ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF NURSING AND MIDWIFERY

CARDIOVASCULAR NURSING GRADUATE PROGRAM

Assessment of Vascular Complication and Associated factors Among Patients who underwent Cardiac Catheterization, A retrospective study at Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

Principal investigator: - Sosina Dejene Gulema (BSc)

A Thesis Submitted to the School of Graduate Program of Addis Ababa University, College of Health Science School of Nursing and Midwifery, for Partial Fulfillment of The Requirements for a Degree of Masters Science in Cardiovascular Nursing.

JUNE, 2025

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APPROVAL BY THE BOARD OF EXAMINATION

This thesis by Sosina Dejene is accepted in its present form by the board of examiners as satisfying thesis requirement for the degree of Masters of Science in cardiovascular nursing.

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STATEMENT OF DECLARATION

By my signature below, I declare and affirm that this thesis is my own work. I have followed all ethical principles of scholarship in the preparation, data collection, data analysis and completion of this thesis. All scholarly matter that is included in the thesis has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this thesis.

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ABBREVIATIONS

AF – Atrial Fibrillation

ASD – Atrial Septal Defect

AVF – Arterio-venous Fistula

BMI – Body Mass Index

BVP – Balloon Valvuloplasty

DM – Diabetes Mellitus

GFR – Glomerular Filtration Rate

MI – Myocardial Infarction

PCI – Percutaneous Coronary Intervention

PDA- Patent Ductus Arteriosus

PMBC – Percutaneous Mitral Balloon Commissurotomy

PTCA – Percutaneous Trans-luminal Coronary Angiography

PVC – Premature Ventricular Contraction

SPSS - Statistical Package for Social Sciences

VCD – Vascular Closure Device

VT – Ventricular Tachycardia

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ABSTRACT

Background: Cardiac catheterization is an invasive procedure performed for diagnosing and treating heart conditions. Its invasive nature can lead to various complications. Vascular complications have been recognized as significant contributors to post-procedural morbidity. They also contribute to increased patient discomfort, prolonged hospital stays, higher treatment costs, and negative patient outcomes. Several studies in other setting have shown that the rate of major vascular complications ranges from 0.3% to 1%. However, their prevalence in Ethiopia remains unknown.

Objective: This study aims to determine the prevalence of vascular complications and identify associated risk factors among patients who underwent cardiac catheterization in Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

Methods: A retrospective study was conducted from January 1, 2020, to December 31, 2024, at the Ethiopian Cardiac Center. Systematic random sampling of 305 patient records was undertaken. Structured checklists were employed to gather information and SPSS version 26 for analysis. Binary logistic regression analysis was performed to find factors associated with vascular complications. Adjusted odds ratios (AORs) with 95% confidence intervals (CI) and p-values < 0.05 were utilized as statistically significant.

Results: The prevalence of vascular complications was 15.1%. The most common complications included hematoma (4.6%), hemorrhage (3.6%), and thromboembolism (1.0%). In Multivariable regression, patients who are females, overweight, and had previous catheterization had over four times the odds of developing vascular complications compared to male (AOR = 4.07, 95% CI: 1.50–11.02, P = 0.006), underweight BMI (AOR = 5.31; 95% CI: 1.38–20.32; *p* = 0.015), and no previous catheterization (AOR = 5.26; 95% CI: 1.59–17.36; *p* = 0.006).

Conclusion: the study suggests moderate prevalence of vascular complication and also that the risk of complications was much higher in female patients, overweight patients, and patients with prior catheterization.

Recommendations: This study recommends giving special attention to female patients, those with higher body mass index, and individuals with a previous cardiac catheterization, as they were found to have a significantly higher risk of vascular complications. Further multicenter studies are needed to assess long-term complications and enhance generalizability.

Key words: Vascular complication and Cardiac catheterization

1 INTRODUCTION

1.1 Background

Cardiac catheterization is invasive technique for diagnosing and treating cardiac disorders. It is the main technique used to identify and treat coronary artery disease (1, 2). Advanced imaging techniques such as 3D angiography, image fusion, 3D printing, and holography enhance understanding of complex congenital heart defects. While traditional fluoroscopy and angiography remain key, innovations in devices and implantation technique have expanded percutaneous therapies, particularly for high-risk surgical patients (3).

Over time, the criteria for cardiac catheterization have expanded from primarily low-risk patients to include those with complex coronary diseases and high-risk situations, such as acute coronary syndromes(4). Its invasive nature can lead to various complications. Common complications associated with cardiac catheterization include infections, pain and injury at the insertion site, blood clots, and kidney damage from contrast dye, particularly affecting patients with kidney diseases or diabetes mellitus (DM). The most frequent complications are vascular, which can lead to increased discomfort, longer hospital stays, and poorer patient outcomes. Vascular complication refers to problems that arise in the blood vessels (1, 2). To address this, multiple studies have been conducted to help cardiologists identify, report, and monitor these complications, aiming to establish performance standards for catheterization labs(5).

Cardiac catheterization is performed through the radial and femoral artery approach. The radial artery is often linked to vascular complications, but these have less occurrence when compared to the femoral approach(6). Injuries to the femoral artery are common following diagnostic and therapeutic cardiac catheterizations(7). Vascular complications have been recognized as significant contributors to post-procedural morbidity. Recent research highlights that bleeding after diagnostic cardiac catheterization and percutaneous coronary interventions (PCI) procedures, especially retroperitoneal bleeding, is a notable source of complications that lead mortality. Since all bleeding incidents are not directly tied to the access site, these complications remain key factor in post-procedural bleeding(8). Common major and minor complications associated with femoral artery access include: hematomas, arteriovenous fistulas (AVF), pseudoaneurysms, retroperitoneal hematomas, and external bleeding, femoral artery dissection, loss of pulse to the distal extremity, mycotic aneurysms (major complication) and ecchymosis,

mild bleeding and swelling (minor complication), other major complications associated with closure devices are thrombosis, infection, and embolism(9). Peripheral vascular complications are increasingly recognized as a significant aspect of traumatic vascular injuries following cardiac catheterization, particularly with coronary angioplasty(10). Complications from the femoral artery can range from minor needing simple interventions to serious conditions requiring invasive procedures or surgery(11).

