VASCULAR ACCESS METHODS AND THEIR PATTERN OF EVOLUTION FOR LEFT HEART CATHETERIZATION AT THE KENYATTA NATIONAL AND KAREN HOSPITALS: A RETROSPECTIVE AUDIT (2015-2020)

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H58/11101/2018

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE

DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS-UNIVERSITY OF NAIROBI

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ACKNOWLEDGEMENT

I would like to thank my supervisors, statistician and the entire faculty of Internal medicine - University of Nairobi for their support and guidance throughout the process of the proposal development. Many thanks to the records department of KNH and Karen Hospital for the support they accorded me as well.

Special thanks to my dear husband Eng. Nuhu Yusuf Ali for his encouragement and support, and to our children Rahma, Hamiche and Ahmed, thank you for teaching me the meaning of selflessness and love.

To my parents, siblings and colleagues, may God bless you abundantly for all the moral support you have accorded me.

Finally, I would like to thank Almighty Allah (swt) for seeing me through this. May you be glorified my Lord.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ACC	America College of Cardiology
ACS	Acute Coronary Syndrome
AHA	American Heart Association
CABG	Coronary Artery Bypass Graft
CVD	Coronary Vascular Disease
CHD	Congenital Heart Disease
ESC	European Society of Cardiology
Fr	French size
KNH	Kenyatta National Hospital
KR	Karen Hospital
LV Dysfunction	Left Ventricular dysfunction
MI	Myocardial Infarction
MRI	Magnetic Resonance Imaging
NYHA	New York Heart Association
PCI	Percutaneous Coronary Intervention
STEMI	ST segment elevation Myocardial Infarction
TRI	Trans-radial Intervention
TFI	Trans-femoral Intervention
TAVR	Transcatheter aortic valve replacement

DEFINITION OF KEY TERMS

Cardiac Catheterization: An invasive procedure involving insertion of catheters into the heart vessels/chamber via a peripheral vascular access for therapeutic and/or diagnostic purposes. Common procedures done through the catheter include coronary angiography, ventriculography, valvuloplasty and valve replacement.

Coronary Angiography: A procedure done during left heart catheterization. A radio contrast is injected through the catheter and real time images show the dye as it flows through the coronary arteries. Occluded vessels can then be visualized and appropriate revascularization procedure instituted.

Trans-radial Arterial Approach: Cardiac catheterization done by insertion of catheters and guide-wire through the radial artery.

Trans-femoral Arterial Approach: Cardiac catheterization done by insertion of catheters and guidewire through the femoral artery.

ABSTRACT

Background: Cardiac catheterization is an invasive procedure that is used for diagnostic and /or interventional purposes for a wide range of cardiac diseases. Left heart cardiac catheterization entails insertion of a fine bore catheter via a peripheral vascular access into the aorta, coronary arteries and/or left heart chambers. The brachial, femoral, radial and/or ulnar arteries are used as peripheral arterial access routes. The increased utilization of trans-radial approach has led to lower rates of major bleeding and vascular complications. Trans-femoral arterial access approach is still used by many operators due to its ease of use and feasibility.

Objectives: To describe the vascular access methods for left heart catheterization and their associated complications at the Kenyatta National Hospital (KNH) and Karen Hospital (KR).

Methodology: Cross sectional retrospective audit that examined health records of cardiac catheterization laboratories at KNH and KR over a 6-year period (1st January 2015 to 31st December 2020).

Results: We analyzed a total of 384 files from the two hospitals: 106 from KNH and 278 from KR. Of the total number of procedures done 62.1 % were via the trans-femoral arterial access while 32.7 % were via the trans-radial arterial access. Most of the procedures done at the KNH were via the trans- femoral access with the adoption of the trans-radial access noted from 2017 and steadily increasing till 2020. The use of trans-femoral in KR was also high but KR had a markedly increasing trend in adoption and incorporation of the use of the trans-radial arterial access over the entire study period. For patients with STEMI AND NSTEMI, the use of the transfemoral access was still higher at 66.2% and 66.7 % respectively. Looking at complications associated with cardiac catheterization (which include anaphylactic shock, bleeding, hematoma formation, pain/arterial spasm, acute kidney injury, acute arterial occlusion, infection, myocardial infarction, stroke/transient ischemia, iatrogenic coronary dissection, cardiac arrythmias, hypotension, cardiogenic shock, pericardial, bleeding necessitating blood transfusion) we noted that 39 (10.7%) patients experienced one or more of the complications, with about 19 (48.7%) of them having severe pain at puncture site. 24 (10.6%) had had a common femoral arterial access. On the length of hospital stay, most patients (50.3%) either stayed for a day or were discharged the same day followed by those that stayed between 2-5 days (32.1%).

Conclusion: Over the entire study period, the use of the trans-femoral arterial access for cardiac catheterization was higher compared to the use of the trans-radial for both KNH and KR. From 2016, there has been a progressive adoption and incorporation of the trans-radial arterial access. The procedures done had minimal complications and a majority of the patients stayed for less than a day in the hospital after undergoing the procedure.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

Globally, diseases of the heart are the leading cause of morbidity and mortality. The cardiovascular system includes the heart and its vasculature. Pathology arising here includes endocarditis, valvular heart disease (arising from rheumatic heart disease) and conduction abnormalities. Other diseases of the cardiovascular system include tumors of the heart or disorders of the heart muscles (cardiomyopathy). Cardiovascular diseases, also include coronary artery disease, cerebrovascular disease, Peripheral artery disease and aortic atherosclerosis (1). Coronary artery disease accounts for up to one third to one half of all cases of cardiovascular disease (1).

The mainstay management of CAD is medical therapy and revascularization. Revascularization can be achieved via a Coronary artery bypass graft or via a percutaneous coronary intervention. Peripheral arteries like the femoral and radial provide access to the coronary arteries to perform diagnostic or therapeutic or both procedures (2).

Cardiac catheterization is an invasive procedure that involves insertion of fine bore tubes into the heart for diagnostic and/or for therapeutic intervention. This is achieved by using a cannula which is inserted into a peripheral artery or vein. Despite the availability of imaging techniques, cardiac catheterization has remained essential in diagnosis and management of coronary artery disease (3) (4) and in evaluation of cardiac hemodynamics (5).

Two types of cardiac catheterization exist: right heart catheterization and left heart catheterization (6). The right heart catheterization uses a venous or flow directional catheter that is advanced into right ventricle and to the pulmonary artery. This enables measurement of right ventricular and pulmonary artery pressure levels. A contrast medium injected into the catheter enables direct visualization of right heart side, the cardiac valves and blood circulation. The left heart catheterization involves advancement of a catheter into the left heart through an artery in femoral region, wrist or elbow. With injection of a radio contrast medium, an examination of the left ventricle, aorta, left cardiac valves performance and blood circulation is enabled (7). During cardiac catheterization, pressures and oxygen saturations in the heart chambers and great vessels are recorded, determining transvalvular gradients, cardiac shunts, and the severity of pulmonary hypertension. Coronary angiography provides details about the coronary vessels' anatomy allowing accurate diagnosis of coronary disease (8). Interventional procedures include percutaneous coronary intervention for occluded vessels, valvuloplasty and valvotomy procedures (8) (9) (10).

Werner Forssmann performed the first human heart catheterization in 1929. He inserted a catheter into his own heart via a cutdown in his left antecubital vein. In the following years, marked developments occurred in the field of cardiac catheterization as seen by Mason Sones (in 1958) utilizing a brachial artery cut down procedure to perform the first selective coronary angiogram. Additionally, in the 1960s there was development of pre-shaped catheters as well as the integration of the Seldinger approach (which involves percutaneous insertion of a catheter into a blood vessel) and the femoral approach becoming the preferred route in cardiac catheterization. In 1989, Campeau introduced the radial artery approach for cardiac catheterization (9).

Cardiac catheterization offers interventional strategies as alternative method to surgical therapy for different diseases of the heart and it is widely known that percutaneous coronary intervention is linked with greater clinical outcomes in patients presenting with acute coronary syndromes (9) (11). Previous research has established the superiority of radial artery access in terms of bleeding and mortality thus creating a need for a paradigm shift in preference to the trans-radial arterial access approach (6) (7). Percutaneous coronary intervention i.e., angioplasty that is done during left heart catheterization unblocks occluded coronary vessels thus improving blood flow and decrease mortality in acute coronary syndrome patients. Angioplasty is currently the preferred method for management of myocardial infarction (6). A study done by Hu Li *et al* on trans-radial versus trans-femoral intervention in ST segment elevation myocardial infarction patients from January 2009 to December 2009 at nine teaching hospitals revealed that trans-radial intervention in STEMI patients undergoing primary percutaneous intervention with drug eluting stents was associated with a lower incidence of access site hematoma, twelve month repeat vascularization and major adverse cardiovascular events in comparison to the transfemoral intervention (6). Left heart catheterization also provides a platform for therapeutic intervention of some cardiac malformations e.g., septal defects, vascular stenosis and valvular defects (12).

Vascular complications associated with these interventional procedures are not uncommon. The complications include hematomas in groin which occur between 5% and 23% or retroperitoneal ranging from 0.15 % to 0.44 %, pseudoaneurysms ranging from 0.5% to 9%, arteriovenous fistulae between 0.2% to around 2.1% , acute arterial occlusion less than 0.8 %, infections with less than 0.1% and cholesterol emboli which was 0.08 % (11). Rarely, during left heart diagnostic catheterization, complications such us myocardial infarction, stroke, iatrogenic coronary dissection or pericardial effusion/tamponade and death may occur. Cardiac

arrythmias, cardiogenic and septic shock are rare causes of in-hospital death after left heart catheterization (13).

A study done on patients who had blood transfusion and undergoing percutaneous coronary intervention (PCI) found that patients who had blood transfusion (regardless of bleeding), were at an increased risk of in-hospital based myocardial infarction (MI) and other conditions such as stroke and congestive heart failure except in patients with bleeding and preprocedural hemoglobin values of less than 10g/dl (14).

Currently, there exists no Kenyan data regarding the vascular access methods for left heart catheterization. As such, this study described the vascular access methods for left heart catheterization at KNH and Karen Hospitals and assessed the evolution of trends in the practice of vascular arterial access methods over the years. In addition, a comparison between complications associated with trans-femoral arterial access and trans-radial arterial access was performed in these two Kenyan facilities.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Coronary Artery Disease (Atherosclerosis)

Industrialization has resulted in a shift from physically demanding activities to sedentary jobs; and this may explain the rising rates of cardiovascular disease during the last decades (1). The intake of high calorie diets, physical inactivity, consumption of saturated fats and sugars have all been associated with development of atherosclerosis and other metabolic disturbances for example metabolic syndrome, diabetes mellitus and hypertension that are highly seen in people with cardiovascular disease (1). In the INTERHEART study (15), nine modifiable risk factors accounted for 90% of the risk of having a first myocardial infarction; smoking, dyslipidemia, hypertension, abdominal obesity, diabetes mellitus, regular alcohol intake, psychosocial factors, consumption of fruits and vegetables and physical inactivity. In the FRAMINGHAM Heart Study (16), 60-90% of coronary heart disease events occurred in patients with at least one risk factor. Non modifiable risk factors for heart disease include family history of cardiovascular disease, age and gender. Premature atherosclerosis or death from cardiovascular disease in a first degree relative before 55 years of age in males and 65 years in females is considered an independent risk factor (16). The prevalence of cardiovascular disease increases significantly with each decade of life as well.

The main site of atherosclerotic disease is in the epicardial coronary arteries. The functionality of the vascular endothelium is disrupted during atherosclerosis. The functions normally include; sustenance of an antithrombotic surface, control of vascular tone and control of inflammatory cell adhesion and diapedesis. A disruption of these functions causes a hypercoagulable state and hypo fibrinolysis. Loss or disruption of the endothelial function results to abnormal interactions of blood cells specifically monocytes, platelets and the activated vascular endothelium (17)(18).

There is an inappropriate vessel constriction and luminal thrombus formation as part of the process. These changes that occur include subintimal collection of fat as well as smooth muscle cells, fibroblasts and intercellular matrix (plaque formation). Further, there are also segmental reductions in cross-sectional area of the vessels such as the epicardial coronary tree where there are major atherosclerotic changes (atherosclerosis developing at uneven rates in different segments of the vessels). A reduction in the diameter of the epicardial artery will markedly affect the performance of the myocardium (17).

A 50% reduction in the vessel diameter limits the ability to increase blood flow to meet the increased myocardial demand. At rest or under reduced stress, an 80 percent reduction in

diameter has a significant impact on coronary flow, resulting in myocardial ischemia. The plaque's cap, which separates it from the bloodstream, is prone to rupture or erosion. The activation and aggregation of platelets, and the activation of the coagulation cascade, results in the deposition of fibrin strands when the contents of the formed plaque are exposed. The platelets accumulate and fibrin strands form a thrombus, trapping erythrocytes and reducing coronary blood flow, resulting in the clinical manifestations of myocardial ischemia (18).

The continued narrowing of the coronary tree and myocardial ischemia is further accompanied by development of collateral vessels. When well-developed, these vessels play a fundamental role. They are essential in the sustenance of myocardial perfusion at rest. In increased demand states, the distal resistance vessels dilate in order to sustain coronary blood flow in keeping with the progressive stenosis in the proximal epicardial artery.

With maximal dilatation of the resistance vessels, myocardial perfusion becomes reliant on the pressure in the coronary artery distal to the obstruction. The resultant effect of this ischemia is manifested clinically as angina or electrocardiographic changes as seen by ST segment deviation, that is precipitated by increased oxygen demand by the myocardium during exercise or emotional stress (18).

Patients with ischemic heart disease can present acutely or insidiously with symptoms over months to years. Patients may have symptoms of a stable disease (here refers to angina occurring on exertion and relieved by rest) in the absence of cardiomyocyte necrosis or unstable angina to mean myocardial ischemia at rest or with minimal exertion in the absence of cardiomyocyte necrosis as well. Ischemic heart disease can also present as ACS and hereby refers to cardiomyocyte necrosis consistent with acute myocardial ischemia.

Chronic CAD may lead to heart failure and arrythmias as well. Commonly presenting with ventricular tachycardia/ ventricular fibrillation and less commonly with supraventricular arrythmia for example atrial fibrillation. Sudden death from ischemic heart disease has been attributed to ischemia induced ventricular tachyarrhythmias, and this occurs in patients having a severe disease affecting the left main coronary or severe disease with a single remaining vessel (17)(18)(19).

2.2 Indications of Cardiac Catheterization

The following are indications for cardiac catheterization:

2.2.1 For Evaluation and Treatment of Coronary Artery Disease.

During coronary angiography, a radio contrast is injected through the catheter and real time images show the dye as it flows through the coronary arteries. Occluded vessels are then visualized and percutaneous interventions can be done in occluded vessels.

2.2.2 Valvulopathies

Pathology includes aortic regurgitation and stenosis, mitral stenosis and regurgitation, pulmonic stenosis and regurgitation, tricuspid regurgitation and stenosis. Cardiac catheterization hereby applies depending on the severity of the disease, for preoperative evaluation or in suspected cases of coronary artery disease (20)(21).

Left heart catheterization together with right heart catheterization is also resourceful when there are discrepancies between clinical and non-invasive findings (20(21) and to facilitate interventional procedures as well.

2.2.3 Assessment of Congenital heart diseases

This is done prior to corrective surgery more so when clinical symptoms or noninvasive imaging conducted indicate presence of coronary artery disease. Left heart catheterization is also done when there is suspicion for congenital coronary abnormalities for evaluation of pulmonary pressures, vascular resistance calculation, assessments of shunts and assessment of complex anatomy.

2.2.4 Assess Pericardial Diseases

By assessing the hemodynamic findings during cardiac catheterization, a distinction between constrictive pericarditis and restrictive cardiomyopathy can be made (12).

2.2.5 Assessment of Myocardial Diseases

Majorly done if the clinical image of a patient with known cardiomyopathy has changed; or to facilitate myocardial biopsy (12).

2.3 Vascular access

2.3.1 Transfemoral Arterial Access

The Trans-femoral arterial access route is considered a classical method over trans-radial approach since it can be repeatedly punctured (22). It is easily palpated and allows easy access. It is universally accepted due to its extensive use, the workforce experience and easy accessibility. It also allows for the use of wider sheaths and other equipment.

The commonly occurring vascular complications associated with the Trans-femoral approach include access site bleeding, formation of a hematoma, a retroperitoneal bleed, arteriovenous fistula and pseudoaneurysm formation. There may be need for blood transfusion to treat the bleeding complication. Retroperitoneal bleeding (post procedurally), has a poor prognosis, and blood transfusion after the operation has a poor prognosis as well; in severe cases resulting in mortality (22) (23).

The vascular bleeding complication at the femoral arterial access site may result in increased morbidity, increased length of hospital stay and increased risk of mortality in patients receiving active anticoagulation and antiplatelet therapy. Ensuring an optimal site for sheath insertion reduces complications. Large punctures below the optimal site result in more bleeding, pseudoaneurysm and arteriovenous fistula formation. High punctures above the optimal site increase the risks for a retroperitoneal hemorrhage.

Using a fluoroscopy-guided method can reduce vascular problems. A micro puncture kit also reduces complications by allowing for the placement of a 4F sheath and femoral sheath angiography to validate location before introducing a larger sheath. Difficult anatomy, morbid obesity, or peripheral vascular disease, on the other hand, may make the procedure difficult. In this case, a trans-radial access or direct visualization of the typical femoral artery with an ultrasound can be considered (24) (25).

For femoral closure, a manual compression or use of a vascular closure device can be used (23) (26). In the ISAR CLOSURE randomized clinical trial, the vascular closure devices were non inferior to manual compression in terms of vascular access site complications (bleeding) and reduced time to achieving hemostasis (27). While a meta- analysis done by Fausto Biancari et al on 56 randomized control trials found that the use of vascular closure devices was associated with a significantly shorter time to hemostasis and thus may shorten recovery ; however the use of the vascular closure devices was associated with a somewhat increased risk of infection, lower limb ischemia ,arterial stenosis, device entrapment in the artery and need of vascular surgery for arterial complications (28).

A metanalysis of seven randomized control trials done by Sabato Sorrentino et al found that there was reduced time to cannulation, reduced vascular complications (i.e., access site hematoma, major bleeding, retroperitoneal hematoma and pseudoaneurysms) in patients undergoing transfemoral access procedures under ultrasound guidance versus standard transfemoral approach (25) (29).

2.3.2 Radial Arterial Access

Trans-radial arterial access is currently the recommended standard route for PCI. Guidelines in other parts of the world indicate a paradigm shift in preference to the radial access. This is due to the fact that randomized control studies done over the years, and specifically in the last decade, show fewer procedural complications associated with the procedure in comparison to the femoral access route. A mortality benefit has even been proven for patients with ACS and ST segment elevation myocardial infarction (30) (31).

The radial artery's anatomy i.e., being superficial with a small caliber, simplifies hemostasis allowing for early patient ambulation. It is therefore appropriate for patients who cannot withstand extended bed rest, are on anticoagulation, or are receiving PCI in a day care setting. Over the last decade, it has been noted that the Trans-femoral access has remained the choice of access for large bore access greater than 6Fr during a transcatheter aortic valve intervention. During a procedure, an unfavorable radial access results to a cross over to the femoral access (26) (32) . It's ease of access and dual blood supply lessen the chances of limb ischemia as well (7).

Instances whereby two arterial accesses are involved include management of coronary chronic total occlusions; a hybrid algorithm approach which has a high PCI success rate and relatively low procedural complications is applied. In this hybrid algorithm, two entry sites are used for catheter insertion (trans-radial and trans-femoral) or both trans-femoral and the blockage targeted from the front and back (antegrade and retrograde) allowing a switch from one technique to another during the procedure in case of failure of the previous one (33).

