

# Incidence of Paravalvular Leak and Prosthetic Valve Stuck within 30 Days After Open Heart Valve Replacement Surgery Retrospective Study in Addis Ababa, Ethiopia 2025.

*by Daniel Tadesse*

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**ADDIS ABABA UNIVERSITY**  
**COLLEGE OF HEALTH**  
**SCIENCE SCHOOL OF MEDICINE**  
**DEPARTMENT**  
**ANESTHESIOLOGY AND CTITICAL CARE**  
**CARDIO VASCULAR PERFUSION**

**Incidence of Paravalvular Leak and Prosthetic Valve Stuck within 30 Days After Open Heart Valve Replacement Surgery Retrospective Study in Addis Ababa, Ethiopia 2025.**

**INVESTIGATOR: DANIEL TADESSE**

**A RESEARCH PROPOSAL TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES, SCHOOL OF MEDICINE IN PARTIAL FULFILLMENT OF THE REQUIREMENT OF A MASTERS DEGREE IN CARDIOVASCULAR PERFUSION.**

**ADDIS ABABA, ETHIOPIA**

**JANUARY 2025**

**ADDIS ABABA UNIVERSITY**  
**COLLEGE OF HEALTH SCIENCE SCHOOL OF MEDICINE**  
**DEPARTMENT ANESTHESIOLOGY AND CTITICAL CARE**  
**CARDIO VASCULAR PERFUSION**  
**PROPOSAL SUBMISSION FORM**

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Title of study	Incidence of Paravalvular Leak and Prosthetic Valve Stuck within 30 Days After Open Heart Valve Replacement Surgery Retrospective Study in Addis Ababa, Ethiopia 2025.
Study period and study area	Eight months, at Elouzeir and Tazma
Proposed budget	<b>29,700 ETB</b>

**Addis Ababa, Ethiopia**  
**January, 2025**

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## **LIST OF ABBREVIATIONS AND ACRONYMS**

1. **ACC** American College of Cardiology
2. **AHA** American Heart Association
3. **CPB**
  - Cardiopulmonary Bypass
4. **DOACs**
  - Direct Oral Anticoagulants
5. **ECG**
  - Electrocardiogram
6. **INR**
  - International Normalized Ratio
7. **LVEF**
  - Left Ventricular Ejection Fraction
8. **NYHA**
  - New York Heart Association
9. **OHVRS**
  - Open Heart Valve Replacement Surgery
10. **PO**
  - Postoperative
11. **PVL**
  - Paravalvular Leak
12. **PVT**
  - Prosthetic Valve Thrombosis.
13. **TEE**
  - Transesophageal Echocardiography
14. **TTE**
  - Transthoracic Echocardiography

15. **THIJ**

- Texas Heart Institute Journal

16. **VHD**

- Valvular Heart Disease.

17. **WHO**

- World Health Organization

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## SUMMARY

### Introduction

Valvular heart disease (VHD) remains a critical global health burden, with causes differing by region: age-related degeneration dominates in high-income countries, while rheumatic heart disease (RHD) drives cases in sub-Saharan Africa, particularly Ethiopia. Open-heart valve replacement, the primary intervention in Ethiopia, faces challenges such as limited access to advanced technologies, inconsistent anticoagulation monitoring (e.g., INR), and inadequate follow-up. Early postoperative complications—paravalvular leak (PVL) and prosthetic valve thrombosis ("stuck valve")—are life-threatening yet understudied in Ethiopia, despite their high incidence linked to resource constraints and surgical limitations. This study investigates the 30-day postoperative incidence of PVL and valve thrombosis in Ethiopian patients, aiming to inform strategies to reduce complications and improve outcomes in low-resource settings.