Several common factors contribute to vascular complications, including advanced age, repeated procedures, frequent use of the same vascular access site, and the use of anticoagulant medications. Numerous studies aimed to identify risk factors for these complications, highlighting factors such as older age, female sex, obesity, smoking, and pre-existing medical conditions like hypertension and renal failure. Additionally, the use of large sheaths, prolonged sheath duration, and excessive coagulation have been implicated(2). Other variables linked to increased risk include hemodynamic instability with shock, elevated creatinine levels, ejection fractions below 20%, recent myocardial infarction, pre-procedural cardiogenic shock, congestive heart failure upon admission, renal impairment requiring dialysis, and the presence of peripheral vascular disease(12). In Ethiopia; Smoking, diuretics use and having chronic kidney disease were found to have a significant association with peri-procedural contrast induced nephropathy and bleeding in population(13).

Cardiac catheterization has been performed at the Ethiopian Cardiac Center for over ten years, with the number of procedures steadily increasing to around 300 patients per year. However, the prevalence of associated complications and contributing factors remain unknown.

1.2 Statement of problem

Cardiac catheterization is a widely performed procedure, with over a million diagnostic and interventional catheterizations conducted each year in the United States for both diagnosis and treatment. Vascular complications are more common after interventional catheterization. According to benchmarks set by the American College of Cardiology, the complication rates for cardiac catheterization should not exceed 1% for diagnostic procedures and 3% for interventional ones. Vascular complications are the most prevalent type, leading to increased discomfort for patients, longer hospital stays, higher costs, and negatively impacting patient outcomes(2, 14).

Large-scale studies of cardiac catheterization have found that the rate of major vascular complications ranges from 0.3% to 1%. Complications related to vascular access occur in 0.8% to 1.8% of diagnostic cardiac catheterizations, and between 1.5% and 9% of cases involving percutaneous coronary interventions (PCI) performed through the trans-femoral approach(10, 15).

Vascular complications following cardiac catheterization vary based on technological and economic development. High-income countries experience fewer vascular complications compared to countries with middle- and low-income economies. These prevalence have been reported as follows: 1% in the northeastern US, 10.5% in Virginia (USA), 32.4% in Canada, 36% in Sweden, 53.3% in Greece, and 66% in Egypt (1, 10, 16-19).

Vascular complications are a significant contributor to morbidity following cardiac catheterization. It is still uncertain whether the strategies i.e. patient history assessment, interventional cardiologist techniques, medications administered during the catheterization, application of manual or mechanical compression at the access site, utilization of closure devices, and nursing interventions; introduced in the past ten years to minimize complications from femoral artery access have improved the safety of these procedures. Recent studies have highlighted that bleeding, especially retroperitoneal bleeding, after diagnostic and interventional cardiac catheterization is a notable source of morbidity and mortality (9, 11).

Despite advancements in techniques and technologies designed to reduce complications, there remains a significant occurrence of vascular complications after cardiac catheterization(14). The differences in complication rates among various patient populations indicate that certain risk

factors—such as age, female sex, obesity, smoking, coexisting conditions like hypertension, renal failure, diabetes mellitus, recent myocardial infarction, as well as the use of large sheaths, excessive coagulation, and hemodynamic instability are linked to an increased risk(2, 9).

In our country, there is a limited study, even not directly related to the topic. Even though cardiac catheterization is doing well for several patients in Ethiopian cardiac center, the prevalence of vascular complication remained unknown. Therefore, this study seeks to close the gap by evaluating vascular complications among patients who underwent cardiac catheterization and associated factors.

1.3 Significance of study

Vascular complication is a serious problem in post cardiac catheterization patients affecting 1% - 66% in different countries. It's associated with different factors such as gender, BMI and prior cardiac catheterization.

The prevalence of vascular complication among patients underwent cardiac catheterization in Ethiopia was unknown. This study obtained the prevalence 15.1%. This finding will contribute to health care providers implement more targeted interventions to prevent these complications, to reduce costs associated with post-cardiac catheterization care, to developing guidelines and protocols to prevent and manage vascular complications in patients after cardiac catheterization patients, help policymakers to standardize care practices and improve overall patient safety. It can also highlight areas for quality improvement in post-cardiac catheterization care, leading to better patient outcomes and higher standards of care.

2 LITERATURE REVIEW

2.1 Introduction

The aim of this literature review is to summarize the information on vascular complication and its risk factors among patients underwent cardiac catheterization globally, regionally and locally. The reviewed literature consists of an overview of vascular complication, the socio-demographic factor, medical factor and procedural and behavioral factors.

2.2 Vascular complications

In this context vascular complication refers to problems that arise in the blood vessels after cardiac catheterization is done, the following are the overview of vascular complication globally, regionally and locally.

A prospective study at Commonwealth University Medical Center in Virginia, USA, found that the overall incidence of vascular access-related complications was 4.3% for patients undergoing atrial fibrillation (AF) ablation, 4.5% for those undergoing ventricular tachycardia/premature ventricular contractions (VT/PVC) ablation, and 1.7% for other procedures. The rates of major complications related to femoral access were lower, recorded at 1.8%, 2.2%, and 1% for the three groups, respectively(16).

A retrospective study conducted at the Medical Center Hospital of Vermont in the northeastern United States examined 7,690 catheterizations over a 40-month period. It identified 111 vascular complications, representing 1% of the procedures, with 41 of these requiring surgical repairs (0.5%). The complications included 10 pseudoaneurysms, 4 arteriovenous fistulas, 9 cases of thromboembolism, 5 infections, and 83 instances of other bleeding complications(10).

A single-center prospective study at St. Jude Medical in Minnetonka, Minnesota, reported that major vascular complications were primarily comprised of pseudoaneurysms and hematomas, which accounted for over 80% of all complications(20).

A prospective study at the Montreal Heart Institute in Montreal, Quebec, Canada, found that complications at the femoral access site occurred in 2.5% of the study population, with 1.8% among diagnostic procedures and 4% among therapeutic procedures. For diagnostic interventions, the most frequent complication was pseudo-aneurysm formation, observed in 0.8% of cases. In therapeutic interventions, hematomas were the most common complication,

occurring in 1.7% of procedures. Additionally, only 0.2% of patients in the study experienced local complications(4).

An analysis of the complications database for catheterization procedures in Toronto, Canada, revealed that vascular complications were the most frequently reported adverse event, accounting for 32.4% of all categories, based on clinical records from 11,073 children who underwent cardiac catheterizations(17).

A retrospective analysis at Athens University in Greece indicated that early-detected complications accounted for 66% of the total. The primary findings at the time of complication presentation included a pulsatile groin mass (n=18, 40%), hematoma (n=9, 20%), hemorrhage (n=6, 13.3%), lower extremity ischemia (n=4, 8.9%), a murmur in the groin area (n=3, 6.7%), and limb edema (n=3, 6.7%) (18).

