SHORT TERM COMPLICATIONS OF VASCULAR ACCESS USING HEMODIALYSIS CATHETERS AT MOI TEACHING AND REFFERAL HOSPITAL IN ELDORET, KENYA

BY

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THIS RESEARCH THESIS IS SUBMITED IN PARTIAL FULFILLMENT FOR THE AWARD OF MASTER OF MEDICINE IN INTERNAL MEDICINE OF MOI UNIVERSITY SCHOOL OF MEDICINE.

DECLARATION

Declaration by the Candidate

This thesis is my original work and has not been presented for a degree or any academic credit in any other University or examining body. No part of this thesis may be reproduced without the prior written permission of the author and/or Moi University.

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DEDICATION

I dedicate this work to my wife Mercy, my two children Leeroy and Leandra and my parents who have stood by me during this period of my studies.

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LIST OF ABBREVIATION

AKI	Acute kidney injury
AVF	Arteriovenous fistula
CKD	Chronic kidney disease
ESI	Exit-site infection
ESRD	End stage renal disease
FV	Femoral vein
HD	Hemodialysis
IDSA	Infectious disease society of America
IJV	Internal jugular vein
IREC	Institutional research and ethics committee
KMTC	Kenya Medical Training College
MTRH	Moi Teaching and Referral Hospital
NKF-DOQI	National Kidney Foundation Disease Outcome Quality Initiative
NTHC	Non tunneled hemodialysis catheter
RF	Renal failure.
RRT	Renal Replacement Therapy.
TDC	Tunneled hemodialysis catheter.

OPERATIONAL DEFINITIONS

Tunnel infection

This is defined as presence of tenderness, erythema, and/or induration >2 cm from the catheter exit site, along the subcutaneous tract of a tunneled catheter (e.g., Hickman or Broviac catheter), with or without concomitant bloodstream infection

Exit site infection.

This is defined as clinical presence of erythema, induration, and/or tenderness within 2 cm of the catheter exit site; it may be associated with other signs and symptoms of infection, such as fever or purulent drainage emerging from the exit site, with or without concomitant bloodstream infection

Catheter dysfunction

This is defined as a catheter that is unable to attain and maintain blood flow rates of at least 200 ml/min. To ensure that catheter malfunction was objectively evaluated, at least one technically efficient hemodialysis procedure with the new catheter needed to have been recorded.

Major bleeding episode

This is defined as prolonged oozing or overt bleeding (lasting more than 15 minutes) that may necessitate a transfusion or other interventions

Difficult cannulation

This is defined as attaining more than two needle passes despite proper identification of the anatomical landmarks of either the internal jugular or the femoral veins without real-time ultrasound guidance.

Arterial puncture

Arterial puncture is identified by the pulsatile flow into the syringe and the bright-red color of the blood noted during catheter insertion.

Short term complications

In this study refers to the period of the first four weeks after catheter insertion, within which a catheter is used. The catheter is either a NTHC or a TDC.

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ABSTRACT

Background: The need for hemodialysis due to kidney disease is steadily rising. A good vascular access is thus vital to prolong the life of these patients. The internal jugular veins (IJV) and femoral vein (FV) are the recommended sites for vascular access. Catheter insertion and dwell in exposes these patients to mechanical and infectious complications. Advanced age, male gender, low or high BMI and comorbidities like diabetes and hypertension have been linked to occurrence of these complications. Paucity of data exists on the incidence and associated factors for these complications in Sub Saharan Africa.

Objectives: To determine the frequency and types of these complications and describe the factors associated with these complications.

Methods: This was a prospective cohort study conducted among patients who required hemodialysis catheter insertion and dialysis at MTRH renal unit from December 2017 to November 2018. Consecutive sampling was used to recruit 85 patients. A data collection form was utilized to record socio-demographic characteristics, doctors' level of expertise, site of vascular access, observed complication and vital signs. A chest radiograph was done on the patients and an assessment of respiratory function over the first 24 hours. Thereafter, a focused weekly assessment for Exit site infection (ESI) and catheter dysfunction was done prior to and during dialysis. Pus swabs for culture collected were analyzed by semi quantitative method. Categorical variables were summarized as frequencies and percentages, Continous variables were summarized as means and standard deviations. Univariate and multivariate logistic regression models were used to check association of variables with mechanical complications.

Results: The mean age was 46.3±17.4 years, 49.4% (42/85) were male and 50.6% (43/85) were female. 72 NTHCs and 13 TDCs were analysed. The most common vascular access site was IJV with 89.4% (76/85) the FV site had 10.6% (9/85). An incidence proportion of 15.3% (13/85) and 4.7% (4/85) for mechanical and ESI complications were recorded respectively. The commonest mechanical complication was difficult cannulation with 8.2% (7/85) followed by catheter dysfunction 2(2.4%) and hematoma with 2(2.4%). 90% (77/85) of catheters were placed by experienced doctors and 95% (81/85) of catheters were inserted as emergency procedures. There was a 96% reduced risk of mechanical complication with IJV compared to FV on multivariate analysis (OR 0.04 (95%CI 0, 0.28) P= 0.001). Age, gender BMI and blood pressure did not show any association with mechanical complications.

Conclusion: The most frequent mechanical complications is difficult cannulation. Vascular access site was associated with occurrence of mechanical complications whereas advanced age, male gender, low or high BMI, diabetes and hypertension had no effect.

Recommendation: The rate of vascular access complications are acceptably low but further comparative studies with ultrasound guided insertion be done to gain comparative advantage. Consider the vascular access site prior to catheter insertion.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information.

In 2010, about 2.62 million people received dialysis worldwide and the need for dialysis was projected to double by the year 2030.(Unpublished, 2016). The use of hemodialysis catheters remains an essential component of dialysis practice, both for the management of acute renal failure and as temporary 'bridging access' for patients with chronic kidney disease (CKD)

Hemodialysis catheters (HC) are usually inserted in an internal jugular or femoral vein. Catheterization of the subclavian vein is however avoided, because this procedure very often causes a subsequent vessel stenosis. (Hryszko, Brzosko, Mazerska, Malyszko, & Mysliwiec, 2004).

