CLINICAL OUTCOME OF PROSTHETIC HEART VALVE REPLACEMENT : A RETROSPECTIVE STUDY AT TIKUR ANBESSA SPECIALIZED HOSPITAL & CARDIAC CENTER OF ETHIOPIA

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A Research manuscript submitted to the Department of Internal Medicine, Faculty of Medicine, Addis Ababa University as partial fulfillment of the requirement for a Fellowship program in Adult Cardiology.

March 06, 2024

Addis Ababa, Ethiopia

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The full title of the project:	Retrospective study of outcomes of prosthetic heart valve replacement in TASH and Cardiac center of Ethiopia
Duration of research	July 2023 –November 2023
Study areas	TASH and Cardiac center of Ethiopia, Addis Ababa, Ethiopia.
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DECLARATION

I, Samson Mulugeta , do hereby declare that this research proposal is a result of the works of my own except where due is made in a review of previous literature in the content and by my knowledge, has never been submitted for any prior academic award or qualification in this Institution.

Signed: _____Date: _____

Department of Internal Medicine Research and Ethics Committee

The undersigned have examined the proposal entitled "**Retrospective study of outcomes of prosthetic heart valve replacement in TASH and Cardiac center of Ethiopia**" presented by Dr. Samson Mulugeta , a candidate for the Fellowship Certificate in cardiology and hereby certify that it is worthy of acceptance

Signed: _____ Date: _____

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ACKNOWLEDGEMENT

I first would like to praise Almighty God, for his unspeakable gifts, help and mercy, next Addis Ababa University, College of Health Science, Department of Internal Medicine and Cardiology unit for giving me the chance to conduct this research. My heartfelt gratitude also goes to my advisors for their valuable comments and guidance. I would like to express my gratefulness to Dr.Dejuma Yadeta and Dr.Senbeta Guteta for their advice on research topic selection and comments

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ACRONYMS AND ABBREVIATIONS

AF - Atrial fibrillation

AVR - Aortic valve replacement

AVR-PVR - Both aortic and pulmonary valve replacement

AVR-TVR - Both and aortic and tricuspid valve replacement

BPV - Bioprosthetic valve

CVD – Cardiovascular disease

MHV-Mechanical heart valves

MVR - Mitral valve replacement

MVR-AVR - Both mitral and aortic valve replacement

MVR-TVR - Both mitral and tricuspid valve replacement

MVR-AVR-TVR - Mitral tricuspid and aortic valve replacement

MVP - Mitral valve repair

NYHA - New York Heart Association

LVOT - Left ventricle outflow tract

PVR - Pulmonary valve replacement

PPM - Prosthetic patient mismatch

PVT – Prosthetic valve thrombosis

PVE – Prosthetic valve endocarditis

POAF - Postoperative atrial fibrillation

RVHD - Rheumatic valvular heart disease

SAS - Severe aortic stenosis

SVD - Structural valve deterioration

TASH – Tikur Anbesa Specialized Hospital

TVR - Tricusid valve replacement

VKA - Vitamin K antagonist

VHD -Valvular heart disease

Abstract

Background. In patients with severe symptomatic valvular heart disease, guideline-based surgical valve replacement or transcatheter implantation of a prosthetic heart valve is associated with improved survival and relief of symptoms. Valve replacement is not a curative procedure but introduces a new disease process with prosthetic valve-related complications. Data regarding clinical outcomes of prosthetic valve replacement in Ethiopia is scarce.

Objective: To assess the outcomes of prosthetic heart valve surgery in TASH and Cardiac Center of Ethiopia, Addis Ababa, Ethiopia.

Method: A Retrospective cross-sectional study was done on all adult patients to whom prosthetic heart valve surgery was performed in Cardiac Center Ethiopia and TASH from December 2017 to December 2022. Data on the outcome of prosthetic heart valve surgery, socio-demographic characteristics, patient clinical presentation, prosthetic heart valve-related features, and patients' clinical characteristics were collected through a pretested questionnaire from patient medical records. Data were analyzed using statistical package for social science and descriptive statistics was used to calculate mean, median, range, frequency, and percentage

Result: Total of 167 adult patients with a mean age (±SD) of 33.45 ±11.95 years were included. And majority of the patient, 106 (63.5%) were females. Most of the patients had CRVHD, 156 (93.4%) followed by DVHD, 6 (3.6%). The overall mortality rate was 33 (19.8%), 27 (16.8%) died due to prosthesis valve-related complications, 5(3%) deaths occurred within 30 days of surgery and 1(0.6 %) died during the surgery. More than one third, 61(35. %) developed at least one prosthesis valve (PV) related complication, and (15.6%) developed in-hospital complications. 17(10.2%) were readmitted within 30 days of discharge.

Conclusion and recommendation: Postoperative mortality rate, prosthetic valve-related complication, and 30-day readmission rate were high among the study population. Good post-operative care, implementing infection prevention protocol and techniques, guidelines based follow up of patients with prosthetic valves and preventing prosthetic valve related complications could decrease death and the 30-day readmission rate.

1. INTRODUCTION

1.1 Background

Valvular heart disease (VHD) is one of the most important cardiovascular diseases and its prevalence varies with age; gender and different societies. Chronic rheumatic valvular heart disease (CRVHD) is the most prevalent VHD in developing countries such as Africa, Pacific Island countries, and Asia and its morbidity and mortality remain high, but it is still overlooked. In most developed countries, degenerative valvular heart disease (DVHD) is main prevalent type of VHD, and its related morbidity and mortality have been increasing in elderly patients over the past two decades.[1]

In patients with symptomatic valvular heart disease, guideline-based surgical valve replacement or transcatheter implantation of a prosthetic heart valve is associated with improved survival and relief of symptoms.

Prosthetic heart valve replacement is the second most common type of heart surgery after coronary artery bypass graft surgery. And prosthetic heart valves are two types, mechanical or bio-prosthetic (also called tissue) valves each with different advantages and disadvantages. [2]

Mechanical heart valves (MHVs) are either caged ball valves, tilting disc valves (mono leaflet valves), or bileaflet valves with various modifications on these designs. Caged ball valves are no longer implanted; bileaflet valves are the most common MHV type used today.[2]

Bio-prosthetic valves can be an autograft, homograft, or xenograft (porcine bovine or equine) based on the origin and stented or stentless based on the supporting structure. Porcine-stented prosthetic valves are the most common bio-prosthetic type used today.[3]

The choice between a mechanical and a biological valve in adults is mainly determined by estimating the risk of anticoagulation-related bleeding and thromboembolism/valve thrombosis with a mechanical valve versus the risk of Structural valve deterioration (SVD) with a bio-prosthesis, and by considering the patient's lifestyle, comorbidity and preferences.[3]

Valve replacement is not a curative procedure but introduces a new disease with prosthetic valve-related complications. SVD is a clinically important long-term complication of bio-prosthetic valves, causing stenosis, regurgitation or a combination of both, ultimately necessitating reintervention. Valve thrombosis, thromboembolic or bleeding complications, and pannus formation occur more frequently with mechanical valves. Mild to moderate paravalvular regurgitation is common in prosthetic valves and has no hemodynamic impact but severe paravalvular regurgitation can lead to heart failure or hemolytic anemia.

