



ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES SCHOOL
OF PUBLIC HEALTH

SURVIVAL AND PREDICTORS OF MORTALITY AMONG PATIENTS WITH
RHEUMATIC HEART DISEASE AWAITING VALVULAR SURGERY AT TIKUR ANBESA
SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA: A RETROSPECTIVE FOLLOW-UP
STUDY, 2025.

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**APPROVAL SHEET ADDIS ABABA UNIVERSITY COLLEGE OF
HEALTH SCIENCES SCHOOL OF PUBLIC HEALTH**

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Thesis title	Survival And Predictors Of Mortality Among Patients With Rheumatic Heart Disease Awaiting Valvular Surgery At Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia: A Retrospective Follow-Up Study, 2025.
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Abbreviations and Acronyms

AAU	_____	Addis Ababa University
AFib	_____	Atrial Fibrillation
AHA	_____	American Heart Association
AR	_____	Aortic Regurgitation
AS	_____	Aortic Stenosis
CI	_____	Confidence Interval
CVD	_____	Cardiovascular disease
DALYs	_____	Disability Adjusted Life Years
EF	_____	Ejection Fraction
GBD	_____	Global Burden of Disease
HR	_____	Hazard Ratio
ICU	_____	Intensive Care Unit
IRB	_____	Institutional Review Board
LMICs	_____	Low and Middle Income Countries
MR	_____	Mitral Regurgitation
MS	_____	Mitral Stenosis
NYHA	_____	New York Heart Association
PHTN	_____	Pulmonary hypertension
RHD	_____	Rheumatic Heart Disease
STATA	_____	Statistics and Data
TASH	_____	Tikur Anbesa Specialized Hospital
TR	_____	Tricuspid Regurgitation
TS	_____	Tricuspid Stenosis

VHD _____ Valvular Heart Disease

WHO _____ World Health Organization

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Abstract

Background: Rheumatic Heart Disease is a condition in which the heart valves are damaged through repeated episodes of rheumatic fever. Globally, around 40.5 million people were affected by the disease, and >306,000 individuals died annually. In most cases, the life-saving treatment for Rheumatic Heart Disease patients is valvular surgery. However, such life-saving cardiac surgeries are limited in resource-limited settings like Ethiopia.

Objective: This study aimed to assess survival and identify predictors of mortality among patients with Rheumatic Heart Disease awaiting valvular surgery at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia.

Methods: A hospital-based retrospective follow-up study was conducted at Tikur Anbesa Specialized Hospital among 436 patients with rheumatic heart disease who were registered for valvular surgery from January 1, 2018, to December 30, 2023. Data were collected through the review of medical records and telephone interviews. The Kaplan-Meier method, life table, and log-rank test were used to estimate survival and comparison. Predictor factors were identified using an adjusted Cox regression model with their corresponding 95% confidence interval; p-value <0.05.

Result: A total of 436 patients with Rheumatic Heart Disease were followed for 1,210.9 person-years, resulting in a mortality incidence rate of 108.89/1,000 person-years. The overall probability of survival at 2 years and 5 years was 80.9% and 59.0%, respectively. Independent predictors included right ventricular dysfunction (Adjusted hazard ratio: 3.03; 95% CI: 1.61–5.73), New York Heart Association class III/IV (Adjusted hazard ratio: 2.94; 95% CI: 1.58–5.46), multivalve lesion indicated for surgery (Adjusted Hazard Ratio: 1.54; CI: (1.05, 2.26), Infective Endocarditis (Adjusted hazard ratio: 2.39; 95% CI: 1.15–4.96), and patients aged <18 years had a significantly higher risk of mortality compared to those aged ≥ 18 with AHR=1.54, 95% CI, (1.01, 2.36).

CONCLUSION: This study underscores the high mortality rate among rheumatic heart disease patients awaiting valvular surgery, emphasizing the need for urgent intervention, risk stratification, and strict patient follow-up.

Keyword: Rheumatic Heart Disease, Cardiac surgery, Ethiopia, Tikur Anbesa.

1. Introduction

1.1. Background

Rheumatic Heart Disease (RHD) is a condition where the heart valves are damaged due to repeated episodes of rheumatic fever. Rheumatic fever is an autoimmune response that can occur after a throat infection caused by the *Group A Streptococcus* bacterium and leads to long-term heart damage if not treated appropriately (1,2).

While the burden is lower in high-income countries, the disease is still prevalent in sub-Saharan Africa, the Middle East, Central and South Asia, and the South Pacific (3). According to the 2019 global burden of disease (GBD), around 40.5 million people were affected by RHD, and more than 306,000 individuals died annually with predominantly in younger and women's population groups (4).

Early diagnosis and timely intervention are necessary for managing rheumatic heart disease. The disease can be prevented through early treatment of streptococcal throat infections with antibiotics. However, once the heart valves are damaged, the effects are permanent, and surgery may be required to repair or replace the damaged valves (5). Unfortunately, many countries with a high burden of RHD, including Ethiopia, have limited access to life-saving cardiac surgery (6).

Worldwide, around six billion people live in scarcity of heart surgery. In high-income countries, there are about seven cardiac surgeons for every one million people. In contrast, in sub-Saharan Africa, there is only one cardiac surgeon for every 4 to 25 million people (7, 8).

Studies show that the prognosis for RHD patients is poor if surgery is delayed. A study by Doh et.al declared that 50% of patients with RHD died within five years of being enrolled on the waiting list for valvular surgery (9). History of infective endocarditis, right ventricular dysfunction, pericardial effusion, multiple valve involvement, advanced heart failure, New York Heart Association class (NYHA Class III/IV), and atrial fibrillation were associated with a higher risk of death before having surgery (9).

1.2. Statement of the problem

RHD is a leading cause of cardiovascular disease in Ethiopia, contributing significantly to the burden on the healthcare system. A 2005 rural study in Gondar reported that the one-year RHD mortality was 12.5% (20).

Tikur Anbesa Specialized Hospital (TASH) in Addis Ababa, the only public hospital in Ethiopia equipped to perform heart valve repairs and replacements. At TASH between 1995 and 2001, in all forms of cardiovascular-related hospital mortality, 26.5% were due to RHD (10). Over 30 years, from 1983 to 2013, only 157 valvular surgeries were performed at TASH, with 92.35% of those surgeries related to RHD (6). More recently, between 2017 and 2021, I performed cardiac surgery at three cardiac centers in Addis Ababa; 92.2% (177) of the 192 valvular surgeries were for rheumatic valvular heart disease (11).

Despite the growing demand for cardiac surgeries, there is a severe shortage of cardiac surgeons and infrastructure in Ethiopia, with only five surgeons available to serve a population of over 120 million people, leading to long waiting lists for surgery, over 15,000 patients on the waiting list for cardiac surgery throughout the country (8).

At TASH, there is one cardiac surgeon; mission-based teams conduct most open-heart surgeries; the local team occasionally performs surgeries when resources are available. The cost of open-heart surgery at Tikur Anbesa ranges between USD\$200- \$ 400+, making it relatively affordable by international standards when compared to another private clinic in Addis Ababa (\$40,000-\$50,000+), but most surgeries at TASH are free due to its mission-based based. The hospital has more than 8,000 patients on the cardiac surgery waiting list. On average, 20 to 30 cardiac surgeries are performed annually (8).

While RHD is a major cause of premature cardiovascular deaths in Ethiopia, there is limited data specifically on the survival and predictors of mortality among RHD patients awaiting valvular surgery at TASH, Ethiopia. This study aims to fill this critical knowledge gap in Ethiopia and similar settings.

1.3 Rationale of the study

The rationale behind this study is to better understand the survival rate and identify the predictors of mortality. Knowing this helps healthcare professionals to make better decisions in caring for high-risk patients with RHD and leads to improved management and treatment strategies during their waiting time, for better outcomes. The study also aims to fill the knowledge gap in the preoperative outcome of RHD patients in Ethiopia and provide baseline data for future prospective studies in a similar setting.

1.4 Significance of the study

This study is important because it gives a clearer picture of the survival rate, incidence of death, and its predictors among patients with Rheumatic Heart Disease (RHD) who are waiting for heart valve surgery in Ethiopia. It could provide important data on how many patients died before receiving surgery and identify the main risk factors that contribute to these poor outcomes. By understanding these factors, healthcare providers could make quicker and more targeted interventions for patients who are at high risk of dying while waiting for surgery.

The study may also be beneficial for public health professionals, as it highlights the unmet needs of RHD patients, raises awareness about the disease, and encourages earlier detection and screening. This could lead to better access to treatment options for people with RHD. Additionally, the study would serve as background for future longitudinal research on RHD in Ethiopia and other countries with similar setups. It could help follow improvements in the care and treatment of RHD patients over time.

2. Literature review

2.1 The Burden of Rheumatic Heart Disease

In the 2019 Global Disease Burden (GDB) report, rheumatic heart disease (RHD) affects more than 40.5 million individuals globally, with 2.8 million new cases each year and 306,000 annual deaths, predominantly affecting young and women with a median age of 28.7 years in low- and middle-income countries. In addition, there were 10.7 million disability-adjusted life-years (DALYs) annually (4). Although the global incidence and mortality of RHD have decreased since 1990, projections for the next decade (2020–2030) indicate a continued rise in prevalence, particularly in low and middle-income countries LMICs, and among younger populations and females (12).

RHD constitutes a significant portion of cardiovascular disease (CVD) cases in African youth, accounting for 17% to 43% of all CVD cases in sub-Saharan Africa and resulting in over 300,000 deaths annually (13).

In Ethiopia, A systematic review of 12 studies conducted from 1992 to 2022 reported that the pooled prevalence of RHD was 3.19% with heterogeneity between studies. The disease was prevalent in hospitals, which was around 5.42% relative to 0.73% in schoolchildren and up to 3.83% in the community. There is also regional variation in Addis Ababa, up to 0.75%, whereas 8.95 % prevalence was observed in the Amhara region (14).