The timely introduction of dialysis has prolonged the lives of end-stage renal disease patients. To maintain these patients on long term dialysis, the catheters should maintain flows of >200ml of blood/minute. (Akwa, 2010)

However, the use of these catheters is often complicated by mechanical or infectious complications which may result in patient morbidity or premature catheter removal. Despite strong recommendations by the National Kidney Foundation – Dialysis Outcome Quality Initiative (NKF-KDOQI) guidelines to reduce the dependence on catheters, More than 80% of all patients initiate hemodialysis using a central venous catheter,(H.S., 2012).

The insertion of hemodialysis catheters is a core procedure of nephrology practice. While urgent dialysis may be life-saving, mechanical and infectious complications related to the insertion of NTHCs can be fatal. (Poinen et al., 2019). In recent years, various techniques that reduce mechanical and infectious complications related to

NTHCs have been described. Evidence now suggests that ultrasound guidance should be used for internal jugular and femoral vein NTHC insertions. This is however still a challenge in resource limited settings like ours and the use of traditional anatomic landmark methods are still widely used. These methods have worked but we still need to ascertain if the complications arising from vascular access are acceptably low or high.

Mechanical complications are multiple and include immediate complications e.g. failed first attempt (difficult cannulations), reactionary hemorrhage, kinked catheters, hematoma formation, hemothorax, arrhythmias and death during insertion. Some mechanical complications occur much later e.g. catheter dysfunction (Raji et al., 2018), (Müller-Ortiz et al., 2019), (Ruesch, Walder, & Tramèr, 2002)

Various factors have been associated with the occurrence of these mechanical complications. They include low or high BMI, advanced age, male gender, vascular site, number of needle punctures, comorbid conditions like diabetes and hypertension.(Eisen et al., 2006)

Catheter-related infections have been associated with high morbidity, mortality and costs. (Kosa et al., 2017) (Sahli, Feidjel, & Laalaoui, 2017) , (Ruesch et al., 2002). The infection complication can be divided into exit site infection (ESI) , tunnel site infection (TSI) or catheter related blood stream infections.

The National Kidney foundation dialysis outcomes quality Initiative recommends that temporary catheters should remain in place no longer than 5 days at the femoral vein and 21 days in the internal jugular. (Oliver, Callery, Thorpe, Schwab, & Churchill, 2000). Prolonged stay of these catheters increases the risk of catheter related infections.

To minimize infectious complications guidelines recommending maximal sterile barrier precautions including wearing a mask, a cap, a sterile gown, sterile gloves, and using a large strerile drape are useful. Povidone or iodine based solution are also used to prepare the skin before insertion of these catheters. (O'Grady et al., 2011) (L. a Mermel et al., 2009). A number of factors have also been thought to be associated with occurrence of the catheter related infections. These include exchange of catheters over a guide wire and presence of cormobidities e.g diabetes and malignancy have been described.

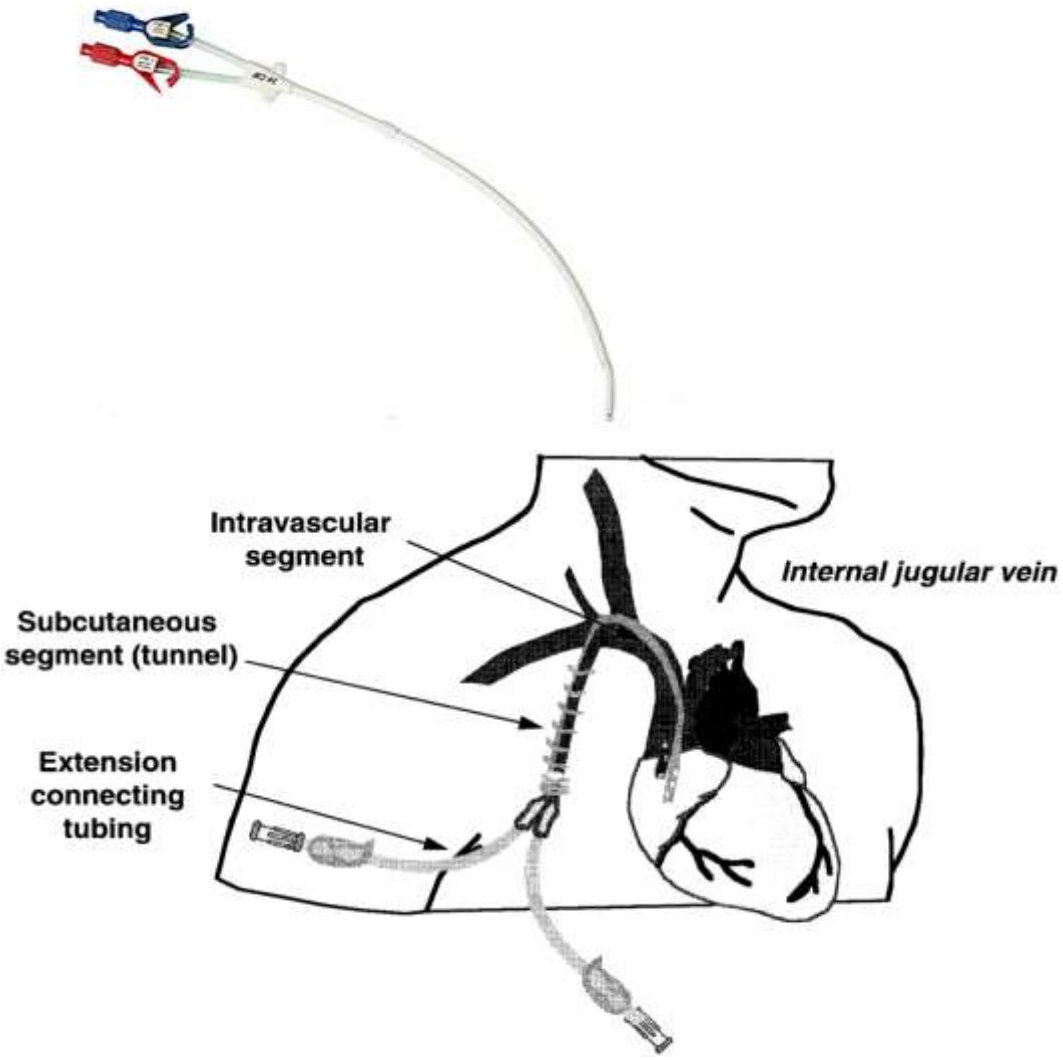


Figure 1: Tunneled hemodialysis catheter and the anatomic considerations of a tunneled cathter. (Adapted from Google images)