Prosthetic valve endocarditis carries a higher mortality and risk of post-treatment complications compared to native valve endocarditis.

A new class of sutureless bio-prostheses has the potential to simplify minimally invasive aortic valve replacement and reduce cross-clamp and cardiopulmonary bypass times. Compared with conventional surgical valves, sutureless valves have a larger effective orifice area which results in lower gradients and may improve left ventricular mass regression. However, higher rates of pacemaker implantation have been reported as compared to conventional bio-prosthesis.[3]

Homografts and pulmonary autografts, mainly used in the aortic position in adults, account for < 1% of aortic valve replaements (AVRs) in large databases. Homografts are subject to SVD, which occurs more rapidly in young patients. A randomized trial showed superior durability of stentless bio-prostheses over homografts. Technical concerns, limited availability, and increased complexity of reintervention restrict the use of homografts. Although debated, the main indication for homografts is acute infective endocarditis with perivalvular lesions.[4]

1.2. Statement of the problem

Valvular heart disease (VHD) is a major contributor to loss of physical function, quality of life, and longevity. The epidemiology of VHD varies substantially around the world, with a predominance of functional and degenerative disease in high-income countries, and a predominance of rheumatic heart disease in low-income and middle-income countries.

Valvular heart disease is a rapidly growing cause of global cardiovascular morbidity and mortality with diverse and evolving geographic distribution. The prevalence of rheumatic heart disease, the most common valvular heart disease, has been rising in developing nations. Rheumatic heart disease has also been rising among the impoverished and, often, indigenous populations of developed nations.

Reflecting this distribution, rheumatic heart disease remains by far the most common manifestation of VHD worldwide and the global RHD prevalence reached 40.5 million in 2019 with an annual mortality rate of 1.5%. By contrast, the prevalence of calcific aortic stenosis and degenerative mitral valve disease is 9 and 24 million people,

respectively. Despite a reduction in global mortality related to rheumatic heart disease since 1900, the death rate has remained fairly static since 2000.

In Africa alone, around 15 million patients are living with rheumatic heart disease of whom 100 000 per year might need a heart valve intervention at some stage of their life. The vast majority of these patients have no access to cardiac surgery or sophisticated cardiac imaging.[5]

A recent systematic review and meta-analysis of sixteen original research articles on the prevalence of rheumatic heart disease in Ethiopia showed that the prevalence of RHD was 49.04 % among all cases of heart disease from nine included studies and the prevalence of rheumatic heart disease in children and asymptomatic participants from seven study included was 2.70 or 27/1000.[6].

Retrospective study of a total of consecutive 457 cardiovascular deaths including cerebrovascular accidents in the medical wards of Tikur Anbassa Teaching Hospital (TAH) from January 1995 to December 2001, 26.5 % (121) were due to RHD. A review of available charts of 115 RHD patients showed that the overall mean age at the time of death was 25.89+/-11.05 years. [7]

Despite CRVHD being the most common CVD in Ethiopia and running a more aggressive course as indicated by death occurring at a much younger age than in even the pre-prophylaxis era in the Western world, heart valve surgery is not accessible to the neediest patients and few lucky patients operated by few local cardiac surgeons and foreign cardiac surgeons coming annually

Despite the marked improvements in prosthetic valve design and surgical procedures over the past decades, valve replacement does not provide a definitive cure to the patient. Instead, native valve disease is traded for “prosthetic valve disease,” and the outcome of patients undergoing valve replacement is affected by prosthetic valve hemodynamics, durability, and thrombogenicity. Moderate patient prosthesis mismatch(PPM) may be quite frequent in both the aortic (20% to 70%) and mitral (30% to 70%) positions, whereas the prevalence of severe PPM which may cause heart failure or hemolytic anemia ranges from 2% to 10% in both positions.[1]

Prosthetic valve endocarditis occurred in 3.7 % of 2443 patients who underwent valve replacements surgery at The Prince Charles Hospital between December 31, 1969, and January 1, 1992, based on a cross-sectional follow-up.[8]

Thrombosis of a prosthetic valve is one of the most severe and fatal complications of cardiac valve replacement. The incidence of prosthetic heart valve thrombosis (PHVT) is highest in first year of surgery and can be as high as 13% in any valve position and even 20% for mechanical prosthesis in the tricuspid position. At any time, for prosthesis in the mitral and/or aortic position, the overall incidence is 0.5% to 6% per patient-year, higher in the mitral position than aortic position.[9]

1.2 Justification of the study

Despite the high prevalence and fatality of chronic rheumatic valvular heart disease, accessibility of the neediest patients to prosthetic heart valve surgery and experience of heart valve surgery is limited in developing countries like Ethiopia. Thus understanding the clinical outcomes of heart valve replacement will help us tackle prosthetic valve-related problems and guide us to improve the practice and effectiveness of prosthetic heart valve replacement surgery and postoperative care of patients with prosthetic heart valves.

1.4 Significant of the study

As heart valve surgery was introduced very recently to Ethiopia, this study will be the first of its kind among public hospitals to provide evidence-based information on outcomes of heart valve replacement surgery, which will help as a springboard for further studying the prosthetic valve-related clinical outcomes at the country level. It may also strengthen the crucial role of good post-operative care, guideline based follow up of patients with prosthetic valves and prevention of prosthetic valve related complications in reducing operative mortality, and overall mortality rate among patient with prosthetic valve replacement. It may guide policymakers and other stakeholders on the supply of consumables of the valve surgery and expansion of the heart valve surgery centers.

2. LITERATURE REVIEW

Approximately 280,000 heart valve replacement surgeries are performed annually worldwide with a predicted increment to 850,000 per year by 2050. [10]

Approximately 90,000 in the United States and 50,000 in Europe prosthetic valve surgeries are performed annually. [11]

Despite the marked improvements in prosthetic valve design and surgical procedures over the past decades, valve replacement does not provide a definitive cure to the patient. Instead, native valve disease is traded for “prosthetic valve disease,” and the outcome of patients undergoing valve replacement is affected by prosthetic valve hemodynamics, durability, and thrombogenicity. Moderate patient prosthesis mismatch(PPM) may be quite frequent in both the aortic (20% to 70%) and mitral (30% to 70%) positions, whereas the prevalence of severe PPM which may cause heart failure or hemolytic anemia ranges from 2% to 10% in both positions.[1]

Prosthetic valve thrombosis (PVT) is a rare but serious complication of valve replacement, most often encountered with mechanical prostheses. The incidence of obstructive PVT for mechanical valves varies between 0.3–1.3% of patient-years. [12] Non-obstructive PVT is a relatively frequent finding in the postoperative period with a reported incidence as high as 10% in recent transoesophageal echocardiography (TOE) studies.[13]

Bio-prosthetic valve thrombosis is a rare occurrence when compared to mechanical prostheses and it is usually diagnosed in the early postoperative period (first three months), particularly for mitral prostheses when endothelialization of the suture zone is not yet complete.