A study at Tikur Anbesa Specialized Hospital (TASH) revealed that 62% of cardiac patients were diagnosed with VHD, and a significant proportion of these cases were rheumatic in origin (15). A review of hospital data from Ethiopia's cardiac center between 2000 and 2022 showed that VHD contributed to 30.8% of hospital admissions, with rheumatic valvular heart disease accounting for 61.8% of these cases (16).

2.2 Preoperative mortality of RHD patients awaiting surgery

The preoperative mortality of RHD patients awaiting surgery, especially in countries with limited healthcare resources, is a greater concern. Surgical delays are common in LMICs due to shortages in both cardiac surgeons and hospital infrastructure. A prospective observational study conducted

across 24 LMICs from 2016 to 2022, including 13,696 RHD patients, found that up to 15% of patients died within 3 years of diagnosis. The study showed that most deaths occurred among those with severe RHD, and only 5% of patients underwent valve surgery within three years (17).

The REMEDY (the Global Rheumatic Heart Disease Registry), a multi-center study, which included 3343 patients from 25 countries, including 400 from Ethiopia, found that 16.9% of RHD patients died within two years, with a median age of death of 28.7 years. The incidence of mortality at the end of one year was 116.3 per 1,000 patient-years. The study shows that individuals from high-income countries and those having interventions are at low risk of mortality (18). In another study from Uganda, a one-year prospective study of 449 RHD patients, 17.8% died (19).

One study conducted in Uganda, Africa, on the pre-interventional survival of RVHD patients after enrolment in the surgical waiting list revealed that the median survival time after enrollment was 4.6 years. The survival probability of individuals with intervention-eligible RHD without receiving surgical treatment at 1, 5, and 10 years after enrollment was 77%, 46%, and 35%, respectively, and 30.6% of patients died without having surgery, while 13.5 % were undergoing surgery within 12 years of follow-up (9).

2.3 Predictors of Mortality in Rheumatic Heart Disease Patients Awaiting Surgery

Many factors have been identified as predictors of poor outcomes and increased mortality in RHD patients. The REMEDY study found that severe valve disease, congestive heart failure, New York Heart Association (NYHA) functional class III/IV, atrial fibrillation, and older age at enrollment were significant risk factors for death, with a range of [HR from 1.02 to 2.36] (18).

In a more recent study of 67.5% of RHD deaths due to vascular causes (mainly heart failure and sudden cardiac death), severe valvular disease, pulmonary hypertension, atrial fibrillation, left ventricular dysfunction, Diabetics, stroke, coronary arterial disease and hypertension were identified as significant mortality risk factors [HR] ranges from (1.18 to 1.57). The number of hospitalizations is also associated with decomposition heart failure and death. While surgical interventions, such as prior valve surgery and valvuloplasty, female sex, and Secondary prophylaxis were shown to lower mortality, with HRs ranging from 0.23 to 0.90, (17,18).

In Uganda, a study of 449 RHD patients found that several factors significantly increased the risk of death. Poor adherence to secondary prophylaxis and the absence of early surgical intervention were found to be major contributors to the development of decompensated heart failure and atrial fibrillation, which significantly increased the risk of mortality. These findings suggest that surgical delay, even in the presence of appropriate prophylaxis, leads to irreversible damage and higher mortality among patients (19).

Similarly, a study of RHD patients awaiting valve surgery in Uganda identified several predictors of mortality, including history of infective endocarditis, right ventricular dysfunction, and multiple valve involvement (HR: 2.38, 2.44, and 1.77) respectively (9).

In Ethiopia, the studies highlighting delays in accessing timely surgery, inadequate secondary prophylaxis, and a lack of consistent medical follow-up have been shown to contribute to the rapid progression of RHD and early mortality(10,20).

2.4 Healthcare System Constraints and Their Impact on Awaiting Surgery

In low- and middle-income countries (LMICs) like Ethiopia, the high death rate from rheumatic heart disease (RHD) is made worse by significant healthcare system challenges. These include a shortage of trained medical professionals, limited healthcare infrastructure, and insufficient financial resources for surgery. The scarcity of cardiologists, cardiac surgeons, and infrastructure results in longer waiting times for surgery. Additionally, there is limited access to essential medications, like antibiotics for secondary prevention, and a shortage of surgical facilities, all of which contribute to poor outcomes for RHD patients. Financial barriers also prevent many patients from affording or accessing timely surgery.

A study in Uganda identified factors like the high cost of surgery, long waiting times, and limited access to specialized care as major obstacles (9). In Ethiopia, these issues are even more severe, with only five cardiac surgeons and 4 cardiac centers; 2 private, one NGO (Ethiopian cardiac center), and one public (TASH) available to serve a population of over 120 million people. At Tikur Anbesa Specialized Hospital (TASH), there is only one cardiac surgeon, 8 cardiologists, and two cardiac anesthetists. The hospital is equipped with just two cardiopulmonary bypass machines, one operating room, and 12 intensive care unit (ICU) beds for post-surgery care.

Most open-heart surgeries are performed by visiting mission-based teams, with the local team conducting surgeries when materials are available(8,11). The study tells that for 30 years, only 157 surgeries have been performed at TASH (21).

The cost of open-heart surgery at TASH is between \$200 and \$400+, which is relatively affordable compared to international prices. However, this remains a financial burden for many patients. In contrast, private hospitals like Tazima and ELouzeir charge significantly higher prices, ranging from \$4,000 to \$50,000+ for surgery. Due to these financial and healthcare system limitations, many patients experience prolonged suffering or die prematurely. Those who do undergo surgery often have poor outcomes, especially when their condition is advanced(8).

2.5 Conceptual framework

This conceptual framework was adapted from available literature (9–11,19,21–24) it describes the relationship between independent variables and dependent variables. In this conceptual framework, **Death is the outcome/dependent** variable, which is directly or indirectly affected by independent variables (Socio-demographic factors, clinical factors, and echocardiographic abnormality). So, based on this conceptual framework, we adapted our questionnaire and applied it to answer the given research questions.

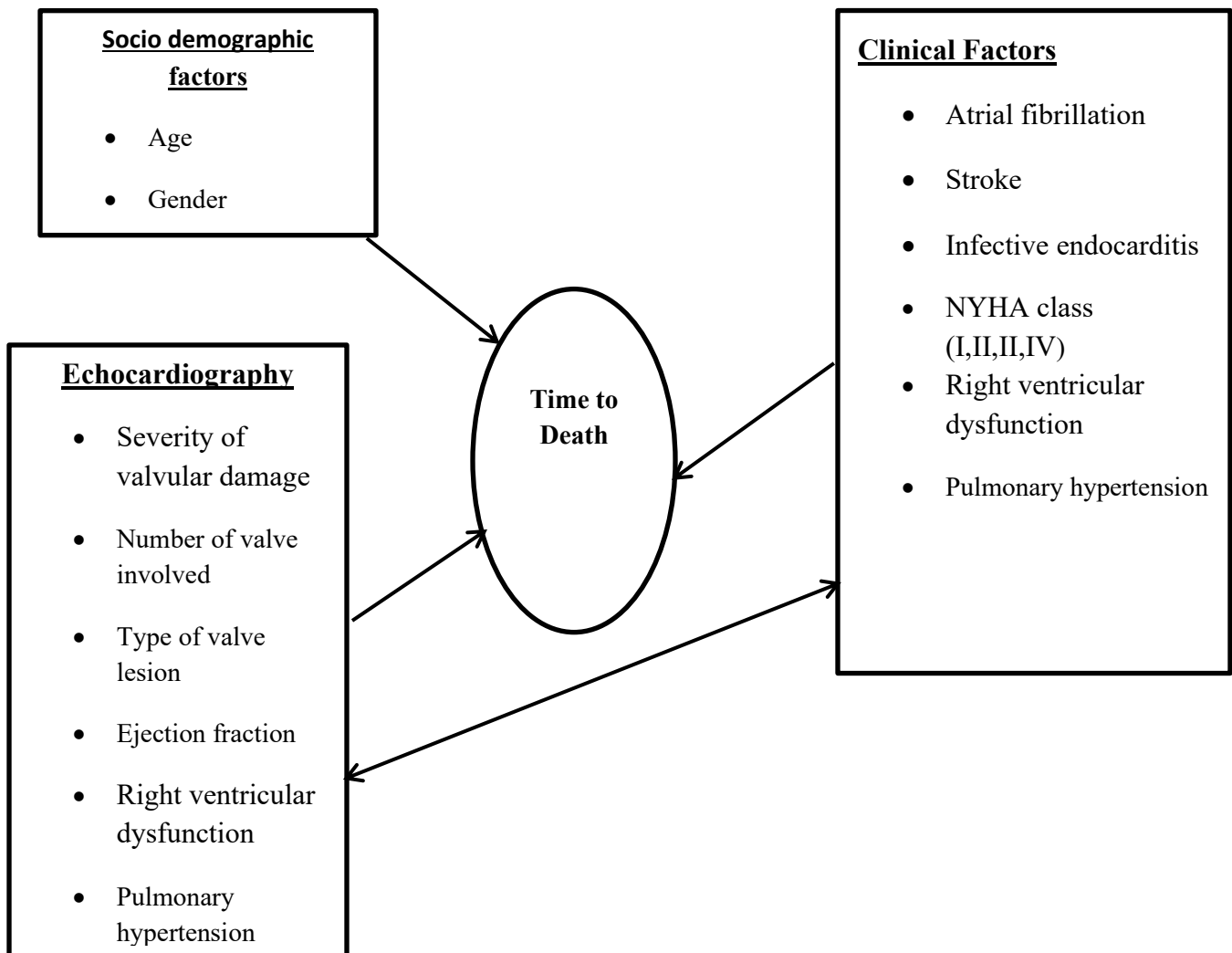


Figure 1 Conceptual framework for the survival of RHD patients who are waiting valvular surgery at TASH, Addis Ababa, Ethiopia, 2025

Source: This conceptual frame is adapted from the available literature (9–11,19,21–24)

3 . Objective of the study

3.1 General objective

To assess survival and identify predictors of mortality among patients with Rheumatic Heart Disease awaiting valvular surgery at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia, 2025. retrospective follow-up study.

