and for the elderly.²¹ Concomitant CABG significantly increases mortality.^{28,29}

Strong evidence exists correlating center's volume with outcome but the effect that individual surgeons experience rather than centers' total volume has on the output is controversial.³⁰ Other studies showed better outcomes were achieved in hospitals specializing in CABG independent of CABG volume or patients' characteristics.^{30,31} When in-hospital risk-standardized mortality rate (RSMR) was taken into consideration, there was only a weak association between volume and mortality rate. In addition, if volume is the only indicator of quality of care, it is possible to misclassify a large proportion of hospitals.³² Volume seems to be a logical metric that is simple to monitor and evaluate, which is why payers and legislators began financing volume minimums as a substitute for the quality of treatment delivered.³³ As small centers and hospitals are the primary service providers in rural and small communities, referral policies that are based on volume can give high-volume centers and hospitals a financial advantage while discouraging smaller ones from competing.³⁴ Most notably, employing volume as the only proxy may be less significant when completely collected and risk-adjusted results are readily accessible.^{35,36}

The etiology of VHD in our cohort is mixed between RHD, as in low-income countries, and degenerative and calcified valves, as in HIC. This is partly due to improvement of health care system as represented by the increase in life expectancy from mid-forties to mid-seventies, in association with westernization of lifestyle.^{24,37}

We performed 10 cases of minimally invasive mitral surgery and 7 cases of mitral valve repair, which is very low when compared with HIC. Valve repair and MIC are not routinely performed due to many reasons such as referral delay, absence of specialized centers and surgeons, lack of enough volume to maintain repair skills, difficulty in performing a conclusive intraoperative echocardiography, and the absence of universal public health insurance for Jordanians and non-Jordanians.

Studies show that valvular surgery, especially aortic valve replacement, is associated with postoperative cerebrovascular incidents that can reach up to 10% of patients and can have a significant effect on patients' survival and quality of life.^{38,39} In our study, only two patients (1.6%) developed stroke as a complication postoperatively, one of which was transient ischemic attack. This could be due to the younger mean age of our cohort.

Furthermore, bleeding is another post-operative complication that 5 patients (4.1%) in our study have suffered from. Bleeding is a serious complication of cardiac surgery that increases the rate of re-exploration, requirement of blood transfusion, length of hospital stay, morbidity, and mortality.⁴⁰ Subsequently, this re-exploration is associated with more complications, like renal impairment, wound infection, and postoperative arrhythmias.⁴¹ In our study, 4 patients (3.3%) have undergone reoperation for bleeding or cardiac tamponade which is similarly low to other studies.^{42,43} As for surgical site infection (SSI), another common complication, literature shows that it ranges from 3% to 10.4% and leads to prolonged hospitalization and increased morbidity and mortality.⁴⁴ Our results show that only one patient (0.8%) had SSI. Interestingly, 4 of our patients (3.3%) were readmitted post-op due to developing warfarin toxicity.

Lastly, some important predictors of outcome with 30-day have been studied. As expected, preoperative respiratory disease, poor mobility, cardiogenic shock, cancer within the last 5 years, and intraoperative intra-aortic balloon pump insertion were significant risk factors for 30-day mortality. Similarly, preoperative atrial flutter, post-operative second-degree and third-degree block, older age, higher platelet count and creatinine level, and decreased ejection fraction are associated with significantly higher 2-year mortality. Similar findings have also been reported in previous studies.⁴⁵

LMICs are currently facing problems similar to the ones that HICs have overcome.⁷ Hence, implementing current HIC standards on old problems may be unfair for LMICs. In conclusion, we think that performing heart valve surgery (HVS) in an LVC in LMICs is feasible without putting patients under increased risk, and LVC will continue to have a role in LMICs even during development from an LMIC to an HIC. Further global studies are needed to assert the safety of HVS in LVC especially in LMICs.^{45,46}

Limitations

This study is subject to a few limitations. It is a single-center study with a small sample size, which limits the national generalizability of our conclusion. Also, this is a retrospective study which led to the exclusion of some patients due to incomplete data.

Data Sharing Statement

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

Disclosure

The authors report no conflicts of interest in this work.

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