Other instances whereby two arterial access sites are used include implantation of intra-aortic balloon pump and use of extracorporeal membrane oxygenation in hemodynamically unstable patients undergoing emergency coronary angiography and PCI. For ergonomic purposes, this arterial access method has gained popularity in the last decade. Since the radial artery is shallow, bleeding is easily regulated by compression. There are no large nerves or veins along the radial artery (anatomically). Nerve and vascular complications are significantly reduced as a result of this. Other benefits of arterial access include reduced bleeding complications and reduced hospital costs as there is early ambulation after the procedure (34) (35) (36).

There exists a learning curve for the practice of trans-radial access approach and a randomized control trial done indicated it to be steeper but shorter in comparison to the Trans-femoral access approach i.e. 20-30 cases for trans-radial access whereas the Trans-femoral access was

41-50 cases (37) and once the skill was acquired, the procedure time for a trans-radial access was significantly shorter with fewer catheter exchanges (37).

A PCI registry evaluation in the United States of America from 2009 to 2019 found that as operator familiarity with trans-radial access improved, higher risk patients and more difficult cases were chosen for the trans-radial access intervention, procedural success rates remained high, with a threshold for overcoming the learning curve of about 30-40 cases (38) and a related study done in Canada found that new radial operators need to perform at least 50 trans-radial interventional procedures to achieve similar procedural outcomes as experienced radial performers (38).

2.4 Trans-radial Arterial Access Procedure

Cardiac catheterization is performed after a patient has received an intravenous conscious sedation. In suspected acute coronary syndrome, a patient is pretreated with aspirin (39) and if the procedure is likely to proceed to a PCI an additional antiplatelet agent is started (clopidogrel, prasugrel or ticagrelor) with loading dose and a maintenance dose administered appropriately (prasugrel is avoided in patients with a prior stroke or a transient ischemic attack). Warfarin is withheld 2-3 days prior to catheterization to limit access site bleeding.

During a trans-radial arterial access procedure, the patient is positioned supine, and arm supported by a board. A contralateral venous access is obtained in anticipation of use if resuscitation may be needed. The right femoral region is also prepared in high-risk cases to facilitate a rapid transition to the femoral access as need arises, thus the operator needs to be oriented in both arterial accesses. The left radial access is preferred and presents a proper basis within which informed decisions could be made especially when the left internal mammary artery graft needs to be imaged or when the right radial pulse is missing. The major benefit in this context is that the operator is less likely to encounter an anatomic problem such as the subclavian tortuosity (30).

Pre-procedural sedation is done, and studies have shown that fentanyl and midazolam use reduce spasm and femoral crossover. Due to its muscular wall and various alpha-adrenergic receptors, the radial artery is vulnerable to spasm. Although an Allen's test is conducted prior to the operation to ensure sufficient patency of the ulnar-palmar arch, several studies have identified no complications while using the trans-radial route in patients with irregular Allen's tests. In the procedure, access is made possible 2cm proximal to the styloid process. The anterior wall of vessel is punctured and guidewire inserted (40). A through and through

technique that involves a catheter over needle advancement through the anterior and posterior wall of the vessel can also be used (41).

2.5 Trans-radial Access Complications

A procedural failure can occur due to radial artery spasm. Spasmolytic agents can be used after sheath insertion. A meta-analysis done showed a combination of nitroglycerin and verapamil as being the most effective. An attempt to minimize radiation exposure can be done initially by advancing a guidewire and catheter up the arm without fluoroscopy. An angiogram will be performed if resistance is felt, or a patient feels uncomfortable.

The anatomic variations of the radial artery can be a challenge. To prevent trauma or spasm, some operators perform a reduced contrast volume arm angiogram. Use of ultrasound guidance is less common though randomized trials indicate faster access and reduced cannulation attempts when done under ultrasound guidance (25) (30). The subclavian tortuosity and a retroesophageal right subclavian can interfere with the success rate of a trans-radial procedure (39). The patient can be asked to take a deep breath in such a situation to make the angle of advancement favorable. An arterial dissection can occur due to advancement of an oversized sheath or catheter in a small caliber artery (26). Dissection is usually accompanied by intense spasm and may necessitate change to an alternative access. Vessel perforation due to significant arterial trauma can occur due to inadvertent advancement of a guidewire into a small side branch or due to a radial anomaly. Of note is that patients with connective tissue disease and serious Raynaud's disease are particularly vulnerable to ischemic complications (30). Patients need to be monitored after the procedure for a forearm hematoma. A conservative management can be done in early detection. On rare circumstances this can cause a compartment syndrome that may further need a surgical intervention.

Radial artery is 2-3mm in diameter and generally larger in males than in females. This may be a barrier to complex interventions requiring larger bore i.e., >6 F guiding catheter. A study done using a 7F glide sheath (Terumo) showed a successful trans-radial access. Another 7F sheath less guide catheter (Sheath less Eacath: Asahi Intec Japan) was successfully used in a complex trans-radial procedure. Other modern guides include the “Railway System” that allows a 7F guide to be used successfully. This proves that the radial access has also had positive changes as the use of trans-radial access becomes rampantly used during cardiac catheterization (26).

Radial artery closure is done using a compressive dressing or with a bracelet compression device to give a continuous two-hour compression. Radial artery occlusion occurrence is

reported in approximately 5% of cases and to reduce this, the use of anticoagulants and patent hemostasis is done (32) (42).

The ESC guidelines recommend a caseload of a minimum of 80 procedures in a year to maintain a trans-radial approach skill level and be able to achieve better results. Past researchers have identified a ten percent operator failure in the initial fifty cases, which decreased significantly to between 3 and 4% after added 500 cases were performed (39).

Acute kidney injury has also been observed as a PCI complication and is associated with higher morbidity and mortality. A trans-radial approach PCI is noted to have reduced vascular complication and bleeding hence reduced acute kidney injury from hemodynamic instability as a result of hemorrhagic complications. The risk of cholesterol embolization to the kidney is also minimized by use of trans-radial PCI that avoids catheterization of descending aorta thus reducing the risk of renal complication after PCI (25).

2.6 Ulnar Arterial Access

This is still a new method of arterial access in practice. It is considered a potential alternative to trans-radial approach. A metanalysis has been done comparing the use of trans-radial and trans ulnar access during coronary angiography and PCI procedures. Reports show that there was no difference in access complications but arterial access cross-over was over- represented with the trans ulnar arm (21)(33).

2.7 Post Procedure Care

Once the left heart catheterization procedure is completed, vascular access sheaths are removed. Direct manual compression or vascular closure that immediately close the arteriotomy site with a staple/clip, collagen plug, or sutures are used to achieve hemostasis (25) (26). These devices reduce the length of supine bed rest improving patient satisfaction but have not been shown to be superior to manual compression with respect to access site complications (26) (27).

Cardiac catheterization is a day procedure and with a trans radial access, bed rest is needed for only two hours. Overnight hospitalization may be needed for high-risk patients with significant comorbidities, patients' complications occurring during the procedure or in patients who have undergone a PCI. Patients who have received more than 2 Gy of radiation during the procedure should be examined for signs of erythema, and if received more than 5 Gy clinical follow up within one month to assess for skin injury is recommended.

2.8 Contraindications for Cardiac Catheterization

Left heart catheterization has no known absolute contraindication although patient refusal remains the major challenge. Relative contraindications include sepsis, acute pulmonary edema, acute renal failure, decompensated heart failure, patients with history of anaphylactic reaction to iodinated contrast agents, acute stroke, severe anemia, and having comorbidities that significantly reduce lifespan, active gastrointestinal bleeding, chronic kidney disease with creatinine values >2.5 mg/dl, extreme brady or tachyarrhythmia (9) (13).

2.9 Problem Statement

Cardiovascular disease is a growing epidemic in Kenya due to the increasing prevalence of risk factors like dyslipidemia, hypertension and diabetes mellitus (44). In Kenya, approximately 25% of hospital admissions and 13 % of deaths are attributed to cardiovascular diseases (19). Cardiac catheterization being both a diagnostic and interventional management procedure, if timely accessed, can improve cardiovascular disease outcomes among patients with cardiovascular disease who have indications for cardiac catheterization.

The vascular access routes used during cardiac catheterization have associated risks and complications that need to be evaluated and documented among our population. Over the years, trans-radial arterial access route has gained fame and become a preferred route of access (46) (47). The trans-radial arterial access is associated with less vascular complications markedly reducing patients' length of stay in hospital despite the fact that it has a prolonged fluoroscopic time, leading to more radiation time exposure in comparison to the femoral access route (22) (31) (47).

There have been major variations concerning the vascular approaches that are being used. The European Society of cardiology (ESC) presented new guidelines in 2015 aimed at providing a clear approach in the management of ACS (the trans-radial arterial access route as the preferred method of access, a class IA indication). In addition, the 2011 American College of Cardiology, Society of Cardiovascular Angiography (SCA) as well as American Heart Association presented essential guidelines which focus on use of trans-radial arterial access in percutaneous coronary intervention (43) (48).

The 2018 scientific statement of the America Heart Association recommends the trans-radial access in the invasive management of patients with Acute Coronary Syndrome. The trans-radial access has also been found to be effective in the aged population i.e., above 85 years or older, obese patients, females and in patients at substantial risk of bleeding complications. The

European Society of Cardiology endorses a minimum of eighty procedures annually to maintain optimum operator skill level (48).

With increasing usage of trans-radial access route, there is need to describe and document the vascular access methods in practice and evolution of the practice in Kenya. The SCA has issued recommendations for best trans-radial intervention practices. Similar guidelines relevant to the Kenyan scenario need to be established. Therefore, this study documented the vascular access methods for left heart catheterization from the year 2015-2020, compared the use of the two methods (trans-radial arterial access and Trans-femoral arterial access), and determined their associated risks and their associated length of hospital stay.

The evolving trend in the use of these vascular access methods with the adoption of the trans-radial access was also described. This study opted to use two hospital models: Kenyatta National Hospital (KNH; a public referral hospital) and Karen Hospital (a private hospital).

2.10 Justification

Data from several studies across the world have pointed out that there has been a marked shift in the choice of vascular access for left heart catheterization: pointing out an evolution from the classical trans-femoral method approach to trans-radial vascular approach. This preference has been attributed to the less complications associated with trans-radial arterial access in comparison to the Trans-femoral arterial access approach. Trans-radial arterial access approach is a class I indication level of evidence A for ACS management according to the 2015 ESC guidelines. The 2018 scientific statement of AHA recommends a default strategy of trans-radial arterial access approach in the invasive management of patients with ACS.

To date, no study has documented the methods of vascular access for left heart catheterization in the Kenyan health facilities. Likewise, the adoption of the trans-radial arterial access in the local Kenyan set up is yet to be described. This study aims to fill this gap by describing the vascular access methods for left heart catheterization in the Kenyan set-up by targeting two health facilities as models: Kenyatta National and Karen Hospitals. The evolution of vascular access methods for left heart catheterization among patients undergoing the procedure during the period of 2015-2020 in these two health facilities was described with the notion to provide the best practices to adopt for trans-radial arterial access in the local Kenyan set up.

2.11 Research Question

What are the vascular access methods and their evolution over time for left heart catheterization at the Kenyatta National and Karen Hospitals?

2.12 Broad Objective

To determine the vascular access methods and their pattern of evolution of use over time, for left heart catheterization at the Kenyatta National and Karen Hospitals cardiac catheterization laboratories during the period of January 2015 to December 2020.

2.13 Specific Objectives

2.13.1 Primary Objectives

- **i.** To determine the proportion of trans-radial versus trans-femoral arterial access methods among patients undergoing left heart catheterization.
- **ii.** To determine the pattern of evolution over time of vascular access methods among patients undergoing left heart catheterization at the Kenyatta National and Karen Hospitals cardiac catheterization laboratories during the period of January 2015 to December 2020.

2.13.2 Secondary Objectives

- **i.** To compare the complications associated with trans-radial versus trans-femoral arterial access methods.
- **ii.** To compare the length of hospital, stay by radial versus femoral arterial access method.

3.0 CHAPTER THREE: STUDY DESIGN AND METHODOLOGY

3.1 Study Design

This was a retrospective study. A comprehensive review of files of patients who underwent left heart catheterization procedure between January 2015 to December 2020 was done.

3.2 Study Sites

This study was done in Kenyatta National Hospital and Karen Hospital, in Nairobi County, Kenya. The KNH is a public referral hospital while Karen is a private facility. Targeting these two facilities provided a broad spectrum between the public and private health facilities, and the data collected should be generalizable across most health facilities conducting the procedure. The patient's charts were accessed from the cardiac catheterization laboratory registers in the two hospitals.

3.3 Study Population

Adult patients who underwent left heart catheterization procedure between January 2015 to December 2020 and having records at KNH records department and Karen Hospital records department.

3.4 Inclusion Criteria

Patients aged 18 years and above who underwent left heart catheterization procedure and have records at the KNH and Karen hospital cardiac catheterization laboratory register.

3.5 Exclusion Criteria

Left heart catheterization procedures done without a well-documented file number / incomplete file numbers recorded in the cardiac catheterization laboratory register were not used for data collection.

3.6 Sample Size Determination

The aim of this study was to evaluate the vascular access methods used in left heart catheterization over a 6-year period.

The sample size was calculated using Fisher's formula (49).

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion. A study done by Santo et al-2014 (37) to assess the trends in arterial access found that 61.5% of procedures done were via the transfemoral arterial access).

d = desired precision (0.05)

$$n = \frac{1.96^2 x\ 0.615(1 - 0.615)}{0.05^2} = 364$$

Records from 2015 to 2020 for Kenyatta National Hospital indicate that a total of 665 procedures were done, while those of Karen Hospital indicate that a total of 1,612 procedures were done which gives a total of 2,277 procedures. Therefore, the number of files retrieved for each hospital was:

Table 1: Number of Files retrieved from each Hospital

Kenyatta National Hospital	**Karen Hospital**
665 / 2277 x 364 = 106	1612 / 2277 x 364 = 258

The proportion of files retrieved for each year was calculated, and is as shown:

Table 2: The proportion of files retrieved for each year

	KNH			**Karen**		
Year	**Number of procedures**	**Percent of total procedures**	**Sample size***	**Number of procedures**	**Percent of total procedures**	**Sample size***
2015	120	18.0%	19	98	6.1%	16
2016	96	14.4%	15	128	7.9%	20
2017	68	10.2%	11	275	17.1%	44
2018	132	19.8%	21	371	23.0%	59
2019	148	22.3%	24	405	25.1%	65
2020	101	15.2%	16	335	20.8%	54
Total	**665**	**100.0**	**106**	**1612**	**100.0**	**258**

**Sample size = Number of procedures x Percent of total procedures*

3.7 Study Procedure and Methods

3.7.1 Sampling Procedure

Files of patients who underwent left heart catheterization in KNH and Karen Hospitals in the period between January 2015 to December 2020 were listed from admission registers from the cardiac catheterization laboratory. This formed the sampling frame. The selected files numbers were listed and handed over to the health information team to retrieve the files from the records department. Files were then coded with unique identification numbers to maintain confidentiality. Nursing cardex was sought for files with incomplete/ post procedural notes.

3.8 Data Collection Procedures

The retrieved files were reviewed by the investigator assisted by two trained research assistants who were clinical officers who had a diploma in clinical medicine and trained on the use of the data collection tools. The relevant information was abstracted from the files and entered into the structured data collection tool.

The tool was used to collect data on the socio-demographic characteristics, risk factors associated with cardiovascular disease, indication for the cardiac catheterization procedure and the complications associated with the procedure as of their last review in the hospital (at two weeks hospital review after the procedure). The investigator continuously reviewed the filled data collection tools to ensure completeness and accuracy. The files were re-checked for completeness and clarity of information before data collection process was completed.

3.9 Study Variables

The investigator documented the date when procedure was done, age, gender, risk factors for cardiovascular disease, length of stay in hospital, vascular access methods used, drugs the patient was taking before and after the procedure was also documented. In addition, the resulting complications were documented and these included: anaphylactic shock, bleeding, hematoma formation, pain/arterial spasm, acute kidney injury, acute arterial occlusion, infection, myocardial infarction, stroke/transient ischemia, iatrogenic coronary dissection, cardiac arrythmias, hypotension, cardiogenic shock, pericardial effusion/tamponade, bleeding necessitating blood transfusion and death (whenever indicated).

3.10 Data Management and Analysis

A study questionnaire with a unique ID for each patient was used to capture the data from the retrieved patient files. Data was then entered into Microsoft Excel. Data verification was done prior to flagging any erroneous entries and corrected appropriately. Data cleaning (entailing correcting for duplicates, missing data and inconsistencies), data coding and statistical analysis was done using SPSS (Version 23.0).

Demographic characteristics and clinical profiles of the patients were analysed and presented as frequencies and percentages, and a chi-square test of homogeneity was used to determine differences in the demographic characteristics of the patients and the facilities, clinical examination profiles of the patients and the facilities, procedures done on the patients with the facilities, and vascular access methods with the facilities. Statistical significance was considered where the p-value < 0.05.

3.11 Study Administration and Quality Assurance

The principal investigator ensured that proper data collection and recording was done. The research assistant was guided by the principal investigator through the entire process. The statistician and supervisors offered guidance to the principal investigator through the whole procedure i.e., from the proposal development to the presentation, statistical analysis and results presentation.

3.12 Ethical Considerations

The protocol document was first presented to the department of Internal Medicine-University of Nairobi for approval. Secondly, ethical approval to conduct this study was sought from Kenyatta National Hospital and University of Nairobi Ethics and Research Committee (KNH/UON ERC). Approval from ERC was submitted to KNH research and programs department and the Karen Hospital to seek clearance to conduct the study and access the patients' records. In addition, permission was sought from the health information department to be allowed to access the unit and retrieve the files. Individual consent was not required because this study relied on secondary data.

Confidentiality was upheld at all stages to ensure that the retrieved files and the information collected were not accessible to unauthorized personnel. Patients' identifiers were used on the data collection forms but a separate record was kept to link study numbers with patients identifying information. The folders were password-protected, and it is only the principal investigator who had access to the folders.

4.0 CHAPTER FOUR: RESULTS

The recruitment of the patients was as shown in Figure 1a and b respectively.