3.2 Specific Objective

1. To estimate the survival probability of patients with rheumatic heart disease awaiting valvular surgery at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia, 2025.
2. To identify predictors of mortality among patients with rheumatic heart disease awaiting valvular surgery at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia, 2025.

4. Methods and Materials

4.1 Study area and period

The study was conducted from February to April 2025 at Tikur Anbesa Specialized Referral and Teaching Hospital (TASH) in Addis Ababa, Ethiopia, which is the largest public referral and teaching hospital in the country. The hospital has an adult cardiology referral clinic, a Cardiac Intensive Care Unit (ICU), and ward beds for inpatient management of patients with CVDs and pre- and post-procedure care of patients with CVD. The hospital also has the facility for catheter intervention, cardiac surgery with one cardiac surgeon and eight adult cardiologists. Patients all over the country are referred for possible surgery. There is no regular cardiac surgery service in the hospital until very recently, and most cardiac surgeries are done by surgical missions coming from abroad (8).

4.2 Study design

A hospital-based retrospective follow-up study was conducted involving RHD patients whose ages were 13 years and above, who had been registered for surgery from January/2018 to December/2023 at Tikur Anbesa Specialized Hospital (TASH), Addis Ababa, Ethiopia.

4.3 Source population

All rheumatic heart disease patients aged 13 and above years who had follow-up at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia.

4.4 Study population

All rheumatic heart disease patients aged 13 and above years, who were registered for valvular surgery from January/2018 to December/2023, and had follow-up at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion criteria

All rheumatic heart disease patients aged 13 and above who were registered on the valvular surgery waiting list from January 2018 to December 2023 and had follow-ups at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia.

4.5.2 Exclusion criteria

All patients with incomplete medical records; including echo findings, relevant clinical information at registry, time of enrollment to the surgery list, and those with no phone number, and a patients had additional cardiac etiology (Ischemic Heart Disease, Hypertensive Heart Disease, Dilated Cardiomyopathy, Congenital Heart Disease) and comorbidity Diabetic mellitus, Hypertension, Chronic kidney disease, RVI and cancer were excluded.

4.6 Sample Size Determination

The sample size was calculated using STATA version 17 and manually with 95% CI, 80% power, 0.05 standard deviation 15% lost to follow-up rate. Probability of death at 2 years of 26% and [HR=1.77] in patients with multivalve lesion indication for surgery, taken from a previous similar Ugandan study (9).

$$e = 4 (Z_{\alpha/2} + Z_B)^2 / (\ln HR)^2 = \underline{96.2} \dots \dots \text{estimated event}$$

$$N = e / p (e) = 96.2 / 0.26 = \underline{370} \text{ And}$$

$$N \text{ adjusted} = n / (1 - \text{loss}), = 370 / 0.85 = \underline{436}, \text{ it had a similar value to STATA calculated.}$$

4.7 Sampling technique and procedure

The sampling process involved identifying patients registered on the surgical waiting list at Tikur Anbessa Specialized Hospital (TASH) from January 2018 to December 2023. Patients were cross-checked against the standard surgical indications outlined in the 2020 American Heart Association (AHA) valve treatment guidelines(23) to ensure they met eligibility requirements for valvular surgery. From the valvular surgery registry log book, there were 2420 patients registered for valvular intervention from 2018 to 2023. Based on our inclusive criteria, 1180 patients were eligible; of these, 436 patients were selected by systematic random sampling after stratifying based on their year of registration.

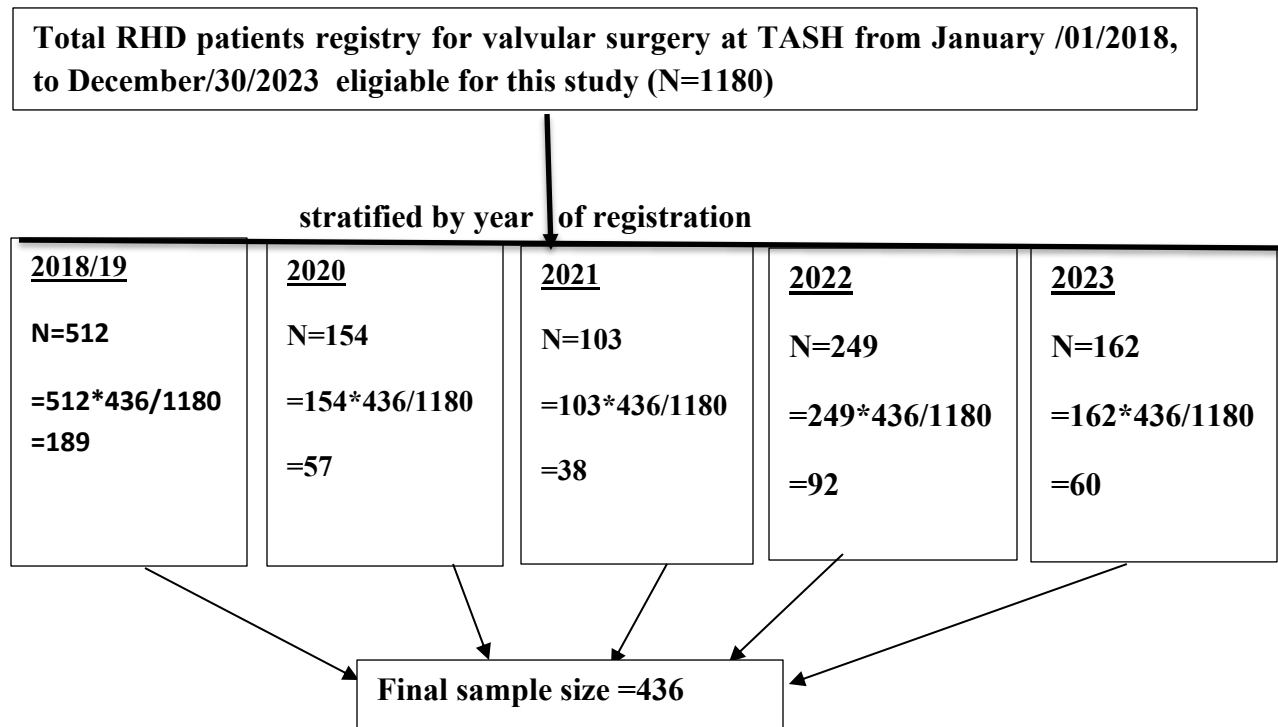


Figure 2 Schematic presentation of sampling procedure to estimate the survival probability and predictors in RHD patients awaiting valvular surgery at TASH, Addis Ababa, Ethiopia,2025.

4.8 Data collection procedure

Data were collected using a structured, pre-tested questionnaire electronically by using a Kobo collector, The questionnaire was adapted from available literature and hospital treatment guidelines (9–11,19,21–24). The questionnaires included socio-demographic, clinical, and Echocardiographic variables at the time of registration for surgery. The deaths of the participants were confirmed from hospital mortality records at medical emergency, medical wards, ICU, and CCU, and the mortality list on the cardiac surgery logbook. For those outcomes that could not be confirmed in the hospital record, phone interviews were obtained. For those not reachable after multiple attempts, we have taken them as lost to follow up.

Data collector

One internist supervisor and one cardiac nurse data collector were hired. The data collector and supervisor underwent a 1-day training session by a cardiologist that covered key topics about how to gather secondary data from patient medical records and phone calls. Pre-tests were conducted on 22-RHD patients registered for surgery by 2024G.c at TASH; were used to identify potential challenges and clarify any ambiguities.

4.9 Variable

4.9.1 Dependent Variable

Time to death (in years)

4.9.2 Independent Variable

- **Demographic factors:** Age, Gender
- **Clinical factors:** New York Heart Association (NYHA) class, Infective endocarditis, Atrial fibrillation, stroke,
- **Echocardiography finding:** Severity of valvular damage, number of valve involvement, Type of valvular lesion, Pulmonary hypertension, Ejection fraction, right ventricular dysfunction,

4.10 Operational definition

- **Rheumatic Heart Disease (RHD):-** Permanent damage to heart valves; confirmed through echocardiography, a documented history of rheumatic fever, and symptoms.
- **Beginning of the study:** - The time of registration to the valvular surgery waiting list between January 01/2018, to December 30/2023.
- **Following up period:-** The time from the time of registration up to the end of the study period, death, or having surgery, from January 01/2018, to December 30/2024
- **Censoring:** - Having intervention within the study follow-up period, alive at the end follow-up or lost to follow-up/drop.
- **Lost follow-up:** For patients discontinued clinical follow-up for more than 6 months before December 30/2024, and were not coming to follow-up within three months of our data clerking time, and we could not reach them after multiple repeated phone calls.
- **Death/Event:** - All causes of mortality within in follow-up period before having surgical intervention.
- **New York Heart Association Functional Classification:** - **Class I** (no symptoms at ordinary activity), **Class II** (Slight limitation on ordinary activity), **Class III** (symptoms in less ordinary activity), **Class IV** (symptoms at rest).
- **Valvular Intervention Criteria:-** Based on Echocardiogram abnormalities findings Valve lesion type/severity is identified by a cardiologist based on the American Society of Echocardiography and the American Heart Association (AHA) guideline used in the Evaluation of Rheumatic Heart Disease, and is identified for valvular intervention (23). which involves either severe aortic or mitral valve lesions or both, and had an additional severe Tricuspid lesion.
- **Multivalvular lesion:-** Valvular surgery was indicated for more than one heart valve, which involves the aortic and mitral valves, and had severe Tricuspid regurgitation and or severe tricuspid stenosis.
- **Single valve lesion:** Valvular surgery was indicated for one heart valve, which involves either the aortic or mitral valves.
- **Valve lesion:** either stenosis or regurgitation of the involved valve

- **Valvular intervention:** Indicates both percutaneous mitral balloon commissurotomy (PMBC) and surgical valve repair or replacement.
- **The main analysis:** In the main analysis, the patients who were lost to follow-up were considered as censored.
- **Worst case scenario:-** In this scenario, we consider the lost to follow up patients whose outcome was not confirmed, were had the highest probability of death, which is used to estimate the maximum probability of death rate (27,28).