Thromboembolic complications including systemic emboli are more frequent and occur at a rate of 0.7–6% patient-years. The risk of thromboembolic complications is similar for patients with mechanical valves on warfarin therapy and bio-prosthetic valves without warfarin therapy. [13]

Transcatheter heart valve thrombosis has also been reported, mainly during the first year following implantation and was successfully treated by prolonged anticoagulation in three-quarters of cases.[14]

In patients with mechanical valves and on long-term anticoagulation, the annual risk of a hemorrhagic event is ≈1% per patient-year.[1]

The rate of SVD in bio-prosthetic valves increases over time, particularly after the initial 7 to 8 years after implantation. With conventional stented bio-prostheses, the freedom from structural valve failure is 70% to 90% at 10 years and 50% to 80% at 15 years [1]

Hence, if the patient survives long enough, there is a mandatory risk of reoperation after SVD. Each subsequent reoperation entails operative risk much higher than the previous one.[3]

The endocarditis rates for most series are below 1% per year; the mechanical mitral valves seem to have rates that are about half that of the aortic position. Infection rates with biological valves are similar to those with mechanical aortic valves but approximately double that with mechanical mitral valves. [15]

The risk of prosthetic valve endocarditis (PVE) is highest in the first 3–6 months after prosthetic valve implantation but thereafter remains relatively constant

Prosthetic valve endocarditis is a lethal disease with mortality rates of 50% to 80% even with appropriate therapy

The mortality rate of heart valve replacement surgery was reported from 4.3% to 14% in the study of Shahian et al. 7 and O'Brien et al.[16]

A cross-sectional prospective study of 320 adult cases who underwent heart valve replacement at Rajaie Cardiovascular Medical and Research Center, Tehran, Iran, from June 2011 to January 2012 showed postoperative mortality of 7.8 %. [17]

The operative mortality increases with increasing number of valves replaced. Reported operative mortality is 3.4 % for isolated surgery. Triple valve surgery is usually complex and carries a reported operative mortality of 13% and 10-year survival of 61%.

Old randomized trials comparing mechanical and biological valves consistently found very close survival rates, no difference between the two groups in the probability of death from any cause and in the probability of any valve-related complication but higher rates of bleeding with mechanical prosthesis and higher rates of SVD and thus reinterventions with bio-prosthesis reported. And there was a greater frequency of paravalvular regurgitation in the mechanical mitral valve than bio-prosthetic mitral valve.[18]

A Systematic Review of four Randomized Controlled Trials showed mortality rate and the risk of thromboembolic events and endocarditis were similar between BPV and MPV patients. The risk of bleeding was approximately one-third lower for BPV patients than for MHP patients, while the risk of reoperations was more than three times higher for BPV patients.[19]

A study of 1533 patients who received primary aortic and/or mitral valve replacement, with or without tricuspid valve surgery or other associated cardiac procedures, at Birmingham School of Medicine and Medical Center, and the Birmingham Veterans Administration Hospital from January 1, 1975, to July 1, 1979, showed actual survival at 5 years of 74%. In-hospital mortality was 4.4% and 17.7% of the patients died later after discharge. [20]

In this study survival after reoperation was less than that after the primary operation; whether the reoperation was the first, second, or third was a risk factor.[20]

4.9% of patients in the above study underwent reoperations on the valves that had been replaced, 3.8 % developed PVE, and 2.0% developed periprosthetic leakage without evident infection. [20]

2.9% of 446 patients receiving a bio-prosthesis in the above study developed bio-prosthetic degeneration, and 1.8% of the 1084 patients receiving mechanical valve developed acute thrombotic occlusion (one patient with a bio-prosthesis developed this complication)[20]

After reoperations in the above article, the actuarial freedom from PVE and periprosthetic leakage was less than that after the original operation.[20]

In an analysis of 2,805 Swedish patients who underwent aortic valve replacement, mitral valve replacement and double (aortic plus mitral) valve replacement between 1969 and 1983, first-month postoperative mortality was 5.6 % and 25% of the patients died later during the follow-up period. The actuarial survival for all patients was 77%, 63%, and 48% at 5. 10, and 15 years after the operation respectively.[21]

In this analysis, the annual incidence of valve-related mortality for AVR MVR and DVR was 0.6 – 0.8 %, 1.1 – 1.5 %, and 1 – 1.6% respectively.[21]

In this study, the relative survival rate did not differ between patients undergoing mitral or double valve replacement, but in both patient groups, the rate was significantly ($p < 0.01$) lower than that for patients undergoing aortic valve replacement. The relative survival rate in patients with aortic regurgitation was significantly ($p < 0.001$) lower than in patients with aortic stenosis and represented a more than doubled mortality rate. [21]

In retrospective, population-based study including all isolated AVR (n = 7038) without a history of preoperative atrial fibrillation (AF) in Sweden 2007-2017 POAF (post-operative atrial fibrillation occurred in 44.5% of AVR patients. POAF was associated with increased long-term risk of death, ischemic stroke, any thromboembolism, heart failure hospitalization and recurrent AF.[22]

In double-center observational registry of 320 consecutive patients with symptomatic severe aortic stenosis (SAS) without other valve disease and/or coronary artery disease, syncope on exertion in patients with SAS did not recur after aortic valve intervention. Syncope at rest recurs in a high proportion of patients (38 % of patient having preoperation syncope at rest)and Only recurrence of syncope was associated with cardiovascular mortality.[23]

The Ethiopian local cardiac surgery four years' experience (from June 2017 to June 2021) at cardiac center of Ethiopia, Tazma cardiac center and Elozouir Cardiac Center showed a 30-day valve replacement surgery mortality rate of 4.7 %. All the deaths occurred for RHD etiology valve surgery and this made the 30-day mortality among RHD etiology valve surgery patients in this study 5.1 % (9 out of 177).[24] In this

study the operative mortality of valve surgery is almost the same as other African countries.

The Rwandan 10-year experience(from 2008 -2017) by missionaries showed 4.7% operative mortality of valve surgery [25]and the 35-year (from 1978 to 2013) cardiac surgery experience report from Cote d'Iviore showed 7 % operative mortality of rheumatic heart disease (RHD) valve replacement surgery.

3. OBJECTIVE

3.1 Aim statement

Our study aims to assess the outcomes of prosthetic heart valve surgery in Tikur Anbessa specialized hospital (TASH) and Cardiac Center of Ethiopia (CCE)

3.2 General Objective

The General objective of this study was to evaluate the outcome of prosthetic heart valve surgery in the TASH and CCE

3.3 Specific objectives

- To assess perioperative and postoperative mortality rates of prosthetic valve surgery
- To determine prosthetic heart valve-related complications rate
- To assess any difference in prosthetic heart valve-related complications and mortality rate with types of prosthetic valves or site of prosthetic valve replacement.

4. Methods and Materials

4.1 Study design

A retrospective cross-sectional study design used to assess the outcome of prosthetic heart valve surgery

4.2 Study area and period

The study was conducted at the Cardiac Center of Ethiopia and Tikur Anbessa Specialized Hospital from August 2023 to November 2023.

Tikur Anbessa Specialized Hospital is one of the oldest and largest university hospitals located in the capital city of Ethiopia, Addis Ababa and it has a well-equipped Catheterization laboratory, Operation Theater, and Cardiac care unit. The cardiac

center of Ethiopia is the largest and oldest cardiac center in Ethiopia dedicated to cardiac interventions and heart surgery and it has a well-equipped Catheterization laboratory, Operation Theater, and Cardiac care unit

4.3 Population

4.3.1 Source population

Adult patients were seen in Cardiac Center Ethiopia and Tikur Anbessa Specialized Hospital from December 2017 to December 2022.