4.1 Recruitment Flow Chart

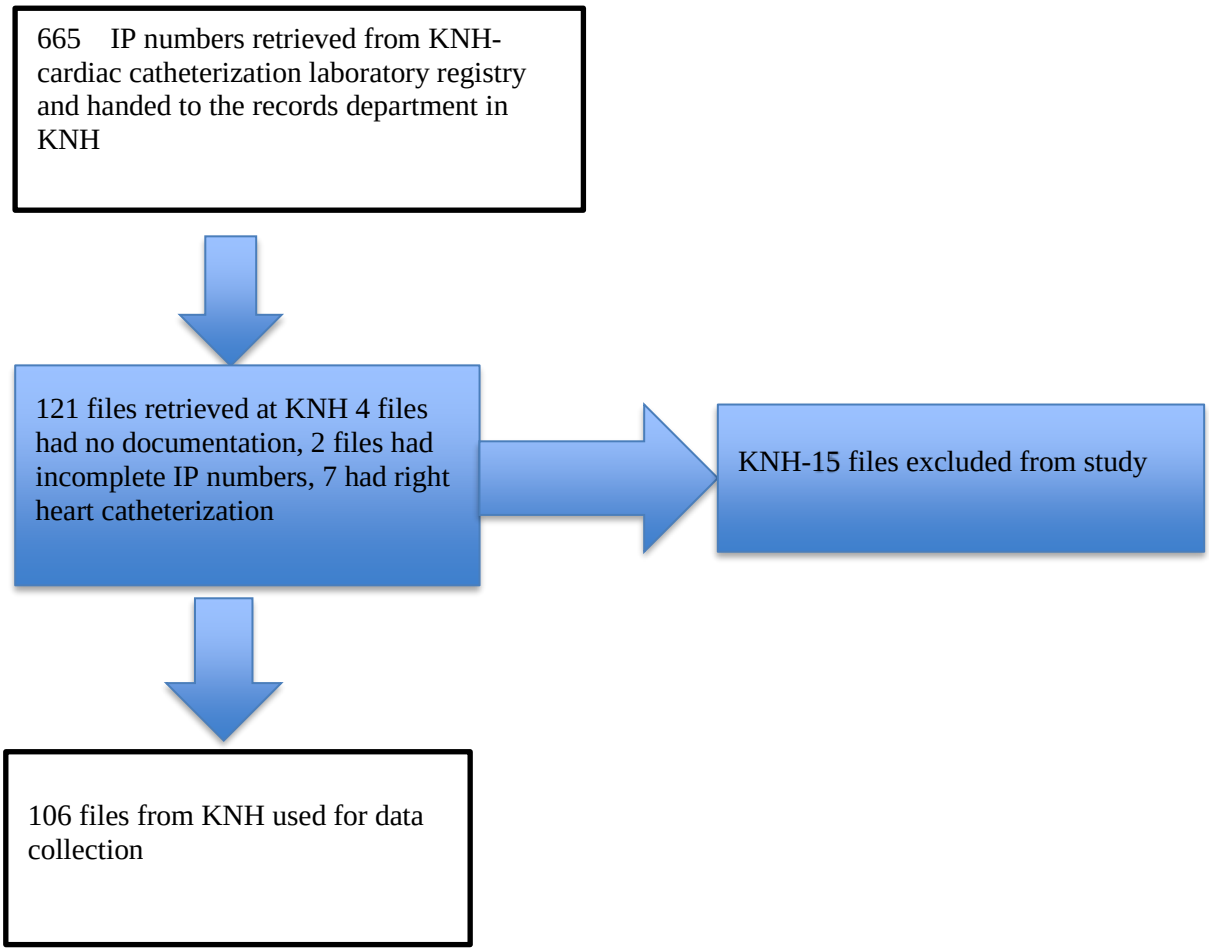

Figure 1: Recruitment flow chart for KNH

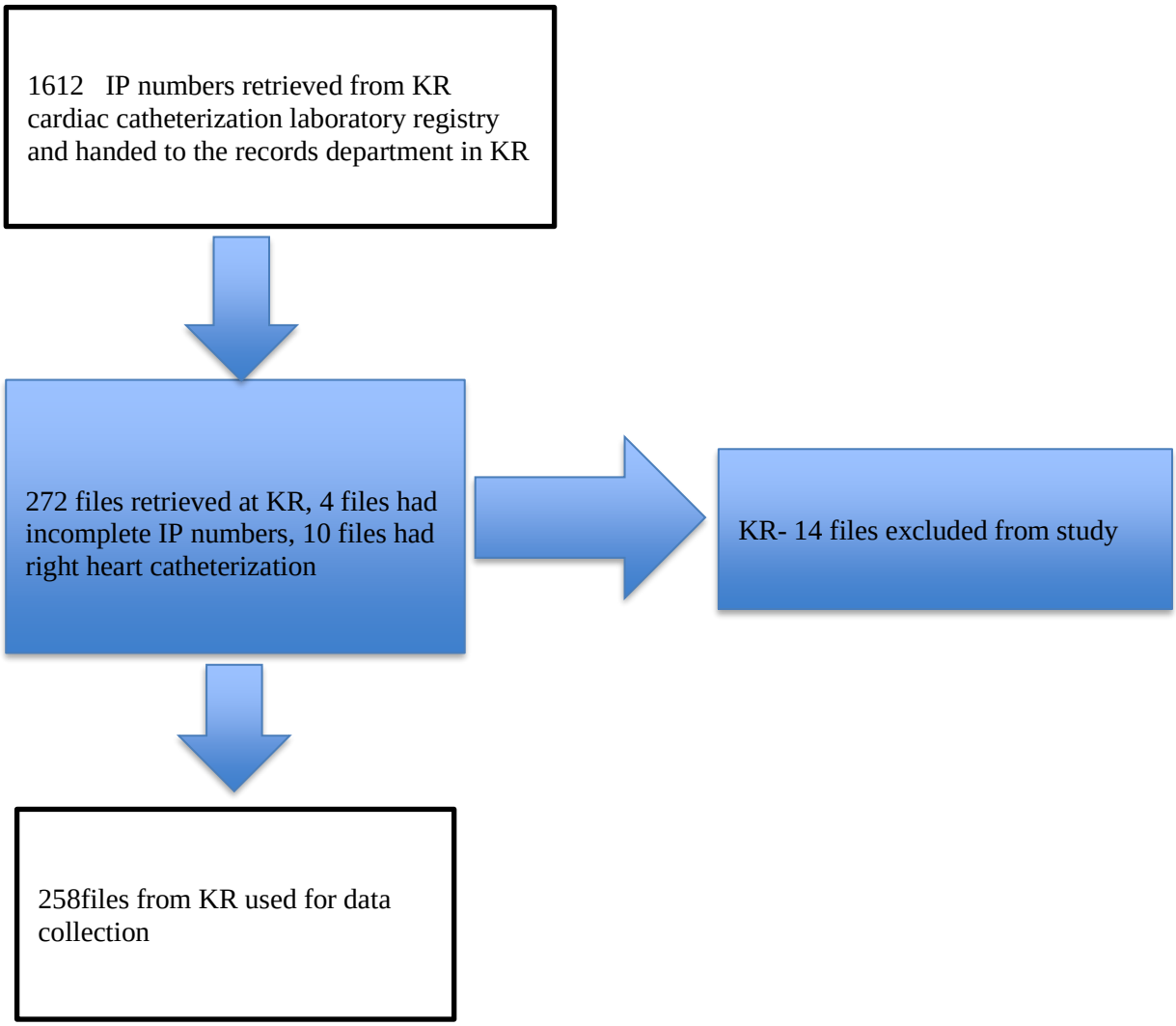

Figure 2:Recruitment flow chart for KR

4.2 Demographic and Clinical Characteristics of Study Participants

The demographic characteristics of the patients show that most of the patients were in the age group 50-59 years (31.6%). On gender, male patients were 237 (65.1%) and female were 127 (34.9%). Majority of the patients were either self-employed (29.9%) or employed (35.4%). The Table 3 shows that there were statistical differences for age, gender, and occupation between the two facilities.

Table 3:Demographic characteristics of patients enrolled in the study

	KNH, ***(n=106)***	**Karen,** ***(n=258)***	**Total,** ***(n=364)***
Characteristic			
Age group, ***n (%)***			
<30	7 (6.6%)	1 (0.4%)	8 (2.2%)
30 – 39	2 (1.9%)	18 (7.0%)	20 (5.5%)
40 – 49	12 (11.3%)	41 (15.9%)	53 (14.6%)
50 – 59	23 (21.7%)	92 (35.7%)	115 (31.6%)
60 – 69	32 (30.2%)	53 (20.5%)	85 (23.4%)
≥70	30 (28.3%)	53 (20.5%)	83 (22.8%)
Gender, *n (%)*			
Male	59 (55.7)	178 (69)	237 (65.1)
Female	47 (44.3)	80 (31)	127 (34.9)
Occupation, *n(%)*			
Employed	11 (10.4)	118 (45.7)	129 (35.4)
Self-employed	32 (30.2)	77 (29.8)	109 (29.9)
Unemployed	34 (32.1)	19 (7.4)	53 (14.6)
Retired	7 (6.6)	30 (11.6)	37 (10.2)
Not indicated	22 (20.8)	14 (5.4)	36 (9.9)

The clinical profile of the patients shows that 280 (76.9%) of the patients were hypertensive, 118 (32.4%) had diabetes mellitus, 43 (11.8%) had dyslipidaemia, and only 3 (0.8%) had CHD. There were statistical differences between the two facilities for all the patient clinical examination profiles (Table 4).

Table 4: Clinical diagnosis of the patients' enrolled in the study

	KNH, *(n=106)*	**Karen, *(n=258)***	**Total, *(n=364)***	**p-value**
Hypertension, *n(%)*	94 (88.7)	186 (72.1)	280 (76.9)	**0.001**
Diabetes, *n (%)*	46 (43.4)	72 (27.9)	118 (32.4)	**0.004**
Dyslipidemia, *n (%)*	5 (4.7)	38 (14.7)	43 (11.8)	**0.007**
CHD, *n (%)*	3 (2.8)	0 (0)	3 (0.8)	**0.024**

The patients had one or more of the indications for procedure, of which the top 3 indications were stable coronary artery disease (CAD/ IHD) 57.7%, Acute coronary syndromes (24.5%) and cardiomyopathy (8.5%).

Table 5:Indication for procedure of cardiac catheterization on the study patients

Indication	**Frequency**	**Percent of patients *(n=364)***
Stable CAD/ IHD	210	57.7%
ACS	89	24.5%
Cardiomyopathy	31	8.5%
Positive EST	18	4.9%
Heart failure	5	1.4%
Others	47	12.9%

Table 6:ACS by subtype in the study patients undergoing cardiac catheterization

ACS	Frequency	Percent of patients *(n=364)*
STEMI	71	19.5%
NSTEMI	18	4.9%

A further detailed look at the acute coronary syndromes indicated that 19.5 % of the ACS' were ST elevation myocardial infarction while 4.9 % were non-ST elevation myocardial infarction. Other indications for the procedures included 10 patients with a diagnosis of arrhythmias, 7 patients with LBBB, 5 patients each for syncope, and complains of severe dyspnoea, 3 patients with aortic stenosis undergoing an evaluation prior to repair, 3 patients each for a pre-operative cardiac evaluation, and ASD, 2 patients each for evaluation post cardiac arrest, palpitations, ventricular tachycardia, and PAH, 1 patient each for AV canal defect, CCF in pregnancy, complete heart block, evaluation pre mitral valve repair, and Takayasu s disease.

A Coronary angiogram was the most common procedure done (79.1%), followed by coronary angiogram with PCI (20.4%).

Table 7:Procedure Done

Procedure, *n (%)*	**KNH, *(n=106)***	**Karen, *(n=258)***	**Total, *(n=364)***
Coronary angiogram	80 (75.5)	208 (80.6)	288 (79.1)
Coronary angiogram + PCI	25 (23.6)	49 (19.0)	74 (20.4)
Balloon Mitral valvuloplasty	1 (0.99)	0 (0.0)	1 (0.3)

4.3 Arterial Access Method

Majority of the vascular arterial access was via the common femoral artery (62.1%), followed by the radial artery (32.7%), and combined (5.2%). There were statistical differences between the 2 facilities for the arterial access methods with the use of the common femoral artery being higher in KNH and the use of the radial artery being higher in KR.

Table 8 :Vascular access method for cardiac catheterization at KNH and KR

Access	Common femoral artery	Radial artery	Combined	p-value
KNH, *(n=106)*	79 (74.5%)	26 (24.5%)	1 (0.9%)	0.002
Karen, *(n=258)*	147 (57.0%)	93 (36.0%)	18 (7.0%)	
Total, *(n=364)*	226 (62.1%)	119 (32.7%)	19 (5.2%)	

Table 9a: Method of vascular access in ACS

ACS	Common femoral artery	Radial artery	Combined	Total	p-value
STEMI	47 (66.2%)	18 (25.4%)	6 (8.5%)	71	0.918
NSTEMI	12 (66.7%)	4 (22.2%)	2 (11.1%)	18	

For patients with STEMI, the use of the transfemoral access was at 66.2% while access via the trans radial route was at 25.4%; for the NSTEMI the use of the transfemoral access was at 66.7% while the use of the trans radial access was at 22.2%. There were no statistical differences between STEMI and NSTEMI for the methods of arterial access.

Table 9b: ACS and vascular access used in KNH and KR hospitals'

ACS	Common femoral artery	Radial artery	Combined	Total
STEMI				
KNH	4	3	1	8
KAREN	43	15	5	63
NSTEMI				
KNH	1	0	0	1
KAREN	11	4	2	17

The common femoral artery was the most common method of vascular access for ACS' in both hospitals.

4.4 Evolution of Choices of Arterial Access in The Study Population

The common femoral arterial access has been the method of vascular access for KNH as from 2015 to 2019 with a decline in 2020, while the same period saw the radial artery increasing. For Karen hospital both the common femoral and radial artery was increasing on a yearly basis.

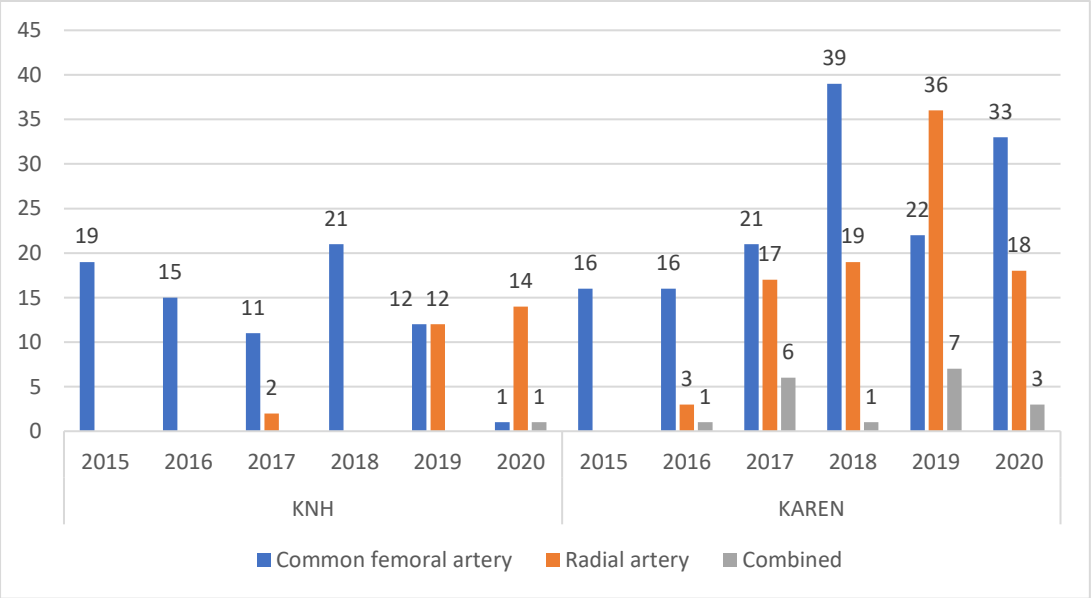

Figure 3:Evolution of vascular access methods over the years for cardiac catheterization at KNH and KR

The trend for KNH shows that the common femoral artery was the mode used for vascular access from 2015 to 2018, and as from 2019 there was a balance of 50.0% each for common femoral artery and radial artery, while in 2020 the radial artery was the most used at 87.4%.

For Karen hospital, of the 16 randomly selected files in 2015, all were common femoral artery. There is variability in the method of vascular access in the following years. In 2016 the most popular method of access was common femoral (80.0%), while in 2017 the common femoral and radial artery methods were used at 47.7% and 38.7% respectively. In 2018, the proportion of use of common femoral artery was double that of radial (66.1% vs. 32.2%), and this reduced in the following year, 2019, where the proportion of common femoral artery was almost half of the radial artery accesses (33.8% vs. 55.4%). In 2020, the proportion of the common femoral artery access was almost twice that of radial access (61.1% vs. 33.3%).

4.5 Complications and Method of Vascular Access

There were 24 (10.6%) complications documented among the common femoral artery method of access while among the radial artery access method there were 7 (5.9%) documented complications, and lastly among the combined modes of access there were 8 (42.1%) cases of complications (Figure 4).

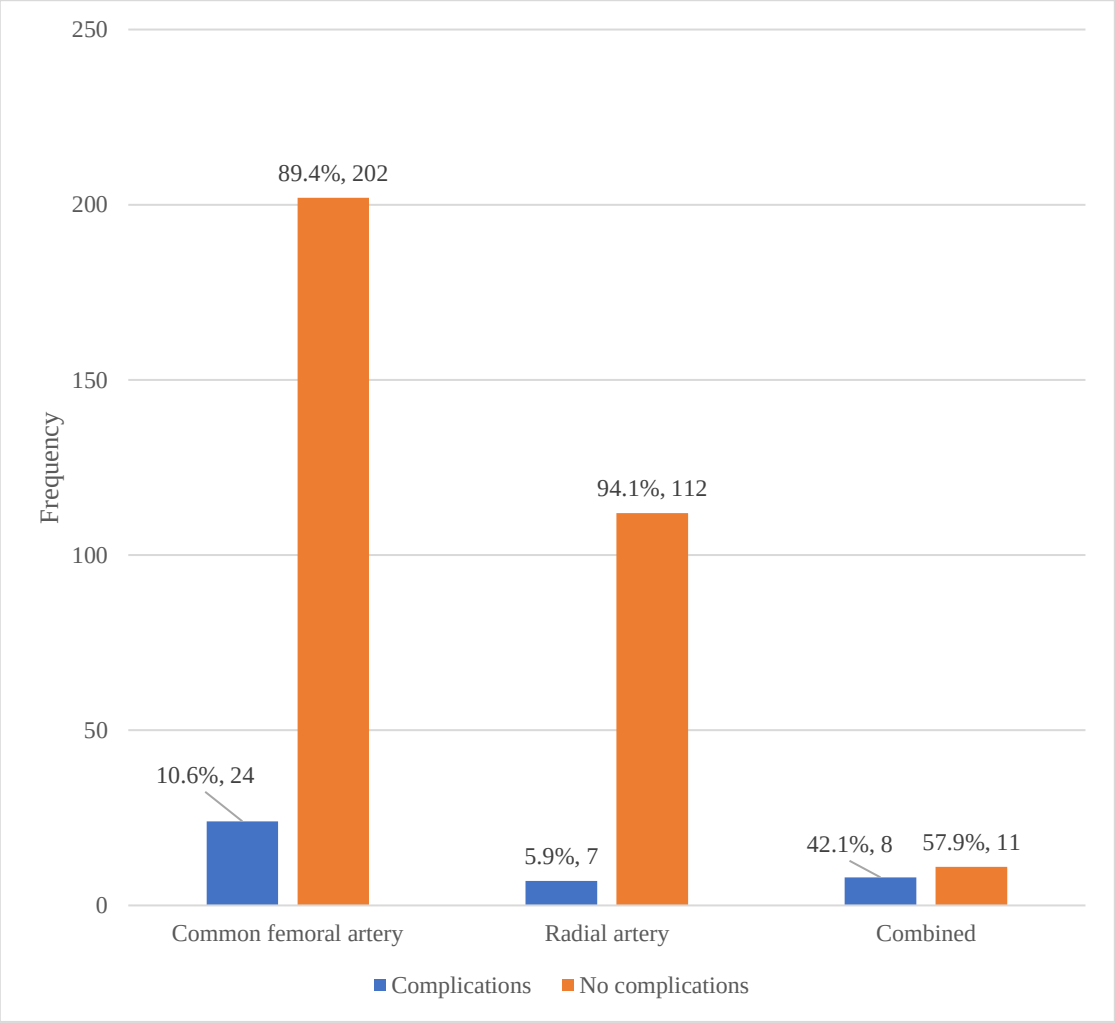

Figure 4:Complications and method of vascular access for cardiac catheterization in the study patients

There were 39 (10.7%) of the total patients who experienced one or more of the complications (Table 10), where of the 39 patients, 19 (48.7%) of them having severe pain as an associated complication and 7 (17.9%) having documented spasms. For this study, procedures done with cross overs from either a transfemoral or a trans radial access were categorized as having had a combined arterial access.

Table 10:Complications associated with each vascular access method in the study patients

Complication	**Common femoral artery (n)**	**Radial artery (n)**	**Combined**	**Proportion of patients *(n=39)* *(n)***
Severe pain	12	2	5	48.7%
Arterial spasm	3	2	2	17.9%
Hematoma formation	3	1	1	12.8%
Bleeding	3	1	0	10.3%
Hypotension	3	1	0	10.3%
Infection	3	1	0	10.3%
Acute kidney injury	3	0	0	7.7%
Ecchymosis	2	1	0	7.7%
Blood transfusion after procedure	0	0	2	5.1%
Cardiac arrythmias/Ventricular Tachycardia	0	1	0	2.6%
Dyspnea	1	0	0	2.6%
Vomiting	1	0	0	2.6%
Cardiogenic shock	0	0	1	2.6%
Hypovolemic shock	0	0	1	2.6%
Arrythmia/Bradycardia	0	1	0	2.6%
Hemoptysis	1	0	0	2.6%

The 39 patients that experienced one or more of the complications, 24 of them had the common femoral artery as their form of vascular access (Table 11).