4.11 Data Management

All collected data were treated with strict confidentiality. After the data was collected, the datasets were reviewed for completeness every day, and refreshments and feedback were given to the data collector every morning. The collected data was extracted into Excel form and entered into STATA. Once the data was entered, coded, and cleaned accurately, ready for analysis.

4.12 Data Analysis

The data was analyzed using STATA version 17, by applying the necessary statistical methods. For continuous variables, the median and range were presented. The categorical variables were summarized by percentages and frequency tables.

For the first objective, to estimate the probability of survival, the survival life table and Kaplan-Meier survival curve were applied. Log-Rank Test was used to compare survival across groups of covariates. The incidence of mortality was calculated. And the worst-case scenarios were considered for patients lost to follow up and their outcomes were not confirmed.

To identify independent predictor factors in the 2nd objective, bivariate and multivariate Cox regression analyses were used. All independent variables were included for both bivariate and multivariate Cox models, and all have clinically significant effects. Finally, the factors that affect the survival of RHD patients during waiting for valvular surgery were identified by considering Adjusted Hazard ratio (AHR) with 95% CI and p-values less than 0.05. The Cox proportional hazard assumptions were checked using Schoenfeld residual regression, the ln-ln(st) graph, and the observed with predictor graph were plotted; all those assumptions were maintained. In addition to this, multicollinearity and interaction effects were checked. The Cox-Snell residual plot was used to fit the final model.

4.13 Data Quality Assurance

To ensure the quality of our data, the questionnaire was adapted from existing literature and hospital treatment guidelines. It was pre-tested in a similar setup. The data collectors were clinically experienced cardiac nurses at TASH, and data were collected from existing medical records and through phone interviews. This approach aims to enhance data quality and minimize the non-response rate. Data were collected electronically using the Kobo Collect app, and the collected data were sent to the central server daily to ensure data security. After collection, the data were checked for completeness, coded and cleaned, and finally, analysis and appropriate interpretation were conducted.

4.14 Ethical Consideration

Ethical approval for this study was obtained from the Institutional Ethical Review Committee of Addis Ababa University, College of Medical Sciences, and the School of Public Health. Additionally, a waiver of informed consent and formal permission was obtained from the Tikur Anbesa Specialized Hospital (TASH) Department of Internal Medicine Review Committee, and verbal consent was collected from participants during phone interviews conducted. Personal data was anonymized with unique study ID numbers and securely stored. The study's benefits and risks were communicated to participants and their relatives during phone interviews, and data collectors shared their grief and expressed sympathy for families and relatives when a participant passed away.

4.15 Dissemination of the result

The study's findings will first be presented to the AAU College of Medicine and the School of Public Health's Department of Epidemiology and Biostatistics. They will then be submitted for publication in high-impact, peer-reviewed medical journals. The results will be presented at key national and international conferences and communicated to stakeholders at Tikur Anbesa Specialized Hospital and public health personnel. By disseminating the findings through these

various channels, the study will help improve healthcare practices, influence policy decisions, and inspire future research aimed at better understanding and managing RHD in Ethiopia and beyond.

5. Result

5.1 Characteristics of study participants

This study included a total of 436 patients with Rheumatic Heart Disease (RHD) who were registered for valvular surgery at Tikur Anbessa Specialized Hospital. The outcome status of 237 patients was confirmed using hospital records, revealing that 62 patients had died during follow-up. For the remaining 199 patients, phone interviews were conducted; among these, 69 patients were confirmed dead, while 45 patients could not be reached despite repeated call attempts over two weeks.

By the end of the study period, 222 (50.92%) remained alive, 131 (30.05%) died during the follow-up period, 38 (8.72%) underwent valvular intervention, and 45 (10.32%) were categorized as lost to follow-up (Figure 3).

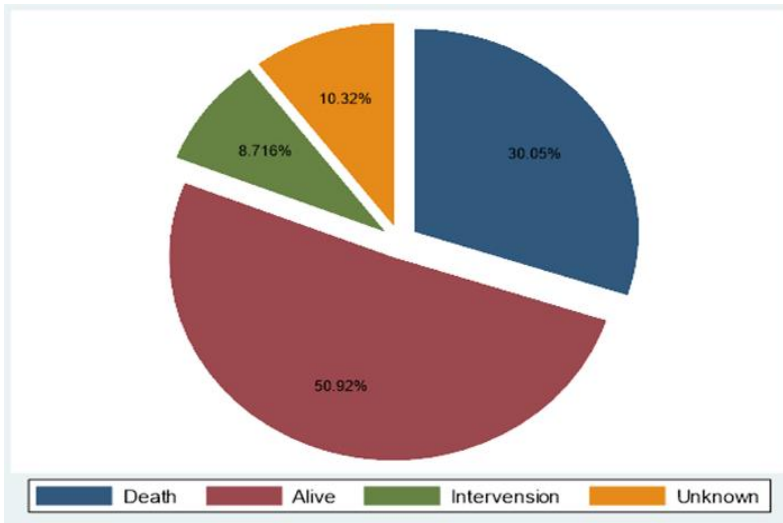


Figure 3 Pie chart for description of outcomes at the end of follow-up for patients with RHD awaiting valvular surgery at TASH 2025.

5.2 Demographic and clinical condition at the time of registration for valvular surgery

The majority of study participants were female, 298 (68.35%), and 70 (16.06%) were under 18 years old at the time of registration. The median age was 25 years, with an age range of 13 to 61 years (Table 1).

Regarding clinical conditions and echocardiographic findings, 296 (67.89%) had advanced heart failure classified as NYHA class III or IV, 237 (54.36%) had severe pulmonary hypertension (PHTN), and 177 patients (40.60%) had multivalve lesions indicated for surgery (Table 1)

Table1. RHD patients' sociodemographic and clinical condition at the time of registration to a valvular surgery awaiting list at TASH, Addis Ababa, Ethiopia from 2018-2023; n=436

Covariates	Category	Out come		Total (%)
		Censored (%)	Death (%)	
Gender	Female	221 (74.16%)	77 (25.83%)	298 (68.35%)
	Male	84 (60.86%)	54 (39.13%)	138 (31.65%)
Age	>=18	268 (73.22%)	98 (26.77%)	366 (83.94)
	<18	37 (52.85%)	33 (47.14)	70 (16.06%)
NYHA class	I&II	126 (90%)	14 (10%)	140 (32.11%)
	III&IV	179 (60.47%)	117 (39.52%)	296 (67.89%)
EF	>=40	299 (73.82%)	106 (26.17%)	405 (92.89%)
	<40	6 (19.35%)	25 (80.64%)	31 (7.11%)
Stroke	No	286 (69.41%)	126 (30.58%)	412 (94.49%)
	Yes	19 (79.16%)	5 (20.83%)	24 (5.5%)
Afib	No	117 (92.18%)	75 (7.81%)	192 (44.03%)
	Yes	88 (61.11%)	56 (38.89%)	144(33.03%)
IE	No	301 (71.49%)	120 (28.50%)	421 (96.56%)
	Yes	4 (26.67%)	11 (73.33%)	15 (3.44%)
Indicated valve lesion	Single	209 (80.69%)	50 (19.30%)	259 (59.40%)
	Multiple	96 (54.23%)	81 (45.76%)	177 (40.60%)
RV.dysfunction	No	301 (72.17%)	116 (27.82%)	417 (95.64%)
	Yes	4 (21.05%)	15 (78.94%)	19 (4.35%)
PHTN	None	73 (91.25%)	7 (8.75%)	80 (18.35%)
	Mild	43 (89.58%)	5 (10.41%)	48 (11.01%)
	Moderat	57 (80.28%)	14 (19.72)	71 (16.28%)

	Severe	132 (55.69%)	105 (44.30%)	237 (54.36%)
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5.2 Survival probability of RHD patients awaiting valvular surgery at TASH

Over a total follow-up period of 1,210.9 person-years, the incidence rate of mortality was 108.89/1,000 person-years, with 131 patients confirmed dead and 45 patients lost to follow-up. The median follow-up duration was 2.8 years. The overall survival probabilities at the end of one, two, and five years were 87.87%, 79.83%, and 59.32%, respectively (Table 2, Figure 4).

When analyzed by clinical subgroups, survival varied significantly: patients with advanced NYHA Class III/IV had two-year and five-year survival probabilities of 72.70% and 41.09%, respectively, and those indicated for multi-valve lesions had 69.25% at two years and 36.81% at five years. Patients with ejection fraction (EF) <40%, right ventricular dysfunction, and infective endocarditis (IE) had median survival times below two years, with survival probabilities at two years of 49.32%, 27.57%, and 31.67%, respectively (Table 2).

In the worst-case scenario, where lost-to-follow-up patients were assumed to have died at their last hospital visit, the mortality incidence rate increased to 145.35/1,000 person-years. Under this assumption, the overall survival probabilities declined to 81.40% at one year, 72.32% at two years, and 51.34% at five years (Figure 4).

Subgroup survival also showed marked declines in this scenario: NYHA Class III/IV patients had 62.75% survival probability at two years and 33.63% at five years. Patients with multivalve lesions indicated for surgery showed 60.42% survival at two years and 31.40% at five years. Patients with right ventricular dysfunction had a 25.26% survival probability at two years.