**Objective:** To assess the incidence paravalvular leak and valvular stuck within 30 days following open-heart valve replacement surgery in Ethiopia

**Methodology:** an institutional -based retrospective study design will be conducted to determine immediate outcome patients who under valve replacement surgery from All patients who underwent valve replacement surgery. During the data collection period included in the study. The sample size calculates to be 192 by reduction formula. The data collection (DC) process will be organized and lead by the PI and patient chart will be reviewed to extract pertinent data from the participants. Before commencing the data, collection process the study objectives will clearly be explained to the respected person who handle the chart.

**WORK PLAN:** The study will be done from March to May 2025.

**BUDGET BREAKDOWN:** The study will be done with a total of 29,700 ETB.

### KEY WORDS:

Valvular heart disease (VHD), Rheumatic heart disease (RHD), Paravalvular leak (PVL) Prosthetic valve thrombosis,

## CHAPTER ONE

### 1. INTRODUCTION

#### 1.1 Background

Valvular heart disease (VHD) is a serious condition affecting the heart valves and remains a major health challenge worldwide. In many developed countries, valve dysfunction commonly arises from age-related degenerative changes, such as calcific aortic stenosis or mitral valve prolapse. Despite advances in surgical techniques and prosthetic valve design, early complications—particularly **paravalvular leak (PVL)** and **prosthetic valve thrombosis (stuck valve)**—continue to pose significant clinical risks, especially within the first 30 days following surgery (1).

Paravalvular leak, which involves blood leaking around rather than through the implanted valve, occurs in up to 17% of mitral valve replacements and up to 10% of aortic valve replacements. (2) Prosthetic valve thrombosis, though less frequent, is often life-threatening and is associated with factors like poor anticoagulation control or surgical technique.

In Africa, especially in sub-Saharan regions, the burden of VHD is largely driven by rheumatic heart disease (RHD), affecting a younger population compared to high-income nations. Due to limited access to advanced technologies, **open heart surgery** remains the only viable method for valve replacement in most centers. As a result, patients face increased risks of postoperative complications, including those seen within the immediate recovery phase. (3)

In Ethiopia, RHD is a leading cause of valve disease requiring surgical intervention. Major hospitals like the Cardiac Center of Ethiopia perform open heart valve replacements to manage these cases. However, challenges such as inadequate INR monitoring, limited access to anticoagulation clinics, and inconsistent follow-up contribute to early postoperative complications. A study conducted at the Cardiac Center of Ethiopia reported a notable rate of prosthetic valve thrombosis within a few weeks after surgery, despite efforts to maintain adequate anticoagulation. (1)

Despite these concerning trends, there is limited data specifically investigating the **immediate (within 30 days)** incidence of PVL and stuck valves following valve replacement surgery in Ethiopia. This study aims to fill that gap by reviewing the early postoperative outcomes of patients undergoing open heart valve replacement in selected Ethiopian hospitals. The findings will help inform improved postoperative care, patient monitoring, and health policy to reduce complications and enhance outcomes.

#### 1.2 Statement of the problem

Valvular heart disease (VHD) continues to pose a significant global health burden, especially in low- and middle-income countries. In high-income countries, VHD is mainly degenerative and occurs in older populations, while in sub-Saharan

Africa, including Ethiopia, the majority of cases are caused by **rheumatic heart disease (RHD)**, affecting much younger individuals. (5)

Valve replacement surgery, often performed via open heart techniques in resource-limited settings, remains a definitive treatment for advanced valvular lesions. (6) However, **early postoperative complications**, particularly **paravalvular leak (PVL)** and **prosthetic valve thrombosis (valve stuck)**, continue to challenge surgical success and patient survival. PVL is the leakage of blood between the prosthetic valve and the native tissue, often due to improper seating or annular calcification. It can result in hemolysis, heart failure, or even require reoperation. (7) Similarly, valve thrombosis can obstruct valve mobility, impairing cardiac output and leading to thromboembolic events or sudden death. (8)

Globally, the reported incidence of PVL after mitral valve replacement ranges from 7% to 17%, and about 2% to 10% for aortic valves. (7) Early valve thrombosis has a reported incidence of 0.3% to 1.3%, though this may be higher in settings with inconsistent anticoagulation management. (9) These complications most frequently occur **within the first 30 days** after surgery, a critical period requiring close monitoring and anticoagulation adjustment. (10)