Figure 2: Non-tunneled hemodialysis catheter kit consisting of a dual lumen polyurethane non-tunneled hemodialysis catheter, introducer needle, dilators, a guide wire and a surgical blade. (Adapted from Google images)

1.2 Problem Statement

Current data points to a rising prevalence of renal failure from varied etiology worldwide. This has translated to an increased need for hemodialysis. In Kenya there are 68 dialysis units with 51 of these in the public hospitals. This was after the ministry of health opened the units in county hospitals in a bid to improve access to dialysis services. By January 2020 there were only 28 registered nephrologists in Kenya, furthermore catheter insertion is done mainly using the blind/ anatomic landmark method in our setup. A local study done in KNH in 2018 assessed the level of preparedness for hemodialysis and incident vascular access for a periods of 3 months and concluded that three of every four patients were initiated on hemodialysis as an emergency. Eighty percent of the patients had a NTHC inserted to initiate HD and by the end of the third month, forty percent still had the NTHC on the same vein. This demonstrates our high level of dependence on these catheters despite recommendations by the NKFDOQI to transition them within the first month of their use to TDC or AVF (Kabinga, Kayima, McLigeyo, & Ndungu, 2019)

In MTRH over 230 patients were on dialysis over the past year alone (2017). There is no data on how many complications were recorded. While Hemodialysis catheters are recommended for initiating dialysis, their use exposes patients to complications during insertion and dwell in. We need to ascertain the burden of these mechanical and infectious complications in our population so that we can adjust policy and procedures appropriately.

1.3 Justification Statement

Prompt renal replacement therapy (RRT) is vital in resolving the underlying metabolic derangements in acute kidney injury or prolonging life in CKD. While AVF is the recommended modality for RRT, Their cost remains prohibitive and we have very few vascular surgeons to fashion the AVF in our setup. The use of catheters hence remains vital as one seeks to initiate renal replacement therapy or plan for AVF.

Preliminary data has shown that we still heavily depend on the hemodialysis catheters, It still remains our duty in the clinical practice to map out the true burden of the complications resulting from this vascular access modality that we still rely on. A significant number of these insertions are still conducted by medical officers and residents working in the renal unit in MTRH. We hope to inform those directly taking care of the patients on the burden of the complications, we shall also be able to align our patient care strategies and develop protocols that are informed by the data generated from our setting. This will eventually improve our intervention and monitoring and prevent the adverse effects of using these catheters. In the research field, this study will also add to the pool of knowledge regarding the presence of these complications in our setup. This will inform the development of policy guidelines in our setup.

1.4 Research Question

1. What are the complications related to vascular access among patients initiated on hemodialysis at MTRH?

1.5 Objectives of Study

1.5.1 Broad

1. To determine the frequency and types of complications and describe the factors associated with vascular access.

1.5.2 Specific

1. To determine the frequency and types of complications related to vascular access in patients with hemodialysis catheters.
2. To describe the factors associated with vascular access site complications

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

The use of central venous catheterization (CVC) was brought to attention in 1929 when Dr. Werner Forsmann self-inserted a ureteric catheter through his cubital vein and into the right side of his heart. Since that time CVC technique has developed further and become essential for treatment of decompensating patients (Patel, Patel, Singh, Singh, & Khawaja, 2019)

The incidence of ESRD is increasing worldwide at an annual growth rate of 8% far in excess of a population growth rate of 1.3% (Bamgboye, 2003). The requirement for Renal replacement therapy (RRT) in the form of hemodialysis (HD) has increased in the last decade and it is expected that it will continue to do so over the next ten years (Children & Hospital, 2019). Vascular access has continued to be the 'Achilles' heel' of chronic maintenance hemodialysis (Akwa, 2010). AV fistulas are the preferred vascular access modality but with few vascular surgeons and the need to get an urgent "Bridging access" for CKD and AKI catheters still play a big role (Menegueti, Betoni, Bellissimo-Rodrigues, & Romão, 2017) There is a shortage of vascular surgeons for AV fistula creation (Raji et al., 2018)

Introduction of dialysis has prolonged the lives of end-stage renal disease patients. To maintain these patients on long term dialysis, permanent vascular access procedures capable of allowing flow of >200ml of blood/minute, are required. Without permanent vascular access therefore, patients are subjected to repeated attempts for cannulation to provide temporary vascular access during every session of HD risked with numerous vascular access related complications (Akwa, 2010)

About 20 – 60% of hemodialysis patients use catheters since their blood vessels are not suitable for arteriovenous fistula (AV fistula). Tunneled hemodialysis catheters (HCs) were initially developed as a means of short to medium term hemodialysis access. The technique gained rapidly in popularity to the extent that many nephrologists chose tunneled HCs over traditional non-cuffed HCs, even for patients with acute renal failure (M.A. et al., 2001). Hemodialysis is the mainstay of therapy in End stage renal disease (ESRD) and it needs effective and long-term vascular access (Children & Hospital, 2019).

While there is consensus on internal jugular (IJV) being the preferred site for catheter insertion, some quarters (Feldman, Kobrin, & Wasserstein, 1996) especially in Africa pointed towards use of the femoral vein access site as common. This is according to a review titled ‘Management problems in developing countries, with Nigeria as a surrogate” (Bamgboye, 2003). Subsequent studies have been conducted mainly in America and Europe that have demonstrated the safety of the internal jugular vein as a preferred site for vascular access.