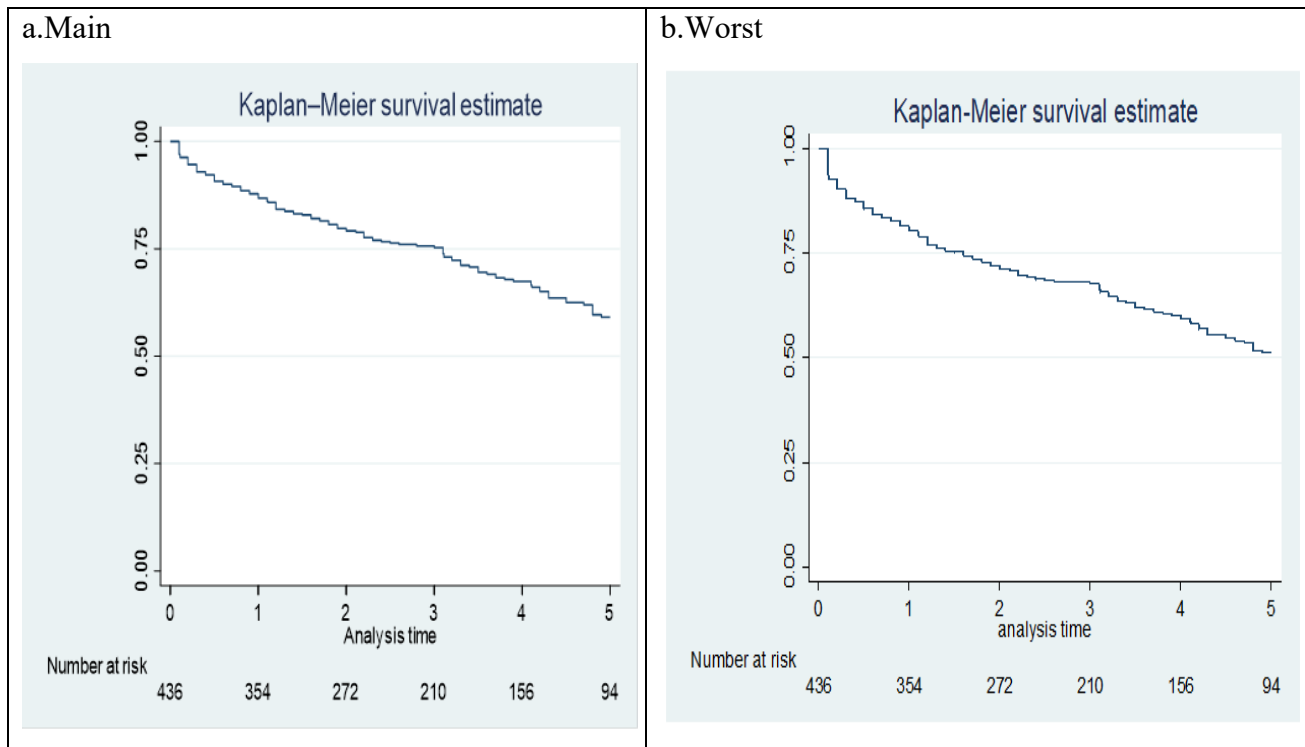


Figure 4 Overall KM- survival estimation curve in patients with RHD registered for valvular surgery waiting list from 2018 -2023 G.C at TASH, Addis Ababa, Ethiopia, follow-up per year n=436 “a” for main analysis and “b” for worst case scenario

5.2.1 Survival analysis using log-rank test

The log-rank test was utilized to assess differences in survival distributions among various clinical and demographic factors in patients with rheumatic heart disease (RHD). The analysis had statistically significant differences in survival outcomes for key predictors including, p-value <0.05 with corresponding χ^2 : Right ventricular dysfunction ($\chi^2 = 63.55$, $p < 0.0000$), NYHA class ($\chi^2 = 59.06$, $p < 0.0000$), number of valve lesion indication for surgery ($\chi^2 = 49.28$, $p < 0.0000$) and others. These results suggest that patients with those conditions experience significantly different survival probabilities compared to their respective subgroups (Table 2).

Table 2 The life table and log rank test for equality of survival function in RHD, a waiting valvular surgery at TASH, Addis Ababa, Ethiopia, enrolled from 2018-2023 (n=436)

Covariates	Probability of survival		Log-rank test			
	2 years (95% CI)	5 years (95% CI)	Observed Death	Expected Death	Chi2	Pr>chi ²
All survival	79.75 (75.44,83.39)	60.54 (55.07,65.57)				
Gender						
Female	82.76 (77.77,86.73)	66.20 (59.16,72.32)	77	93.69		
Male	73.94 (65.13,80.84)	44.64 (33.64, 55.03)	54	37.31	10.21	<0.001*
Age						
>=18	83.38,(78.94,86.96)	63.47,(56.94, 69.28)	98	114.87		
<18	62.56 (0.49, 0.73)	36.24,(21.27,51.04)	33	16.13	19.02	<0.001*
NYHA Class						
I&II	94.13 (88.61,97.02)	88.07 (80.41,92.87)	14	56.52		
III&IV	72.70 (66.83,77.71)	41.09 (33.20, 48.81)	117	74.48	59.06	<0.0000*
EF						
>=40	82.47 (78.18,85.99)	64.61 (58.45,75.10)	106	124.57		
<40	49.32 (30.39,65.74)	4.50 (0.32, 18.68)	25	6.43	57.53	<0.0000*
IE						
No	81.55 (77.31,85.07)	61.03 (54.89,66.59)	121	128.87		
Yes	31.67 (8.87, 57.95)	0	10	2.13	29.88	<0.0000*
AF						
No	80.60 (75.30,84.87)	65.52 (58.11,71,93)	75	85.79		
Yes	79.16 (71.24,85.13)	49.74 (39.58, 59.09)	56	45.39	3.51	0.0601
Valve lesion						
Single	88.74 (83.77,92.25)	76.80 (69.51, 82.57)	50	81.47		
Multiple	69.25 (61.84,75.50)	36.81 (27.89,45.73)	81	43.57	49.28	<0.0000*
RV.dysfunction						
No	82.47 (78.25,85.94)	61.76 (55.58, 67.35)	116	128.43		
Yes	27.57 (9.69,49.09)	0	15	2.57	63.55	<0.0000*
PHTN						
None	95.92 (87.88,98.67)	88.03 (76.53, 94.11)	7	30.02		
Mild	95.45 (83.02,98.84)	86.30 (70.17,94.06)	5	17.75		
Moderate	84.25 (72.71,91.20)	72.28 (57.73,82.54)	14	21.78		
Severe	69.94 (63.30,75.62)	39.04 (30.88, 47.11)	105	61.45	61.94	<0.0000*

N.B. *P-value <0.05, statistically significant

5.2.2 Kaplan- Meier survival graphs for selected predictors

The Kaplan-Meier survival curves below illustrate that RHD patients with right ventricular dysfunction, advanced heart failure (NYHA class III/IV), Age <18, and who had surgery indicated for multivalve lesion at the time of registration for surgery experience significantly lower survival rates compared to their respective subgroups (Figure 5).

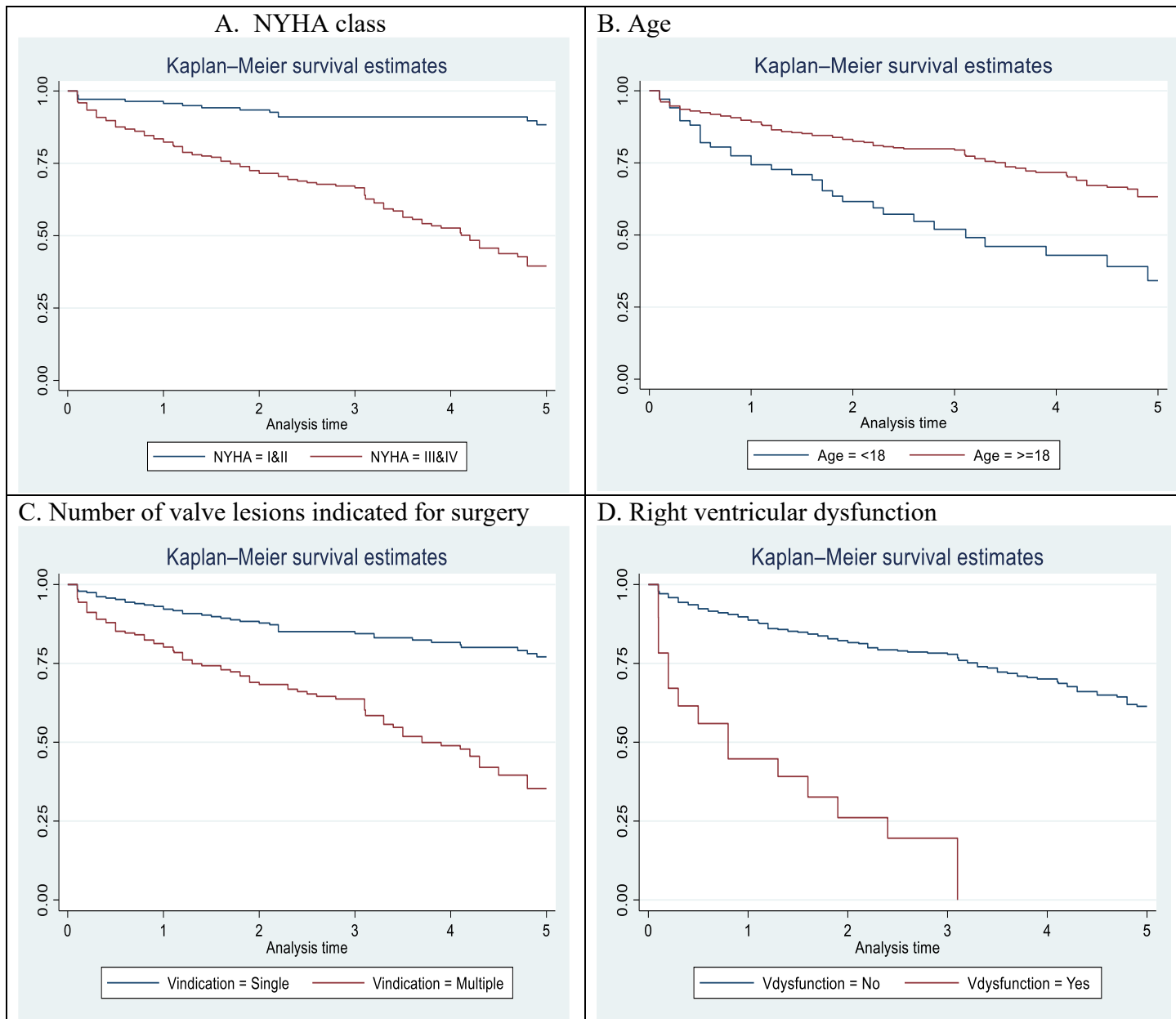


Figure 5 Kaplan-Meier survival estimates for selected predictors in the main analysis of RHD patients registered for valvular surgery at TASH from 2018-2023, follow-up pre-year n=436

5.3 Predictors of mortality in RHD patients registered for valvular surgery

The independent predictors of mortality were identified using multivariate Cox regression models. All variables were included in both bivariate and multivariable Cox models, considering their clinical significance.