A study conducted in Linköping University Hospital in Sweden revealed that the frequency of vascular complications among patients undergoing cardiac catheterization and/or coronary angiography ranged from 0% to 36%. Specifically, complications occurred in 0.19% of coronary angiography cases, 2-7% when coronary angiography was combined with hemodynamic cardiac catheterization, and 0-77% for percutaneous trans-luminal coronary angioplasty (PTCA)(19).

A study conducted at Cairo University in Egypt, using a descriptive cross-sectional design, assessed the prevalence of major and minor complications among patients before and after sheath removal. It found that the most frequent minor complication was oozing, occurring in 20% of cases before sheath removal, compared to 12% after. In contrast, the most common major vascular complication, hematoma, was observed only after sheath removal, affecting 22% of patients(2).

A descriptive study conducted at Zagazig University in Egypt found that 54% of the patients studied experienced arterial occlusion before sheath removal. Additionally, kidney damage was observed in only 16% of patients before sheath removal and 18% after. Furthermore, pseudo-aneurysm was noted in only 12% of the patients after sheath removal(1).

A retrospective cohort study conducted in Ethiopia results prevalence of contrast induced nephropathy and minor bleeding, which is observed blood loss ≥3 g/dl to 5 g/dl, were 9% and 9.8%, respectively(13).

In summary, the rate of vascular complication is lower in developed countries than underdeveloped and developing countries.

2.3 Risk factors

2.3.1 Socio-demographic factor

A prospective study carried out in Germany over a three-year period found a total of 334 complications (1.8%) and identified significant independent risk factors, including female gender, which was associated with a higher risk (OR = 1.65). Similarly, a study at Kaiser Hospital in San Francisco, CA, USA reported that serious local vascular events occurred in 3.54% of patients, with women having a relative risk of 1.40 (p = 0.0002) for experiencing vascular complications after cardiac catheterization, indicating a significantly higher risk for women in both studies(21, 22).

A retrospective study conducted at Christ Medical Center in the USA found that women had a 2.1% higher likelihood of experiencing bleeding complications. The highest risk for vascular bleeding complications was observed in patients over 80 years old, with a 1.7% chance of developing such complications after cardiac catheterization in this age group(23).

A prospective multicenter cohort study in Europe conducted a univariate analysis of the derivation cohort, which identified several potential risk factors for vascular complications ($p<0.05$): (a) age 60 years or older, (b) female sex, and (c) higher body mass index (BMI)(12).

A retrospective descriptive study conducted in the USA identified several demographic variables as significant predictors of complications: age over 70 years (odds ratio [OR] = 2.4, $P < 0.01$), female gender (OR = 1.6, $P < 0.01$), and higher body mass index (BMI) (OR = 5.8, $P < 0.05$)(9).

A study conducted at Cairo University in Egypt, using a descriptive cross-sectional design, found that older patients, with an average age of 58±6.38 years, were more likely to experience a femoral hematoma in relation to demographic risk factors. In addition female patients were more prone to developing femoral hematoma than were male patients ($\chi 2 = 5.2$, $P=0.030$), With regard to the BMI, two-thirds of the study sample was overweight (64%) (2).

A descriptive study conducted at Zagazig University in Egypt, found that 70% of studied patients were less than 60 years of age, mean age of male patients was 53.22± 8.9. 48% of studied patients were obese while 60 % of studied patients were not working (1).

In summary, studies consistently highlight older age, female gender, and higher BMI as major risk factors for complications during cardiac catheterization.

2.3.2 Medical factor

A retrospective descriptive study conducted in the USA found that the most common comorbidities were hypertension (68%) and hypercholesterolemia (68%). Additionally, 32% of patients were recorded as having diabetes mellitus, 11% had peripheral vascular disease, and 9% had renal failure(9).

A study conducted in Istanbul, Turkey, identified several factors that were independently associated with femoral pseudo-aneurysm (FPA) complications: hypertension (P = 0.011; odds ratio = 1.52), diabetes mellitus (P = 0.035; odds ratio = 1.11), and coronary artery disease (P = 0.022; odds ratio = 1.21)(24).

A study conducted in Helsinki, Finland, analyzed data to assess the combined endpoint of in-hospital death related to the cardiac catheterization procedure, which includes myocardial infarction (MI) and stroke (25).

The study, conducted in the Cardiac Care Units at Zagazig University Hospital, Egypt, employed a descriptive design. It reported that 100% of the patients studied had hypertension, 90% had a history of myocardial infarction (MI), and 88% were diagnosed with diabetes mellitus and high cholesterol (1).

Overall, hypertension, diabetes, and coronary artery disease are common comorbidities associated with complications in patients undergoing cardiac catheterization across these studies.

2.3.3 Procedural and behavioral factors

A prospective multicenter cohort study in Europe found that access was achieved through the femoral route in 1,485 patients (55%) and the radial route in 1,207 patients (45%). The study identified several independent risk factors for vascular complications, including the use of introducer sheaths larger than 6F, undergoing a PCI procedure, a history of vascular complications following previous interventional cardiology procedures, and prior use of anticoagulants such as warfarin (Marevan) or phenprocoumon (Marcoumar)(12).

A research carried out in Toledo, Ohio, USA revealed that using preprocedural (OR = 2.41, $p < 0.044$) and intraprocedural (OR = 24.4, $p < 0.001$) combined antithrombotic agents (antiplatelet and/or anticoagulants), intraprocedural clopidogrel (OR = 2.98, $p = 0.017$), and post procedural heparin (OR = 29.4, $p = 0.002$) were associated with increased risk. prior catheterization (OR = 0.033, $p < 0.001$) were protective (11).

A descriptive study conducted at Cairo University in Egypt, there was a significant statistical difference among the patients' development of a femoral hematoma by femoral sheath size after sheath removal ($\chi 2 = 10.7$, P=0.001). As the patients who had a sheath size of 7 Fr. developed femoral hematoma after sheath removal when compared with patients who had a sheath size of 6 Fr. $\chi 2 = 6.3$, P=0.040), as the current smokers developed higher frequencies of oozing than did previous smokers and nonsmokers (2).

A descriptive study conducted at Zagazig University in Egypt found that 72% of the patients used two catheters. In addition, in 62% of the patients, the catheter was inserted within 10–14 minutes. Furthermore, 74% of the patients were smokers, which was associated with an increased risk of vascular complications (1).