4.3.2 Study population

All adult patients to whom prosthetic heart valve surgery were performed in Cardiac Center Ethiopia and TASH from December 2017 to December 2022.

4.4 Eligibility criteria

4.4.1 Inclusion criteria

Any adult patients, age ≥ 18-year-old to whom prosthetic heart valve surgery was done in Cardiac Center Ethiopia and Tikur Anbessa Specialized Hospital.

4.4.2 Exclusion criteria

Patient without prosthetic heart valve

Patients who underwent prosthetic heart valve surgery outside study sites

4.5 Sample size determination and Sampling technique

The sample size was determined by using the single population proportion formula.

n= (Z α/2) 2 p (1-p)/ d2

Where: -

- o n = is the calculated sample size
- o Z = Confidence interval [95%]
- o p = event rate of 14% from previous study [16]
- o d2 = marginal error [5%]

n = ((1.96) 2 x 0.31 [1-0.14])/(0.05)2 = 186

All patient who underwent prosthetic valve replacement surgery in the study sites from December 2017 to December 2022 were included.

4.6 Study variables

4.6.1 Dependent variable

Outcome of prosthetic heart valve surgery

4.6.2 Independent variables

- **Socio-demographic variables**

  Age, sex, body weight, address, marital status and occupation

- **Patient clinical presentation related data**

  Duration of VHD before the surgery, symptomatic improvement after the surgery, LVEF (Left ventricular ejection fraction) before and after the intervention, NYHA (New York heart association) class before and after the surgery, and new-onset postoperative atrial fibrillation

- **Prosthetic heart valve related data**

  Indication for the intervention, type of prosthetic heart valves used (bio-prosthetic vs mechanical valves), name of prosthetic valve used and location of prosthetic heart valve implanted

- **Clinical characteristics of the patient**

  Comorbidities

4.7 Operational Definition

The outcome of prosthetic heart valve surgery was assessed in terms of perioperative and postoperative mortality and prosthetic heart-related complications including valve thrombosis, thromboembolism, bleeding complications, prosthetic valve endocarditis, structural valve degeneration, prosthesis patient mismatch, severe paravalvular regurgitation

Prosthetic heart surgery is prosthetic heart valve replacement either mechanical or bio-prosthetic valve with or without tricuspid valve repair and ring annuloplasty.

4.8 Data collection techniques

The questionnaire was prepared by the principal investigator, pretested, and was filled out by a trained data collector. Data on all variables were collected through chart abstraction by trained data collectors using the questionnaire. Demographic characteristics (age and sex), symptomatic improvement after the surgery, NYHA class and left ventricular ejection fraction before and after the surgery, indication for prosthetic valve surgery, area of PV implantation, type of prosthetic valves, presence of comorbid conditions and prosthetic valve-related complications within study period were collected.

4.9 Data quality and management

To ensure the quality of the data, pre-test data were collected on 5% of the sample size population from patients' medical records retrospectively in Tikur Anbessa Hospital, Addis Ababa University and training was given to data collectors in Addis Ababa for one day before the survey to ensure consistency and reduce intra and inter observation difference on the measurement of variables. The collected data were checked for completeness and consistency on each day of data collection. Supervision and monitoring was made every day by the assigned supervisors and principal investigators.

4.10 Data processing and analysis

After data collection, data were double-entered in Epidata software v4.6.0.2 and was exported to statistical package for social science for analysis using descriptive statistics. Continuous variables were expressed as mean (SD) or median (IQR) and categorical variables were described in percentage or frequency.

4.11 Ethical consideration

Ethical clearance was obtained from the AAU CHS Institutional Review Board. The safety and privacy of subjects was protected by using their identification numbers in the data collection and analysis process.

4.12 Dissemination and Utilization of Results

The result will be submitted to the Department of Internal Medicine, Faculty of Medicine as a baseline study for future prospective research and will be published online.

5. Results

5.1 Pre-operative demographic and clinical characteristics

Total of 167 adult VHD patients were included in the study, 118 (70.7%) from Ethiopia Cardiac Center and the rest 49 (29.3%) from TASH. The mean age (SD±) was 33.45 ±11.95 years and two third of the study population were females .106 (63.5%). The youngest and oldest patients in the study were 18 and 81 years old respectively. Almost half of the patients, 80 (47.9 %), lived outside of Addis Ababa, the majority of them, 38 (22.7 %), coming from Oromia region, followed by Amhara region, 32 (19.2%), and the rest, 10 (6%), from other parts of the country. More than three-forth, 137(82%) study population had a body mass index less than 18.5 kg/m2 before the operation. (See Table 1)

Table 1: Demographic clinical characteristics of the study population

Variables	**Frequency**	**Percentage**
Age groups		
18 -29	42	25.1
30-39	20	12.0
40-49	8	4.8
>50	97	58.1
Marital status		
Single	65	38.9
Ever Married	102	61.1
Residence		
Addis Ababa	87	52.1
Out-Addis Ababa	80	47.9
Occupations		
Governmental employee	31	18.6
Private employee	26	15.6
Student	51	30.5
Housewife	53	31.7
Farmer	6	3.6
Body Mass Index (BMI)		
<18.5	137	82.0
18.5-24.9	24	14.4
25-29.99	5	3.0
>30	1	0.6

5.2 Preoperative clinical presentation

More than half of study population, 110 (65.9 %) had either class III or IV NYHA heart failure symptoms. Almost all, 162(97%) of the study population had a pre-operative left ventricular ejection fraction greater than 50% and half of the study population 89 (53.3%) had severe pulmonary hypertension. Atrial fibrillation was documented in nearly one-third of the study population, 46(27.5%). Four (1.2%) patients had comorbidity with two diabetes and the remaining two hypertension.

Table 2: Pre-operative clinical characteristics of study population

Variables	Frequency	Percentage
Preoperative NYHA class		
Class -II	57	34.1
Class -III	100	59.9
Class-IV	10	6.0
Preoperative Arrhythmia		
Atrial fibrillation	46	27.5
No atrial fibrillation	121	72.5
Ejection fraction (%)		
≤ 40	4	2.4
41-49	1	0.6
≥50	162	97.0
Systolic pulmonary arterial pressure		
< 35 mmHg	2	1.2
35-50 mmHg	40	24.0
50-70 mmHg	36	21.5
≥70 mmHg	89	53.3
Preop medications		
Digitalis	55	32.9
Beta-blockers	119	71.3
Diuretics	153	91.6
ACEI	34	20.4
BPG	107	64.1
Anticoagulant	46	27.5

5.3 Type of VHD and valvular lesions

Most of the study population had chronic rheumatic valvular heart disease (CRVHD), 156 (93.4%), followed by degenerative valvular heart disease (DVHD), 6 (3.6%), Bicuspid Aortic Valve (BAV), 3 (1.8%), 1 (0.6%) had mitral valve prolapse and 1 (0.6%) infective endocarditis.