In Ethiopia, open heart surgery remains the **only available method** for valve replacement due to the lack of catheter-based interventions. Despite progress in surgical capacity, postoperative follow-up is often compromised by **limited access to echocardiography, inadequate INR monitoring, and delayed complication recognition**. A recent study from the Cardiac Center of Ethiopia highlighted multiple cases of **early prosthetic valve thrombosis** associated with subtherapeutic INR values. (11) However, data on **immediate PVL and combined complication incidence** remains lacking.

This knowledge gap hinders evidence-based improvements in postoperative protocols and leaves clinicians reliant on international data that may not reflect the Ethiopian context. Hence, there is an urgent need to **evaluate the incidence and potential predictors of PVL and valve stuck within the first 30 days post-surgery** to enhance early detection, guide anticoagulation strategies, and reduce morbidity and mortality in this vulnerable patient group.

### 1.3 Significance of the study

This study is important because it focuses on a life-threatening issue that affects heart patients in Ethiopia—complications like **valve leakage** and **stuck valves** shortly after surgery. These problems can lead to serious health issues or even death if not detected early. Yet, in our country, there's very little information about how often these issues happen and how they can be prevented.

By studying real cases from our hospitals, this research will help doctors and health professionals catch these complications sooner and treat patients more effectively. It will also guide hospitals on how to better follow up with

patients, especially during the first month after surgery, when they're most at risk. The findings can lead to better care, fewer repeat surgeries, and ultimately, **more lives saved**.

Most importantly, it gives a voice to Ethiopian patients and ensures that their care is informed by local evidence—not just global data that doesn't always match our reality.

## CHAPTER TWO

### 2.1 LITERATURE REVIEW

Heart valve replacement surgery has saved countless lives worldwide. It is often the only option for people suffering from advanced valvular heart disease—whether caused by aging, infection, or diseases like rheumatic fever. But even after successful surgery, serious complications like paravalvular leak (PVL) and valve thrombosis (commonly called a stuck valve) can occur, especially during the first 30 days after surgery, which is considered the critical recovery phase. (12)

In high-resource settings, surgeons and cardiologists are well aware of these early complications and have developed systems to detect and manage them. A paravalvular leak occurs when blood flows around—not through—the new valve due to an incomplete seal with the surrounding tissue. Studies show PVL can develop in 2% to 17% of cases, depending on the valve type and surgical technique (13) Mild leaks may be asymptomatic, but moderate or severe PVL can cause heart failure, hemolytic anemia, or the need for reoperation.

Valve thrombosis, particularly with mechanical valves, is another early complication. It occurs when a clot forms on the valve, interfering with its movement and impeding blood flow. The early incidence is reported between 0.3% and 1.3%, often due to sub therapeutic anticoagulation. (14) In resource-rich countries, regular monitoring of INR (a measure of blood thinning) and access to imaging reduce the risk and consequences.

In many African countries, rheumatic heart disease (RHD) remains the main cause of valve damage. It often affects younger people, especially women of childbearing age. These patients typically present late, with severe valve damage that requires urgent replacement. (15)

Open-heart surgery is the standard treatment in most sub-Saharan countries because transcatheter valve replacement is either unavailable or unaffordable. However, due to limited resources, complications like PVL and stuck valves are harder to prevent or manage. Access to echocardiography, INR testing, and postoperative education is often lacking.

A study from Sudan emphasized that valve thrombosis was common in patients who lacked regular follow-up and couldn't monitor their INR properly. (16) This issue is echoed across sub-Saharan countries, where infrastructure for postoperative care is underdeveloped.

In Ethiopia, heart surgery services have expanded, especially at institutions like the Cardiac Center of Ethiopia. But despite this progress, early postoperative complications still pose significant risks. Most patients receive mechanical valves, which require lifelong anticoagulation. However, due to inconsistent INR monitoring, many develop complications early in the recovery process.