2.4 Conceptual framework

The conceptual framework for this study is built upon thorough review of existing literature and is designed to illustrate how various categories of independent variables may influence the occurrence of a dependent variable; vascular complication. The independent variables are: socio-demographic factors (e.g., age, gender, BMI, occupation), medical factors (e.g., comorbid conditions like diabetes or hypertension), procedural factors (e.g., prior catheterization, duration of procedure, access site, use of anticoagulant, size of sheath), behavioral risk factors (e.g., smoking, alcohol consumption)

This framework helps clarify which factors are expected to have an impact, how they might be interrelated, and why they are important in the context of vascular complications following cardiac catheterization (1, 2, 9, 12).

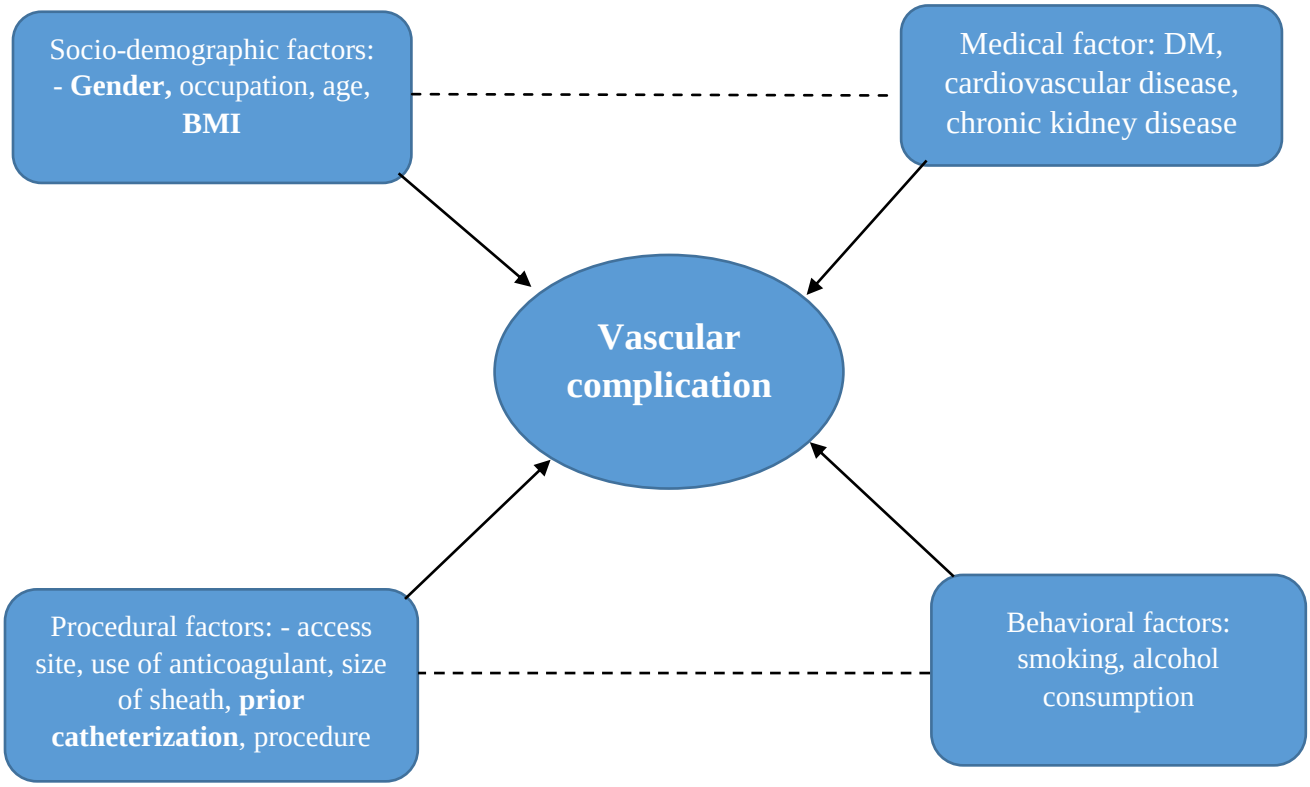

Figure 1: Conceptual frame work to assess vascular complication and associated factors of post cardiac catheterization patients developed from literature

3 OBJECTIVES

3.1 General objective

- To assess vascular complications and associated factors among patients who underwent cardiac catheterization in the Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

3.2 Specific objectives

- To identify the prevalence of vascular complications among patients who underwent cardiac catheterization in the Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

- To determine associated factors of patients who underwent cardiac catheterization in Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

4 METHODS AND MATERIALS

4.1 Study Area and Period

This study was conducted in Ethiopian cardiac center in Addis Ababa, Ethiopia, from January 20 to February 20, 2025. There are over 52 hospitals in Addis Ababa, 13 are government hospitals Ethiopian cardiac center is a non-governmental, non-profit humanitarian organization, established by Dr. Belay Abegaz in 1989 as a children's heart fund with in Zewditu Memorial Hospital, the center was renamed Cardiac Center Ethiopia in 2009 and relocated to TASH, where it has a capacity of 50 beds. It provides open-heart surgeries, interventional and diagnostic procedures, making it the largest and most reputable cardiac center in the country.

4.2 Study Design

A retrospective cross sectional study design was used.

4.3 Population

4.3.1 Source of population

All patients who underwent the cardiac catheterization procedure at Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025

4.3.2 Study Population

All patients who underwent cardiac catheterization procedure in Ethiopian cardiac center from January 1, 2020 to December 31, 2024, Addis Ababa, Ethiopia

4.4 Eligibility criteria

4.4.1 Inclusion criteria

All patients who underwent cardiac catheterization in Ethiopian cardiac center from January 1, 2020 to December 31, 2024, and with complete medical documentation.

4.4.2 Exclusion criteria

Patients with age of below 18 and patients who have unclear and unreadable information in the record was excluded from the study.

4.5 Sample Size Determination

The sample size was calculated using the single population proportion formula, based on a significance level (α) of 0.05 and a margin of error of 5% and prevalence of vascular complication 66% from previous research done in Zagazig University Hospital, Egypt (2021).

$$\text{Sample size (n)} = \frac{(Z\ \alpha/_2)^2 * P\ (1-P)}{d^2}$$

p= prevalence from previous research 66%

d= margin of sampling error which is 0.05

z=Value of z at 95% confidence interval level which is 1.96

$$n = \frac{(1.96)^2 * 0.66\ (1-0.66)}{(0.05)^2}$$

$$n = \frac{3.84 * 0.66\ (0.34)}{0.0025}$$

n = 344

Ethiopian cardiac center cardiac catheterization laboratory works two days per week and 3 patients per day. Then,

2 * 3 * 4 = 24

24 * 12 * 5 = 1440 is the total source population over five years.