TYPES OF VASCULAR ACCESS COMPLICATIONS.

There are two main types of vascular access: temporary access via insertion of catheter into blood vessel (femoral vein or internal jugular vein), and permanent access (arterio-venous fistula and arterio-venous graft) (Akwa, 2010) Complications of vascular access for hemodialysis have been widely studied in other settings. These complications arising from catheter insertion and dwell in are classified as either mechanical or infectious complications (Müller-Ortiz et al., 2019)(Akmal, Hasan, & Mariam, 2007). Complications associated with HD vascular access represent one of the most important source of morbidity among ESRD patients in the United states (Feldman et al., 1996). Traditionally, the number one cause of mortality in CKD is

cardiovascular diseases. Bloodstream infections key among them resulting from catheter related infection is regarded the second highest cause of morbidity and mortality in CKD patients on hemodialysis (Menegueti et al., 2017)

Data for much of the developing world are often unavailable, In sub-Saharan Africa, economic and manpower factors dictate a conservative approach. It is also unclear how many get the complications from catheters (Bamgboye, 2003). There is high level of dependence on these catheters (M.A. et al., 2001). There is real danger of increase in mortality from access complications. (Kabinga et al., 2019)

2.2 Infections

Intravascular catheter–related infections are a major cause of morbidity and mortality in the United States (Lok & Mokrzycki, 2011) (O'Grady et al., 2011). CVC related infection (CRI) includes CVC related local site infection (CSI) and CVC related bloodstream infection (CRBI). These CRI are responsible for a considerable increase in health care costs, morbidity, and mortality (Sahli et al., 2017).

NTHCs are associated with higher risk of infection compared with both tunneled hemodialysis catheters and non-tunneled central venous catheters(Clark et al., 2016)

2.2.1 Epidemiology and Associated factors of infectious complications

The data is varied. Complications are reported to occur in 5 to 26 % in the United states (Mcgee & Gould, 2003) In yet another study in Nigeria, (Raji et al., 2018) infectious complications were reported to be 10.1%. Out of the 147 patients studied, (94 females and 53 males) the study also found that being diabetic increased the risk of getting infection as a complication.

In a study conducted by (Oliver et al., 2000) that analyzed risk of bacteremia in temporary catheters, The incidence of bacteremia was 5.4% after three weeks of placement in internal jugular vein and 10.7% after one week in femoral vein. The incidence of bacteremia was 1.9% one day after the onset of an exit site infection but increased to 13.4% by the second day if the catheter was not removed. Guide wire exchange for malfunction and patient factors did not significantly affect the risk of bacteremia. The risk of bacteremia increased weekly for femoral catheters but did not increase until the third week for internal jugular catheters.

(M.A. et al., 2001) in USA found the incidence of catheter infections of 1.3/ 1000 catheter days The one year survival with these catheters was 47.5% this study sampled 573 patients consecutively and followed them up. It also showed the high level of dependence of the tunneled catheters in the setup.

A study by (Kairaitis & Gottlieb, 1999) on 105 temporary catheter (79 subclavian and 26 IJV sites.) The rate of CSI was 8% and CRB was 16%. Looking at associated factors, age, diabetes and exchange over a guidewire did not alter CRB risk, however diabetes was associated with increased risk of CSI out of the overall rate of 16 %. However this study was conducted only on temporary catheters and noted the high failure rate due to infections from the catheters. Another study in Algeria on 152 catheters recorded an incidence rate of 16.6per 1000 catheter days and also linked diabetes and duration of catheter use to CSI but did not show association with age, sex or catheter site (Sahli et al., 2017). Closer home in Africa, few studies have looked at the infectious complications from HD catheters. In Nigeria (Akwa, 2010) on 60 patients, 1.6% had CSI. Most of the complications reported were mechanical. A study by (Akmal et al., 2007)found infection at 9.7% in IJV and 15% on FV.

No Kenyan studies have been done to map out the true burden of infections from HD catheters. This study is thus timely to help shed light on the rate of this complication in our setup.

2.2.2 Pathogenesis of catheter related infections

The pathogenesis of non-tunnelled catheter infection is often related to extraluminal colonization of the catheter, which originates from the skin and, less commonly, from hematogenous seeding of the catheter tip, or intraluminal colonization of the hub and lumen of the CVC. In comparison, for tunnelled CVCs contamination of the catheter hub and intraluminal infection is the most common route of infection (Mcgee & Gould, 2003) The microorganisms most commonly associated with peripheral vascular and CVC infection are coagulase-negative staphylococci, S. aureus, different species of aerobic gram-negative bacilli, and C. albicans (O'Grady et al., 2011)

2.2.3 Diagnosis Of catheter related infections

To Diagnose Catheter related infections, clinical findings, of fever, have poor specificity, and inflammation or purulence around the intravascular device and bloodstream infection have greater specificity but poor sensitivity. Semiquantitative (roll plate) or quantitative catheter culture techniques are the most reliable diagnostic methodologies, because they have greater specificity in the identification of catheter-related infection. (L. A. Mermel et al., 2018) (Sahli et al., 2017). Drainage at the CVC exit site should be cultured as the diagnosis of CRI is strengthened by a positive culture of the same organism at the exit site and in the blood (Lok & Mokrzycki, 2011). Cultures on the catheter tip and blood yielded both gram positive and gram negative bacteria (Kairaitis & Gottlieb, 1999) (Sahli et al., 2017), A study in Brazil noted predominantly gram negative isolates (Menegueti et al., 2017)

2.2.4 Treatment and Prevention of infection complications

National kidney foundation kidney disease outcomes quality initiative, NKF-DOQI recommendation that NTHCs should be used for less than 1 week for femoral vein and 3 weeks for IJV. Most studies of the use of prophylactic antibiotics have demonstrated that this strategy is associated with reductions in the rate of catheter-related blood- stream infections (Mcgee & Gould, 2003) Antimicrobial or heparin-impregnated catheters have been reported to decrease incidence of catheter-related infections in the short term (Clark et al., 2016) In CSI empirical antibiotic therapy should be begun to treat Staphylococcus epidermidis or S. aureus infections. Antibiotic therapy for gram-negative organisms should be added, especially if the patient is immunocompromised or has neutropenia or has other risk factors for infection with gram-negative organisms (Mcgee & Gould, 2003).