Mitral valve lesion was the most common valve lesion, 152 (91.0 %), among study population, and isolated mitral regurgitation (MR) in 4(2.5%) of the population but no isolated mitral stenosis (MS) was found. Aortic valve was affected in 94 (56.3 %) and two had isolated aortic stenosis (AS) and only one patient had isolated AR. Nearly two third of the study population, 120 (71.9) had both mitral and tricuspid lesion. Tricuspid and pulmonic valve lesions were found in 121(72.5%) and 9(5.4%) of the study population respectively. Combined mitral and aortic valves lesion was seen in 80 (47.9%) and three valve lesions (mitral, aortic, and tricuspid) were found in 58(34.7%) (See Table 3)

Table 3: **Type of valvular lesion among study population**

Valves lesion	Frequency	Percentage
Mitral Valve lesion (n=152)		
Isolated MR	4	2.4
Combined MS and MR	98	58.7
Aortic valve lesion (n=94)		
Isolated AS	2	1.2
Combines AS and AR	26	15.6
One valve		
Mitral valve only	9	5.4
Aortic valve only	13	7.8
Two valves		
Mitral and aortic valve	80	47.9
Mitral and tricuspid	120	71.9
Three valves		
Aortic, mitral, and tricuspid	58	34.7

5.4 Type of heart valve surgery and prosthetic valves

The mean(±SD) duration of valvular heart disease before valve surgery was 11.98 ± 7.1 yeas with a range from 1 to 23 years. Mitral valve surgery was done in 134 (80.2%) of the study population and among these, mitral valve replacement and mitral valve repair were performed in 130 (97%) and 4 (3%) respectively. Mitral valves were replaced with mechanical valves, 118 (88%) and bioprosthetic valves, 12 (9%) and mitral valve rings were placed in 4 (2.9 %) of patients with mitral valve surgery. Aortic valves were replaced in 54 (32.3 %) of the study participants with mechanical valve,46 (85.2 %) and bioprosthetic valve 8 (14.8 %).Tricuspid surgery was performed in 44 (26.3 %) of study participants and among these annuloplasty without ring placement in 32 (72.7), annuloplasty with ring placemen in 9 (20.5) and bioprosthetic valve replacement in 3 (6.8%). Only two surgeries were done on the pulmonic valve, one was a mechanical prosthesis and other ring prosthesis. (See Table 4)

Table 4: Type of heart valve surgery done among study population

Variables	Frequency	Percentage
Location and type of valve surgery done		
Mitral valve (n=134)	**134**	**80.2**
Mitral valve replacement	130	97
Mitral valve repair	4	3
Aortic valve (n=54)	**54**	**32.3**
Aortic valve replacement	54	100
Tricuspid valve (n=44)	**44**	**26.3**
Annuloplasty without ring placement	32	72.7
Annuloplasty with ring placement	9	20.5
Replacement	3	6.8
Type of prosthesis		
Mitral (n=134)		
Mechanical valve replacement	118	88.0
Bioprosthetic valve replacement	12	9.0
Ring placement	4	3.0
Aortic (n=54)		
Mechanical valve replacement	46	85.2
Bioprosthetic valve replacement	8	14.8
Tricuspid (n= 12)		
Ring placement	9	75

Bioprosthetic valve replacement	3	25

5.5 Outcome of prosthetic valve replacement

The overall average hospital stay was 25.5(±12.7) days, ranging from 1 to 45 days. Surgery was performed on average 50 hours (2.5 days) after admission, with two-thirds (61.1%) undergoing surgery within 24 hours of admission.

The overall mortality rate for patients undergoing heart valve surgery was 33 (19.8%). Among these, 27 (16.8%) were due to prosthesis valve-related complications, 5(3%) deaths occurred within 30 days of surgery and only one death (0.6 %) occurred intraoperatively. The major specific cause of death was cardiac,21(63.3%) (see table 6). Approximately one-third (28.2%) of the deaths occurred within two years after surgery, and the average hospital stay for patients who died after surgery was three weeks (22.2 days). Among postoperative deaths; 20 (62.5%) had mitral valve replacement (MVR) , 18 (90%) mechanical and 2 (10%) bioprosthetic valves,.4(12.5 %) had aortic valve replacement (AVR), 3 (75%) mechanical and 1 (25%) bioprosthetic valves and 8 (25 %) had both aortic and mitral valve replacement (DVR) , all mechanical valves (See Table 7)

More than one-third, 61(36.5 %) developed at least one prosthesis valve (PV) related complication. The most common PV-related complication was obstructive prosthetic valve thrombosis, 25(41.0%) followed by bleeding, 13(21.3%). Twenty-six (15.6%) developed in-hospital complications with 11(42.3%) having complete heart block. Within 30 days of discharge, 17(10.2%) were readmitted and 10(58.8%) were readmitted due to massive pericardial effusion.

The heart failure symptoms were improving after valve surgery in almost all the patient. More than two-thirds (68.3%) of post-surgery patients had NYHA class-I and about one-third (26.9%) had NYHA class-II. However, before surgery, all patients had NYHA class II and above heart failure symptoms. The NYHA class before and after surgery is presented in Figure 1.

Table 5: Clinical outcome of prosthetic valve replacement of study population

Variables	Frequency	Percentage
Prosthetic valve-related complication (n=61)	**61**	**36.5**
Obstructive prosthetic valve thrombosis	25	41.0
Bleeding	13	21.3
PV related Left ventricular systolic function	9	14.8
Infective endocarditis	6	9.8
Paravalvular regurgitation	3	4.9
Structural valvular deterioration	2	3.3
New onset AF	1	1.6
Systemic embolization	2	3.3
In-Hospital complication	**26**	**15.6**
Complete Heart block	11	42.3
Pneumonia	9	34.6
Re-operative	3	11.5
Surgical site infection	2	7.7
Stroke	1	3.8
Hospital-readmission within 30 days	**17**	**10.2**
Massive pericardial effusion	10	58.8
Infection	4	23.5
Others*	3	17.6
Cause of death		
Cardiac-related	21	63.6
Neurological related	6	18.2
Infection-related	6	18.2
Postoperative Hospital stay		
1-9 days	47	28.1
≥10days	120	71.9

*1, HF, 1, over coagulation and 1, valve dysfunction

Table 6 Mortality rate of the study population

Mortality	Frequency	Percentage
Overall mortality	33	19.8
Intraoperative mortality	1	0.6
Postoperative mortality	32	19.2
First month postoperative mortality	5	3.0