Patients with the following clinical conditions at the time of registration for valvular surgery were at increased risk of death than those without the condition. Right ventricular dysfunction increased by 3 times (AHR: 3.03; 95% CI: 1.61–5.73), NYHA class III/IV by 2.94 times than NYHA class I/II (AHR: 2.94; 95% CI: 1.58–5.46), Infective Endocarditis (IE) by 2.39 times (AHR: 2.39; 95% CI: 1.15–4.96), Ejection Fraction (EF) <40% by 2.78 times (AHR: 2.78; 95% CI: 1.77–4.37), multivalvular lesion indicated for surgery by 1.54 times than indicated for single-valve lesion (AHR: 1.54; 95% CI: (1.05, 2.26), severe pulmonary hypertension (PHTN) by 2.99 times (AHR: 2.99; 95% CI: 1.31–6.81) and patients aged <18 years had a significantly higher risk of mortality compared to those aged ≥ 18 with AHR=1.54, 95% CI, (1.01, 2.36). However, variables such as stroke, atrial fibrillation (AFib), and gender did not show statistically significant associations with mortality risk in this analysis ([Table 3](#)).

Table 3 Bivariate and multivariate Cox-regression analysis model for predictors of survival in RHD patients waiting for valvular surgery at TASH, Addis Ababa, Ethiopia. registered from 2018 -2023 G.C. n=436

Covariates	Category	Censored	Death	Bivariate analysis	Multivariable analysis	
				CHR (95% CI)	AHR	P-value
Gender	Female	221	77	Ref	Ref	
	Male	84	54	1.76 (1.25, 2.49)	1.28 (0.89, 1.84)	0.181
Age	>=18	268	98	Ref	Ref	
	<18	37	33	2.34 (1.57, 3.49)	1.54 (1.01 2.36)	0.043*
NYHA class	I&II	126	14	Ref	Ref	
	III&IV	179	117	6.65 (3.80, 11.62)	2.94 (1.58, 5.46)	0.001*
EF	>=40	299	106	Ref	Ref	
	<40	6	25	4.64,(2.99,7.21)	2.78 (1.77, 4.37)	0.000*
Stroke	No	286	126	Ref	Ref	
	Yes	19	5	0.77 (0.32, 1.89)	0.45 (0.18, 1.12)	0.089
Afib	No	117	75	Ref	Ref	
	Yes	88	56	1.41 (0.99, 1.99)	1.25 (0.87, 1.81)	0.227
IE	No	301	120	Ref	Ref	
	Yes	4	11	4.91 (2.61, 9.22)	2.39 (1.15, 4.96)	0.019*
Indicated valve lesion	Single	209	50	Ref	Ref	
	Multiple	96	81	3.31 (2.32, 4.71)	1.54 (1.05, 2.26)	0.027*
RV.dysfunction	No	301	116	Ref	Ref	
	Yes	4	15	6.88(3.94, 12.02)	3.04 (1.61, 5.73)	0.001*
PHTN	None	73	7	Ref	Ref	
	Mild	43	5	1.24 (0.39, 3.92)	0.94(0.29, 3.05)	0.930
	Moderat	57	14	2.77 (1.12, 6.88)	1.51 (0.59,3.89)	0.384
	Severe	132	105	3.63 (2.06, 6.38)	2.98(1.32, 6.79)	0.009*
Age	Median=25 year			0.97 (0.95, 0.98)	0.98 (0.96, 0.99)	0.035*

N.B *significant at p-value of 0.05; CHR=Crude hazard ratio; AHR= adjusted hazard ratio; CI: Confidence interval, Ref=Reference, RV.dysfunction=right ventricular dysfunction

5.3.1 Cox regression model fitness and PH assumption

For checking model goodness of fit, the Schoenfeld residual was performed for each covariate and the overall model, confirming that the Cox proportional hazards assumption was maintained and the model was fitted which yielded $\chi^2 = 13.57$ and a p-value of 0.2576, which is greater than 0.05, indicating no significant violation of proportionality in the model. Additionally, the Cox-Snell

residuals plot was closely aligned with a 45-degree diagonal line against the Nelson-Aalen cumulative hazard estimate, indicating that the residuals follow an exponential distribution. This confirms that the Cox model is appropriately specified and satisfies the proportional hazards assumption (Figure 6).

Furthermore, the graphical methods for the proportional hazard assumption checker were plotted for each independent predictor were parallel. The multicollinearity was checked, and the Variance Inflation Factor (VIF) was calculated as 1.17, well below the accepted threshold of 10, confirming no collinearity concerns among the included covariates. Additionally, interaction effects among variables were not observed.

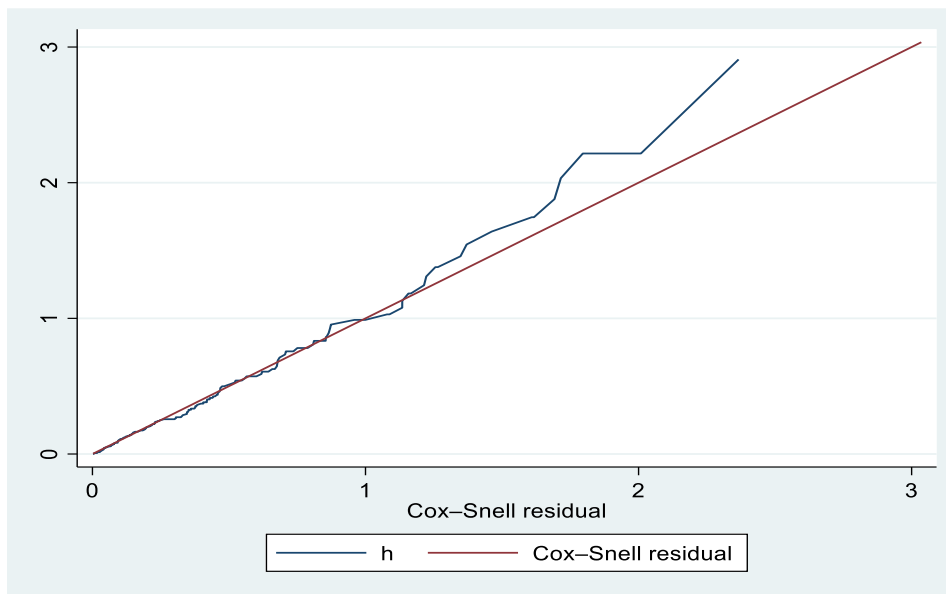


Figure 6 Cox-Snell residual graph for checking the multivariable Cox regression model fitness

6 Discussion

This study assessed the survival probability and identified key predictors of mortality among Rheumatic Heart Disease (RHD) patients waiting for valvular surgery at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, Ethiopia. The findings indicate that the overall survival rates at the end of one, two, and five years were 87.87%, 79.83%, and 59.32%, respectively. Several independent risk factors associated with increased mortality include ventricular dysfunction, New York Heart Association (NYHA) class III/IV, multivalve surgical indication, ejection fraction (EF) <40%, severe pulmonary hypertension, and infective endocarditis (IE).

The one-year mortality rate observed in this study (12.13%) closely aligns with findings from an Ethiopian study, conducted in 2005 at Gondar, which reported an annual mortality rate of 12.5% among all RHD cases (10). However, since this study focused specifically on advanced RHD patients requiring surgical intervention, a higher mortality rate was anticipated. The lower observed mortality might be attributed to patients lost to follow-up, potentially underestimating the actual mortality rate.

This is also in contrast with the Ugandan prospective follow-up study, which reported a one-year mortality rate of 17.8% (19). This study's findings indicate a lower mortality rate, suggesting possible regional differences in patient profiles and study design. The retrospective nature of our follow-up study may have led to the exclusion of incomplete medical records and uncertain outcomes among lost follow-up patients, potentially underestimating the actual mortality rate. In contrast, the prospective approach used in the Ugandan study mitigates these limitations, offering a more comprehensive assessment of survival outcomes. Implementing a prospective study design in our setting could enhance the accuracy of long-term survival estimates and address challenges related to data completeness.

Additionally, the first-year incidence of death in this study (144.19 deaths per 1,000 person-years) was higher than that reported in the REMEDY study (116.3 deaths per 1,000 person-years) (18). This discrepancy likely arises from differences in patient selection criteria our study primarily included patients with advanced disease, whereas the REMEDY study incorporated RHD patients across all severity levels. Healthcare accessibility also varied in the REMEDY study, which

included high-, middle-, and low-income countries, with patients from high-income settings potentially benefiting from improved cardiac care and lower mortality rates.

In this study, the overall one-year survival probability (87.89%) was higher than a Ugandan pre-interventional RHD survival study (77%) (9). This difference could be attributed to variations in sample size and registry duration. The Ugandan study utilized a 10-year registry database, whereas this study was based on a five-year registry. Similarly, the five-year survival probability in this study (59.32%) exceeded that reported in Uganda (46%) (9). Reinforcing the potential influence of study duration and population characteristics.