Since, this total number is below 10,000, correction formula were used:

$$n_f = \frac{n}{1 + n/N}$$

Where n_f = the final sample size

n= initial sample size

N= study population

$$n_f = \frac{344}{1 + \frac{344}{1440}}$$

= 277

Adding 10% (28) incomplete/ missed document the required sample size for this research will be 277+28=305.

4.5.1 Sampling technique

Prior to data collection, a sampling frame of the study population was created using records from the procedure registration book covering the study period. Study participants were then selected using a systematic random sampling method.

K=N/n

K- Interval

N- Total number of population

n- Sample size

1440/305=4.7≈ 5

Therefore, the study subjects were selected with the interval of five and the initial document was chosen using a simple random sampling method. If the selected individual did not meet the inclusion criteria, they were replaced by the next eligible subject at the K+1 interval.

4.6 Variables

4.6.1 Dependent variables

- Vascular complication

4.6.2 Independent variables

Socio demographic factor

- Age
- Sex
- Body mass index
- Occupation

Medical history

- History of cardiovascular disease
- History of DM
- History of chronic kidney disease
- Previous cardiac catheterization

Procedural and behavioral factors

- Access site
- Duration of the procedure
- Use of anticoagulants
- Smoking status
- Alcohol consumption
- Size of sheath
- Type of procedure

4.7 Operational definition

- ✓ Vascular complication: refer to any adverse event affecting the blood vessels (such as arteries or veins) that occurs during the cardiac catheterization procedure.
- ✓ Major vascular complications: Vascular events that require significant medical intervention, prolong hospitalization, or result in substantial morbidity(2).
- ✓ Minor vascular complications: Vascular issues that are self-limiting or require minimal intervention without long-term impact(2).
- ✓ Cardiac catheterization: Patients who underwent cardiac catheterization are those who have gone through the procedure of inserting and advancing thin plastic tubes (catheters)in to the arteries and veins that lead to the heart(26).
- ✓ Age Group interval: the age of patients classified to 4 groups by 16 interval which is obtained by the formula below

$$\text{Age interval} = \frac{\text{maximum - minimum}}{\text{Number of group}} = \frac{82-18}{4} = 16$$

Therefore: 18–34, 35–50, 51–66, and 67–82

- ✓ BMI Group: body weight status of patients who underwent cardiac catheterization. < 18.5 (underweight), 18.5–24.9(normal weight), 25–29.9(over weight), > 29.9 (obesity) which is obtained from world health organization classification.

4.8 Data collection method

4.8.1 Data collection tool

The data was gathered from medical records using structured data extraction checklists that have been adapted from published literature sources (1, 2, 10, 12). The checklists were made up of questions on the vascular complication and associated factors among patients who underwent cardiac catheterization. The questions addressed were three sections socio demographic characteristics 9 questions, vascular complication 2 questions and associated factors 18 questions.

4.8.2 Data collection procedure

One supervisor and two data collectors, all BSc. nurses with prior data collection experience, were selected. Before the data collection began, they received a one-day training on the study's objectives, data collection procedures, and how to accurately complete the questionnaire. The principal investigator was tasked with overseeing the data collection process daily to ensure the data completeness.

4.8.3 Data quality control

Data quality was ensured at all stages: before, during, and after collection. Prior to data collection, the data collectors received training. The questionnaire was pretested on 5% (15 participants) of the total sample size at Tikur Anbessa Specialized Hospital two weeks before the actual data collection. The result of the pre-test was used to correct some unclear ideas and statements and the data was not incorporated into the main result. The internal consistency of the questionnaire was 0.7. During the process of data collection, the completeness of the checklists verified by principal investigator and supervisor each day. Before entering it into the computer software the principal investigator rechecked the data for completeness and consistency.

4.8.4 Data processing, analysis and presentation

The data were cleaned and coded to prepare it for processing and analysis. SPSS version 26 software were employed for analysis. Descriptive statistics summarized the result in percentages and frequencies. In statistical analysis binary logistic analysis were done. Initially, bi-variable analysis were used to identify candidate significant independent variables that have association with independent and dependent variables. Factors showing an association with a p-value less than 0.25 were selected for multivariable logistic regression analysis to account for confounding variables. The strength of associations among the independent variables and dependent variable

was assessed using adjusted odds ratios (AOR) along with a confidence interval of 95%, with p-values < 0.05 deemed statistically significant. The findings were displayed using descriptive text and tables. Conclusions were drawn based on the findings.

4.9 Ethical consideration

An official letter of ethical approval and clearance was obtained from the Institutional Review Committee of the Nursing Department Addis Ababa University (IRC-N AAU) with protocol number 166/22. Once the Department of Nursing grants approval, the proposal were submitted to Ethiopian Cardiac Center for their endorsement. Data were collected and stored anonymously. All information remained confidential.

4.10 Result dissemination

The study findings will be submitted to the School of Nursing and Midwifery, College of Health Sciences, Addis Ababa University, in Partial Fulfillment of the Requirements for a Master's degree in Cardiovascular Nursing. Finally, the manuscript will be submitted to a peer-reviewed scientific journal for possible publication.

5 RESULT

5.1 Socio-demographic Characteristics

A total of 305 eligible documents engaged in the study, yielding a response rate of 100% (305/ 305).The study sample included 182 (59.7%) females and 123 (40.3%) males. The mean age of patients was 38 ± 17.33 years. Approximately half of the patients were between the ages of 18 and 34 years.

In terms of occupation, 155 (50.8%) patients were not working, while 79 (25.9%) were daily laborers and 71 (23.3%) were office workers. Regarding body mass index (BMI) the mean was 22±4.68, 91 (29.8%) patients were underweight, 149 (48.9%) had normal weight, 43 (14.1%) were overweight, and 22 (7.2%) were classified as obese. (Table 1)

Table 1. Socio-demographic characteristics of patients who underwent cardiac catheterization (n=305)

Variables		Frequency	Percent
Gender	Female	182	59.7%
	Male	123	40.3%
Age Group interval	18–34	163	53.4%
	35–50	69	22.6%
	51–66	49	16.1%
	67–82	24	7.9%
Occupation	Daily laborer	79	25.9%
	Not working	155	50.8%
	Office working	71	23.3%
BMI Group	< 18.5 (underweight)	91	29.8%
	18.5–24.9(normal weight)	149	48.9%
	25–29.9(over weight)	43	14.1%
	> 29.9 (obesity)	22	7.2%

5.2 Information on vascular complication

Out of the 305 patients included in the study, 46 (15.1%) experienced vascular complications following the procedure, while the majority**,** 259 (84.9%) patients did not report any such complications (Fig 2). Regarding the minor types of vascular complications, 7 (2.3%) patients experienced ecchymosis and 11 (3.6%) had mild bleeding. In terms of major vascular complications**,** 14 (4.6%) developed hematomas, 3 (1.0%) had thromboembolism, and 11 (3.6%) suffered from hemorrhage. (Table 2)