2.3 Mechanical Complications

2.3.1 Types of mechanical complications.

Acute mechanical complications related to hemodialysis catheter insertion include vascular injury and hematomas (Poinen et al., 2019)(Clark et al., 2016) Other mechanical complications such as pneumothorax, pneumopericardium, air and guidewire embolism and arrhythmias are less frequent (Poinen et al., 2019) (Schummer, Schummer, Rose, Niesen, & Sakka, 2007). The incidence of pneumothorax varies between 1% and 6.6% (Tsotsolis et al., 2015). Hematoma and arterial puncture are common during femoral venous catheterization (Mcgee & Gould, 2003).

Catheter dysfunction is another mechanical complication. A broad range of definitions for CVC dysfunction have been documented in the literature and include; VA low blood flow rates, frequent HD machine arterial and venous pressure alarms, poor conductance during HD, and poor urea clearance based on decreasing URR or Kt/V calculations (*Managing catheter dysfunction for better patient outcomes.pdf*, n.d.). The NKF⁄DOQI guidelines define VA dysfunction as failure to attain a sufficient extracorporeal blood flow of > 300 mL/min with a pre-pump arterial pressure more than negative -250 mmHg (States, Hd, & Guidelines, 2006). CVC dysfunction is a common complication encountered in clinical practice (Griffiths, Newsome, Block, Herbert, & Danese, 2011). Early CVC dysfunction can occur from mechanical factors like mal-positioning of the distal tip, kinking in the subcutaneous tissue, tight ligature or early fibrin sheath formation (Griffiths et al., 2011). Thrombosis which occurs later can be intraluminal or periluminal and is the primary reason for CVC dysfunction. This leads to untimely removal of 17% to 33% of CVCs (Mcgee & Gould, 2003) (Janne, Tham, & Sheiman, 2000).

2.3.2 Epidemiology and associated factors.

Several studies have identified factors associated with mechanical complications. These factors include low or high patient body mass index (BMI), prior catheterization, prior surgery, prior radiotherapy, number of venipuncture, advanced age, and the time needed for catheter placement. Other factors of potential interest, such as the emergent indication for the CVC, the time of day the catheter was placed, the patient's state of consciousness, and the supervisor's training level, have not been fully explored. Furthermore, prior studies differ on whether complication rates are influenced by the training level of the operator and whether ultrasonography should be used to locate the vessel cannulated. Internal jugular catheterization can be difficult

in morbidly obese patients, in whom the landmarks of the neck are often obscured (Mcgee & Gould, 2003).

A systematic review done by (Ruesch et al., 2002) looked at 17 prospective studies comparing IJV and subclavian catheters 6 studies OF 2010 catheters had arterial punctures as the commonest mechanical complication in IJV than subclavian site (3.0 Vs 0.5%, RR 4.70 [95%CI, 2.05 – 10.77]). It however did not assess the studies that had femoral vein catheters. It further concluded a higher rate of infectious complications occurred in the IJV compared to the subclavian vein in 3 of the studies. The proportions were 8.6% against 4.0% respectively. A study in Chile by *Muller et al* in 2019 to assess mechanical complications on 100 IJV catheters inserted by anatomic method found a rate of 18%. Arterial puncture accounted for 95% of these complications, followed by hematomas and 5% of these were pneumothorax. The mechanical complications were greater in patients who required emergency line insertions and there was a direct association between the number of attempts and the mechanical complications reported.(Müller-Ortiz et al., 2019)

A study by *Poinen et al* found stenosis to be the most prevalent mechanical complication at 15%. It was a prospective study done over a two year period on 1041 patients in 5 dialysis programmes. These patients were > 18 years of age. Patients <60 years of age had a higher complication rate than those above 60 years (Poinen et al., 2019).

In a study in Pakistan in a paediatric population with temporary catheters, recorded difficult insertion in 64.4%. 104 patients were recruited in this study 62 males and 42 females by consecutive sampling. The mean age was 11.1 years. Those in the IJV were 85.6% and 7.7% were in the femoral route (Children & Hospital, 2019)

A study by *Eisen et al* in Pennsylvania in 2006 on 385 catheters found 22.3% had difficult cannulation, 4.6% arterial punctures, 3.6% had catheter malpositioning, 0.7% had hematoma. IJV had higher rate of complications than FV (33% Vs 24% p = 0.02). Gender was associated with complications with males having higher mechanical complications p = 0.04. Age, High or low BMI and level of consciousness were not associated with mechanical complications (L.A. et al., 2006)

(Schummer et al., 2007) reported mechanical complications of 3.3% with arterial punctures accounting for 2.9%. pneumothorax and catheter malpositioning were the other recorded mechanical complications. This was a 5-year prospective study involving 1794 patients. It concluded that even experienced operators can cause considerable complications. The rate of catheter malfunction was 31.5% in a polish study on 73 HD catheters with more femoral catheters malfunctioning (Hryszko et al., 2004)

A retrospective study in the university of Ibadan, Nigeria by (Raji et al., 2018) assessing outcomes of tunnelled catheters on IJV site 147 patients showed 7(4.7%) patients had failed first attempts, 5(3.4%) had major bleeding episodes , 5(3.4%) had arrhythmias, 2(1.4%) had hemothorax and death occurred in 2(1.4%). Catheter related infections complications were also analysed and accounted for 10.1%. Diabetes was associated with increased risk of infectious complications. The study concluded that IJV is a safe vascular access site.

Another African study done in Nigeria found mechanical complications at 16.9%. out of the 77 catheters studied, out of which 73 were non tunnelled and 4 tunnelled, in a prospective study over 2 years (Edaigbini et al., 2019).