A study conducted at the Cardiac Center of Ethiopia in 2023 found that prosthetic valve thrombosis was a leading cause of readmission within the first month after surgery. (17) Several patients experienced severe symptoms like shortness of breath, and some required reoperation. Importantly, this study confirmed that most patients who developed a stuck valve had subtherapeutic INR levels, indicating inadequate anticoagulation.

Globally, mechanical valves are preferred in younger patients due to their durability, but they require lifelong anticoagulation. In contrast, bioprosthetic valves, which are made from animal tissue, are less thrombogenic but tend to wear out over time. Studies have shown that mechanical valves are more prone to valve thrombosis, especially when INR is not well managed (18). Bioprosthetic valves, while safer in terms of thrombosis, may be associated with mild PVL due to their flexibility and softer seating (21).

INR (International Normalized Ratio) is a major predictor of prosthetic valve thrombosis. A subtherapeutic INR (usually  $<2.0$  for mechanical valves) increases the risk of clot formation on the valve, leading to it getting stuck. Roudaut et al. (19) emphasized that up to 75% of stuck valve cases were due to inadequate anticoagulation. This makes INR monitoring a critical independent variable. In low-resource settings like Ethiopia, limited access to INR testing and patient non-adherence to warfarin regimens worsen this risk (23).

Longer CPB and cross-clamp times are associated with increased tissue trauma, inflammation, and higher risk of annular injury or poor healing, predisposing to PVL. A study by Genovese et al. (20) found that CPB time over 120 minutes significantly increased PVL incidence. Inadequate myocardial protection or poor de-airing techniques during surgery may also contribute.

Heavy calcification of the valve annulus, especially in rheumatic heart disease (common in Africa), can make it harder to seat the valve properly, increasing the chance of paravalvular leak. Similarly, improper valve sizing—either too small or too large—can result in incomplete sealing and PVL (22).

Patients with conditions such as atrial fibrillation, diabetes, or hypertension have higher risks of both bleeding and clotting. Atrial fibrillation, in particular, increases the risk of thrombus formation on mechanical valves, especially if anticoagulation is not well-managed (18).

Younger patients are more likely to receive mechanical valves and may tolerate complications better. Older age has been associated with higher PVL risk due to friable tissue, while female sex has been weakly linked to higher rates of valve thrombosis, potentially due to body size differences affecting valve fit (20).

Experience of the surgical team and quality of postoperative care influence outcomes. A well-trained team can reduce CPB time, improve valve seating, and ensure proper anticoagulation instructions. In Ethiopia, Tazma and Eliezer Cardiac Centers are among the few centers performing open-heart valve surgeries, making it important to understand complication patterns in these settings (23).

The study focused on valve thrombosis, no comprehensive study has yet examined the combined burden of PVL and valve stuck within the first 30 days post-surgery in Ethiopia. This early period is critical, and better data could inform improved management strategies for Ethiopian hospitals.

By identifying how common these complications are and what causes them, we can improve surgical outcomes, reduce hospital readmissions, and ultimately save more lives.

## 2.2 CONCEPTUAL FRAMEWORK

**Patient-Related Factors:** Age, Sex, Type of valve pathology (rheumatic, degenerative, etc.), Type of valve (mechanical vs. bioprosthetic), Comorbidities (e.g., atrial fibrillation, hypertension), Preoperative

**Surgical Factors:** Type of valve replaced (mitral, aortic, double), Valve size and fit, Surgeon experience, Duration of cardiopulmonary bypass, Intraoperative complications

**Incidence of Paravalvular leak and stuck valve**

**Postoperative Factors:** INR levels Adherence to anticoagulation, Presence of infection (endocarditis), Echocardiographic follow-up availability

Figure 1: The framework below shows that the independent variables do not in isolation but interact with each other to influence the dependent variable.