Consistent with previous studies (4, 9, 14, 15, 17,19) RHD in this cohort was predominantly observed among female patients, with a median age of 25 years. These findings align with global patterns, emphasizing the high burden of RHD among younger individuals, particularly women.

In this study, RHD patients with advanced heart failure (NYHA Class III/IV) had an increased risk of death by 2.94 times than earlier stages (NYHA Class I/II), which is consistent with findings from the REMEDY study (17,18). This underscores the progressive nature of heart failure in RHD, highlighting the critical need for medical management and timely surgical intervention to improve survival outcomes.

Patients with infective endocarditis had 2.39 times the increased risk of death than those without the condition, which aligns with findings from Uganda (9). Due to the severe complications associated with IE, emphasizing the importance of early detection, prophylactic antibiotic use, and optimized preoperative care may help reduce infection-related mortality.

Patients had right ventricular dysfunction at the time of surgical registration increased the risk of death three times, which is consistency with studies from Uganda and the REMEDY cohort (9, 17,18). This underscores the necessity of preoperative case stratification, particularly for patients with severely impaired cardiac function; those patients with right ventricular dysfunction exhibit a lower survival rate than other clinical conditions (27.57% probability of survival at the end of 2 years).

Patients who were indicated for multiple valvular lesion surgeries had a 1.54 times higher mortality risk than single valvular lesion. This is consistent with findings from Ugandan pre-interventional

RHD studies (9). This indicates that patients with more than one valve damage require complex surgery, may experience advanced disease stage, and have increased perioperative as well as postoperative mortality risks, indicating the necessity of close follow-up and timely intervention.

Patients' Ejection Fraction (EF) <40% at registry had a 2.67 times increased risk of death in this study. In contrast, this factor was not shown to be statistically significant in the Ugandan pre-interventional RHD survival study (9). The discrepancy may be due to differences in sample size and regional disparities, which may necessitate further investigation.

Patients with severe pulmonary hypertension (PHTN) had a 2.99 times higher mortality risk, which aligns with findings from both Uganda and the REMEDY study (17,18). PHTN significantly contributes to worsened survival outcomes by imposing right heart strain and impaired oxygen delivery, reinforcing the need for advanced pulmonary and cardiovascular care.

Additionally, this study found that patients aged <18 years at the surgical registry experienced significantly higher mortality than their adult counterparts, AHR=1.54 (1.01, 2.36). Which is in contrast to the REMEDY studies, which identified older age as a predictor of higher mortality among patients with rheumatic heart disease(18). This inverse age effect may reflect the different population studied that REMEDY included broader RHD cohorts with multiple comorbidities and varying treatment histories; our cohort focused solely on patients awaiting surgical intervention and excluded major non-communicable comorbidities.

The observed higher mortality in younger patients may reflect more aggressive disease progression, late presentation, and delays in surgical access. Notably, the Kaplan–Meier curves remained similar in earlier follow-up but diverged within months, suggesting that pediatric and adolescent patients are vulnerable to rapid clinical decline without timely surgery. These findings support prioritization of younger patients in surgical waiting lists and investment in earlier RHD screening and referral strategies for children and adolescents in resource-limited settings.

7 Strengths and Limitations of the Study

7.1 Strength of the study

The strength of this study lies in the use of appropriate advanced statistical analysis and design. The optimal sample size and follow-up period were used, ensuring the representativeness of the sample. A mixed approach was used for data collection; both reviewing patients' medical records and conducting phone interviews, to increase the data reliability and reduce missing data. Considering the worst case analysis, for patients' unknown survival status enables to estimation maximum probability of mortality rate in this cohort.

The study answered the research questions by estimating the survival probability of RHD patients waiting for valvular surgery in Ethiopia and their independent predictors. Through addressing those critical knowledge gaps in the survival of RHD patients, this research enables better patient care, surgical prioritization, and policymaking. While the study was conducted in a low-resource setting, the findings were used to reflect real-world challenges regarding scarcity in cardiac surgery, especially in RHD patients, and inform policy decisions for improving RHD care, early screening, and timely intervention in resource-limited settings like Ethiopia.

7.2 Limitations and challenges of the study

While this study provides valuable insight into RHD patients' survival and predictor factors. There are limitations to be considered; Due to the study was a retrospective follow-up, using hospital record data, most patients were excluded due to incomplete relevant medical records. Other predictors of survival, like socioeconomic and demographic factors, patients' lifestyle, and health care system-related factors, were not assessed in this study. Data cleaning on the hospital Iw-care system was a big challenge as the system needs a wifi connection, and some hospital mortality reports, especially in the medical and emergency ward, were not available due to this, for some individual while we calling patients who had hospital deaths, their families was offended by our call.

8. Conclusion and recommendation

8.1 Conclusion

This study reflects the high mortality rate in RHD patients awaiting valvular surgery at TASH, Ethiopia. The findings highlight the importance of addressing such particular patient conditions at a registry, patients presented with advanced heart failure (NYHA class III/IV), right ventricular dysfunction, Ejection Fraction <40%, Infective Endocarditis, multivalvular lesion indicated for surgery, younger age groups, and severe pulmonary hypertension. which significantly influences survival outcomes in RHD patients who are waiting for valvular surgery.

Overall the study findings underscore the need for healthcare system improvements such as strengthening early screening programs, strict and continuous patient follow-up and monitoring strategies, the need of stronger and urgent surgical intervention strategies in resource-limited settings like Ethiopia, the need for further research which considering additional predictor factors and using a longitudinal prospective follow-up study, and the need for organized national registration book for RHD patients are indicated.

8.2 Recommendation

Ministry of Health (MoH)

- Increase funding for cardiac surgery and infrastructure to reduce long waiting periods and improve patient access to treatment.
- Create community awareness to educate patients on early signs, prevention, and treatment adherence of RHD.

Tikur Anbessa Specialized Hospital (TASH)

- Identifying high-risk patients, and providing earlier intervention with responsible bodies.
- Enhance proper data documentation systems to ensure complete and reliable patient records.
- Engage in continuous research to refine treatment protocols and surgical techniques for RHD patients

Non-Governmental Organizations (NGOs) & International Partners

- Provide financial and logistical support to increase access to cardiac surgery and imaging in our country.
- Create community awareness to educate patients on early signs, prevention, and treatment adherence of RHD.
- Funding and supporting research to better understand RHD progression and surgical outcomes in Ethiopia.
- Collaboration with national and international cardiac center teams for further clinical and health care system skill exchange and resource sharing.

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Annex

I. Information sheet, consent form, and questionnaire English version

Addis Ababa University College of Health Science, School of Public Health

Introduction

Thank you for considering participating in this study. This information sheet is designed to provide you with details about the research project.

Research topic: Assessing survival of patients with rheumatic heart disease awaiting valvular surgery at Tikur Anbesa specialized hospital, Addis Ababa, Ethiopia, a retrospective follow-up study.

Hello, my name is (Data collector name), and I am conducting a research study as part of **“Assessing survival of patients with RHD awaiting valvular surgery at TASH.”** before we begin the interview, I would like to provide you with some important information and ask for your consent to participate.

The primary purpose of the study is to determine the time to death of RHD patients awaiting valvular surgery, with its mortality rate and predictor factors at TASH. We are conducting this interview to gather information about the overall health condition and the follow-up of patients at TASH. Your participation is completely voluntary. You are free to choose whether or not you wish to participate. You can withdraw at any time without any consequences or loss of benefits. All information shared during this interview will be kept confidential. Your responses will be recorded and used only for the purposes of this study. No identifying information will be shared, and all data will be stored securely.

The research has no significant risks associated with your participation in this interview. However, there are no direct benefits to you, but your participation will contribute to the overall research,

which may help improve the health outcome of RHD patients in TASH and for Ethiopians. You have the right to ask any questions you may have before, during, or after the interview.

Person to contact: This research proposal will be reviewed and approved by the institutional review board of Addis Ababa University School of Public Health Research Review Committee and TASH. Should you require any further details or clarification regarding the research methodology, ethical considerations, or any other aspects of the study, please feel free to contact us at For any additional information about the research content, you can contact us.

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Now, I would like to ask for your consent to proceed with the interview. Do you understand the information I have provided, and do you consent to participate in this study?

- a. Yes: _____ Proceed interview
- b. No: _____ Stop interview and say

Thank you for your time and consideration. Your participation, if you choose to proceed, is greatly appreciated.

II. Waiver of Consent

From: Bizunesh Akele

To: School of Public Health IRB

Dear chair;

This letter is to request a waiver of ethical clearance for a study on “**Assessing survival of patients with RHD awaiting valvular surgery at TASH, Addis Ababa, Ethiopia.**”

Investigator: Bizunesh Akele Reta, **Sponsor:** Addis Ababa University School of Public Health.

The data of this study will be collected by trained data collectors and supervisor, from patients’ medical records at TASH with additional phone interviews to confirm the survival status; when the outcome is not found in the hospital.

Purpose of the study: The primary purpose of the study is to determine the time to death of RHD patients awaiting valvular surgery including its mortality rate and predictor factors at TASH. The study results were primarily used for partial fulfillment of a Master's Degree in Public Health with the specialty of Epidemiology and Biostatistics from the Addis Ababa University School of Public Health.

Procedure: All adult patients with RHD enrolled in a waiting list of Valvular surgery from January 01/2019, up to December 30/2022, will be extracted from patient medical records and identified as eligible participants based on inclusive and exclusive criteria.

Risk: This study poses no significant risk to participants. However, there may be minimal emotional distress for the participants' families during phone interviews, particularly if the participant has passed away. To minimize this, data collectors will introduce themselves, ask for permission to inquire about the individual’s medical follow-up, and seek to understand why they lost contact and the participant's current status. If the individual has passed away, the data collector will express sympathy, saying, "I’m so sorry to hear about Mr./Ms..... I am deeply sorry for your loss. I understand this may be a difficult time." They will then offer a moment to share their grief and attempt to gather information about when and how the participant passed away.