No study has been conducted in Kenya and the East African region to assess these complications. There is heavy reliance of NTHC in our setup (Kabinga et al., 2019) published a study that evaluated the level of preparedness for RRT at Kenyatta national hospital followed up 82 patients who had developed renal failure over a period of 3 months and found that up to About 80% were initiated hemodialysis via acute catheters placed in the jugular and subclavian veins (p value<0.001). It further found that at least 3 months later, 40% still had acute catheters on the same veins (p value<0.001). Acute venous catheters in the femoral veins were in 9.2% at initiation and 6.6% of the patients at least 3months later. Less than 2% of the patients had AVF at initiation, which rose to 14.5% in 3 months. The study concluded that these patients many of whom were drawn from the hypertension and diabetes clinic needed better vascular access planning and stated that these patients were at risk of vascular access complications as well as exhaustion of their vascular capital. In yet another unpublished study conducted in Kenyatta national hospital in 2016 as part of a masters dissertation, on adequacy of vascular access function among 150 dialysis patients, 30.7% of patients had NTHCs malfunction and delivered poor dialysis dose compared to THCs or AVF. (Unpublished, 2016)This data is in the university of Nairobi repository.

2.3.3 Factors that influence vascular access site selection:

(Internal Jugular versus Femoral Vein)

Before catheter insertion, some of the factors to consider before settling on the vascular site are as follows;

Internal jugular – This is chosen for ambulatory patients and those for whom lower extremity mobility is required for rehabilitation, patients who have immediate postoperative major abdominal surgery (eg, abdominal aortic aneurysm repair), active infections affecting groin area, such as acute diarrheal illness or fungal infections, those patients with morbid obesity with pannus, the patients who had prior vascular surgeries (eg, bypass) affecting the groin or lower leg and local expertise and an ultrasound available.(Clark et al., 2016)

Femoral vein route – considered for chronic dialysis patients in whom a functional fistula, graft, or peritoneal dialysis catheter is present or possible in the near future, for patients requiring emergency hemodialysis when the operator is inexperienced or does not have access to ultrasound and in those who have severe coagulopathy. (Mcgee & Gould, 2003)

NTHCs should be converted to tunneled catheters as soon as it becomes clear that renal recovery is unlikely in the near term in patients on management for AKI. (Khwaja, 2012)

2.3.4 Indications for tunneled dialysis catheter Use

Catheters are an important option for vascular access. They can be used immediately after insertion, can be used for long periods of time assuming there are no complications. TDC are useful in the following situations

- Increasing age of patients initiating hemodialysis
- Increasing number of comorbid conditions including significant vascular disease
- Inadequate preparation prior to the need to initiate hemodialysis
- Inability of patient/family to make a modality choice in a timely manner
- Scheduled living donor transplant
- Patient choice
- Fear of needles
- Late referral.

Clinical situations where tunneled cuffed hemodialysis catheter use may be appropriately considered include the following:

- Access of choice for temporary hemodialysis for longer than 2 to 3 weeks
- Permanent hemodialysis access when no other access (including peritoneal dialysis) is possible
- When a fistula or graft is maturing or healing
- When a peritoneal dialysis catheter is planned or healing
- When a live donor transplant is scheduled

However TDCs are contraindicated where the patient has coagulation problems i.e International normalized ratio, (INR, >1.5 or platelet count, $<50 \times 10^9$/L) and active septicemia. In these situations, temporary, noncuffed, nontunneled hemo-dialysis catheters should be used.(Malloy et al., 2009)

2.3.5 Catheter placement technique.

Informed consent is required before any catheter insertion. Sterile technique should be followed in the interventional radiology or operating room. Pre procedure sedation with fentanyl and/or midazolam should be considered for patient comfort.

The catheter is inserted percutaneously using a modified Seldinger guidewire technique using either fluoroscopy or ultrasound. Ultrasound-guided puncture of all venous sites is mandatory. If available, fluoroscopy should be used to position the tip of the catheter in the mid–right atrium when the patient is supine and at the junction of the superior vena cava and right atrium when the patient is sitting. If fluoroscopy is not used during insertion, a chest x-ray is recommended post procedure to ensure proper position and avoid complications. There should be an anchor suture at the exit site and a closure suture at the puncture site. The puncture-site sutures can generally be removed in 10 to 14 days (H.S., 2012)

2.3.6 Management of mechanical complications.

Early detection of CVC dysfunction is essential as it is easier to salvage and thus leads to preservation of future VA sites and prevention of under dialysis. Assessment of a CVC can be done at the bedside to identify dysfunction. Clues include: HD blood pump flow rates below 200 mL/min.

In prolonged bleeding, when application of pressure dressings and/or local pressure remains ineffective at stemming oozing or bleeding, placement of a purse-string suture at the tunnel exit site can often facilitate hemostasis (Clark et al., 2016). Large pneumothorax will require insertion of chest tube (Tsotsolis et al., 2015)

2.3.7 Using ultrasound to reduce mechanical complications

The use of real-time ultrasound guidance when inserting catheters has been shown to dramatically reduce the risk of mechanical complications. This table summarises evidence for the use of ultrasound is detailed according to the site of catheter insertion

Table 1. Advantages of Ultrasound Use for NTHC Insertion.

NTHC site	Advantages of ultrasound use
Internal jugular	Reduced arterial punctures, hematomas
	Faster catheter insertions
	Catheter insertions more likely to be successful on the first attempt
	Use is widely considered to be the standard of care
Femoral vein	Significant reduction in complications
	Increased first-attempt successful catheter insertion and overall insertion success
	Some authors advocate real-time ultrasound should be the standard of care for femoral NTHC insertions
Subclavian vein	Avoid whenever possible due to increased risk of central venous stenosis
	Should be performed by operators experienced with this approach

Note. NTHC = nontunneled hemodialysis catheter.