## CHAPTER THREE

### OBJECTIVE OF THE STUDY

#### 3.1. General objective

- To assess the incidence paravalvular leak and valvular stuck within 30 days following open-heart valve replacement surgery in Ethiopia.

#### 3.2. Specific objective

- ✓ 1. To determine the 30-day incidence of paravalvular leak PVL and valvular stuck in patients undergoing open-heart valve replacement surgery.
- ✓ 2. To identify patient-specific risk factors associated with PVL or valvular stuck.
- ✓ 3. To compare 30-day clinical outcomes, including mortality and reintervention rates, between patients with and without PVL or valvular stuck.

## CHAPTER FOUR

### METHODS

#### 4.1. Study Setting

The study area will be conducted at 2 centers in Addis Ababa Cardiac Center of Ethiopia, Elozouir Cardiac Center and Tazma Cardiac Center) that are conducting heart surgery. All patients who underwent heart surgery during the period from January 2023 february2024 performed 2 centers will be included in the study Those cardiac centers are located in Addis Ababa, the capital city of Ethiopia.

Elouzouir Cardiac Center was established in 2016. There are 15 cardiothoracic surgeons, from all, five can do open-heart surgery, one specialist might serve at more than one center. Tazma Medical & Surgical Specialized Center, located in Addis Ababa, Ethiopia, is a leading healthcare facility offering advanced cardiac care, open-heart surgery, and specialized medical services, including endocrinology, gastroenterology, neurology, and general surgery. Established in 2009, it is a pioneer in private cardiac surgery for both adults and children. Equipped with state-of-the-art medical technology and intensive care units, the center is committed to delivering high-quality healthcare. It actively engages in community health initiatives, providing accessible and compassionate medical services.

#### 4.2 Study Design and Period

An institution-based retrospective study design will be conducted from March to May 2025.

### 4.3 Population

#### 4.3.1 Source Population

. The source population where all patients who following open valve replacement surgery to Tazma and Elouzeir cardiac center from JAN, 2023 to FBE, 2024

#### 4.3.2 Study Population

- ✓ All patients who the following open-heart valve replacement surgery.
- ✓ Complete 30-day follow-up data available.

#### 4.3.3 Inclusion Criteria

- ✓ Patients undergoing open heart valve replacement surgery with mechanical/bioprosthetic implants, and having complete 30-day postoperative follow-up data at tazma and elouzer.

#### 4.3.4 exclusion criteria

- ✓ Prior valve replacement/repair.
- ✓ Intraoperative/postoperative death within 24 hours.
- ✓ Preoperative anticoagulant use (unless discontinued).
- ✓ Lost to follow-up/incomplete data.

### 4.4 Sample Size Determination

The sample size was determined using a single population proportion formula, since the main objective is to estimate the proportion (incidence) of paravalvular leak or valvular stuck within 30 days after open-heart valve replacement surgery.

Formula

$$n = Z^2 \times p \times (1 - p) / d^2$$

Where:

**n** = required sample size

**Z** = Z-score for 95% confidence level = **1.96**

**p** = estimated proportion of early complication (PVL or valve stuck).

**d** = margin of error (precision), typically set at **5% (0.05)**

**Assumption:**

Since there is limited local data in Ethiopia, we use a previous study estimate from Egypt which reported a 13.5% incidence of early prosthetic valve complications (including PVL and stuck valve) within 30 days (El-Gamel et al., 2020). Thus:

$$p = 0.135$$

$$d = 0.05$$

**Calculation:**

$$n = \frac{(1.96)^2 \times 0.135 \times (1 - 0.135)}{(0.05)^2} = \frac{3.8416 \times 0.135 \times 0.865}{0.0025} = \frac{0.448}{0.0025} = 179.2$$

$$n_{\text{adjusted}} = 180 + (10\% \text{ of } 180) = 180 + 18 = 198$$

$n = 179.2$  So,  $n \approx 180$

**Adjusting for 10% Incomplete Charts:**

$$n_{\text{adjusted}} = 180 + (10\% \text{ of } 180) = 180 + 18 = 198$$

**4.5 Sampling Techniques**

A proportionally stratified systematic sampling method will be used. Out of a total of **380** patients who underwent open-heart valve replacement:

**Tazma Cardiac Center (218 cases):** 113 patients will be selected.

**Eliezer Cardiac Center (162 cases):** 85 patients will be selected.

Using systematic sampling, every 2nd chart will be reviewed from each center's surgical registry after randomly selecting a starting point. This ensures fair representation and minimizes bias in the retrospective review.