Benefit: This study has no direct medical or financial benefits to participants during the study period, but the study will provide indirect long-lasting benefit for their health improvement when the study results used to provide valuable insights in improve healthcare planning and patient outcomes for RHD patients at TASH and throughout the country.

Confidentiality: Confidentiality will be strictly maintained throughout the study. Personal data will be anonymized with unique study ID numbers to protect participants' identities. Data will be stored securely in password-protected files and will only be accessible to authorized researchers. During phone interviews, verbal informed consent will be received from each participant and will be assured that their responses will remain confidential, and no identifiable information will be shared or published.

Sincerely

Thank you for your consideration

Bizunesh Akele

III. Questioners; English Version

Table 4. English Version Questioner

English Version Questioner			
S.no	Question	Answer	Remark
s.no 1	Baseline personal and sociodemographic information		
101	Participant ID number		
102	medical record number		
103	phone number	1. Primary:..... 2. Secondary:.....	
104	Gender	1. Male 2. Female	
105	Residency	1. Urban 2. Rural	Write the specific place.
106	Age at enrolment to surgery		
S.no 2	Baseline clinical characteristics at enrollment		
201	Date of first diagnosis of rheumatic heart disease		DD/MM/YY
202	Date of enrollment to surgical waiting list		DD/MM/YY
	Cardiac-related comorbidity at enrollment		
203	New york Functional, (NYHA) class	1. II 2. III 3. IV	
204	Does the patient have history of congestive heart failure (CHF)	1. Yes 2. No	
205	Classification of Heart Failure According to Ejection Fraction	1. Preserved >55% 2. Mid-range 40-55 3. reduce <40%	
206	Dose the patient have atrial fibrillation	1. Yes 2. No	
207	Dose the patient have history of infective endocarditis	1. Yes 2. No	
208	Dose the patient have history of stroke	1. Yes 2. No	

209	Does the patient have history of peripheral arterial embolism	1. Yes 2. No	
210	Does the patient have history of pulmonary hypertension	1. Yes 2. No	
211	What is the level of PHTN	1. Mild 2. Moderate 3. Severe	
The severity and pattern of valve lesion indicated for surgery			
212	Mitral regurgitation	1. Mild 2. Moderate 3. Severe	
212	Mitral stenosis	1. Mild 2. Moderate 3. Severe 4. Very severe	
213	Aortic regurgitation	1. Mild 2. Moderate 3. Severe	
214	Aortic stenosis	1. Mild 2. Moderate 3. Severe	
215	Tricuspid regurgitation	1. Mild 2. Moderate 3. Severe	
216	Tricuspid stenosis	1. Mild 2. Moderate 3. Severe	
217	Pulmonic regurgitation	1. Mild 2. Moderate 3. Severe	
Treatment related			
218	Is the patient on secondary prophylaxis	1. Yes 2. No	
219	History of cardiac related hospital admission	1. Yes 2. No	
Non-cardiovascular related comorbidity			
220	Does the participant have a history of acute kidney injury (AKI)	1. Yes 2. No	
221	Does the participant have a history of anemia	1. Yes 2. No	

S.no 03	Outcome of the participant		
301	The outcome of participants during the waiting period for surgery	<ol style="list-style-type: none"> 1. Death 2. Alive 3. Having surgery 4. Lost follow-up/withdrawal 	
303	After how long of waiting did the patient die (in years and months		
304	Source of survival status	<ol style="list-style-type: none"> 1. From the hospital medical and death records 2. Through phone calls 	
305	Reason for withdrawal from or loss to follow up	<ol style="list-style-type: none"> 1. Due to unmet surgical and medical needs 2. Due to starting follow-up in another cardiac center 3. Due to travel to a foreign country 4. Other specific 	
306	Time of withdrawal/ in months and years		
307	If surgery was done, specify the date.		

IV. Information sheet, and consent form and Questioner in Amharic የመረጃ መስጫ ገጽ እና የስምምነት መግለጫ ቅጽ

በዚህ ጥናት ውስጥ ለመሳተፍ ስላሰቡ እናመሰግናለን። ይህ የመረጃ ሉህ የተነደፈው ስለ የምርምር ፕሮጀክቱ ዝርዝሮችን ለእርስዎ ለማቅረብ ነው።

ጤና ይስጥልኝ ስሜ (መረጃ ሰብሳቢው ስም) _____ ነው እና ቃለ መጠይቁን ከመጀመሪያውን በፊት "የሻል-ቭላር ቀዶ ጥገና የሚጠባበቁ የቁርጥማት የልብ ሕመም ያለባቸው ህሙማን መትረፍ" በሚለው ርዕስ ዙሪያ የምርምር ጥናት እያካሄድኩ ነው፤ አንዳንድ ጠቃሚ መረጃዎችን ላቀርብላችሁ እና እጠይቃለሁ።

የጥናቱ ዋና ዓላማ:-

የሻል-ቭላር ቀዶ ጥገናን የሚጠባበቁ የቁርጥማት የልብ ሕመም ያለባቸው ታካሚዎች የሚሞቱበትን ጊዜ፣ የሚችነት መጠን እና መንስኤዎቹ በ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ትንበያዎች ላይ ለመወሰን ነው። ይህንን ቃለ መጠይቅ እያደረግን ያለነው ስለ አጠቃላይ የጤና ሁኔታ እና የታካሚዎችን ክትትል በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል መረጃ ለመሰብሰብ ነው። የእርስዎ ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት የተመሰረተ ነው። ለመሳተፍ መፈለግዎን ወይም አለመፈለግን ለመምረጥ ነፃ ነዎት። ያለ ምንም ችግር በማንኛውም ጊዜ ከጥናቱ መውጣት ይችላሉ። በዚህ ቃለ መጠይቅ ወቅት የሚጋሩት ሁሉም መረጃዎች ሚስጥራዊ ይሆናሉ። የእርስዎ ምላሾች ይመዘገባሉ እና ለዚህ ጥናት ዓላማዎች ብቻ ጥቅም ላይ ይውላሉ። ምንም መለያ መረጃ አይጋራም እና ሁሉም መረጃ ደህንነቱ በተጠበቀ ሁኔታ ይከማቻል።

ጥናቱ በዚህ ቃለ መጠይቅ ከእርስዎ ተሳትፎ ጋር የተገናኘ ምንም ጉልህ አደጋዎች የሉትም። ሆኖም፣ ለእርስዎ ምንም አይነት ቀጥተኛ ጥቅማጥቅሞች የሉም፤ ነገር ግን የእርስዎ ተሳትፎ ለአጠቃላይ ምርምሮች አስተዋፅዖ ያደርጋል፤ ይህም በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል እና በኢትዮጵያውያን የቁርጥማት የልብ ሕመም ያለባቸው ሕመምተኞች የጤና ውጤትን ለማሻሻል ይረዳል። ከቃለ መጠይቁ በፊት፣ በጊዜው እና ከቃለ መጠይቁ በኋላ የሚኖርዎትን ማንኛውንም ጥያቄ የመጠየቅ መብት አልዎት።

የሚያነጋግረው ሰው፡- ይህ የጥናት ሃሳብ በአዲስ አበባ ዩኒቨርሲቲ የህዝብ ጤና ጥናትና ምርምር ኮሚቴ ተቋማዊ ግምገማ ቦርድ ታይቶ ይፀድቃል። ስለ የምርምር ዘዴ፣ ስነ-ምግባራዊ ጉዳዮች፣ ወይም ሌሎች የጥናቱ ገጽታዎችን በተመለከተ ተጨማሪ ዝርዝሮችን ወይም ማብራሪያ ክፈለጉ እባክዎን ሊያገኙት ስለሚችሉት የምርምር ይዘት ተጨማሪ መረጃ በ ላይ ለማግኘት ነፃነት ይሰጣል።

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አሁን፣ በቃለ መጠይቁ ለመቀጠል ፍቃድህን ልጠይቅህ እፈልጋለሁ። ያቀረብኩትን መረጃ ተረድተሃል፣ እና በዚህ ጥናት ለመሳተፍ ተስማምተሃል?

1. አዎ ቃለ መጠይቁን ይቀጥሉ
2. አይ ቃለ መጠይቁን አቁም

ለጊዜዎ እና ለአስተያየትዎ እናመሰግናለን። ለመቀጠል ከመረጡ የእርስዎ ተሳትፎ በጣም እናመሰግናለን።

Table 5 Amharic version Questioner

S.no 01	የተሳታፊው ውጤት		
101	በመጠባበቅ ቀዶ ጥገና ወቅት የተሳታፊው ውጤት	<ol style="list-style-type: none"> 1. ሞት 2. ሕያው 3. ቀዶ ጥገና ማድረግ 4. የጠፋ ክትትል / መውጣት 5. ያልታወቀ 	
102	Q.no 301 መልሱ ሞት ከሆነ የሞተበትን ቀን ዳፍ		Write in DD/MM/YY
103	በሞተበት ወቅት የተሳታፊው ዕድሜ		Write in MM/YY
104	የሞት ሁኔታን እንዴት ማረጋገጥ እንደሚችሉ	<ol style="list-style-type: none"> 1. ከሆስፒታል ህክምና እና ሞት መዝገብ 2. 4. በስልክ በመደወል 	
105	Q.no 301 መልሱ የጠፋ ክትትል/መውጣት ከሆነ መከታተል የጠፋ ክትትል/መውጣት ምክንያቱ ምን ነበር?	<ol style="list-style-type: none"> 1. ባልተሟላ የቀዶ ጥገና እና የሕክምና ፍላጎት ምክንያት 2. በሌላ የልብ ማእከል ውስጥ ክትትል በመጀመሩ ምክንያት 3. ወደ ውጭ አገር በመጓዝ ምክንያት 4. ሌላ የተለየ 	
106	Q.no 301 መልስ በክትትል ወቅት ቀዶ ጥገና እያደረገ ከሆነ የጣልቃ ገብነት ጊዜን ይጻፉ		Write in DD/MM/YY