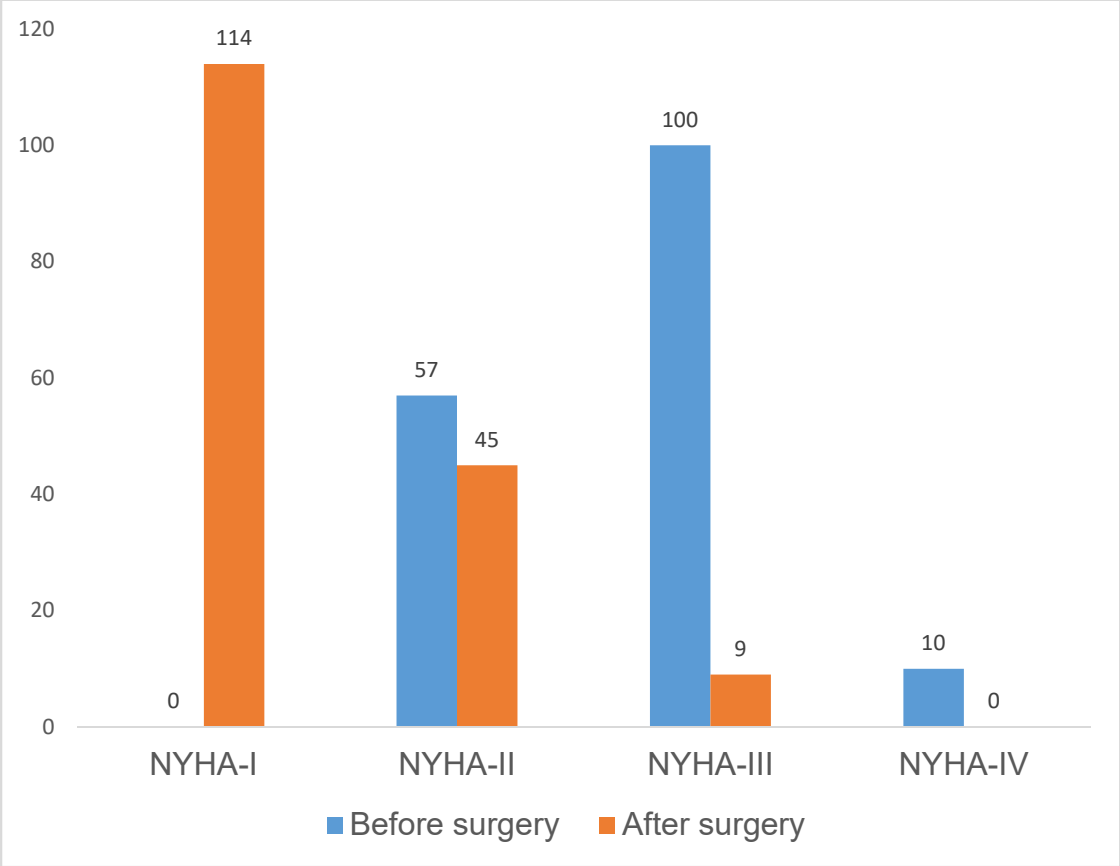
Table 7 ; Types of valvular surgery and prosthetic valves among postoperative death

Variables	Frequency	Percentage (%)
MVR only (n = 20)	**20**	**62.5**
Mechanical valve	18	90.0
Bioprosthetic valve	2	10.0
AVR only (n = 4)	**4**	**12.5**
Mechanical valve	3	75.0
Bioprosthetic valve	1	25.0
MVR and AVR (n=8)	**8**	**25.0**
Mechanical valve	8	100
Bioprosthetic valve	0	0

Table 8 Postoperative Mortality and types of heart valve surgery

Variable	Frequency	Percentage
MVR only (n=107)		
Death	20	18.7
Alive	87	81.3
AVR only (n= 31)		
Death	4	12.9
Alive	27	87.1
AVR and MVR (n= 24)		
Death	8	33.3
Alive	16	66.4

Figure 1: The NYHA class heart failure symptoms before and after surgery among study population



6. Discussion

The study assessed the clinical outcome of adult patients underwent prosthetic heart valve replacement surgery over five years in Tikur Anbessa Specialized Hospital and Cardiac Center of Ethiopia. During the study period, 165 patients underwent valve surgery and the majority of the participant had chronic rheumatic valvular heart disease. Prosthesis valve (PV) related complications occurred in 36.5 % of study participants,15.6 % had in hospital complication, and 10.2% were readmitted within 30 days of discharge, The overall mortality was 19.8% with intraoperative, 30 days after discharge and postoperative mortality rate of 0.6%, 3 % and 19.2 % respectively.

One third of the study population developed prosthetic valve-related complication, prosthetic valve obstruction and bleeding being the most common complications and followed by prosthetic valve related left ventricular systolic function and infective endocarditis.

Prosthetic valve thrombosis and bleeding complication accounts for 62 % of prosthetic valve related complications in this study. This is higher than the one reported from review of articles published since 1979 indicating that thrombotic and bleeding complications account for about 50% of valve-related complications in patients with aortic and mitral prosthetic valves.[23] 15% of the study population over 5 years of period developed obstructive prosthetic valve thrombosis (PVT). In most studies the incidence of obstructive PVT for prosthetic valves varies between 0.3–1.3% of patient-years. [12] So the incidence of obstructive prosthetic valvular thrombosis in this study is more than the expected rate. Bleeding events occurred in 7.7 % of the participants, higher that the annual risk of a hemorrhagic event in patients with mechanical valves a ≈1% per patient-year. [1]

Prosthetic valve related left ventricular systolic dysfunction occurred in 5.4 % of the study population. Because of the very limited access to valve surgery in our country most of the patient have valve surgery at late stage of valve disease. In this study the average duration of valvular disease before the surgery was 12 years and most of the patient had NYHA class III or IV heart failure symptoms. Patient with advanced valvular heart disease even though they have normal left ventricular ejection fraction they may not have myocardial reserve and at risk to develop post-surgery left ventricular systolic dysfunction. This may explain the higher prosthetic valve related left ventricular systolic dysfunction in this study.

3.6 % of the study participants developed prosthetic valve infective endocarditis (PVE). This finding is comparable to PVE rate in other studies. The review including 26 580 patients underwent bioprosthetic and mechanical valves surgery, 3.5% were hospitalized for infective endocarditis during a mean follow-up of 6.2 years.[23] Prosthetic valve endocarditis occurred in 3.7 % of 2443 patients who underwent valve replacements surgery at The Prince Charles Hospital between December 31, 1969, and January 1, 1992, based on a cross-sectional follow-up.[8]

15.6% of patients developed in-hospital complications, complete heart block and pneumonia were the most complications occurring 6.7 % and 5.4 % of study participants. Similarly another study conducted to determine an immediate outcome following valve surgery for rheumatic heart disease in Ethiopia revealed that 16.7% of patients developed in hospital complication [26]. Other studies conducted elsewhere showed that about 3 to 6 % of patients undergoing surgical replacement of aortic valve developed complete heart block (CHB)[27] and up to 15.08% of patients undergoing open surgery developed pulmonary complications during the postoperative period [28].

10.2% of them were readmitted within 30 days of the discharge and the majority were readmitted due to massive pericardial effusion. In a previously conducted study in Ethiopia the magnitude of 30-day readmission who underwent cardiac surgery was 8.0% and the major cause of readmission was pericardial effusion [29].

Intraoperative mortality rate in this study was 0.6 %. This is lower than reported operative mortality of 3.4 % for isolated valve surgery and 13 % for triple valve surgery. And postoperative mortality in this study was 19.2% . This is higher when compared to postoperative mortality of most prosthetic valve studies. The mortality rate of heart valve replacement surgery was reported from 4.3% to 14% in the study of Shahian et al. 7 and O'Brien et al.[16] A cross-sectional prospective study of 320 adult cases who underwent heart valve replacement at Rajaie Cardiovascular Medical and Research Center, Tehran, Iran, from June 2011 to January 2012 showed postoperative mortality of 7.8 %. [17] A study of 1533 patients who received primary aortic and/or mitral valve replacement, with or without tricuspid valve surgery or other associated cardiac procedures, at Birmingham School of Medicine and Medical Center, and the Birmingham Veterans Administration Hospital from January 1, 1975, to July 1, 1979, showed in-hospital mortality was 4.4% and 17.7% of the patients died later after discharge. [20] In an analysis of 2,805 Swedish patients who underwent aortic valve replacement, mitral valve replacement and double (aortic plus mitral) valve replacement between 1969 and 1983, first-month postoperative mortality was 5.6 % and 25% of the patients died later during the follow-up period, higher than in our study (first month postoperative mortality and mortality after first month of surgery 3 % and 16.2 % respectively).