**4.6 Study Variables**

**Paravalvular Leak (PVL)** within 30 days following open valve replacement surgery.

**Stuck Valve (Valvular Thrombosis)** within 30 days following open valve replacement surgery.

**4.6.1 Independent variables****A. Socio-demographic Variables:**

✓ Age

- ✓ Sex

### **B. Clinical and Surgical Variables:**

- ✓ Type of valve replaced (Mitral, Aortic, Double)
- ✓ Type of prosthetic valve (Mechanical or Bioprosthetic)
  
- ✓ Indication for valve replacement (e.g., Rheumatic disease, Degenerative)
- ✓ Comorbidities (e.g., Hypertension, Diabetes, Atrial fibrillation)
- ✓ Preoperative anticoagulation status
- ✓ Cardiopulmonary bypass (CPB) time
- ✓ Cross-clamp time

### **C. Postoperative Variables:**

- ✓ INR level within 30 days
  
- ✓ Presence of infection or endocarditis
- ✓ Echocardiographic findings (e.g., leak size, valve mobility)
- ✓ Need for reoperation or re-intervention
- ✓ In-hospital mortality

#### **4.7 Operational Definitions**

##### **Paravalvular Leak (PVL):**

This refers to a leak that occurs around the edges of a replaced heart valve not through it when the new valve doesn't seal perfectly with the surrounding heart tissue. It's usually detected by echocardiography within the first 30 days after surgery and can range from mild (with no symptoms) to severe (requiring medical attention or even a second surgery).

##### **Stuck Valve (Valve Thrombosis):**

A stuck valve happens when the moving parts of a prosthetic heart valve especially mechanical ones can't open or close properly. This is usually due to a blood clot or tissue growth, and it can cause symptoms like shortness of breath or even heart failure. It's often confirmed by echo or imaging during the early post-op period.

##### **Valve Replacement Surgery:**

This is a major heart operation where a damaged or diseased valve is surgically removed and replaced with an artificial

one—either mechanical (metal) or bioprosthetic (tissue-based). In Ethiopia, this is typically done through open-heart surgery.

**Early Postoperative Period:**

The first 30 days after surgery, a critical window for detecting immediate complications like leaks or thrombosis.

**Cardiopulmonary Bypass (CPB) Time:**

The length of time the patient’s heart and lungs are supported by a machine during surgery. Longer bypass times are linked to more risks.

**INR (International Normalized Ratio):**

A blood test that checks how well the blood is thinning, especially in patients with mechanical valves. Too low, and clots can form; too high, and bleeding becomes a risk Comorbidities:

These are other medical conditions a patient may have—like high blood pressure, diabetes, or irregular heartbeat—that could influence recovery after surgery

**4.8 Data collection tools and procedures**

**4.8.1 Data collection tools**

The data collection was carried out using specifically designed checklist. The checklist was prepared in English. In addition, materials such as patient’s charts. stationery materials, operation-room logbook, ICU registration books, laptop, Data was collected by trained BSc nurses who will receive training for two days on how to collect the data Using the checklist, the chart was reviewed and patient how to collect the data. Supervision will be made by the primary investigator to check the completeness and consistency of data. If incomplete data found, it will be analyzed as missed data.

The tool was adapted and modified from a previously conducted study at the, which can ensure its relevance, reliability, and applicability to the Ethiopian healthcare context.