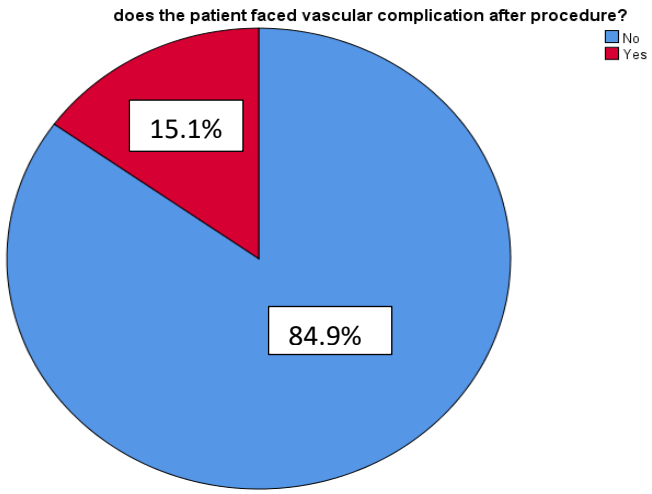

Figure 2: vascular complication of patients who underwent cardiac catheterization

Table 2. Vascular Complications faced among patients who underwent cardiac catheterization (n = 305)

Complication Type	Subcategory	Frequency	Percent
Minor Complications	None	287	94.1%
	Ecchymosis	7	2.3%
	Mild bleeding	11	3.6%
Major Complications	None	277	90.8%
	Hematoma	14	4.6%
	Thromboembolism	3	1.0%
	Hemorrhage	11	3.6%

5.3 Medical factors of patients

Among the patients document, several had pre-existing medical conditions. The most frequently reported condition was coronary artery disease, present in 61 (27.0%) individuals, followed by hypertension in 58 (25.7%) individuals, and diabetes mellitus in 44 (19.5%) individuals**.** A history of hypercholesterolemia was reported by 25 (11.1%) patients and atrial fibrillation by 22 (9.7%)**.** Fewer patients reported a history of myocardial infarction 9 individuals (4.0%) and chronic kidney disease 7 individuals (3.1%). These figures represent the number of respondents who indicated "yes" to each condition, with percentages calculated from the total valid responses. Notably, due to multiple conditions being reported by some patients, the total percentage exceeds 100%. (Table 3)

Table 3. Medical history of patients who underwent cardiac catheterization (n = 305)

Medical Condition	Frequency (N)	Percent (%)	Percent of Cases (%)
History of Coronary Artery Disease (CAD)	61	27.0%	52.1%
History of Hypertension	58	25.7%	49.6%
History of Diabetes Mellitus (DM)	44	19.5%	37.6%
History of Hypercholesterolemia	25	11.1%	21.4%
History of Atrial Fibrillation (A-fib)	22	9.7%	18.8%
History of Myocardial Infarction (MI)	9	4.0%	7.7%
History of Chronic Kidney Disease	7	3.1%	6.0%
Total	**226**	**100.0%**	**193.2%***

- *Percent of cases exceeds 100% due to respondents reporting more than one condition.*

5.4 Procedural and behavioral factors of patients

Among the 305 patient documents, only 6 (2.0%) had a history of smoking, and 4 (1.3%) reported alcohol consumption, indicating that such lifestyle risk factors were rare in the study population.

A previous cardiac catheterization was 24 (7.9%) patients, while the majority, 281(92.1%), and were undergoing the procedure for the first time. Regarding the vascular access site, the femoral artery was used in 285 (93.4%) patients, whereas the radial artery was accessed in 20 (6.6%) patients

The purpose of catheterization was predominantly interventional (81.3%), with diagnostic procedures accounting for the remaining 18.7%. The most common procedure performed was percutaneous trans-venous mitral commissurotomy/percutaneous mitral balloon commissurotomy (PTMC/PMBC), done in 158 (51.8%) cases, followed by coronary angiography (57, 18.7%) and PCI (33, 10.8%). Less frequent procedures included BPV (25, 8.2%), ASD device closure (19, 6.2%), PDA device closure (11, 3.6%), and coarcoplasty (2, 0.7%).

In terms of sheath size, 57.4% of procedures used 4–6 Fr sheaths, 41.0% used 7–8 Fr, and a small fraction used 9–10 Fr (0.7%) or >10 Fr (1.0%). Most procedures (78.0%) lasted between 30 minutes and 1 hour, while 12.8% exceeded 1 hour, and 9.2% were completed within 30 minutes.

Nearly all procedures (99.0%) involved a single femoral or radial puncture, with multiple punctures being extremely rare. Regarding anticoagulation, Heparin alone was used in the vast majority of cases 257(84.2%), followed by combinations such as Heparin with Clopidogrel 42(13.8%) and Heparin with Clopidogrel and Aspirin 6(2%). (Table 4)

Table 4. Summary of behavioral and Procedural Characteristics of patients underwent cardiac catheterization (n = 305)

Category	Subcategory	Frequency	Percent
Smoking	No	299	98.0%
	Yes	6	2.0%
Alcohol Use	No	301	98.7%
	Yes	4	1.3%
Previous Catheterization	No	281	92.1%
	Yes	24	7.9%

Access Site	Femoral	285	93.4%
	Radial	20	6.6%
Purpose of Catheterization	Interventional	248	81.3%
	Diagnostic	57	18.7%
Type of Procedure	PTMC/PMBC	158	51.8%
	Coronary Angiography	57	18.7%
	PCI	33	10.8%
	BVP	25	8.2%
	ASD D/C	19	6.2%
	PDA D/C	11	3.6%
	Coarcoplasty	2	0.7%
Sheath Size	4–6 Fr	175	57.4%
	7–8 Fr	125	41.0%
	>10 Fr	3	1.0%
	9–10 Fr	2	0.7%
Procedure Duration	30–60 minutes	238	78.0%
	>1 hour	39	12.8%
	30 minutes	28	9.2%
Puncture Frequency	Single femoral/radial puncture	303	99.3%
	Multiple femoral/radial puncture	2	0.7%
Anticoagulant Used	Heparin only	257	84.2%
	Heparin + Clopidogrel	42	13.8%
	Heparin + Clopidogrel + Aspirin	6	2.0%

5.5 Factors associated with vascular complication among patients underwent cardiac catheterization

The following socio-demographic, medical, procedural and behavioral factors were analyzed. Among these; gender, age, occupation, BMI, history of alcohol use, history of hypercholesterolemia, history of DM, history of hypertension, previous cardiac catheterization, size of sheath, time taken for the procedure, sheath removal time and type of anticoagulant used were significant at P< 0.25 by bi-variable analysis. All these factors were entered to multivariable analysis by controlling the effect of confounding factors gender, BMI and previous cardiac catheterization were found to have significantly high odds of vascular complication at P< 0.05.