7. Limitations of the study

The study tried to assess the patient's clinical outcome of prosthetic valve replacement patients using compressive and detailed information. Their study also includes five years of data from two referral centers. The study has the following limitations. It did not address well long-term outcomes of patients undergoing surgery in the last 02 years of the study period. The study was retrospective and some important variables such as detailed echocardiographic finding and pregnancy not collected.

8. Conclusion and recommendation

Chronic rheumatoid valvular heart disease was the most common indication for prosthetic valve replacement surgery. The average duration of valvular disease before the surgery was 12 years,and most of the patient had NYHA class III and IV heart failure symptoms before surgery. This showed that most of the patient had valve surgery at late

stage of valve disease which could have affected the clinical outcome of valve surgery. Postoperative mortality surgery, prosthetic valve-related complications particularly obstructive PVT and 30-day readmission were high among the study population. Therefore, we suggest to have guidelines based follow up of patients with prosthetic valves, improving postoperative care and implementing infection prevention protocol. The policymakers and health planners should develop strategy to establish additional heart valve surgery centers and to have adequate and sustainable supply of resources for heart valve surgery.

Reference

1. Prosthetic Heart Valves | Circulation. Accessed August 21, 2023. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.108.778886

2. Choice of Prosthetic Heart Valve in Adults: An Update | Journal of the American College of Cardiology. Accessed August 13, 2023. https://www.jacc.org/doi/abs/10.1016/j.jacc.2009.10.085

3. Choice of Prosthetic Heart Valve in Adults: An Update | Journal of the American College of Cardiology. Accessed August 13, 2023. https://www.jacc.org/doi/abs/10.1016/j.jacc.2009.10.085

4. Iung B, Sjögren J. Prosthetic valves. In: Baumgartner H, Camm AJ, Lüscher TF, Maurer G, Serruys PW, eds. *The ESC Textbook of Cardiovascular Medicine*. Oxford University Press; 2018:0. doi:10.1093/med/9780198784906.003.0772

5. Novel heart valve replacement offers hope for thousands with rheumatic heart disease. Accessed August 10, 2023. https://www.escardio.org/The-ESC/Press-Office/Press-releases/novel-heart-valve-replacement-offers-hope-for-thousands-with-rheumatic-heart-disease, https://www.escardio.org/The-ESC/Press-Office/Press-releases/novel-heart-valve-replacement-offers-hope-for-thousands-with-rheumatic-heart-disease

6. Asfaw T. Prevalence of rheumatic heart disease in Ethiopia: A systematic review and meta-analysis. *SAGE Open Med*. 2023;11:20503121231169388. doi:10.1177/20503121231169389

7. Oli K, Asmera J. Rheumatic heart disease in Ethiopia: could it be more malignant. *Ethiop Med J*. 2004;42(1):1-8.

8. Agnihotri AK, McGiffin DC, Galbraith AJ, O'Brien MF. The prevalence of infective endocarditis after aortic valve replacement. *The Journal of Thoracic and Cardiovascular Surgery*. 1995;110(6):1708-1724. doi:10.1016/S0022-5223(95)70035-8

9. Cáceres-Lóriga FM, Pérez-López H, Santos-Gracia J, Morlans-Hernandez K. Prosthetic heart valve thrombosis: Pathogenesis, diagnosis and management. *International Journal of Cardiology*. 2006;110(1):1-6. doi:10.1016/j.ijcard.2005.06.051

10. Nath SS, Parashar S. Perioperative Management of Patients with Prosthetic Heart Valves-A Narrative Review. *Ann Card Anaesth*. 2022;25(3):254-263. doi:10.4103/aca.aca_109_21

11. Butchart: Recommendations for the management of patients... - Google Scholar. Accessed August 14, 2023.

https://scholar.google.com/scholar_lookup?title=Recommendations%20for%20the%20management%20of%20patients%20after%20heart%20valve%20surgery.&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&publication_year=2005&journal=Eur%20Heart%20J&volume=&pages=

12. Horstkotte D, Burckhardt D. Prosthetic valve thrombosis. *J Heart Valve Dis*. 1995;4(2):141-153.

13. Choice of prosthetic heart valves: 20-year results of the Edinburgh Heart Valve Trial - Reply. Accessed August 13, 2023. https://www.researchgate.net/publication/278012333_Choice_of_prosthetic_heart_valves_20-year_results_of_the_Edinburgh_Heart_Valve_Trial_-_Reply

14. Mylotte: Transcatheter heart valve failure: a systematic... - Google Scholar. Accessed August 14, 2023. https://scholar.google.com/scholar_lookup?title=Transcatheter%20heart%20valve%20failure%3A%20a%20systematic%20review.&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&author=%20&publication_year=2015&journal=Eur%20Heart%20J&volume=&pages=

15. Grunkemeier GL, Li HH, Naftel DC, Starr A, Rahimtoola SH. Long-term performance of heart valve prostheses. *Current Problems in Cardiology*. 2000;25(2):78-154. doi:10.1053/cd.2000.v25.a103682

16. O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 2—Isolated Valve Surgery. *The Annals of Thoracic Surgery*. 2009;88(1, Supplement):S23-S42. doi:10.1016/j.athoracsur.2009.05.056

17. Chiang YP, Chikwe J, Moskowitz AJ, Itagaki S, Adams DH, Egorova NN. Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years. *JAMA*. 2014;312(13):1323-1329. doi:10.1001/jama.2014.12679

18. Hammermeister KE, Sethi GK, Henderson WG, Oprian C, Kim T, Rahimtoola S. A Comparison of Outcomes in Men 11 Years after Heart-Valve Replacement with a Mechanical Valve or Bioprosthesis. *New England Journal of Medicine*. 1993;328(18):1289-1296. doi:10.1056/NEJM199305063281801

19. Kiyose AT, Suzumura EA, Laranjeira L, et al. Comparison of Biological and Mechanical Prostheses for Heart Valve Surgery: A Systematic Review of Randomized Controlled Trials. *Arq Bras Cardiol*. 2019;112:292-301. doi:10.5935/abc.20180272

20. Blackstone EH, Kirklin JW. Death and other time-related events after valve replacement. *Circulation*. 1985;72(4):753-767. doi:10.1161/01.cir.72.4.753

21. Lindblom D, Lindblom U, Qvist J, Lundström H. Long-Term relative survival rates after heart valve replacement. *Journal of the American College of Cardiology*. 1990;15(3):566-573. doi:10.1016/0735-1097(90)90627-2

22. Rezk M, Taha A, Nielsen SJ, et al. Associations between new-onset postoperative atrial fibrillation and long-term outcome in patients undergoing surgical aortic valve replacement. *Eur J Cardiothorac Surg*. 2023;63(5):ezad103. doi:10.1093/ejcts/ezad103