Table 11:Complication and method of vascular access

	Common femoral artery (n=226)	Radial artery (n=129)	p-value
Yes, *n (%)*	24 (10.6%)	7 (5.9%)	**0.144**

There was no statistically significant difference (using the Pearson Chi-square test) in the proportions of patients who developed complications from the two methods of vascular access.

Table 12:Complication and method of vascular access including the combined access

	Complications			
	Common femoral artery	Radial artery	Combined	p-value
Yes, *n (%)*	24 (10.6%)	7 (5.9%)	8 (42.1%)	**<0.001**
No, *n (%)*	202 (89.4%)	112 (94.1%)	11(57.9%)	

Incorporating the patients who had had a combined arterial access during the cardiac catheterization procedure, we noted that there was a statistically significant difference in the proportions for complications of the methods of vascular access, where the combined method had the highest proportion of complications, and not comparable with the proportions of the other two methods of vascular access.

4.6 Length of Hospital Stay

Most patients in the study (50.3%) either stayed for a day or were discharged the same day followed by those who (32.1%) stayed between 2-5 days.

Table 13:Arterial access and length of hospital stay in days

Length of stay (days)	Common femoral artery	Radial artery	Combined	Total, n (%)
0-1	106 (46.9%)	73 (61.3%)	4 (21.1%)	**183(50.3%)**
2-5	79 (35.0%)	30 (25.2%)	8 (42.1%)	**117 (32.1%)**
6-10	26 (11.5%)	11 (9.2%)	6 (31.6%)	**43 (11.8%)**
>10	15 (6.6%)	5 (4.2%)	1 (5.3%)	**21 (5.8%)**
Total	226	119	19	**364**

ANOVA (Analysis of Variance) test was performed to determine if there were statistical differences for the length of stay (in days) in the three methods of vascular access. There were no statistical differences (Table 14).

Table 14:Analysis of variance for the length of stay in the three methods of vascular access

	Sum of squares	df	Mean square	F	p-value
Between Groups	80.1	2	40.0	2.32	0.100
Within Group	6230.7	361	17.3		
Total	6310.8				

Results of Table 15 indicate that the largest mean number of days at the hospital was observed with the combined method of vascular access (4.6 days), followed by combined femoral (3.5 days), and lastly by radial artery (2.8 days).

Table 15:Mean length of hospital stay in days for the three methods of vascular access for cardiac catheterization in the study patients.

Access	n	Mean (SD)
Common femoral artery	226	3.5 (4.5)
Radial artery	119	2.8 (3.5)
Combined	19	4.6 (3.9)

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

In this retrospective audit, a total of 364 files (106 files from KNH and 258 files from Karen hospital) were reviewed. Cardiac catheterization is an important part of diagnosis and management of cardiovascular diseases (that warrant it) and is one of the most widely performed procedures. Our study was set out to document the vascular access methods used for left heart catheterization at the KNH and Karen Hospitals. We also looked at the adoption of the trans radial access method due to the fact that the 2015 ESC guidelines for the management of ACS that actually recommend 'a radial first strategy' and has been described as a 'class 1 indication level of evidence A' for ACS management during cardiac catheterization.

While most of the western world data indicate increased ages (50) (3) for patients undergoing cardiac catheterization, in our study the age range of most patients undergoing the procedure was 50-59 years with males constituting a majority of the patients at 65.1%. In a retrospective study done by Jean Claude Ambassa et al (51) to analyse the results of heart catheterization in the cardiac centre Shisong, Kumbo in Cameroon from December 2010 till December 2017 it was also noted that the mean age of patients undergoing the procedure was 52.6 +/- 12.9 years with a majority being the male gender (51) (52). A retrospective study (1996-2001 done by Kamotho, Ogola et al (3) in Kenya at the Nairobi hospital on coronary angiography also found majority of the patients had a mean age of 54.4 years with a predominantly a male population. This can be attributed to the fact that most male patients have more cardiovascular risk factors including smoking than their female counterparts.

In Kenya, we presumed that most working class are of the male gender and this may also contribute to better and faster access to a health provider and awareness of cardiovascular risk factors. The slightly lower age in comparison to the west was hypothesized that Africa (Kenya included) mostly has a youthful-middle age population while the west has a good number of the aged population as well. In terms of age distribution and employment, we noted a statistically significant difference between patients in KNH and KR hospital, and this can be due to the fact that most employed people may easily access the private hospital than the unemployed who would prefer a public hospital as it is economically affordable.

In our study most of the patients undergoing cardiac catheterization procedures had hypertension at 76.9% followed by diabetes mellitus at 32.4%. Studies done on heart

catheterization also do indicate that majority of patients undergoing this procedure have established risk factors for cardiovascular disease with a majority of the patients being hypertensive (53) (3). Hypertension has been noted to be a leading risk factor for coronary artery disease, more so when involved with an end organ target (3)(52). Prevalence of hypertension as a risk factor for cardiovascular disease is also high among our Kenyan population (3) and this could explain why a majority of the patients in the study were found to have hypertension.

The commonest indication for the procedure was coronary artery disease at 57.7%, acute coronary syndromes (24.5%) and cardiomyopathy (8.5%). Coronary angiography was the commonest procedure done for 79.1 % of the study patients while coronary angiography with PCI was at 20.4%. This is in comparison to a study done on coronary angiography by Kamotho et al (3) which also noted that stable angina was the leading indication for coronary angiography at 38.5%, myocardial infarction at 15.4 % and unstable angina at 3.8 %.

The arterial access used for a majority of the procedures done was via the transfemoral route (62.1%) while trans radial route was used at 32.7%. For this study, procedures done with cross overs from either a transfemoral or a trans radial access were categorized as having had a combined arterial access; for 5.2% of the study patients. While we appreciated the progressive adoption of the trans radial approach (though slow), our use of the trans radial access was lower in comparison to the global data. It is now well agreed globally that the radial first strategy is standard practice (56).

A retrospective study done by Tewari, Satyendra et al (54) from 2004-2011 at North Indian Cardiology centre in India found the use of trans radial arterial access to be at 44.35% while a systematic review and meta-analysis study done by Pietro Di Santo et al (55) looking at 14 randomized control studies published at inception till January 2020 in the MEDLINE, Cochrane Central Register of controlled trials found that up to 49.6 % of patients had their PCI done via the trans radial approach. The trans radial has become a default arterial approach site for PCI in Europe, Asia and the USA (56).

Contrast to our study where the use of the transfemoral access was at 62.1 %, a study done in the USA in 2016 by Abdulla, Damluji et al (57) on transfemoral approach for coronary angiography and intervention (using a study survey tool administered to operators) with an aim to examine the current practice and use of transfemoral artery approach found that, of the 987 operators, only 18% identified themselves solely as femoralists, 38% as radialists while 42 % as both (57). Another nationwide study by Khalid Changal et al (56) in the USA in 2020 to assess the current training preference, expertise, and comfort with transfemoral and transradial

among cardiovascular training fellows found that up to 95 % of trainees chose trans radial as their default arterial access and the reasons cited by the trainees included patient satisfaction, low complications and the training centres 'radial first' policy.

Contrast to our study where we found more of transfemoral access procedures, we hypothesized this could be related to level of operators training and comfort in use of the trans radial method. In our study again we noted that a number of cross overs were from transradial to transfemoral access and documented reasons were severe pains at site of puncture inducing spasms and then hindering catheter advancement or simply difficulty in engaging the coronaries and this warranted a change over to the transfemoral access which was then successful. Of course, there was a documented attempt of conservative management with additional dose of dormicum, fentanyl or nitroglycerin which worked in some instances but in some procedures did not fully work and required a cross over to the transfemoral arterial access. Similarly, it has been noted that transfemoral access method is still a preferred method for cardiac catheterization even with the increasing uptake of the trans radial access and this could be attributed to the user preference (53) (58) and experience or need for use of large bore catheters during the procedure. Again, the transfemoral access still remains the preferred method of access choice during cross over procedures (59) when complete total occlusions of vessels are noted during the interventional procedures. To note is that the distribution of participants who underwent transfemoral access and trans radial arterial access procedures differed significantly between Kenyatta National Hospital and Karen Hospital; the use of transfemoral access was higher at KNH while the use of trans-radial access was higher at KR. Thus, this study hypothesizes that the increased adoption of trans radial access by private hospitals may be in an attempt to comply with the radial-first strategy as per the ESC cardiac catheterizations guidelines (47) and with the rest of the world at large. Similarly, a study done on evolution of arterial access for cardiac catheterization by Ziakis et al (60) to reveal volumes and trends in interventions performed on trans-radial access in Northern Greece in the selected years of 2004, 2009 and 2013 indicated that it was at 0% in 2004 to approximately 40% in 2013; the adoption being higher in private hospitals as compared to the public hospitals' cardiac catheterization laboratories.

Over time, we noted an increase in the utilization of cardiac catheterization laboratory services in these two hospitals (KNH and KR) from the years 2017 to 2020 as demonstrated by increasing number of patients' undergoing left heart catheterization over the mentioned years. A retrospective review done in Uganda by Joselyn Rwebembera et al (53) at the Uganda Heart institute between the period of February 2012-December 2019 also noted an increasing trend

in the utilization of cardiac catheterization laboratory over their study period. This could be attributed to industrialization and change in lifestyle in our population including eating habits that then predispose to the cardiovascular risk factors.

In terms of the arterial access use and evolution over time, the uptake in use of the trans radial access has demonstrated a slow but progressive uptake in both KNH and KR hospitals, the uptake noted to be higher in KR. Data from several studies indicate a rise in the use of the trans radial arterial access over time. A study done by Santo et al (45) found a rise in the use of trans radial access from 0.2% to 37.2 % over their study period time. Similarly, in our study we noted an increase in use of trans radial arterial access over our 6-year study duration. This again we attributed to the fact that operators may be doing this in an attempt to comply with the 'radial first strategy' as per the ESC guidelines and in keeping with the global trend. Though the decline in 2020 on the number of the procedures done could be related to the fact that there was an overall decline in the number of procedures done for that particular year likely attributed to the effects of the covid 19 pandemic.

In our study, very few patients experienced post procedural related complications. There were 39 (10.7%) of the total patients who experienced one or more of the complications where of the 39 patients that experienced one or more of the complications, 24 of them had the common femoral artery as their form of vascular access. This proves the generally known fact that cardiac catheterization is a safe and sterile procedure (20). Severe pain at puncture site were the commonest complications noted to the point that stronger analgesics including morphine, pethidine or tramadol had to be given to these patients and a re-assessment of the puncture site done. Bleeding and hematoma formation at puncture site occurred in 3 of the patients who had had a transfemoral access and this necessitated change of dressing in order to apply adequate pressure and stop the bleeding.

In some instances, we noted that the documentation of integrillin infusion or the low molecular weight heparin was put on hold till resolution of the bleeding complication. Three patients who had a cross over to the transfemoral access had a documented severe chest pain due to a noted coronary spasm upon catheter engagement into the coronaries making it difficult for catheter advancement. 2 patients had a documented cardiac arrest and were successfully reversed and transferred to the intensive care unit. Of note again is that a majority of the patients with complications were the ones who had undergone a procedure via the transfemoral route.

Some patients developed hypotension post-procedural and had to be transferred to the high dependency unit for intravenous fluids and dobutamine administration. Three patients developed infection within two to three days after the procedure and this was documented as

hotness of body and chills and intravenous antibiotics were prescribed. A patient developed chills and vomiting during the procedure that resolved after administration of intravenous hydrocortisone and this we attributed could be an allergic reaction to administered contrast during the procure. A prospective study done by Baskaran et al (61) on complications of cardiac catheterization at the Montreal heart institute in Canada between April 1996 and March 1998 found complications occurred in 8% of cardiac catheterization procedures done, with local complications accounting for 2.5%. In their study, deaths occurred in 0.6 % of the study participants.

Studies done also indicate that majority of the complications are noted among patients who have had a common femoral arterial access (20). Deaths related to complications were not documented in our study population again confirming that this is a rare complication comparable to previous studies done (24) (31) (62).

Majority of the patients were either discharged on the same day or had a one-day hospital stay. Again, conforming to the standard practice that cardiac catheterization is a safe procedure (63) (64). We noted that some of the patients who had more than a day hospital stay had other underlying comorbidities including chronic kidney disease and thus needed continuity of care after the procedure. Two patients with stable chronic kidney disease needed haemodialysis after the procedure due to an acute kidney injury, while two patients with normal kidney functions prior to the procedure developed acute kidney injury after the procedure and this automatically equated to prolonged hospital stay for stabilization. Three patients needed blood transfusion after the procedure as they were noted to have low haemoglobin levels after the bleeding complications and there was a delay in sourcing for blood for them with one of the patients staying in the ward for up to 10 days waiting for a blood transfusion. We also noted that some patients had come from far away counties and three other patients had come from neighbouring countries and as such could not travel back to their referring facility/ home till travel arrangements made in the following days. Three patients had to stay longer and wait for a recommended CABG procedure.

For this particular study, patients who had a crossover from a trans radial access to a trans femoral access or from a transfemoral to a trans radial access during the procedure were categorized as having had a combined arterial access. This group of patients constituted a 5.2 %. A two-year prospective study done by Aldoori, J.S et al (59) on trans radial approach for coronary angiography and PCI in the Slemani Cardiac hospital in Iraq (2015-2016) also found a cross over from a trans radial to a transfemoral arterial access to be at 4.4%. We hypothesized that the crossover to transfemoral approach could be attributed to tortuosity of the aorta and

brachiocephalic trunk, radial artery spasm, puncture failure or due to a radial loop. Patients who had a combined arterial access in our study were noted to have more complications as compared to the others that had only had a one arterial access use. This we hypothesized that it could be due to the fact that patients having a crossover have a prolonged exposure to the radiocontrast material during the procedure or there's exchange of more catheters during the procedure hence theoretically having more related complications. Of note is that in our study, we did not come a single file with a trans ulnar arterial access which is still a new arterial access in practice. We theorize that it will be a method to be considered for cardiac catheterization in the future as it has been shown to be safe and a potential alternative to the trans radial approach (21) (33).

5.2 Conclusion

Cardiac catheterization is in use for both diagnostic and interventional purposes. Of the procedures done 79.1 % were coronary angiograms while 20.4 % were coronary angiograms with PCI. The vascular access routes in use for KNH and KR included the trans radial and trans femoral routes, and as from 2016, there has been a progressive adoption and incorporation of the trans-radial arterial access in practice. The complications profile was low. Finally, most of the patients were discharged within the same day of the procedure or within a day.

5.3 Study Limitations

The study only incorporated files of patients from KNH and KR hospital. The study entirely depended on documentation done by others and in some instances; all the relevant needed information could miss. Files lacking useful information were excluded and replaced with other files. Of note is that it was difficult to assess the post procedural related complications more so of patients who were discharged on the same day after the procedure and got lost to follow up.

5.4 Recommendations from the Study

Cardiac catheterization offers an invasive form of therapy for heart diseases. The vascular access methods used during this 'surgical' procedure have had a progressive shift to the trans-radial access which has been demonstrated to be associated with better outcome in terms of complications and patients' short hospital stay. The adoption of the trans-radial vascular access in KNH and KR is 'wanting' especially its incorporation among patients with ACS; there is need to have more procedures done via the trans-radial access especially among patients with ACS and this is in keeping with the 2015 ESC guidelines. All included, we thereby recommend the following,

a) Prospective audit studies to determine the vascular access methods for cardiac catheterization and the associated complications with each method.

b) Study to determine the factors influencing the choice of vascular access approach and associated barriers to the adoption of the trans radial arterial access.

c) Since trans-femoral access is still vital in left heart catheterization, techniques for example, routine ultrasound guidance and adjunctive tools for femoral access should be adopted to make it safer and reduce vascular complications.

REFERENCES

1. Olvera Lopez E, Ballard BD, Jan A. Cardiovascular Disease. Treasure Island (FL): StatPearls Publishing; 2022.
2. Kolkailah AA, Alreshq RS, Muhammed AM, et al. Transradial versus transfemoral approach for diagnostic coronary angiography and percutaneous coronary intervention in people with coronary artery disease. Cochrane Database Syst Rev. 2018;4:CD012318.
3. Kamotho, C; Ogola, EO; Joshi, M; et al. Cardiovascular risk factor profile of black Africans undergoing coronary angiography. East African Medical Journal. 2004;2.
4. Deepak G, Karim R, Rajay R, et al. Cardiac catheterization. Medicine.2010;7:390–394.
5. Schwarz, K., Ul Haq, M. A., et al. Cardiac catheterization. Medicine.2018;8: 488-493.
6. Li H, Rha SW, Choi BG, et al. Transradial versus transfemoral intervention in ST-segment elevation myocardial infarction patients in Korean population. Korean J Intern Med. 2018; 4:716-726.
7. Lee MS, Wolfe M, Stone GW. Transradial versus transfemoral percutaneous coronary intervention in acute coronary syndromes: re-evaluation of the current body of evidence. JACC Cardiovasc Interv. 2013; 11:1149-1152.
8. Campeau L. Percutaneous radial artery approach for coronary angiography. Cathet Cardiovasc Diagn. 1989; 1:3-7.
9. Ahmed I, Hajouli S. Left Heart Cardiac Catheterization. Treasure Island (FL): StatPearls Publishing; 2022.
10. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation. 2011;23: e574-e651.
11. Nasser TK, Mohler ER 3rd, Wilensky RL, et al. Peripheral vascular complications following coronary interventional procedures. Clin Cardiol. 1995; 11:609-614.
12. Pinte L., P. F., Cristian A.M., Mocanu I., Murgu V, et al. Right Heart Pathology Cardiac Catheterization and Angiography. Right Heart Pathology, 2018; 625-640.
13. Al-Hijji MA, Lennon RJ, Gulati R, et al. Safety and Risk of Major Complications with Diagnostic Cardiac Catheterization. Circ Cardiovasc Interv. 2019;7: e007791.

14. Sherwood MW, Wang Y, Curtis JP, et al. Patterns and outcomes of red blood cell transfusion in patients undergoing percutaneous coronary intervention. JAMA 2014; 8:836-843.
15. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. The Lancet. 2004; 9438:937-952.
16. Wong ND, Levy D. Legacy of the Framingham heart study: rationale, design, initial findings, and implications. Glob Heart. 2013; 1:3-9.
17. Ambrose JA, Singh M. Pathophysiology of coronary artery disease leading to acute coronary syndromes. F1000Prime Rep. 2015; 7:08.
18. Malakar, A. K., Choudhury, D., Halder, B., et al. A review on coronary artery disease, its risk factors, and therapeutics. J Cell Physiol. 2019; 10:16812-16823.
19. Kenya National Guidelines for Cardiovascular Diseases Management Division of Non-Communicable Diseases Ministry of Health (Internet). www.health.go.ke. 2018; 47-61.
20. Scanlon PJ, Faxon DP, Audet AM, et al. ACC/AHA guidelines for coronary angiography. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on Coronary Angiography). Developed in collaboration with the Society for Cardiac Angiography and Interventions. J Am Coll Cardiol. 1999; 6:1756-1824.
21. Brown KN, Ahmed I, Kanmanthareddy A. Catheter Management of Mitral Stenosis. StatPearls. Treasure Island (FL): StatPearls Publishing; 2022.
22. Anjum I, Khan MA, Aadil M, et al. Transradial vs. Transfemoral Approach in Cardiac Catheterization: A Literature Review. Cureus. 2017;6: e1309.
23. Sherwood MW, Wang Y, Curtis JP, et al. Patterns and outcomes of red blood cell transfusion in patients undergoing percutaneous coronary intervention. JAMA. 2014; 8:836-84.
24. Oweida SW, Roubin GS, Smith RB 3rd, et al. post-catheterization vascular complications associated with percutaneous transluminal coronary angioplasty. J Vasc Surg. 1990; 3:310-315.
25. Sorrentino S, Nguyen P, Salerno N, et al. Standard Versus Ultrasound-Guided Cannulation of the Femoral Artery in Patients Undergoing Invasive Procedures: A Meta-Analysis of Randomized Controlled Trials. J Clin Med. 2020; 3:677.