Female patients were 4 times more prone to experience vascular complications than males (AOR = 4.07, 95% CI: 1.50–11.02, P = 0.006). Patients with BMI of25–29.9 (overweight) had 5.3 times more likely in developing vascular complications rather than those with a BMI of <18.5 (AOR = 5.31, 95% CI: 1.38–20.32, P = 0.015). Additionally, patients with a previous cardiac catheterization were nearly 5.2 times more likely to experience vascular complications than those without such a history (AOR = 5.26, 95% CI: 1.59–17.36, P = 0.006). (Table 5)

Table 5. Bi-variable and multivariable analysis of factors associated with vascular complication in patients who underwent cardiac catheterization (n=305)

Variable	Category	Vascular complication		COR (95% CI)	P-value	AOR(95 % CI)	P-Value
		Yes	no				
Gender	Male	13(4.2%)	110(36%)	1	1	1	1
	Female	33(10.8%)	149(49%)	1.87(0.94-3.72)	0.073**	4.07(1.503-11.024)	0.006*
Age	18-34	18(5.9%)	145(47.5%)	1	1	1	1
	35-50	12(3.9%)	57(18.7%)	1.69(0.76-3.74)	0.191**	1.227(0.397-3.792)	0.723
	51-66	12(3.9%)	37(12%)	2.6(1.15-5.9)	0.021**	1.445(0.297-7.03)	0.648
	67-82	4(1.3%)	20(6.5%)	1.6(0.49-5.24)	0.428	0.183(0.019-1.805)	0.146
Occupation	Daily laborer	7(2.3%)	72(23.6%)	1	1	1	1
	Not working	23(7.5%)	132(43.3%)	1.79(0.73-4.37)	0.201**	1.72(0.44-6.707)	0.433
	Office	16(5.2%)	55(18%)	2.99(1.15-	0.024	2.58(0.84	0.095

	working			7.77)		-7.89)	
BMI	<18.5	7(2.3%)	84(27.5%)	1	1	1	1
	18.5-24.9	15(4.9%)	134(43.9%)	1.34(0.52-3.43)	0.537	1.233(0.408-3.725)	0.710
	25-29.9	18(5.9%)	25(8%)	8.64(3.24-23.03)	0.000**	5.31(1.388-20.329)	0.015*
	>29.9	6(2%)	16(5.2%)	4.5(1.33-15.15)	0.015**	3.66(0.754-17.775)	0.108
History of alcohol use	Yes	2(0.6%)	2(0.6%)	5.84(0.80-42.55)	0.082	2.64(0.147-47.548)	0.510
	No	44(14.4%)	257(84.2%)	1	1	1	1
History of hypercholesterolemia	Yes	9(2.9%)	16(5.2%)	3.69(1.52-8.96)	0.004**	1.056(0.264-4.227)	0.939
	No	37(12%)	243(79.6%)	1	1	1	1
History of DM	Yes	14(4.5%)	30(9.8%)	3.34(1.60-6.96)	0.001**	1.729(0.510-5.860)	0.379
	No	32(10.5%)	229(75%)	1	1	1	1
History of hypertension	Yes	15(4.9%)	43(14%)	2.43(1.20-4.88)	0.013**	1.797(0.554-5.833)	0.329
	No	31(10%)	216(70.8%)	1	1	1	1
Previous cardiac catheterization	Yes	13(4.2%)	11(3.6%)	8.88(3.67-21.43)	0.000**	5.269(1.599-17.363)	0.006*
	No	33(10.8%)	248(81%)	1	1	1	1
Size of sheath	4 -6 Fr	27(8.8%)	148(48.5%)	1.15(0.60-2.23)	0.659	1.31(0.524-3.275)	0.564
	7 – 8 Fr	17(5.5%)	108(35.4%)	1	1	1	1
	9 – 10 Fr	0	2(0.6%)	0.000	0.999	0.000	0.999
	>10 Fr	2(0.6%)	1(0.3%)	12.7(1.09-147.8)	0.042**	15.4(1.098-216.5)	0.042*
Time taken for the procedure	>1 hr	4(1.3%)	35(11.4%)	3.08(0.326-29.22)	0.326	6.50(0.509-83.274)	0.150
	30-60 min	41(13.4%)	197(64.5%)	5.61(0.74-42.53)	0.095**	7.44(0.77-71.32)	0.082
	30 min	1(0.3%)	27(8.8%)	1	1	1	1
Type of anticoagulant	Heparin	31(10%)	226(74%)	1	1	1	1
	Heparin + Clopidogrel + Asprin	3(0.9%)	3(0.9%)	7.29(1.40-37.72)	0.018**	6.80(0.772-59.914)	0.084
	Heparin + Clopidogrel	12(3.9%)	30(9.8%)	2.91(1.35-6.28)	0.006**	1.899(0.621-5.810)	0.261

Note: AOR= COR= Crude Odd Ration, Adjusted Odd Ratio, CI= Confidence Intervals, *Statistically significant at ($p<0.05$), **Statistically significant at ($p<0.2$), 1= reference

6 DISCUSSION

This study assessed the vascular complication and associated factors among patients who underwent cardiac catheterization at Ethiopian cardiac center. The findings revealed that 15.1% of patients developed vascular complications. These rates are higher than those reported in high income countries, where vascular complication rates typically range between 1-5%; studies in the United States and Canada have reported vascular complication rates as low as 1.0-4.5%, depending on the nature of the procedure (16, 10, 4). This variation may be due to differences in procedural techniques, patient comorbidities, or post procedural care quality between high-income and low- to middle-income setting.

On the other hand other studies in Greece, Sweden, and Egypt had vascular complication of 60%, 0-36%, and 54% respectively (18, 19, 1). The possible explanation for this difference may result from variation in patient population, sample size and study design. Where a study in Greece, Sweden and Egypt had sample size of 10,450, 4487, and 50 respectively, and employed retrospective and descriptive study designs. Compared to these, the relatively smaller

In line with global findings, this study found that female gender was significantly associated with an increased risk of vascular complications. Female patients were 4 times more likely to develop such complications compared to males. This is consistent with findings from Germany and the USA, where female sex was an independent risk factor of vascular complications (21, 22). The increased risk among females may be attributed to anatomical differences in which females had tiny vessels, anticoagulant sensitivity females are more sensitive's and hormonal influences particularly estrogen in females that affect vascular integrity.