**4.9 Data Collection procedures**

The data collection (DC) process will be organized and lead by the PI with a secondary data to extract pertinent data from the participants chart. Data extraction will be done from secondary data (from medical chart). The data that will be taken from the participants chart will kept confidentially within the DC team and interpretation of the data will consider personal identifiers. Two trained data collectors (nurses) and one DC supervisor will be recruited and participate in the data collection process. One day training will give for data collectors before the initiation of data collection to level up their understanding on the DC tools sections accordingly. In addition, their division of work in study settings will be clarified

#### 4.10 Data quality control measures

Before data collection, the primary investigator will ensure and choose an appropriate study design, study participants, and organize the tools accordingly. To ensure the quality of data, data collectors was trained for 1 days and pre-test of check list was tested on 5% samples to assess for clarity, length and completeness. Then after, some possible adjustment/correction was made. Daily meeting was held between the principal investigator, supervisor and the data collectors to discuss any problems in the data collection. The collected data was checked for completeness and consistency. The data entry was done weekly the data will be checked for its completeness before entry to SPSS software for analysis. It will be checked for the completeness in every data collection day then if there is any incomplete data, it will be replaced

#### 4.11 Statistical Analysis

Data will be collected by google docx and exported to SPSS version 27 for cleaning and analysis. A Descriptive and inferential statistics will be calculated. In descriptive statistical analysis, the data will be summarized in percentage, frequency and/or mean and standard deviation then the results will be described and presented using frequency tables, figures and charts Data the variable Chi square test with P-value will be used when appropriate to test the significance of changes in these variables. The strength of an association between dependent and independent variables and its significance will be computed using odds ratio with 95% confidence interval and Bivariate Logistic regression analyses will be carried out to assess the association between the dependent and independent variables and to identify candidate for multivariate analysis

#### 4.12 Ethical Considerations

Ethical approval will be obtained from the Ethical Review Board of the School of Medicine, College of Health Sciences (CHS), and Addis Ababa University (AAU) with a reference number. Then a letter will be written by the Dean Office of the School of Medicine to obtain permission from Tazma and Elouzeir cardiac center for conducting the study. After gaining the approval letter from the study area the data will be collected starting from the month of March to April by getting an agreement from each study unit through written informed consent. participant. Confidentiality

### **Dissemination of Results**

The finding of this study will be disseminated to AAU, School of Medicine and the two hospitals will receive a copy of the final thesis report. Based on their permission the PI will present the research findings to the hospitals' community. To communicate the information on a broader scale, it will be published in a reputable scientific journal

## 5 CHAPTER FIVE

### 5.1.WORK PLAN

**Table 1:** Research Work Plan/Timelines

SN	Activities	Responsibility	Timeline (2024/2025)							
			Dec	Jan	Feb	Mar	Apr	May	Jun	July
1	Proposal write-up	PI	■							
2	Proposal Defense & IRB Approval	PI		■	■					
3	Securing Research Fund	AAU			■					
4	Pre-test	PI				■				
5	Training for DC	PI				■				
6	Data Collection	DC				■	■			
7	Data Entry & cleaning	PI					■			
8	Statistical Analysis	PI						■		
9	Report Write-up	PI						■		
10	First Draft submission	PI							■	
11	Manuscript write-up	PI								■
12	Final Draft Submission	PI								■
13	Defense	PI								■
14	Manuscript Submission for Publication	PI								■

**Key:** PI: Principal Investigator, DC: Data Collector

## 5.2. BUDGET BREAKDOWN

**Table 2:** Budget Breakdown

Budget category		Required	Unit price/ in	Rating	Total Expense
SN		amount	ETB		in ETB
<b>1</b>	<b>Personnel Expense</b>				
	Data collectors	2	80/1patient	160x132	<b>21,840</b>
	Data Collection supervisors	1	150/day	250x20	<b>5000</b>
<b>2</b>	<b>Internet</b>		600		<b>600</b>
<b>3</b>	<b>Stationary</b>		600		<b>600</b>
<b>4</b>	<b>Transportation</b>		1500		<b>1500</b>
<b>5</b>	<b>Contingency</b>		1000		<b>1000</b>
<b>6</b>	<b>Grand Total</b>				<b>29,700</b>