26. Dorman SH, Obaid DR. Vascular access, and closure for cardiovascular intervention. Heart. 2019; 16:1279-1288.
27. Schulz-Schüpke S, Helde S, Gewalt S, et al. Comparison of vascular closure devices vs manual compression after femoral artery puncture: the ISAR-CLOSURE randomized clinical trial. JAMA. 2014; 19:1981-1987.
28. Biancari F, D'Andrea V, Di Marco C, et al. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. Am Heart J. 2010; 4:518-531.
29. Moussa Pacha H, Alahdab F, Al-Khadra Y, et al. Ultrasound-guided versus palpation-guided radial artery catheterization in adult population: A systematic review and meta-analysis of randomized controlled trials. Am Heart J. 2018; 204:1-8.
30. Sultan EM, Rabea HM, Abdelmeguid KR, et al. Transradial artery approach in STEMI patients reperfused early and late by either primary PCI or pharmaco-invasive approach. Egypt Heart J. 2018; 1:1-7.
31. Brueck M, Bandorski D, Kramer W, et al. A randomized comparison of transradial versus transfemoral approach for coronary angiography and angioplasty. JACC Cardiovasc Interv. 2009; 11:1047-1054.
32. Vescovo, G. M., Zivelonghi, C., Scott, B, et al. Percutaneous Coronary Intervention for Chronic Total Occlusion. US Cardiology Review. 2020;14: e11.
33. Choi, C., Agarwal, N., Park, K., & Anderson, R. D. Coronary Artery Chronic Total Occlusion. Cardiovascular Innovations and Applications. 2016;3: 325-335.
34. Alkhouli M, Cohen HA, Bashir R. Radial artery avulsion--a rare complication of transradial catheterization. Catheter Cardiovasc Interv. 2015;1: E32-E34.
35. Zencirci E, Değirmencioğlu A. Can radial artery pulse grading predict radial artery spasm during transradial approach? Kardiol Pol. 2017; 4:360-367.
36. Kiemeneij F, Laarman GJ, Odekerken D, et al. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. J Am Coll Cardiol. 1997; 6:1269-1275.
37. Peterson EC. Commentary: The Learning Curve in Transradial Access: One Time When a Novice Interventionist May Shine. J Endovasc Ther. 2019; 5:725-726.
38. Hess CN, Peterson ED, Neely ML, et al. The learning curve for transradial percutaneous coronary intervention among operators in the United States: a study from the National Cardiovascular Data Registry. Circulation. 2014; 22:2277-2286.39.

39. Zaman AG, Aleem Q. Pharmacology before, during and after percutaneous coronary intervention. Heart. 2020; 7:585-592.
40. Satheesh S, Subramanian A. How to do radial coronary angiogram? Indian Heart J. 2015; 2:170-174.
41. Cai G, Huang H, Li F, et al. Distal transradial access: a review of the feasibility and safety in cardiovascular angiography and intervention. BMC Cardiovasc Disord. 2020; 1:356.
42. Kooiman J, Seth M, Dixon S, et al. Risk of acute kidney injury after percutaneous coronary interventions using radial versus femoral vascular access: insights from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium. Circ Cardiovasc Interv. 2014; 2:190-198.
43. Goel PK, Menon A, Mullasari AS, et al. Transradial access for coronary diagnostic and interventional procedures: Consensus statement and recommendations for India: Advancing Complex CoronariES Sciences through TransRADIAL intervention in India - ACCESS RADIAL™: Clinical consensus recommendations in collaboration with Cardiological Society of India (CSI). Indian Heart J. 2018; 6:922-933.
44. Chege, P. M. Multiple cardiovascular disease risk factors in rural Kenya: evidence from a health and demographic surveillance system using the WHO STEP-wise approach to chronic disease risk factor surveillance. South African Family Practice, 2016; 2:54-61.
45. Santo, C. V. A. d. E., de Melo, P. H. M. C., Takimura, C. K., et al. Trends in the Use of the Transradial Approach in More Than a Decade: The InCor's Experience. Revista Brasileira de Cardiologia Invasiva (English Edition), 2014; 2:120-124.
46. Brilakis ES, Karatasakis A. The evolution of arterial access for cardiac catheterization: Lessons from Central and Northern Greece. Hellenic J Cardiol. 2016; 5:329-330.
47. Mehta SR, Jolly SS, Cairns J, et al. Effects of radial versus femoral artery access in patients with acute coronary syndromes with or without ST-segment elevation. J Am Coll Cardiol. 2012; 24:2490-2499.
48. Roffi M, Patrono C, Collet JP, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC). Eur Heart J. 2016; 3:267-315.

49. Jung SH. Stratified Fisher's exact test and its sample size calculation. Biom J. 2014;1:129-140.
50. Slicker K, Lane WG, Oyetayo OO, et al. Daily cardiac catheterization procedural volume and complications at an academic medical center. Cardiovasc Diagn Ther. 2016; 5:446-452.
51. Ambassa J.C, Charles M, Jacques Cabral T.T. Heart catheterization in adults in a sub-Saharan tertiary centre: 8 years' experience. Cardiovasc Diagn Ther. 2019; 2:173-178.
52. Collins R, Peto R, MacMahon S., et al. Blood pressure, stroke, and coronary heart disease: Part 2, short-term reductions in blood pressure: overview of randomised drug trials in their epidemiological context. The Lancet. 1990; 8693: 827–838.
53. Rwebembera J, Aliku T, Kayima J, et al. Starting and Operating a Public Cardiac Catheterization Laboratory in a Low Resource Setting: The Eight-Year Story of the Uganda Heart Institute Catheter Laboratory. Glob Heart. 2021; 1:11.
54. Tewari S, Sharma N, Kapoor A, et al. Comparison of transradial and transfemoral artery approach for percutaneous coronary angiography and angioplasty: a retrospective seven-year experience from a north Indian center. Indian Heart J. 2013; 4:378-387.
55. Di Santo P, Simard T, Wells GA, et al. Transradial Versus Transfemoral Access for Percutaneous Coronary Intervention in ST-Segment-Elevation Myocardial Infarction: A Systematic Review and Meta-Analysis. Circ Cardiovasc Interv. 2021;3: e009994.
56. Changal K, Syed MA, Atari E, et al. Transradial versus transfemoral access for cardiac catheterization: a nationwide pilot study of training preferences and expertise in The United States. BMC Cardiovasc Disord. 2021; 1:250.
57. Damluji, A. A., Nelson, D.W., Valgimigli, M., et al. Transfemoral Approach for Coronary Angiography and Intervention. Cardiovascular Interventions. 2017: 22;2269–2279.
58. Deora, S., Transradial versus transfemoral approach in STEMI: Choice is with the operator. Indian Heart Journal. 2020; 4, 327–328.
59. Aldoori, J.S. and Mohammed, A.I. Transradial approach for coronary angiography and percutaneos coronary intervention: personal experience. Egypt Heart J. 2019: 1; 10.
60. Ziakas, A., Katranas, S., Bobotis, G., et al. The TRACE registry (Trans-Radial Approach in Central and northErn Greece). Hellenic Journal of Cardiology. 2016: 5; 323-328.

61. Baskaran C., Serge D., Luc B., et al. Complications of cardiac catheterization in the current era: A single-center experience. , 2001; 3; 289–295.
62. Doyle, B. J., Ting, H. H., Bell, M. R., et al. Major femoral bleeding complications after percutaneous coronary intervention: incidence, predictors, and impact on long-term survival among 17,901 patients treated at the Mayo Clinic from 1994 to 2005. JACC Cardiovasc Interv. 2008; 2: 202-209.
63. Antonsen, L., Jensen, L. O., Thayssen, P. Outcome and safety of same-day-discharge percutaneous coronary interventions with femoral access: a single-center experience. Am Heart J: 2013; 3: 393-399.
64. Shroff, A., Kupfer, J., Gilchrist, I. C., et al. Same-Day Discharge After Percutaneous Coronary Intervention: Current Perspectives and Strategies for Implementation. JAMA Cardiology. 2016; 2: 216-223.

APPENDICES

Appendix I: KNH/UoN-ERC Letter of Approval

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Ref: KNH-ERC/A/327

17th September, 2021

Dr. Faridah Nafula Ahmed
Reg. No.H58/11101/2018
Dept. of Clinical Medicine and Therapeutics
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 17 SEP 2021 KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Ahmed

RESEARCH PROPOSAL: VASCULAR ACCESS METHODS AND THEIR PATTERN OF EVOLUTION FOR LEFT HEART CATHETERIZATION AT THE KENYATTA NATIONAL AND KAREN HOSPITALS: A RETROSPECTIVE AUDIT (2015-2020) (P430/06/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above research proposal. The approval period is 17th September 2021 – 16th September 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoNERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M.L CHINDIA
SECRETARY, KNH- UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Clinical Medicine and Therapeutics, UoN
Supervisors: Prof. Elijah S.N.Ogola, Dept. of Clinical Medicine and Therapeutics, UoN
Dr. Peter Muriithi Nyamu, Dept. of Medicine, KNH
Dr. Syokau Ilovi, Dept.of Clinical Medicine and Therapeutics, UoN

Appendix II: Certificate of Plagiarism

Turnitin Originality Report

VASCULAR ACCESS METHODS AND THEIR PATTERN OF EVOLUTION FOR LEFT HEART CATHETERIZATION AT THE KENYATTA NATIONAL AND KAREN HOSPITALS: A RETROSPECTIVE AUDIT (2015-2020) by Dr. Faridah Nafula Ahmed

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APPROVAL OF LEAD SUPERVISOR AND CHAIR OF THE DEPARTMENT

Lead Supervisor:

Prof. Elijah S.N. Ogola, MBChB, MMED, FACC

Associate Professor, Consultant Cardiologist

Department of Clinical Medicine and Therapeutics

University of Nairobi

Signature..... Date 01/08/2022

Chairman of the Deparment:

Prof. Erastus Olonde Amayo,

Chairman, Department of Internal Medicine and Therapeutics

Professor Internal Medicine and Neurology

University of Nairobi

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
DEPARTMENT OF CLINICAL MEDICINE & THERAPEUTICS

Signature ..... Date 9/08/2022

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18 < 1% match (Deepthi Sudhakar, John M. Suffredini, Charles E. Howard, Hani Jneid. "Distal Radial Artery Cannulation for Challenging Radial Anatomy", Cardiology, 2021)
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19 < 1% match ("Monday, 31 August 2009", European Heart Journal, 09/02/2009)
"Monday, 31 August 2009", European Heart Journal, 09/02/2009

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https://tehj.springeropen.com/articles/10.1186/s43044-019-0006-2

21 < 1% match (student papers from 19-Jul-2021)
Submitted to Barry University on 2021-07-19

22 < 1% match (Eric Holroyd, M. Adnan Nadir, Karim Ratib, Jim Nolan. "Cardiac catheterization", Medicine, 2014)
Eric Holroyd, M. Adnan Nadir, Karim Ratib, Jim Nolan. "Cardiac catheterization", Medicine, 2014

23 < 1% match ()
Giovanni Maria Vescovo, Carlo Zivelonghi, Benjamin Scott, Pierfrancesco Agostoni. "Percutaneous Coronary Intervention for Chronic Total Occlusion", US Cardiology Review, 2020

24 < 1% match (Internet from 17-Mar-2023)
https://www.ajol.info/index.php/ljm/article/download/81928/72080

25 < 1% match (Mahesh Kumar Batra, Lajpat Rai, Naveed Ullah Khan, Muhammad Naeem Mengal et al. "Radial or Femoral Access in Primary Percutaneous Coronary Intervention (PCI): Does the Choice Matters?", Indian Heart Journal, 2020)
Mahesh Kumar Batra, Lajpat Rai, Naveed Ullah Khan, Muhammad Naeem Mengal et al. "Radial or Femoral Access in Primary Percutaneous Coronary Intervention (PCI): Does the Choice Matters?", Indian Heart Journal, 2020

26 < 1% match ("Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque", Catheterization and Cardiovascular Interventions, 2014)
"Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque", Catheterization and Cardiovascular Interventions, 2014

27 < 1% match (Jean Claude Ambassa, Mvondo Charles, Tantchou Tchoumi Jacques Cabral. "Heart catheterization in adults in a sub-Saharan tertiary centre: 8 years' experience", Cardiovascular Diagnosis and Therapy, 2019)

Jean Claude Ambassa Mvondo Charles, Tantchou Tchoumi Jacques Gabriel. "Heart catheterization in adults in a sub-Saharan tertiary centre: 8 years' experience", Cardiovascular Diagnosis and Therapy, 2019

28 < 1% match (Judith Koolman, Milan Seth, Simon Dixon, David Wohns, Thomas LaLonde, Sunil V. Rao, Hitinder S. Gurm. "Risk of Acute Kidney Injury After Percutaneous Coronary Interventions Using Radial Versus Femoral Vascular Access", Circulation: Cardiovascular Interventions, 2014)

Judith Koolman, Milan Seth, Simon Dixon, David Wohns, Thomas LaLonde, Sunil V. Rao, Hitinder S. Gurm. "Risk of Acute Kidney Injury After Percutaneous Coronary Interventions Using Radial Versus Femoral Vascular Access", Circulation: Cardiovascular Interventions, 2014

29 < 1% match (Connie N. Hess, Eric D. Peterson, Megan L. Neely, David Dai et al. "The Learning Curve for Transradial Percutaneous Coronary Intervention Among Operators in the United States", Circulation, 2014)

Connie N. Hess, Eric D. Peterson, Megan L. Neely, David Dai et al. "The Learning Curve for Transradial Percutaneous Coronary Intervention Among Operators in the United States", Circulation, 2014

30 < 1% match ()

Kathiravan, S. "A Study of the correlation between Potassium Dip and Severity of Acute Ischemic Stress in patients with Acute Coronary syndrome", 2014

31 < 1% match ()

[redacted] "Transradial intervention as the first choice of treatment for ST elevation myocardial infarction patients: editorial comment", Korean Association of Internal Medicine

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Submitted to Ain Shams University on 2020-07-23

33 < 1% match (Internet from 13-Feb-2023)

https://www.researchgate.net/publication/285925757_Cardiac_Catheterization_in_Congenital_Heart_Disease_Pediatric_and_Adult

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https://www.reliasmedia.com/articles/145131-suspected-acute-coronary-syndrome

36 < 1% match ("2000 Transcatheter cardiovascular therapeutics", The American Journal of Cardiology, 2000)

"2000 Transcatheter cardiovascular therapeutics", The American Journal of Cardiology, 2000

37 < 1% match (student papers from 12-Jan-2022)

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38 < 1% match (Deepak Goyal, Karim Ratib, Rajay Narain, Jim Nolan. "Cardiac catheterization", Medicine, 2010)

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41 < 1% match ("Tuesday, 4 September 2007", European Heart Journal, 09/02/2007)

"Tuesday, 4 September 2007", European Heart Journal, 09/02/2007

42 < 1% match (student papers from 15-Jan-2010)

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43 < 1% match ("The Aesthetic Society's Cosmetic Surgery National Data Bank: Statistics 2019", Aesthetic Surgery Journal, 2020)

"The Aesthetic Society's Cosmetic Surgery National Data Bank: Statistics 2019", Aesthetic Surgery Journal, 2020

44 < 1% match (Bonow, Robert O.. "ACC/AHA guidelines for the management of patients with valvular heart disease", Journal of the American College of Cardiology, 19981101)

Bonow, Robert O.. "ACC/AHA guidelines for the management of patients with valvular heart disease", Journal of the American College of Cardiology, 19981101

45 < 1% match (Internet from 12-Oct-2022)
https://www.jmra.us/project%20doc/2019/JMIE_JANUARY2019/JMIEJan19-BinoJM.pdf

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48 < 1% match (Lucy W. Meng'anyi, Lilian A. Omondi, Margaret N. Mulva. "Assessment of nurses interventions in the Management of Clinical Alarms in the critical care unit, Kenyatta National Hospital, a cross sectional study", BMC Nursing, 2017)
Lucy W. Meng'anyi, Lilian A. Omondi, Margaret N. Mulva. "Assessment of nurses interventions in the Management of Clinical Alarms in the critical care unit, Kenyatta National Hospital, a cross sectional study", BMC Nursing, 2017

49 < 1% match (Internet from 18-Jul-2020)
https://www.medscape.com/viewarticle/820935

50 < 1% match (Abdulla A. Damluji, Daniel W. Nelson, Marco Valgimigli, Stephan Windecker et al. "Transfemoral Approach for CoronaryAngiography and Intervention", JACC: Cardiovascular Interventions, 2017)
Abdulla A. Damluji, Daniel W. Nelson, Marco Valgimigli, Stephan Windecker et al. "Transfemoral Approach for CoronaryAngiography and Intervention", JACC: Cardiovascular Interventions, 2017

51 < 1% match (student papers from 25-Sep-2015)
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53 < 1% match (Internet from 02-Mar-2022)
https://www.pubfacts.com/author/Feo%20Mi4

54 < 1% match (Antonios Ziakas, Sotirios Katranas, Georgios Bobotis, Aggeliki-Despoina Mavrogianni et al. "The TRACE registry (Trans-Radial Approach in Central and northErn Greece)", Hellenic Journal of Cardiology, 2016)
Antonios Ziakas, Sotirios Katranas, Georgios Bobotis, Aggeliki-Despoina Mavrogianni et al. "The TRACE registry (Trans-Radial Approach in Central and northErn Greece)", Hellenic Journal of Cardiology, 2016

55 < 1% match (Herbert French. "Mitral Stenosis and Pregnancy*", BJOG An International Journal of Obstetrics and Gynaecology, 9/1906)
Herbert French. "Mitral Stenosis and Pregnancy*", BJOG An International Journal of Obstetrics and Gynaecology, 9/1906

56 < 1% match (Internet from 12-Feb-2022)
https://abcagripol.org/wp-content/uploads/2022/02/Revista_ABC_Ingles_janeiro_1180Lx44344.pdf

57 < 1% match (Internet from 28-Aug-2015)
http://retirement.answers.com/401-k/what-is-a-designated-roth-contribution?page=227

58 < 1% match ("IR Playbook", Springer Science and Business Media LLC, 2018)
"IR Playbook", Springer Science and Business Media LLC, 2018

59 < 1% match (Archie, J.P.. "Some determinants of papaverine-induced femoral artery pressure gradients", Journal of Surgical Research, 199003)
Archie, J.P.. "Some determinants of papaverine-induced femoral artery pressure gradients", Journal of Surgical Research, 199003

60 < 1% match (Rolf P. Kreutz, Sujoy Phookan, Hamid Bahrami, Anjan K. Sinha et al. "Femoral Artery Closure Devices vs Manual Compression During Cardiac Catheterization and Percutaneous Coronary Intervention", Journal of the Society for Cardiovascular Angiography & Interventions, 2022)
Rolf P. Kreutz, Sujoy Phookan, Hamid Bahrami, Anjan K. Sinha et al. "Femoral Artery Closure Devices vs Manual Compression During Cardiac Catheterization and Percutaneous Coronary Intervention", Journal of the Society for Cardiovascular Angiography & Interventions, 2022

< 1% match (Internet from 14-May-2020)

61 https://www.researchsquare.com/article/rs-8911/v2

62 < 1% match ("Tuesday, 2 September 2008", European Heart Journal, 09/02/2008)
"Tuesday, 2 September 2008", European Heart Journal, 09/02/2008

63 < 1% match (Ahmed M. Adlan, Timothy Campbell, Timothy Fairbairn, Sunell Aggarwal, Omar Nawaytou, Diana Penha, Derick Todd, Saagar Mahida. "Retrograde aortic access during ventricular tachycardia ablation: indications, techniques, and challenges", Journal of Cardiovascular Electrophysiology, 2019)
Ahmed M. Adlan, Timothy Campbell, Timothy Fairbairn, Sunell Aggarwal, Omar Nawaytou, Diana Penha, Derick Todd, Saagar Mahida. "Retrograde aortic access during ventricular tachycardia ablation: indications, techniques, and challenges", Journal of Cardiovascular Electrophysiology, 2019

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Jaafar Sadeq Aldoori, Ali Ibrahem Mohammed. "Transradial approach for coronary angiography and percutaneous coronary intervention: personal experience", The Egyptian Heart Journal, 2019

65 < 1% match (Kai Wang, Jun-Jun Cai, Yang Wu, Yu Wang, Lei-Lei Liu, Lei Shi, Xian Wang. "Prospective randomized controlled trial study of Luofengning granule in the treatment of unstable angina", Medicine, 2020)
Kai Wang, Jun-Jun Cai, Yang Wu, Yu Wang, Lei-Lei Liu, Lei Shi, Xian Wang. "Prospective randomized controlled trial study of Luofengning granule in the treatment of unstable angina", Medicine, 2020

66 < 1% match ("Interventional Cardiology", Wiley, 2011)
"Interventional Cardiology", Wiley, 2011

67 < 1% match (Anatol Kontush, M. John Chapman. "Functionally Defective High-Density Lipoprotein: A New Therapeutic Target at the Crossroads of Dyslipidemia, Inflammation, and Atherosclerosis", Pharmacological Reviews, 2006)
Anatol Kontush, M. John Chapman. "Functionally Defective High-Density Lipoprotein: A New Therapeutic Target at the Crossroads of Dyslipidemia, Inflammation, and Atherosclerosis", Pharmacological Reviews, 2006

68 < 1% match (Yader Sandoval, Fred S Apple, Stephen W Smith. "High-sensitivity cardiac troponin assays and unstable angina", European Heart Journal: Acute Cardiovascular Care, 2016)
Yader Sandoval, Fred S Apple, Stephen W Smith. "High-sensitivity cardiac troponin assays and unstable angina", European Heart Journal: Acute Cardiovascular Care, 2016

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121.0 CHAPTER ONE: INTRODUCTION 1.1 Background Information Globally, diseases of the

heart

41are the leading cause of morbidity and mortality. The cardiovascular system includes the

heart and its vasculature. Pathology arising here includes endocarditis, valvular heart disease (arising from rheumatic heart disease) and conduction abnormalities. Other diseases of the cardiovascular system include tumors of the heart or disorders of the heart muscles (cardiomyopathy).