A 2011 systematic review by Rabindranath et al had 7 randomized controlled trials of hemodialysis patients (n = 767 with 830 internal jugular catheter insertions) requiring catheter insertion. Studies of patients with both tunneled dialysis catheters and NTHCs were included in the analysis. They concluded that real-time ultrasound significantly reduced arterial punctures (Relative risk, RR, 0.22; 95% confidence interval [CI], 0.06-0.81) and hematomas (RR, 0.27; 95% CI, 0.08-0.88). In addition, catheter insertions using ultrasound were significantly faster and more likely to be associated with successful insertion on the first attempt (RR, 0.40; 95% CI, 0.29-

2.3.8 Accidental Removal of dialysis catheters

Temporary NTHCs and TDC are occasionally, unintentionally dislodged by patients or staff in the hospital. A study of patients with nontunneled catheters (but not necessarily hemodialysis, HD catheters) in intensive care unit showed that the rate of accidental removal of internal jugular catheters and femoral catheters was 0.26 and 0.16 per 100 catheter days, respectively. Death from exsanguination has been reported following accidental temporary HD catheter removal in the inpatient setting. It is very important to ensure that HD catheters remain adequately secured using sutures or an adhesive device specifically intended for that purpose, for the entire duration that they remain in place.

0.56). The use of real-time ultrasound for internal jugular NTHC insertions is now widely considered to be the standard of care.(Lorente, Huidobro, Martín, Jiménez, & Mora, 2004)

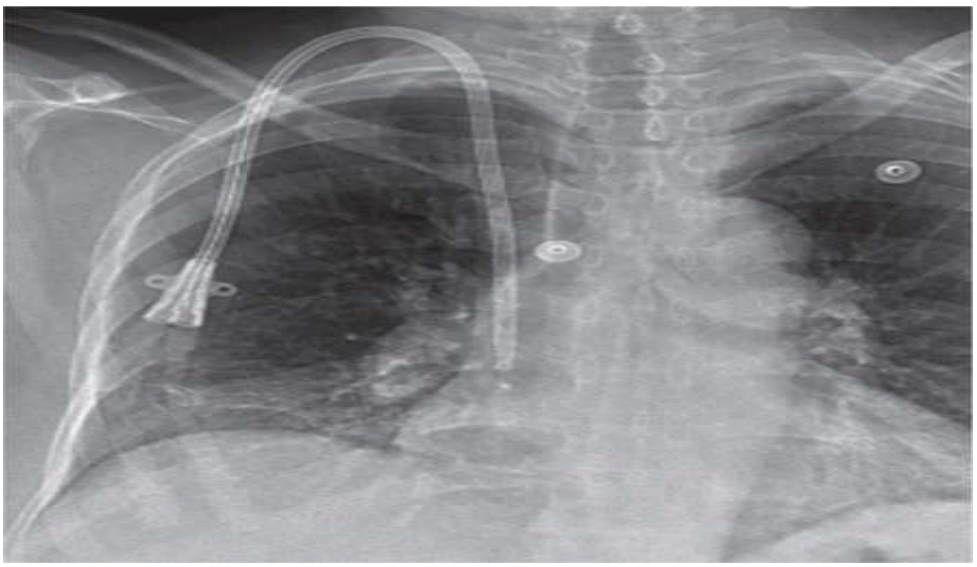


Figure 3: Radiograph of a right internal jugular tunneled central venous catheter with catheter tip placed in right atrium.

Source. Atlas of Dialysis Vascular Access. esrdncc.org/wp-content/uploads/2015/12/Access-Atlas.pdf.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was a prospective cohort study conducted among patients who required hemodialysis catheter insertion and dialysis at MTRH renal unit from December 2017 to November 2018.

3.2 Study Site

The study was conducted at the renal unit of The Moi Teaching and Referral Hospital (MTRH).

The hospital is located in Eldoret town, which is 350 Kilometers northwest of the capital Nairobi. MTRH is a tertiary (level 6) health facility serving as a teaching hospital for Moi University School of Medicine, Public Health and Dentistry; Kenya Medical Training College (Eldoret campus) and University of Eastern Africa-Baraton School of Nursing. MTRH is also a training center for medical, clinical and nursing officer interns. It is the referral hospital for the western part of Kenya and north Rift and has a catchment population of approximately 13 million people. The facility has several departments including Medicine under which the renal unit falls; the unit operates 24 hours a day with renal staff including3 consultants, 2 medical officers and 15 renal nurses. There are 2 medical registrars on postgraduate training always attached to the renal unit on rotational basis. Chronic kidney disease patients currently are 300 on continuous renal replacement therapy. Renal transplants are also done in the hospital. The other major departments are surgery, pediatrics and obstetrics and gynecology.

3.3 Participant selection

3.3.1 Study Population

It included patients referred to the renal unit for vascular access for haemodialysis. This included both acute kidney injury and chronic kidney disease patients who needed dialysis. The study subjects were recruited based on an inclusion and exclusion criteria.

3.3.2 Inclusion criteria

All patients admitted for initiation of dialysis using a tunnelled or non-tunnelled hemodialysis catheter were included in the study.

3.3.2 Exclusion criteria

Patients who were brought for conversion of a catheter from acute to permanent were excluded in the study.

Patients who required re-insertion on a vascular site previously utilized for hemodialysis.

3.4 Sampling

Consecutive vascular access procedures conducted among patients who required hemodialysis were recruited until the desired sample size was attained. This method was chosen due to small numbers of patients with renal disease at the hospital.

3.5 Data collection

3.5.1 Data collection procedure and handling

All consenting patients who require a vascular access point for renal replacement therapy and had satisfied the inclusion criteria were recruited. Socio demographic data was recorded into an interviewer administered questionnaire. This information included the serial code for the form, the age, gender, weight and height of the patient. A body mass index was then calculated using the anthropometric measurements and expressed as Kg/M2. The patients diagnosis was also recorded and the vascular access site used. The medical qualification of the doctor conducting the procedure was also recorded. These were three categories of the medical Officer, Medical registrar or the nephrologist.