23. Román JAS, Ybarra-Falcón C, García-Gómez M, et al. Recurrence of syncope after valve replacement in severe aortic stenosis. *Heart*. Published online June 6, 2023. doi:10.1136/heartjnl-2023-322859

24. Agwar FD, Tekleab AM. Heart surgery by the locals in resource-limited settings: The experience from Ethiopia. *JTCVS Open*. 2022;9:98-105. doi:10.1016/j.xjon.2022.01.004

25. Swain JD, Sinnott C, Breakey S, et al. Ten-year clinical experience of humanitarian cardiothoracic surgery in Rwanda: Building a platform for ultimate sustainability in a resource-limited setting. *The Journal of Thoracic and Cardiovascular Surgery*. 2018;155(6):2541-2550. doi:10.1016/j.jtcvs.2017.11.106

Annex I :Questionnaire

1- Sociodemographic data

MRN _____

Age in years _____

Marital Status _____

Occupation_____

Sex Male _____ Female _____

Address Addis Ababa_____

Outside Addis Ababa _____ Specify _____

2. **Pre-Operative Cardiac Status**

Heart failure Yes _____ NYHA I ____ II _____ III _____ IV _____

No _____

Arrhythmia Yes ___Type: (Sust VT/VF) ___(Heart Block)____ (AFib/Flutter)____

No _____

Echocardiographic study **:** Left ventricular function (LVEF)_____, Systolic Pulmonary artery pressure_____ ,Left Atrial size_____, LV chamber dimensions(diastole /systole_____/_____)

Pre-Operative Hemodynamics or Type of valve disease:

AS: No Yes? If yes, Gradient: _____, **AR**: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	**MS**: No Yes , **MR**: 0=None 1=Trivia l 2=Mild 3= Moderate 4= Severe
TS: No Yes ,	**PS**: No Yes ,

TR: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	**PR**: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe

Pre-Operative Medications

Digitalis: No____ Yes ____ Beta Blockers: No___ Yes __ Anticoagulants: No__ Yes__	Steroids: No___ Yes ___ Aspirin: No___ Yes___ Ace Inhibitors: No__ Yes_	Diuretics: No Yes

3. Operative information

a. Status of the procedure: Emergent ___urgent____ Elective_____

b. Indication for the intervention _____

c. Location and type of Valve surgery:

Aortic:	**Mitral:**	**Tricuspid:**	**Pulmonic:**
A. No	A. No	A. No ,	A. No
B. Replacement	B. Annuloplasty only	B. Annuloplasty Only	B. Replacemer
C. Repair/Reconstruction	C. Replacement	C. Replacement	C. Reconstruc
D. Root Reconstruction Valve Conduit	D. Reconstruction w/ Annuloplasty	D. Reconstruction w/ Annuloplasty	

4. Hospitalization

Hospital name BLH _____ CCE_____

Date of Admission for surgery _____

Date of surgery _____

Date of Discharge _____+

5. Type and size of prosthesis

Valve Surgery : ↓ Key M = Mechanical, B = Bioprosthesis, H = Homograft, A = Autograft, R = Ring	
A. Aortic Prosthesis - Implant Type: None M B H A R	Implant Size: _____(mm)
B. Mitral Prosthesis - Implant Type: None M B H A R	Implant Size: _____(mm)
C. Tricuspid Prosthesis - Implant Type: None M B H A R	Implant Size: _____(mm)
D. Pulmonic Prosthesis - Implant Type: None M B H A R	Implant Size: _____(mm)

6. PV related complication

No_____

Yes _____If yes specify , time of occurrence _____ and type of complication:

i. Paravalvular regurgitation____ Severity _____progressive _____

ii. Valve obstruction: thrombus /pannus formation_____, If yes, INR at the time of diagnosis_____ Outcome of Treatment _____

iii. Systemic embolization _____if yes specify, type (cerebrovascular events / PAD/CA), and Source (valve thrombosis , vegetations, or left atrial thrombus), and added risk factor (pregnancy, surgical procedures, Presence of AF)

iv. Bleeding ____ if yes specify degree and site _____

v. Infective endocarditis _____,if yes, risk factors identified _____antibiotic prophylaxis regimen _____

vi. Left ventricular systolic dysfunction with or without heart failure_____if present specify cause (Preoperative LV dysfunction that persists or partially improves, Perioperative MI, Progression of other valve disease, complications of the prosthetic valve)

vii. Structural failure_____ time since surgery _____

viii. Replacement of a prosthetic valve____if yes specify, date of replacement_____, and reason (prosthetic valve dysfunction or dehiscence, endocarditis, recurrent thromboembolism, severe hemolysis, severe and recurrent bleeding, valve obstruction, prosthetic valve-patient mismatch.)

ix. New onset postoperativeatrial fibrillation _____

x. If patient died _____ If yes specify, date of death_____ and cause of death_____

7. Patient clinical presentation related data

Duration of VHD before the surgery _____

Symptomatic improvement after the surgery Yes ____ No _____

NYHA before surgery I ____ II _____ III _____ IV _____

NYHA class after surgery I ____ II _____ III _____ IV _____

8. **Readmission** (Note: this section is blank if patient dies during initial hospital stay)

a. Readmit <=30 Days from Date of Procedure:

No_____

Yes_____ if yes, select the most predominate reason

b. Readmission Reason:

(Anticoagulant Complications) (Arrhythmias/Heart Block/Pacemaker Insertion/AICD) (CHF)
(MI/Recurrent Angina) (Pericardial Effusion/Tamponade) (Pneumonia/ Respiratory Complication)(Valve Dysfunction) (Infection Deep Sternum) (Infection Leg) (R e n al Failure)(TIA) (Reop for Bleeding)(Permanent CVA) (Acute Vascular Complication) (Other)

9. **In hospital Complications**:

No___

Yes____ if yes, at least one complication below must be selected

1. Operative	**2. Infection**
A. ReOp for Bleeding /Tamponade	A. Sternum – Deep
B. ReOp for Valvular Dysfunction	B. Thoracotomy
C. ReOp for Other Cardiac Problem	C. Septicemia
D. ReOp for Other Non Cardiac Problem	D. Leg
E. Perioperative Myocardial Infarction	E. Urinary Tract Infection
3. Neurologic	**4. Pulmonary**
A. Stroke	A. Prolonged Ventilation
B. Transient	B. Pulmonary Embolism
C. Continuous Coma >=24Hrs	C. Pneumonia
5. Renal	**6. Other**
A. Renal Failure	A. Heart Block
B. Dialysis	B. Cardiac Arrest
7. Vascular	C. Gastro -Intestinal Complication
A. Vascular - Aortic Dissection	D. Anticoagulant Complication
B. Illiac/Femoral Dissection	E. Multi -System Failure
C. Acute Limb Ischemia	

10. **Clinical characteristic of the patient**

Comorbidities Yes _____, (Specify)_____

No _____

11. Mortality

a. Discharge Status: Alive Dead (Operative Death: No Yes) Status at 30 days after surgery: Alive Dead
b. Death : No_____ Yes _____ (Date __ __/__ __/__ __ __ __ (mm/dd/yyyy))
c. Location of Death: (OR) (Hospital) (Home) (Other Facility)
d. Primary Cause of Death (select only one): (Cardiac) (Neurological) (Renal) (Vascular) (Infection) (Pulmonary) (Bleeding (Other)