40Cardiovascular diseases, also include coronary artery disease, cerebrovascular disease, Peripheral artery disease and aortic atherosclerosis (1). Coronary artery disease

accounts for up to

15one third to one half of all cases of cardiovascular disease

(1). The mainstay

21management of CAD is medical therapy and revascularization. Revascularization can be achieved via a Coronary artery bypass graft or via a percutaneous coronary intervention. Peripheral arteries like the femoral and

radial provide access to the coronary arteries to perform diagnostic or therapeutic or both procedures

(2). Cardiac catheterization is an invasive procedure that

22involves insertion of fine bore tubes into the heart

for diagnostic and/or for therapeutic intervention. This is achieved by using a cannula which is

22inserted into a peripheral artery or vein

. Despite the availability of imaging techniques, cardiac catheterization has remained essential in

26diagnosis and management of coronary artery disease

(3) (4) and in evaluation of cardiac hemodynamics (5). Two types of cardiac catheterization exist:

19right heart catheterization and left heart catheterization

(6). The right heart catheterization uses a venous or flow directional catheter that is advanced into

2right ventricle and to the pulmonary artery. This enables measurement of right ventricular and

pulmonary artery pressure levels. A contrast medium injected into the catheter enables direct visualization of right heart side, the cardiac valves and blood circulation. The

22left heart catheterization involves advancement of a catheter into the left

heart through an artery in femoral region, wrist or elbow. With injection of a radio contrast medium, an examination

17of the left ventricle, aorta, left cardiac valves performance and

blood circulation is enabled (7). During cardiac catheterization, pressures and oxygen saturations

33in the heart chambers and great vessels are recorded, determining transvalvular gradients, cardiac shunts, and the severity of pulmonary hypertension. Coronary angiography provides details about the coronary vessels' anatomy allowing accurate diagnosis of

coronary disease (8). Interventional procedures include percutaneous coronary intervention for occluded vessels, valvuloplasty and valvotomy procedures (8) (9) (10). Werner Forssmann performed

38the first human heart catheterization in 1929. He inserted a catheter into his own heart via a cutdown in his left antecubital vein

. In the following years, marked developments occurred in the field of cardiac catheterization as seen by Mason Sones (

22In 1868) utilizing a brachial artery cut down procedure to perform the

first selective coronary angiogram. Additionally, in the 1960s there was

22development of pre-shaped catheters as well as the

integration of the Seldinger approach (which involves percutaneous insertion

2of a catheter into a blood vessel) and the femoral approach becoming the

preferred route in cardiac catheterization.

2In 1888, Campeau introduced the radial artery

approach for cardiac catheterization (9). Cardiac catheterization offers interventional strategies as alternative method to surgical therapy for different diseases of the heart and it is widely known that

41percutaneous coronary intervention is linked with greater

2Oclinical outcomes in patients presenting with acute coronary syndromes

(9) (11). Previous research has established the superiority of radial artery access in terms of bleeding and mortality thus creating a need for a paradigm shift in preference to the trans-radial arterial access approach (6) (7). Percutaneous coronary intervention i.e., angioplasty that is done during left heart catheterization unblocks occluded coronary vessels thus improving blood flow and decrease mortality in acute coronary syndrome patients. Angioplasty is currently the preferred method for management of myocardial infarction (6). A study done by Hu LI et al on trans-radial

31versus trans-femoral intervention in ST segment elevation myocardial infarction patients

from January 2009 to December 2009 at nine teaching hospitals revealed that trans-radial intervention in

318TEMI patients undergoing primary percutaneous intervention with drug eluting stents was associated with a lower incidence of access site hematoma, twelve month repeat vascularization and

major adverse cardiovascular events in comparison to the transfemoral intervention (6). Left heart catheterization also provides a platform for therapeutic intervention of some cardiac malformations e.g., septal defects, vascular stenosis and valvular defects (12). Vascular complications associated with these interventional procedures are not uncommon. The complications include hematomas in groin which occur between 5% and 23% or retroperitoneal ranging from 0.15 % to 0.44 %, pseudoaneurysms ranging from 0.5% to 9%, arteriovenous fistulae between 0.2% to around 2.1% , acute arterial occlusion less than 0.8 %, infections with less than 0.1% and cholesterol emboli which was 0.08 % (11). Rarely, during left heart diagnostic catheterization, complications such us myocardial infarction, stroke, 1 latrogenic coronary dissection or pericardial effusion/tamponade and death may occur. Cardiac arrythmias, cardiogenic and septic shock are rare causes of in-hospital death after left heart catheterization (13). A study done on patients who had blood transfusion and

19undergoing percutaneous coronary intervention (PCI) found that patients

who had blood transfusion (regardless of bleeding), were at an

19increased risk of in-hospital based myocardial infarction (MI

) and other conditions such as stroke and congestive

19heart failure except in patients with bleeding and

preprocedural hemoglobin values of less than 10g/dl (14). Currently, there exists no Kenyan data regarding the vascular access methods for left heart catheterization. As such, this study described the vascular access methods for left heart catheterization at KNH and Karen Hospitals and assessed the evolution of trends in the practice of vascular arterial access methods over the years. In addition, a comparison between complications associated with trans-femoral arterial access and trans-radial arterial access was performed in these two Kenyan facilities.

152.0 CHAPTER TWO: LITERATURE REVIEW 2.1

Coronary Artery Disease (Atherosclerosis) Industrialization has resulted in a change of activities to sedentary jobs; and this may explain the rising rates of cardiovascular disease during the last decades (1).

The intake of high calorie diets, physical inactivity, consumption of

32saturated fats and sugars have all been associated with development of atherosclerosis and other metabolic disturbances for example metabolic syndrome, diabetes mellitus and hypertension that are highly seen in people with cardiovascular

disease (1). In the INTERHEART study (15), risk factors amounting to nine modifiable accounted for

6780% of the risk with a first myocardial infarction

; abdominal obesity, diabetes mellitus, regular alcohol intake,

16psychosocial factors, consumption of fruits and vegetables and physical inactivity

. In the FRAMINGHAM Heart Study (16), 60-90% of coronary heart disease

46events occurred in patients with at least one risk factor. Non modifiable risk factors

57for heart disease include family history of cardiovascular disease, age and

gender. Premature atherosclerosis

16or death from cardiovascular disease in a first degree relative before 65 years of age in males and 65 years in females is considered an independent risk factor

(16). The prevalence of cardiovascular disease

16increases significantly with each decade of life as well. The main site of

atherosclerotic disease is in the epicardial coronary arteries. The functionality of the vascular endothelium is disrupted during atherosclerosis. The functions normally include; sustenance of an antithrombotic surface, control of vascular tone

30and control of inflammatory cell adhesion and diapedesis

.Disrupting the functions causes a hypercoagulable state and hypo fibrinolysis. Loss or disruption of the endothelial function results to abnormal behavior of blood cells specifically monocytes, platelets and the activated vascular endothelium (17)(18). There is an inappropriate vessel constriction and luminal thrombus formation as part of the process. These changes that occur include subintimal collection of fat as well as smooth muscle cells, fibroblasts and intercellular matrix (plaque formation). Further, there are also segmental reductions in cross-sectional area of the vessels such as the epicardial coronary tree where there are major atherosclerotic changes (atherosclerosis developing at uneven rates in different segments of the vessels). A reduction in the diameter of the epicardial artery will markedly affect the performance of the myocardium (17). A 50% reduction in the vessel diameter limits probability of increase of blood flow to meet the increased myocardial demand. At rest or under reduced stress, an 80 percent reduction in diameter has a significant impact on coronary flow, resulting in myocardial ischemia. The plaque's cap, which separates it from the bloodstream, is prone to rupture or erosion. The activation and aggregation of platelets, and the activation of the coagulation cascade, results in the deposition of fibrin strands when the contents of the formed plaque are exposed. The platelets accumulate and fibrin strands form a thrombus, trapping erythrocytes and reducing

30coronary blood flow, resulting in the clinical manifestations of myocardial ischemia (18). The continued narrowing of the

coronary tree

51and myocardial ischemia is further accompanied by development of collateral vessels. When

well-developed, these vessels play a fundamental role. They are essential in the sustenance of myocardial perfusion at rest. In increased demand states, the distal resistance vessels dilate in order to sustain coronary blood flow in keeping with the progressive stenosis in the proximal epicardial artery. With maximal dilatation of the resistance vessels, myocardial perfusion becomes reliant

42on the pressure in the coronary artery distal to the obstruction. The resultant effect of this ischemia

is manifested clinically as angina or electrocardiographic changes as seen by ST segment deviation, that is precipitated by increased oxygen demand by the myocardium during exercise or emotional stress (18). Patients with ischemic heart disease can present acutely or insidiously with symptoms over months to years. Patients may have symptoms of a stable disease (here refers to angina occurring on exertion and relieved by rest)

35In the absence of cardiomyocyte necrosis or unstable angina

to mean

35myocardial ischemia at rest or with minimal exertion in the absence of cardiomyocyte necrosis

as well. Ischemic heart disease can also present as ACS and hereby refers to cardiomyocyte necrosis

68consistent with acute myocardial ischemia. Chronic CAD may

lead to heart failure and arrythmias as well. Commonly presenting with ventricular tachycardia/ ventricular fibrillation and less commonly with supraventricular arrythmia for example atrial fibrillation. Sudden death from ischemic heart disease has been attributed to ischemia induced ventricular tachyarrhythmias, and this occurs in patients having a severe disease affecting the left main coronary or severe disease with a single remaining vessel (17)(18)(19). 2.2 Indications of Cardiac Catheterization The following are

44Indications for cardiac catheterization: 2.2.1 For

44Evaluation and Treatment of Coronary Artery Disease

. During coronary angiography, a radio contrast is injected through the catheter and real time images show the dye as it flows through the coronary arteries. Occluded vessels are then visualized and percutaneous interventions can be done in occluded vessels. 2.2.2 Valvulopathies Pathology includes

55aortic regurgitation and stenosis, mitral stenosis and regurgitation, pulmonic stenosis and regurgitation, tricuspid regurgitation and stenosis

. Cardiac catheterization hereby applies depending on the severity of the disease, for preoperative evaluation or in suspected cases of coronary artery disease (20)(21). Left heart catheterization together with right heart catheterization is also resourceful when there are discrepancies between clinical and non-invasive findings (20)(21) and to facilitate interventional procedures as well. 2.2.3 Assessment of Congenital heart diseases This is done prior to corrective surgery more so when clinical symptoms or noninvasive imaging conducted indicate presence of coronary artery disease. Left heart catheterization is also done when there is suspicion for congenital coronary abnormalities for evaluation of pulmonary pressures, vascular resistance calculation, assessments of shunts and assessment of complex anatomy. 2.2.4 Assess Pericardial Diseases By assessing the hemodynamic findings during cardiac catheterization, a distinction between constrictive pericarditis and restrictive cardiomyopathy can be made (12). 2.2.5 Assessment of Myocardial Diseases Majorly done if the clinical image of a patient with known cardiomyopathy has changed; or to facilitate myocardial biopsy (12). 2.3 Vascular access 2.3.1 Transfemoral Arterial Access The Trans-femoral arterial access route is considered a classical method over trans-radial approach since it can be repeatedly punctured (22). It is easily palpated and allows easy access. It is universally accepted due to its extensive use, the workforce experience and easy accessibility. It also allows for the use of wider sheaths and other equipment. 5 The commonly occurring vascular complications associated with the Trans-femoral approach include

60access site bleeding, formation of a hematoma, a retroperitoneal

bleed, arteriovenous fistula and pseudoaneurysm formation. There may be need for blood transfusion to treat the bleeding complication. Retroperitoneal bleeding (post procedurally), has a poor prognosis, and blood transfusion after the operation has a poor prognosis as well; in severe cases resulting in mortality (22) (23). The vascular bleeding complication at the femoral arterial access site may result in increased morbidity,

17increased length of hospital stay and

17increased risk of mortality in patients

receiving active anticoagulation and antiplatelet therapy. Ensuring an optimal site for sheath insertion reduces complications. Large punctures below the optimal site result in more bleeding, pseudoaneurysm and arteriovenous fistula formation. High punctures above the optimal site increase the risks for a retroperitoneal hemorrhage. Using

3a fluoroscopy-guided method can reduce vascular

problems. A micro puncture kit also reduces complications by allowing for the placement of a 4F sheath

3and femoral sheath angiography to validate location before introducing a larger sheath

. Difficult anatomy,

3morbid obesity, or peripheral vascular disease

, on the other hand, may make the procedure difficult. In this case, a trans-radial access or direct visualization of the typical femoral artery with an ultrasound can be considered (24) (25). For femoral closure, a

63manual compression or use of a vascular closure

device can be used (23) (26). In the ISAR CLOSURE randomized

39clinical trial, the vascular closure devices were non inferior to manual compression in terms of vascular access site complications (bleeding) and reduced time to

achieving hemostasis (27). While

2a meta- analysis done by Fausto Biancari et al on

56 randomized control trials found

52that the use of vascular closure devices was associated with a significantly shorter

24time to hemostasis and thus may shorten recovery ; however the use of the vascular closure devices was associated with a somewhat increased risk of infection, lower limb ischemia ,arterial stenosis, device entrapment in the artery and need of vascular surgery for arterial complications

(28). A metanalysis of seven randomized control trials done by Sabato Sorrentino et al found that there was reduced time to cannulation, reduced vascular complications (i.e., access site hematoma, major bleeding, retroperitoneal hematoma and pseudoaneurysms) in patients undergoing transfemoral access procedures under ultrasound guidance versus standard transfemoral approach (25) (29). 2.3.2 Radial Arterial Access Trans-radial arterial access is currently the recommended standard route for PCI. Guidelines in other parts of the world indicate a paradigm shift in preference to the radial access. This is due to the fact that

randomized control studies done over the years, and specifically in the last decade, show fewer procedural complications associated with the procedure in comparison to the femoral access route. A mortality benefit has even been proven especially for people affected by ACS and ST segment elevation myocardial infarction (30) (31). The radial artery's anatomy i.e., being superficial with a small caliber, simplifies hemostasis allowing for early patient ambulation. It is therefore appropriate

4for patients who cannot withstand extended bed rest, are on anticoagulation, or are receiving PCI in a day care setting

. Over the last decade, it has been noted that the Trans-femoral access has remained the choice of access for large bore access greater than 6Fr during a transcatheter aortic valve intervention. During a procedure, an unfavorable radial access results to a cross over to the femoral access (26) (32) . It's ease of access and dual blood supply lessen the chances of limb ischemia as well (7). Instances whereby two arterial accesses are involved include

23management of coronary chronic total occlusions; a

23hybrid algorithm approach which has a high PCI success rate and relatively low procedural complications

is applied. In this hybrid algorithm, two entry sites are used for catheter insertion (

25trans-radial and trans-femoral) or both trans-femoral and the

blockage targeted from the front and back (antegrade and retrograde) allowing a

23switch from one technique to another during the procedure in case of failure of the previous one

(33). Other instances whereby two arterial access sites are used include implantation

53of intra-aortic balloon pump and use of extracorporeal membrane oxygenation

in hemodynamically unstable patients undergoing emergency coronary angiography and PCI. For ergonomic purposes, this arterial access method has gained popularity in the last decade. Since the radial artery is shallow, bleeding is easily regulated

20by compression. There are no large nerves or veins along the radial artery

(anatomically). Nerve and vascular complications are significantly reduced as a result of this. Other benefits of arterial access include reduced bleeding complications and reduced hospital costs as there is early ambulation after the procedure (34) (35) (36). There exists a learning curve for the practice of trans-radial access approach and a randomized control trial done indicated it to be steeper but shorter in comparison to the Trans-femoral access approach i.e. 20-30 cases for trans-radial access whereas the Trans-femoral access was 41-50 cases (37) and once the skill was acquired, the procedure time for a trans-radial access was significantly shorter with fewer catheter exchanges (37). A PCI registry evaluation in the United States of America from 2009 to 2019 found that as operator familiarity with trans-radial access improved,

29higher risk patients and more difficult cases were chosen for

the trans-radial access intervention, procedural success rates remained high, with a

29threshold for overcoming the learning curve of

about 30-40 cases (38) and a related study done in Canada found that new radial operators need to perform at least 50 trans-radial interventional procedures

29to achieve similar procedural outcomes as experienced radial performers

(38). 2.4 Trans-radial Arterial Access Procedure Cardiac catheterization Done when a patient has received an intravenous conscious sedation. In suspected acute coronary syndrome, a patient is pretreated with

aspirin (39) and when the procedure is likely to proceed to a PCI an additional antiplatelet agent is started (clopidogrel, prasugrel or ticagrelor) with loading dose and a maintenance dose administered appropriately (prasugrel is

49avoided in patients with a prior stroke or a transient ischemic attack

). Warfarin is withheld 2-3 days

2prior to catheterization to limit access site bleeding. During a

trans-radial arterial access procedure, the patient is positioned supine, and arm

3supported by a board. A contralateral venous access is obtained in anticipation of

use if resuscitation may be needed. The right femoral region is

4also prepared in high-risk cases to facilitate a rapid transition to the femoral

access as need arises, thus the operator needs to be oriented in both arterial accesses. The left radial access is preferred and presents a proper basis within which informed decisions could be made especially when the left internal mammary artery graft needs to be imaged or when

3the right radial pulse is missing. The

major benefit in this context is that

3the operator is less likely to encounter

an anatomic problem such as the subclavian tortuosity (30). Pre-procedural sedation is done, and studies have shown

4that fentanyl and midazolam use reduce spasm and femoral

crossover. Due to its muscular wall and various alpha-adrenergic receptors, the radial artery is vulnerable to spasm. Although an Allen's test is conducted

58prior to the operation to ensure sufficient patency of the

ulnar-palmar arch, several studies have identified no complications while using the trans-radial route in patients with irregular Allen's tests. In the procedure, access is made possible 2cm proximal to the styloid process. The anterior wall of vessel is punctured and guidewire inserted (40). A through and through technique that involves a catheter over needle advancement is done. 8 2.5 Trans-radial Access Complications A procedural failure can occur due to radial artery spasm. Spasmolytic agents can be used after sheath insertion. A meta-analysis done showed a combination of nitroglycerin and verapamil as being the most effective. An attempt to minimize radiation exposure can be done initially by advancing a guidewire and catheter up the arm without fluoroscopy. An angiogram will be performed if resistance is felt, or a patient feels uncomfortable. The anatomic variations of the radial artery can be a challenge. To prevent trauma or spasm, some operators perform a reduced contrast volume arm angiogram. Use of ultrasound guidance is less common though randomized trials indicate faster access and reduced cannulation attempts when done under ultrasound guidance (25) (30). The subclavian tortuosity and a retroesophageal right subclavian can interfere with the success rate of a trans-radial procedure (39). The patient can be asked to take a deep breath in such a situation to make the angle of advancement favorable. An arterial dissection can occur due to

4advancement of an oversized sheath or catheter in a small caliber artery (26). Dissection

is usually

4accompanied by intense spasm and may necessitate change

to an alternative access. Vessel perforation due to significant arterial trauma can occur due to

4inadvertent advancement of a guidewire into a small side branch or due to a radial anomaly

. Of note is that

3patients with connective tissue disease and serious Raynaud's disease are

particularly vulnerable to ischemic complications (30). Patients need to be monitored after the procedure for a forearm hematoma. A conservative management can be done in early detection. On rare circumstances this can cause a compartment syndrome that may further need a surgical intervention. Radial artery is 2-3mm

3in diameter and generally larger in males than in females. This

may be a barrier to complex interventions requiring larger bore i.e., >6 F guiding catheter. A study done using a 7F glide sheath (Terumo) showed a successful trans-radial access. Another 7F sheath less guide catheter (Sheath less Eacath: Asahi Intec Japan) was successfully used in a complex trans-radial procedure. Other modern guides include the "Railway System" that allows a 7F guide to be used successfully. This proves that the radial access has also had positive changes as the use of trans-radial access becomes rampantly used during cardiac catheterization (26). Radial artery closure is done using

4a compressive dressing or with a bracelet compression device to give

a continuous two-hour

3compression. Radial artery occlusion occurrence is reported in approximately 6% of cases

and to reduce this, the use of anticoagulants and patent hemostasis is done (32) (42). The ESC guidelines recommend a caseload of a minimum of 80 procedures in a year to maintain a trans-radial approach skill level and be able to achieve better results. Past researchers have identified a ten percent operator failure in the initial fifty cases, which decreased significantly to between 3 and 4% after added 500 cases were performed (39).