Additionally, body mass index (BMI) was significantly associated with vascular complications. Patients categorized as overweight (BMI 25-29.9) had 5.3 times more likely to experience complications than those with BMI < 18.5. This finding is supported by previous studies from Europe, USA and Egypt that identified higher BMI as a significant predictor of post catheterization complication (12, 9, 1). Excess adipose tissue may hinder vascular access, impair hemostasis, and increase the risk of hematoma formation due to higher venous pressure and altered pharmacokinetics of anticoagulants.

The study also identified a history of previous cardiac catheterization as a strong predictor of vascular complications. This aligns with findings from multicenter studies in Europe, which reported previous vascular complications or procedures as significant predictors of recurrent adverse event (12). Repeated access through the same vascular site may result in fibrosis, vessel trauma, or scarring, which can compromise subsequent procedural safety.

A study in Europe emphasized that larger sheath sizes associated with increased risk of vascular complications (12). Similarly, in this study, patients with larger sheath sizes had a notably higher risk of vascular complication consistent with findings from Cairo University, which reported a significant association between larger sheath sizes and femoral hematoma formation after sheath removal (2). This trend supports the notion that minimizing sheath size when possible could mitigate complication risks.

The finding of this study highlights that female sex**,** overweight, and prior catheterization history are key independent predictors of vascular complications following cardiac catheterization.

7 STRENGTHS AND LIMITATION OF THE STUDY

7.1 Strengths

This study had high data retrieval rate minimizes the risk of data retrieval bias and enhances the reliability of the findings. It can also serve as a baseline for future researches, as it is new study.

7.2 Limitations

Despite its strengths, this study is not without limitations. A key limitations of this study is document review, which may affect the data quality, as it relies on how healthcare professionals documented patient information during routine care. Additionally the assessment was limited to immediate or short-term post-procedural complications, so any delayed vascular events may have gone undetected.

8 CONCLUSION AND RECOMMENDATION

8.1 Conclusion

This study found that 15.1% of patients who underwent cardiac catheterization had vascular complications. The most common major complications were hematoma, hemorrhage, and thromboembolism. Multivariable analysis revealed that female gender, overweight, and a history of prior cardiac catheterization were risk factors for vascular complications. Although some behavioral and medical factors did not reach statistical significance in the final model, their potential role should be considered from other studies.

8.2 Recommendations

For Health Care Providers:

- **Conduct risk stratification:** Identify high-risk individuals particularly females, overweight patients, and those with previous catheterizations for enhanced monitoring and preventive measures.
- **Optimize procedural practices:** consider using smaller sheath sizes, prior catheterization, and ensuring skilled vascular access to minimize trauma.
- **Enhance post procedural monitoring:** establish protocols for early detection and management of complications, especially in patients with known risk factors.

For Patients:

- **Engage in Pre-Procedural Preparation:** Patients should actively participate in discussions about their health status, including disclosing any history of prior catheterizations or other vascular issues.
- **Adopt Healthy Lifestyle Habits:** Overweight individuals should be encouraged to pursue weight management through proper diet and physical activity to lower their risk of vascular complications.

For Future Research:

- **Expand to Multicenter Studies:** Conduct larger, multicenter studies to improve generalizability and validate findings across different clinical settings.
- **Investigate Long-Term Outcomes:** Future studies should explore delayed or long-term vascular complications that may not be apparent immediately after the procedure.

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ANNEXES

Annex I: Data extraction checklist

This is a data collection format Data Extraction Checklist to assess vascular complications and associated factors among patients who underwent cardiac catheterization in the Ethiopian Cardiac Center, Addis Ababa, Ethiopia, 2025.

Name of Datacollector_____Date_____Qualification_____

Data Collector agreement: “I certify that I have filled the questionnaire in accordance with the training that is given to me and instructions stated in it.

Signature _____Date_____

Checked by supervisor for completeness: - Supervisors Name_____ signature _____

Part 1 Socio-Demographic and physical characteristics

No	Question	Answer	Remark
1.	Card number		
2.	Gender	1. Female 2. Male	
3.	Age	……..	
4.	Occupation	1. Daily laborer 2. Office working 3. Not working	
5.	Weight	…….	
6.	Height	…….	
7.	Date of admission		
8.	Date of procedure done		
9.	Date of discharge/ death		

Part 2: vascular complication related

No	Question	Answer	Remark
1	Does the patient faced vascular complication after procedure	1. Yes 2. No	
2	If yes, What type of vascular complication?	Minor 1. Ecchymosis 2. Swelling 3. Mild bleeding (oozing) Major 1. Hematoma 2. Pseudo aneurysm 3. Arteriovenous fistula 4. Thromboembolism (occlusion) 5. Embolization 6. Access site infection 7. Vascular injury (dissection) 8. Retroperitoneal hemorrhage	

Part 3 information on risk factor of vascular complication

No	Question	Answer	Remark
1	History of tobacco/cigarette smoking	1. Yes 2. No	
2	History of alcohol drinking	1. Yes 2. No	
3	History of hypercholesterolemia	1. Yes 2. No	
4	History of DM	1. Yes 2. No	
5	History of cardiovascular disease	1. Yes 2. No	
6	If yes for Q 5. Specify it	1. Heart failure 2. Hypertension 3. RHD 4. MI 5. Other ……	
7	History of chronic kidney disease	1. Yes 2. No	
8	Previous history of cardiac catheterization	1. Yes 2. No	
9	If yes for Q 8. History of previously experienced vascular complication	1. Yes 2. No	
10	Catheterization access site	1. Femoral 2. Radial 3. Brachial	
11	Purpose of catheterization	1. Diagnostic 2. Interventional	
12	Type of procedure	1. PCI 2. PTMC/ PMBC	

		3. BPV 4. ASD D/C 5. PDA D/C 6. Other…….	
12	Size of sheathe	1. 4 -6 Fr 2. 7 – 8 Fr 3. 9 – 10 Fr 4. >10 Fr	
13	Sheathe removal time	1. Immediately after procedure 2. One hour after procedure	
14	Time taken for the procedure	1. 30 min 2. 30min – 1hour 3. >1 hour	
15	Type of anticoagulant used in the procedure	……	
16	Amount of anticoagulant used	----------	
18	Frequency of puncture	1. Single femoral puncture 2. Multiple femoral puncture	