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31. ) (Ref: Charlson Comorbidity Index, 2023; WHO Global Health Estimates)

## ANNEXES

**Questionnaires for the topic to assess the incidence paravalvular leak and valvular stuck within 30 days following open-heart valve replacement surgery in Ethiopia**

### Section A: Demographic and Clinical Background

1. Patient ID (for anonymity):
2. Age:
3. Gender:
  - Male
  - Female
  - BMI body mass index (kg/m<sup>2</sup>) \_\_\_\_\_

#### 4. Clinical Comorbidities

- Hypertension
  - Diabetes mellitus
  - Chronic kidney disease
  - Atrial fibrillation
5. intra op
- Bypass time (minutes): \_\_\_\_\_
- Cross-clamp time (minutes)
- Valve size/mm

#### 6.Type of valve replaced:

- Mitral
- Aortic
- Pulmonary
- Tricuspid
- Multiple

#### 7.Type of prosthetic valve implanted:

- Mechanical
- Bioprosthetic

**Section B: Objective 1 – Assessment of Valve Stuck Within 30 Days**

9. Was the prosthetic valve stuck within 30 days post-surgery?

- Yes
- No (*Skip to Section C*)

10. Date of detection: \_\_\_\_\_

11. Suspected/confirmed cause of stuck valve (*select all that apply*):

- Thrombosis
- Pannus formation
- Infective endocarditis
- Structural valve deterioration
- Other: \_\_\_\_\_

12. Symptoms leading to detection (*select all that apply*):

- Dyspnea
- Chest pain
- Syncope
- New murmur
- Other: \_\_\_\_\_

13. Diagnostic method used:

- Echocardiography (TTE/TEE)
- Fluoroscopy
- Clinical examination
- Other: \_\_\_\_\_

14. Intervention performed:

- Medical (e.g., thrombolytics)
- Reoperation
- No intervention
- Other: \_\_\_\_\_

15. Outcome of intervention within 30 days

- Resolved
- Persistent dysfunction

- Death
- 

**Section C: Objective 2 – Assessment of Paravalvular Leak Within 30 Days**

16. Was a paravalvular leak detected within 30 days post-surgery?

- Yes
- No (*Skip to Section D*)

17. Date of detection: \_\_\_\_\_

18. Severity of leak:

- Mild
- Moderate
- Severe

19. Symptoms associated with the leak (*select all that apply*):

- Hemolysis
- Heart failure symptoms (e.g., edema, fatigue)
- New murmur
- Asymptomatic
- Other: \_\_\_\_\_

20. Diagnostic method used:

- Echocardiography (TTE/TEE)
- Angiography
- Clinical examination
- Other: \_\_\_\_\_

21. Intervention performed:

- Medical management
- Reoperation
- No intervention
- Other: \_\_\_\_\_

22. Outcome of intervention within 30 days:

- Resolved
- Persistent leak
- Death
- If death primary Cause \_\_\_\_\_

23. Echocardiography and imaging finding

Date of the first post-op echo \_\_\_\_\_

Ejection fraction \_%

25. Evidence of thrombosis or mass on valves?

Yes

No

Not assessed

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**Section D: Objective 3 – Incidence of Complications**

*(Note: This section will be auto-calculated during data analysis by aggregating responses from Sections B and C.)*

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**Section E: Additional Observations of post -op**

23. Other postoperative complications within 30 days (e.g., stroke, infection, bleeding):

- None
- Stroke
- Surgical site infection
- Major bleeding
- Other: \_\_\_\_\_

# Incidence of Paravalvular Leak and Prosthetic Valve Stuck within 30 Days After Open Heart Valve Replacement Surgery Retrospective Study in Addis Ababa, Ethiopia 2025.

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