2Acute kidney injury has also been observed as a

PCI complication

2Sand is associated with higher morbidity and mortality. A

trans-radial approach PCI is noted to have reduced vascular complication and bleeding hence reduced acute kidney injury from hemodynamic instability as a result of

2Shemorrhagic complications. The risk of cholesterol embolization to the kidney is also minimized by use of trans-radial PCI that avoids catheterization of descending aorta

thus reducing

2Sthe risk of renal complication after PCI

(25). 2.6 Ulnar Arterial Access This is still a new method of arterial access in practice. It is considered a potential alternative to trans-radial approach. A metanalysis has been done comparing the use of trans-radial and trans ulnar access during coronary angiography and PCI procedures. Reports show that there was no

3difference in access complications but arterial access cross-over was over-represented with the trans ulnar

arm (21)(33). 2.7 Post Procedure Care 2.8 Contraindications for Cardiac Catheterization Left heart catheterization has no known absolute contraindication although patient refusal remains the major challenge. Relative contraindications include sepsis,

17acute pulmonary edema, acute renal failure

, decompensated heart failure, patients with history of

17anaphylactic reaction to iodinated contrast agents

, acute stroke, severe anemia, and having comorbidities that significantly reduce lifespan, active gastrointestinal bleeding, chronic kidney disease with creatinine values >2.5 mg/dl, extreme brady or tachyarrhythmia (9) (13). 2.9 Problem Statement Cardiovascular disease is a growing epidemic in Kenya due to the increasing

30prevalence of risk factors like dyslipidemia, hypertension and diabetes mellitus

(44). In Kenya, approximately 25% of hospital admissions and 13 % of deaths are attributed to cardiovascular diseases (19). Cardiac catheterization being both a diagnostic and interventional management procedure, if timely accessed, can improve cardiovascular disease outcomes among patients with cardiovascular disease who have indications for cardiac catheterization. The vascular access routes used during cardiac catheterization have associated risks and complications that need to be evaluated and documented among our population. Over the years, trans-radial arterial access route has gained fame and become a preferred route of access (46) (47). The trans-radial arterial access is associated with less vascular complications markedly reducing patients' length of stay in hospital despite the fact that it has a prolonged fluoroscopic time, leading to more radiation time exposure in comparison to the femoral access route (22) (31) (47). There have been major variations concerning the vascular approaches that are being used.

17The European Society of cardiology (ESC) presented new guidelines

in 2015 aimed at providing a clear approach in the management of ACS (the trans-radial arterial access route as the preferred method of access, a class IA indication). In addition, the 2011

29American College of Cardiology, Society of Cardiovascular Angiography (SCA) as

well as American Heart Association presented essential guidelines which focus on

25use of trans-radial arterial access in peroutaneous coronary intervention

(43) (48). The 2018

2scientific statement of the America Heart Association recommends the

trans-radial access in the invasive

2management of patients with Acute Coronary Syndrome. The

25trans-radial access has also been found to be effective in

the aged population i.e., above 85 years or older, obese patients, females and

66in patients at substantial risk of bleeding

complications.

2The European Society of Cardiology endorses a minimum of

eighty procedures annually to maintain optimum operator skill level (48). With increasing usage of trans-radial access route, there is need to describe and document the vascular access methods in practice and evolution of the practice in Kenya. The SCA has issued recommendations for best trans-radial intervention practices. Similar guidelines relevant to the Kenyan scenario need to be established. Therefore, this study documented the vascular access methods for left heart catheterization from the year 2015-2020, compared

the use of the two methods (trans-radial arterial access and Trans-femoral arterial access), and determined their associated risks and their associated length of hospital stay. The evolving trend in the use of these vascular access methods with

18the adoption of the trans- radial access was

also described. This study opted to use two hospital models: Kenyatta National Hospital (KNH; a public referral hospital) and Karen Hospital (a private hospital). 2.10 Justification Data from several studies across the world have pointed out that there has been a marked shift in the choice of vascular access for left heart catheterization: pointing out an evolution from the classical trans-femoral method approach to trans-radial vascular approach. This preference has been attributed to the less complications associated with trans-radial arterial access in comparison

47to the Trans-femoral arterial access approach. Trans-radial arterial access approach is a

2class I indication level of evidence

A for ACS management according to the 2015 ESC guidelines. The 2018 scientific statement of AHA recommends a default strategy of trans-radial arterial access approach in the invasive management of patients with ACS. To date, no study has documented the methods of vascular access for left heart catheterization in the Kenyan health facilities. Likewise,

18the adoption of the trans-radial arterial access in the

local Kenyan set up is yet to be described.

5This study aims to fill this gap by describing the

vascular access methods for left heart catheterization in the Kenyan set-up by targeting two health facilities as models: Kenyatta National and Karen Hospitals. The evolution of vascular access methods for left heart catheterization among patients undergoing the procedure during the period of 2015-2020 in these two health facilities was described with the notion to provide the best practices to adopt for trans-radial arterial access in the local Kenyan set up. 2.11 Research Question What are the vascular access methods and their evolution over time for left heart catheterization at the Kenyatta National and Karen Hospitals? 2.12 Broad Objective To determine the vascular access methods and their pattern of evolution of use over time, for left heart catheterization at the Kenyatta National and Karen Hospitals cardiac catheterization laboratories during the period of January 2015 to December 2020.

52.13 Specific Objectives 2.13.1 Primary Objectives i. To determine the proportion of

trans-radial versus trans-femoral arterial access methods among patients undergoing left heart catheterization. ii. To determine the pattern of evolution over time of vascular access methods among patients undergoing left heart catheterization at the Kenyatta National and Karen Hospitals cardiac catheterization laboratories during the period of January 2015 to December 2020.

52.13.2 Secondary Objectives i. To compare the complications associated with

trans-radial versus trans-femoral arterial access methods. ii. To compare the length of hospital, stay by radial versus femoral arterial access method.

73.0 CHAPTER THREE: STUDY DESIGN AND METHODOLOGY 3.1 Study Design This was a retrospective study

. A comprehensive review of files of patients who underwent left heart catheterization procedure between January 2015 to December 2020 was done.

63.2 Study Sites This study was done in Kenyatta National Hospital and Karen Hospital

, in Nairobi County, Kenya. The KNH is a public referral hospital while Karen is a private facility. Targeting these two facilities provided a broad spectrum between the public and private health facilities, and the data

collected should be generalizable across most health facilities conducting the procedure. The patient's charts were accessed from the cardiac catheterization laboratory registers in the two hospitals. 3.3 Study Population Adult patients who underwent left heart catheterization procedure between January 2015 to December 2020 and having records at KNH records department and Karen Hospital records department.

63.4 Inclusion Criteria Patients aged 18 years and above who

underwent left heart catheterization procedure and have records at the KNH and Karen hospital cardiac catheterization laboratory register. 3.5 Exclusion Criteria Left heart catheterization procedures done without a well-documented file number / incomplete file numbers recorded in the cardiac catheterization laboratory register were not used for data collection. 3.6 Sample Size Determination

56The aim of this study was to evaluate the

vascular access methods used in left heart catheterization over a 6-year period. The

11sample size was calculated using Fisher's formula (49). $Z?x\ P(1-P)\ n=d?$ Where, n = Desired sample size 14 Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI) P = expected true proportion

. A study done by Santo et al-2014 (37) to assess the trends in arterial access found that 61.5% of procedures done were via the transfemoral arterial access). d = desired precision (0.05) 1.96?x 0.615(1 − 0.615) n= 0.05? = 364 Records from 2015 to 2020 for Kenyatta National Hospital indicate that a total of 665 procedures were done, while those of Karen Hospital indicate that a total of 1,612 procedures were done which gives a total of 2,277 procedures. Therefore, the number of files retrieved for each hospital was: Table 1: Number of Files retrieved from each Hospital Kenyatta National Hospital Karen Hospital 665 / 2277 x 364 = 106 1612 / 2277 x 364 = 258 The proportion of files retrieved for each year was calculated, and is as shown: Table 2: The proportion of files retrieved for each year KNH Karen Year

43Number of procedures Percent of total procedures Sample size* Number of procedures Percent of total procedures

Sample size* 2015 120 18.0% 19 98 6.1% 16 2016 96 14.4% 15 128 7.9% 20 2017 68 10.2% 11 275 17.1% 44 2018 132 19.8% 21 371 23.0% 59 2019 148 22.3% 24 405 25.1% 65 2020 101 15.2% 16 335 20.8% 54 Total 665 100.0 106 1612 100.0 258 *Sample size = Number of procedures x Percent of total procedures 3.7 Study Procedure and Methods 3.7.1 Sampling Procedure Files of patients who underwent left heart catheterization in KNH and Karen Hospitals in the period between January 2015 to December 2020 were listed from admission registers from the cardiac catheterization laboratory. This formed the sampling frame. The selected files numbers were listed and

1handed over to the health information team to retrieve the files from the records department

. Files were then coded with unique identification numbers to maintain confidentiality. Nursing cardex was sought for files with incomplete/ post procedural notes. 3.8 Data Collection Procedures The retrieved files were reviewed by the investigator assisted by two trained research assistants who were clinical officers who had a diploma in clinical medicine and trained

1on the use of the data collection tools

.

1The relevant information was abstracted from the files and entered into

the

10structured data collection tool. The tool was used to collect data on the socio-demographic characteristics

, risk factors associated with cardiovascular disease, indication for the cardiac catheterization procedure and the complications associated with the procedure as of their last review in the hospital (at two weeks hospital review after the procedure).

10The investigator continuously reviewed the filled data collection tools to ensure completeness and accuracy. The

files were re-checked for completeness and clarity of information before data collection process was completed. 3.9 Study Variables The investigator documented the date when procedure was done, age, gender, risk factors for cardiovascular disease, length of stay in hospital, vascular access methods used, drugs the patient was taking before and after the procedure was also documented. In addition, the resulting complications were documented and these included: anaphylactic shock, bleeding, hematoma formation, pain/arterial spasm, acute kidney injury, acute arterial occlusion, infection, myocardial infarction, stroke/transient ischemia, iatrogenic coronary dissection, cardiac arrythmias, hypotension, cardiogenic shock, pericardial effusion/tamponade, bleeding necessitating blood transfusion and death (whenever indicated). 3.10 Data Management and Analysis A study questionnaire with a unique ID for each patient was used to capture the data from the retrieved patient files.

9Data was then entered into Microsoft Excel. Data verification was

done prior to flagging any erroneous entries and corrected appropriately. Data cleaning (entailing correcting for duplicates, missing data and inconsistencies), data coding and

13statistical analysis was done using SPSS (Version 23.0). Demographic characteristics and clinical profiles of the

patients were analysed and presented as

8frequencies and percentages, and a chi-square test of homogeneity was used to determine differences in the demographic characteristics of

the patients and the facilities, clinical examination profiles of the patients and the facilities, procedures done on the patients with the facilities, and vascular access methods with the facilities.

61Statistical significance was considered where the p-value < 0.05

. 3.11 Study Administration and

13Quality Assurance The principal investigator ensured that proper data collection and recording was

done. The research assistant was guided by the principal investigator through the entire process. The statistician and supervisors offered guidance to the principal investigator through the whole procedure i.e., from the proposal development to the presentation, statistical analysis and results presentation. 3.12 Ethical Considerations The protocol document was first presented to the department of Internal Medicine-University of Nairobi for approval. Secondly,

37ethical approval to conduct this study was sought from Kenyatta National Hospital and University of Nairobi Ethics and Research Committee (KNH/UON ERC

).

10Approval from ERC was submitted to KNH research and programs department

and the Karen Hospital to seek clearance

1to conduct the study and access the patients' records. In addition, permission was sought from the health information department to be allowed to access the unit and retrieve the files. Individual consent was

not required because this study relied on secondary data.

1Confidentiality was upheld at all stages to ensure that the retrieved files and the

information collected were

34not accessible to unauthorized personnel. Patients' identifiers were used on the data collection forms but a separate record was kept to link study numbers with patients

identifying information. The folders were password-protected, and it is only the principal investigator who had access to the folders. 17 4.0 CHAPTER FOUR: RESULTS The recruitment of the patients was as shown in Figure 1a and b respectively. 4.1 Recruitment Flow Chart 665 IP numbers retrieved from KNH-cardiac catheterization laboratory registry and handed to the records department in KNH 121 files retrieved at KNH 4 files had no documentation, 2 files had incomplete IP numbers, 7 had right KNH-15 files excluded from study heart catheterization 106 files from KNH used for data collection Figure 1: Recruitment flow chart for KNH 1612 IP numbers retrieved from KR cardiac catheterization laboratory registry and handed to the records department in KR 272 files retrieved at KR, 4 files had incomplete IP numbers, 10 files had KR- 14 files excluded from study right heart catheterization 258files from KR used for data collection Figure 2:Recruitment flow chart for KR 4.2 Demographic and Clinical Characteristics of Study Participants The demographic characteristics of the patients show that most of the patients were in the age group 50-59 years (31.6%). On gender, male patients were 237 (65.1%) and female were 127 (34.9%). Majority of the patients were either self-employed (29.9%) or employed (35.4%). The Table 3 shows that

36there were statistical differences for age, gender, and

occupation between the two facilities. Table 3:

36Demographic characteristics of patients enrolled in the

30 7 (6.6%) 1 (0.4%) 8 (2.2%) 30 – 39 2 (1.9%) 18 (7.0%) 20 (5.5%) 40 – 49 12 (11.3%) 41 (15.9%) 53 (14.6%) 50 – 59 23 (21.7%) 92 (35.7%) 115 (31.6%) 60 – 69 32 (30.2%) 53 (20.5%) 85 (23.4%) ≥70 30 (28.3%) 53 (20.5%) 83 (22.8%) Gender, n (%) Male 59 (55.7) 178 (69) 237 (65.1) Female 47 (44.3) 80 (31) 127 (34.9) Occupation, n(%) Employed 11 (10.4) 118 (45.7) 129 (35.4) Self-employed 32 (30.2) 77 (29.8) 109 (29.9) Unemployed 34 (32.1) 19 (7.4) 53 (14.6) Retired 7 (6.6) 30 (11.6) 37 (10.2) Not indicated 22 (20.8) 14 (5.4) 36 (9.9) The clinical profile of the patients shows that 280 (76.9%) of the patients were hypertensive, 118 (32.4%) had diabetes mellitus, 43 (11.8%) had dyslipidaemia, and only 3 (0.8%) had CHD. There were statistical differences between the two facilities for all the patient clinical examination profiles (Table 4). Table 4: Clinical diagnosis of the patients' enrolled in the study KNH, (n=106) Karen, (n=258) Total, (n=364) p-value Hypertension, 94 (88.7) 186 (72.1) 280 (76.9) 0.001 n(%) Diabetes, n (%) 46 (43.4) 72 (27.9) 118 (32.4) 0.004 Dyslipidemia, n 5 (4.7) 38 (14.7) 43 (11.8) 0.007 (%) CHD, n (%) 3 (2.8) 0 (0) 3 (0.8) 0.024 The patients had one or more of the indications for procedure, of which the top 3 indications were stable coronary artery disease (CAD/ IHD) 57.7%, Acute coronary syndromes (24.5%) and cardiomyopathy (8.5%). Table 5:Indication for procedure of cardiac catheterization on the study patients Indication Frequency Percent of patients (n=364) Stable CAD/ IHD 210 57.7% ACS 89 24.5% Cardiomyopathy 31 8.5% Positive EST 18 4.9% Heart failure 5 1.4% Others 47 12.9% Table 6:ACS by subtype in the study patients undergoing cardiac catheterization ACS Frequency Percent of patients (n=364) STEMI 71 19.5% NSTEMI 18 4.9% A further detailed look at the acute coronary syndromes indicated that 19.5 % of the ACS' were ST elevation myocardial infarction while 4.9 % were non-ST elevation myocardial infarction. Other indications for the procedures included 10 patients with a diagnosis of arrhythmias, 7 patients with LBBB, 5 patients each for syncope, and complains of severe dyspnoea, 3 patients with aortic stenosis undergoing an evaluation prior to repair, 3 patients each for a pre-operative cardiac evaluation, and ASD, 2 patients each for evaluation post cardiac arrest, palpitations, ventricular tachycardia, and PAH, 1 patient each for AV canal defect, CCF in pregnancy, complete heart block, evaluation pre mitral valve repair, and Takayasu s disease. A Coronary angiogram was the most common procedure done (79.1%), followed by coronary angiogram with PCI (20.4%). Table 7:Procedure Done Procedure, n (%) KNH, (n=106) Karen, (n=258) Total, (n=364) Coronary angiogram Coronary angiogram + PCI Balloon Mitral valvuloplasty 80 (75.5) 208 (80.6) 288 (79.1) 25 (23.6) 49 (19.0) 74 (20.4) 1 (0.99) 0 (0.0) 1 (0.3) 4.3 Arterial Access Method Majority of the vascular arterial access was via the common femoral artery (62.1%), followed by the radial artery (32.7%), and combined (5.2%). There were statistical differences between the 2 facilities for the arterial access methods with the use of

2the common femoral artery being higher in KNH and the

use of the radial artery being higher in KR. Table 8 :Vascular access method for cardiac catheterization at KNH and KR Access Common femoral artery Radial artery Combine d p-value KNH, (n=106) Karen, (n=258) Total, (n=364) 79 (74.5%) 147 (57.0%) 226 (62.1%) 26 (24.5%) 93 (36.0%) 119 (32.7%) 1 (0.9%) 18 (7.0%) 19 (5.2%) 0.002 Table 9a: Method of vascular access in ACS ACS Common Radial artery Combined Total p-value femoral artery STEMI 47 (66.2%) 18 (25.4%) 6 (8.5%) NSTEMI 12 (66.7%) 4 (22.2%) 2 (11.1%) 71

0.918 18 For patients with STEMI, the use of the transfemoral access was at 66.2% while access via the trans radial route was at 25.4%; for the NSTEMI the use of the transfemoral access was at 66.7% while the use of the trans radial access was at 22.2%. There were no statistical differences between STEMI and NSTEMI for the methods of arterial access. Table 9b: ACS and vascular access used in KNH and KR hospitals' ACS Common Radial artery Combined Total femoral artery STEMI KNH 4 3 1 8 KAREN 43 15 5 63 NSTEMI KNH 1 0 0 1 KAREN 11 4 2 17 The common femoral artery was the most common method of vascular access for ACS' in both hospitals. 4.4 Evolution of Choices of Arterial Access in The Study Population The common

2femoral arterial access has been the method of vascular access for

KNH as from 2015 to 2019 with a decline in 2020, while the same period saw the radial artery increasing. For Karen hospital

59both the common femoral and radial artery was increasing on

a yearly basis. 45 40 35 30 25 39 36 33 20 17 18 19 21 21 19 22 15 15 14 16 16 11 12 12 10 6 7 5 2 1 1 3 1 1 3 0 2015 2016 2017 2018 2019 2020 2015 2016 2017 2018 2019 2020 KNH KAREN Common femoral artery Radial artery Combined Figure 3:Evolution of vascular access methods over the years for cardiac catheterization at KNH and KR The trend for KNH shows that the common femoral artery was the mode used for vascular access from 2015 to 2018, and as from 2019 there was a balance of 50.0% each for common femoral artery and radial artery, while in 2020 the radial artery was the most used at 87.4%. For Karen hospital, of the 16 randomly selected files in 2015, all were common femoral artery. There is variability in the method of vascular access in the following years. In 2016 the most popular method of access was common femoral (80.0%), while in 2017 the common femoral and radial artery methods were used at 47.7% and 38.7% respectively. In 2018, the proportion of use of common femoral artery was double that of radial (66.1% vs. 32.2%), and this reduced in the following year, 2019, where the proportion of common femoral artery was almost half of the radial artery accesses (33.8% vs. 55.4%). In 2020, the proportion of the common femoral artery access was almost twice that of radial access (61.1% vs. 33.3%). 4.5 Complications and Method of Vascular Access There were 24 (10.6%) complications documented among the common femoral artery method of access while among the radial artery access method there were 7 (5.9%) documented complications, and lastly among the combined modes of access there were 8 (42.1%) cases of complications (Figure 4). 89.4%, Frequency 94.1%, 10.6%, 5.9%, 42.1%, 57.9%, Common femoral artery Complications No complications Radial artery Combined Figure 4:Complications and method of vascular access for cardiac catheterization in the study patients There were 39 (10.7%) of the total patients who experienced one or more of the complications (Table 10), where of the 39 patients, 19 (48.7%) of them having severe pain as an associated complication and 7 (17.9%) having documented spasms. For this study, procedures done with cross overs from either a transfemoral or a trans radial access were categorized as having had a combined arterial access. Table 10:Complications associated with each vascular access method in the study patients Complication Common Radial Combined Proportion femoral artery of patients artery (n=39) (n) (n) (n) Severe pain Arterial spasm Hematoma formation Bleeding Hypotension Infection Acute kidney injury Ecchymosis Blood transfusion after procedure Cardiac arrythmias/Ventricular Tachycardia Dyspnea Vomiting Cardiogenic shock Hypovolemic shock Arrythmia/Bradycardia Hemoptysis 12 2 5 48.7% 3 2 2 17.9% 3 1 1 12.8% 3 1 0 10.3% 3 1 0 10.3% 3 1 0 10.3% 3 0 0 7.7% 2 1 0 7.7% 0 0 2 5.1% 0 1 0 2.6% 1 0 0 2.6% 1 0 0 2.6% 0 0 1 2.6% 0 0 1 2.6% 0 1 0 2.6% 1 0 0 2.6% The 39 patients that experienced one or more of the complications, 24 of them had the common femoral artery as their form of vascular access (Table 11). Table 11:Complication and method of vascular access Common femoral artery (n=226) Radial artery (n=129) p-value Yes, n (%) 24 (10.6%) 7 (5.9%) 0.144

26There was no statistically significant difference (using the

0.001 incorporating the patients who had had a combined arterial access during the cardiac catheterization procedure, we

48noted that there was a statistically significant difference in the proportions for complications of the methods of

vascular access, where the combined method had the highest proportion of complications, and not comparable with the proportions of the other two methods of vascular access. 4.6 Length of Hospital Stay Most patients in the study (50.3%) either stayed for a day or were discharged the same day followed by those who (32.1%) stayed between 2-5 days. Table 13:Arterial access and length of hospital stay in days Length Common femoral Radial Combined Total, n (%) of stay artery artery (days) 0-1 106 (46.9%) 2-5 79 (35.0%) 6-10 26 (11.5%) >10 15 (6.6%) Total 226 73 (61.3%) 30 (25.2%) 11 (9.2%) 5 (4.2%) 119 4 (21.1%) 8 (42.1%) 6 (31.6%) 1 (5.3%) 19 183(50.3%) 117 (32.1%) 43 (11.8%) 21 (5.8%) 364 ANOVA (Analysis of Variance)

14test was performed to determine if there were statistical differences for the

length of stay (in days) in the three methods of vascular access. There were no statistical differences (Table 14). Table 14:Analysis of variance for the length of stay in the three methods of vascular access

458um of df Mean F p-value squares square Between Groups Within Group Total

80.1 2 6230.7 361 6310.8 40.0 2.32 0.100 17.3 Results of Table 15 indicate that the largest mean number of days at the hospital was observed with the combined method of vascular access (4.6 days), followed by combined femoral (3.5 days), and lastly by radial artery (2.8 days). Table 15:Mean length of hospital stay in days for the three methods of vascular access for cardiac catheterization in the study patients. Access n Mean (SD) Common femoral artery Radial artery Combined 226 119 19 3.5 (4.5) 2.8 (3.5) 4.6 (3.9) 5.0

12CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS 5.1 Discussion in this

retrospective audit, a total of 364 files (106 files from KNH and 258 files from Karen hospital) were reviewed.

27Cardiac catheterization is an important part of diagnosis and management of

cardiovascular diseases (that warrant it)

27and is one of the most widely performed prooedures

. Our study was set out to document the vascular access methods used for left heart catheterization at the KNH and Karen Hospitals. We also looked at

18the adoption of the trans radial access method due to the fact that the

652016 ESC guidelines for the management of

ACS that actually recommend 'a radial first strategy' and has been described

2as a 'class 1 indication level of evidence

A' for ACS management during cardiac catheterization. While most of the western world data indicate increased ages (50) (3) for patients undergoing cardiac catheterization, in our study the age range of most patients undergoing the procedure was 50-59 years with males constituting a majority of the patients at 65.1%. In a retrospective study done by Jean Claude Ambassa et al (51) to analyse

27the results of heart catheterization in the cardiac centre Shisong, Kumbo in Cameroon from December 2010 till December 2017

It was also noted that

19the mean age of patients undergoing the procedure was 52.8 +/- 12.9 years

with a majority being the male gender (51) (52). A retrospective study (1996-2001 done by Kamotho, Ogola et al (3) in Kenya at the Nairobi hospital on coronary angiography also found majority of the patients had

2a mean age of 54.4 years with a predominantly a

male population. This can be attributed to the fact that most male patients have more cardiovascular risk factors including smoking than their female counterparts. In Kenya, we presumed that most working class are of the male gender and this may also contribute to better and faster access to a health provider and awareness of cardiovascular risk factors. The slightly lower age in comparison to the west was hypothesized that Africa (Kenya included) mostly has a youthful-middle age population while the west has a good number of the aged population as well. In terms of age distribution and employment, we noted a statistically significant difference between patients in KNH and KR hospital, and this can be due to the fact that most employed people may easily access the private hospital than the unemployed who would prefer a public hospital as it is economically affordable. In our study most of the patients undergoing cardiac catheterization

procedures had hypertension at 76.9% followed by diabetes mellitus at 32.4%. Studies done on heart catheterization also do indicate that majority of patients undergoing this procedure have established

62risk faotors for oardiovasoular disease with a majority of the

patients being hypertensive (53) (3). Hypertension

36has been noted to be a leading risk faotor for ooronary artery

disease, more so when involved with an end organ target (3)(52). Prevalence of hypertension

19as a risk faotor for oardiovasoular disease

is also high among our Kenyan population (3) and this could explain why a majority of the patients in the study were found to have hypertension. The commonest indication for the procedure was coronary artery disease at 57.7%, acute coronary syndromes (24.5%) and cardiomyopathy (8.5%). Coronary angiography was the commonest procedure done for 79.1 % of the study patients while coronary angiography with PCI was at 20.4%. This is in comparison to a study done on coronary angiography by Kamotho et al (3) which also noted that stable angina was the leading indication for coronary angiography at 38.5%, myocardial infarction at 15.4 % and unstable angina at 3.8 %. The arterial access used for a majority of the procedures done was via the transfemoral route (62.1%) while trans radial route was used at 32.7%. For this study, procedures done with cross overs from either a transfemoral or a trans radial access were categorized as having had a combined arterial access; for 5.2% of the study patients. While we appreciated the progressive

18adoption of the trans radial approach (though slow

), our use

18of the trans radial aooess was lower in comparison to the

global data. It is now well agreed globally that the radial first strategy is standard practice (56). A retrospective study done by Tewari, Satyendra et al (54) from 2004-2011 at North Indian Cardiology centre in India found

26the use of trans radial arterial aooess to

be at 44.35% while

26a systematio review and meta-analysis

study done by Pietro Di Santo et al (55) looking at 14 randomized control studies published at inception till January 2020 in the MEDLINE, Cochrane Central Register of controlled trials found that up to 49.6 % of patients had their PCI done via the trans radial approach. The trans radial has become a default arterial approach site for PCI in Europe, Asia and the USA (56). Contrast to our study where the use of the transfemoral access was at 62.1 %, a study done in the USA in 2016 by Abdulla, Damluji et al (57) on

26transfemoral approaoh for ooronary angiography and intervention (using a

study survey tool administered to operators) with an aim

50to examine the current praotioe and use of transfemoral artery approaoh

found that, of the 987 operators, only 18% identified themselves solely as femoralists, 38% as radialists while 42 % 31 as both (57). Another nationwide study by Khalid Changal et al (56) in the USA in 2020 to assess the current training preference, expertise, and comfort with transfemoral and transradial among cardiovascular training fellows found that up to 95 % of trainees chose trans radial as their default arterial access and the reasons cited by the trainees included patient satisfaction, low complications and the training centres 'radial first' policy. Contrast to our study where we found more of transfemoral access procedures, we hypothesized this could be related to level of operators training and comfort in use of the trans radial method. In our study again we noted that a number of cross overs were from transradial to transfemoral access and documented reasons were severe pains at site of puncture inducing spasms and then hindering catheter advancement or simply difficulty in engaging the coronaries and this warranted a change over to the transfemoral access which was then successful. Of course, there was a documented attempt of conservative management with additional dose of dormicum, fentanyl or nitroglycerin which worked in some

instances but in some procedures did not fully work and required a cross over to the transfemoral arterial access. Similarly, it has been noted that transfemoral access method is still a preferred method for cardiac catheterization even with the increasing uptake of the trans radial access and this could be attributed to the user preference (53) (58) and experience or need for use of large bore catheters during the procedure. Again, the transfemoral access still remains the preferred method of access choice during cross over procedures (59) when complete total occlusions of vessels are noted during the interventional procedures. To note is that the distribution of participants who underwent transfemoral access and trans radial arterial access procedures differed significantly between Kenyatta National Hospital and Karen Hospital; the use of transfemoral access was higher at KNH while the use of trans-radial access was higher at KR. Thus, this study hypothesizes that the increased adoption of trans radial access by private hospitals may be in an attempt to comply with the radial-first strategy as per the ESC cardiac catheterizations guidelines (47) and with the rest of the world at large. Similarly, a study done on evolution of arterial access for cardiac catheterization by Ziakis et al (60)

54to reveal volumes and trends in interventions performed on

trans-radial access in Northern Greece in the selected years of 2004, 2009 and 2013 indicated that it was at 0% in 2004 to approximately 40% in 2013; the adoption being higher in private hospitals as compared to the public hospitals' cardiac catheterization laboratories. Over time, we noted an increase in the utilization of cardiac catheterization laboratory services in these two hospitals (KNH and KR) from the years 2017 to 2020 as demonstrated by increasing number of patients' undergoing left heart catheterization over the mentioned years. 32 A retrospective review done in Uganda by Joselyn Rwebembera et al (53) at the Uganda Heart Institute between the period of February 2012-December 2019 also noted an increasing trend in the utilization of cardiac catheterization laboratory over their study period. This could be attributed to industrialization and change in lifestyle in our population including eating habits that then predispose to the cardiovascular risk factors. In terms of the arterial access use and evolution over time, the uptake in use of the trans radial access has demonstrated a slow but progressive uptake in both KNH and KR hospitals, the uptake noted to be higher in KR. Data from several studies indicate a rise in the use of the trans radial arterial access over time. A study done by Santo et al (45) found a rise in the use of trans radial access from 0.2% to 37.2 % over their study period time. Similarly, in our study we noted an increase in use of trans radial arterial access over our 6-year study duration. This again we attributed to the fact that operators may be doing this in an attempt to comply with the 'radial first strategy' as per the ESC guidelines and in keeping with the global trend. Though the decline in 2020 on the number of the procedures done could be related to the fact that there was an overall decline in the number of procedures done for that particular year likely attributed to the effects of the covid 19 pandemic. In our study, very few patients experienced post procedural related complications. There were 39 (10.7%) of the total patients who experienced one or more of the complications where of the 39 patients that experienced one or more of the complications, 24 of them had the common femoral artery as their form of vascular access. This proves the generally known fact that cardiac catheterization is a safe and sterile procedure (20). Severe pain at puncture site were the commonest complications noted to the point that stronger analgesics including morphine, pethidine or tramadol had to be given to these patients and a re-assessment of the puncture site done. Bleeding and hematoma formation at puncture site occurred in 3 of the patients who had had a transfemoral access and this necessitated change of dressing in order to apply adequate pressure and stop the bleeding. In some instances, we noted that the documentation of integrilin infusion or the low molecular weight heparin was put on hold till resolution of the bleeding complication. Three patients who had a cross over to the transfemoral access had a documented severe chest pain due to a noted coronary spasm upon catheter engagement into the coronaries making it difficult for catheter advancement. 2 patients had a documented cardiac arrest and were successfully reversed and transferred to the intensive care unit. Of note again is that a majority of the patients with complications were the ones who had undergone a procedure via the transfemoral route. Some patients developed hypotension post-procedural and had to be transferred to the high dependency unit for intravenous fluids and dobutamine administration. Three patients developed infection within two to three days after the procedure and this was documented as hotness of body and chills and intravenous antibiotics were prescribed. A patient developed chills and vomiting during the procedure that resolved after administration of intravenous hydrocortisone and this we attributed could be an allergic reaction to administered contrast during the procure.

17A prospective study done by Baskaran et al

(61) on complications of cardiac catheterization

17at the Montreal heart institute in Canada

between April 1996 and March 1998 found complications occurred in 8% of cardiac catheterization procedures done, with local complications accounting for 2.5%. In their study, deaths occurred in 0.6 % of the study participants. Studies done also indicate that majority of the complications are noted among patients who have had a common femoral arterial access (20). Deaths related to complications were not documented in our study population again confirming that this is a rare complication comparable to previous studies done (24) (31) (62). Majority of the patients were either discharged on the same day or had a one-day hospital stay. Again, conforming to the standard practice that cardiac catheterization is a safe procedure (63) (64). We noted that some of the patients who had more than a day hospital stay had other underlying comorbidities including chronic kidney disease and thus needed continuity of care after the procedure. Two

patients with stable chronic kidney disease needed haemodialysis after the procedure due to an acute kidney injury, while two patients with normal kidney functions prior to the procedure developed acute kidney injury after the procedure and this automatically equated to prolonged hospital stay for stabilization. Three patients needed blood transfusion after the procedure as they were noted to have low haemoglobin levels after the bleeding complications and there was a delay in sourcing for blood for them with one of the patients staying in the ward for up to 10 days waiting for a blood transfusion. We also noted that some patients had come from far away counties and three other patients had come from neighbouring countries and as such could not travel back to their referring facility/ home till travel arrangements made in the following days. Three patients had to stay longer and wait for a recommended CABG procedure. For this particular study, patients who had a crossover from a trans radial access to a trans femoral access or from a transfemoral to a trans radial access during the procedure were categorized as having had a combined arterial access. This group of patients constituted a 5.2 %. A two-year prospective study done by Aldoori, J.S et al (59) on trans radial

64approach for 34 coronary angiography and PCI in

the Slemani Cardiac hospital in Iraq (2015-2016) also found a cross over from a trans radial to a transfemoral arterial access to be at 4.4%. We hypothesized that the crossover to transfemoral approach could be attributed to

20tortuosity of the aorta and brachiocephalic trunk, radial artery spasm, puncture failure

or due to a radial loop. Patients who had a combined arterial access in our study were noted to have more complications as compared to the others that had only had a one arterial access use. This we hypothesized that it could be due to the fact that patients having a crossover have a prolonged exposure to the radiocontrast material during the procedure or there's exchange of more catheters during the procedure hence theoretically having more related complications. Of note is that in our study, we did not come a single file with a trans ulnar arterial access which is still a new arterial access in practice. We theorize that it will be a method to be considered for cardiac catheterization in the future as it has been shown to be safe and a potential alternative to the trans radial approach (21) (33). 5.2 Conclusion Cardiac catheterization is in use for both diagnostic and interventional purposes. Of the procedures done 79.1 % were coronary angiograms while 20.4 % were coronary angiograms with PCI. The vascular access routes in use for KNH and KR included the trans radial and trans femoral routes, and as from 2016, there has been a progressive adoption and incorporation of the trans-radial arterial access in practice. The complications profile was low. Finally,

20most of the patients were discharged within the same day

of the procedure or within a day. 5.3 Study Limitations The study only incorporated files of patients from KNH and KR hospital. The study entirely depended on documentation done by others and in some instances; all the relevant needed information could miss. Files lacking useful information were excluded and replaced with other files. Of note is that it was difficult to assess the post procedural related complications more so of patients who were discharged on the same day after the procedure and got lost to follow up. 5.4 Recommendations from the Study Cardiac catheterization offers an invasive form of therapy for heart diseases. The vascular access methods used during this 'surgical' procedure have had a progressive shift to the

25trans- radial access which has been demonstrated to be associated with better outcome in terms of complications and patients

' short hospital stay.

18The adoption of the trans-radial vascular access in

KNH and KR is 'wanting' especially its incorporation among patients with ACS; there is need to have more procedures done via the trans-radial access especially among patients with ACS and this is in keeping with the 2015 ESC guidelines. All included, we thereby recommend the following, a) Prospective audit studies to determine the vascular access methods for cardiac catheterization and the associated complications with each method. b) Study to determine the factors influencing the choice of vascular access approach and associated barriers to the adoption of the trans radial arterial access. c) Since trans-femoral access is still vital in left heart catheterization, techniques for example, routine ultrasound guidance and adjunctive tools for femoral access should be adopted to make it safer and reduce vascular complications. 0 2 3 4 6 7 9 10 11 12 13 15 16 18 19 20 21 22 23 24 25 26 27 28 29 30 33 35 36