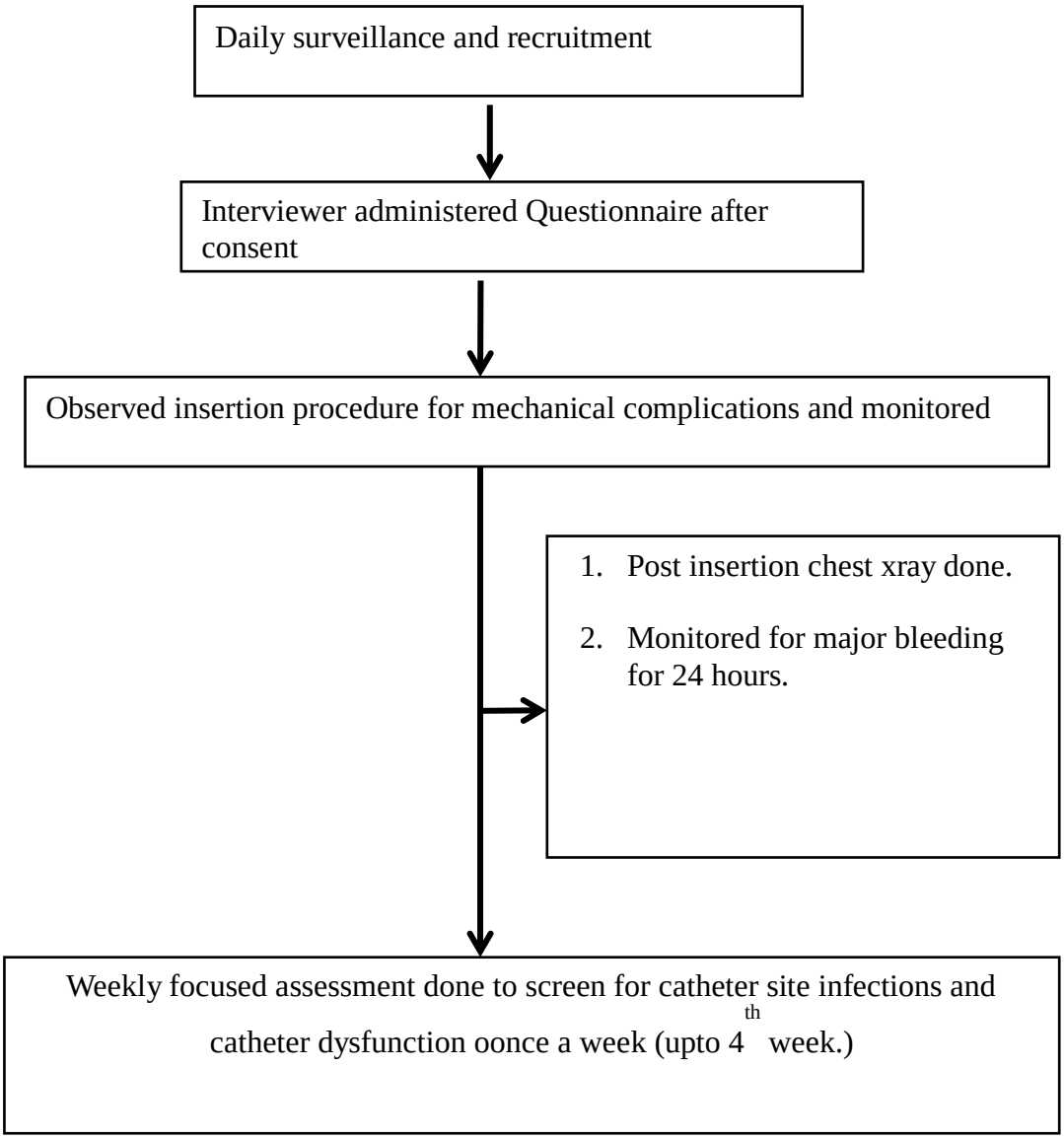
Thereafter acute mechanical complications were recorded as observed. Vital signs of the patients were also recorded. Difficult cannulation was defined as failure to obtain vascular access after 2 attempts at insertion using the finder needle. Monitoring was done on the site of cannulation in the first 4 hour for major bleeding episodes and for hematoma formation. A Chest radiograph was done after catheter insertion to asses for proper placement and to rule out development of pneumothorax or hemothorax. A radiologist reviewed all the radiographs and gave an independent report. Catheter dysfunction was also assessed and a catheter was recorded as dysfunctional if it was unable to sustain a flowrate of >200ml/minute. Vital signs of blood pressure, temperature and pulse rate were also recorded. These mechanical complications were identified using published diagnostic and procedural codes of the National Kidney Foundation-Dialysis Outcome Quality Initiative (NKF-DOQI).

To asses exit site and tunnel site infections, patients were on follow-up and once every week for a total of four weeks. A weekly assessment was done to check for

catheter site infection (ESI). This involved inspecting the catheter site for signs of local inflammation (erythema, induration and oozing of pus). blood samples from two sites were obtained and the catheter tip taken for culture studies by semiquantitative method if the catheters site or tunnel site had met the above criteria. The definitions for the infectious complications are based on the clinical practice guidelines for the diagnosis and management of intravascular catheter related infections(IDSA) update by the Infectious disease society of America.(L. a Mermel et al., 2009).

In instances where I encountered these catheter related complications, instituted the first aid for all mechanical complications as per the guidelines and immediately relayed the information to the primary care physician in the renal unit who would proceed with other medical interventions. In case any chest radiograph had catheter malpositioning The medical officer was informed to determine the next step of management.

All infection complications and results from the catheter tips and blood cultures were similarly relayed to the nephrologist in the unit to institute the appropriate



3.6 Quality control

All chest radiographs done after catheter insertion were reported by two independent radiologists. Blood and catheter tip samples obtained were processed by the MTRH laboratory which undergoes regular internal quality control as per protocols.

3.7 Data analysis and presentation

The data obtained was entered into Ms excel software application of Microsoft. It was analysed on R software version 3.4.3. The continuous variables were analysed using means, standard deviation and percentages. Categorical variables were summarized as proportions and percentages. The fisher's exact test was used to compare the categorical variables and a logistic regression model was used to study the associations. A *p* value of less than 0.05 was then considered to be statistically significant. The data was presented in form of tables and charts. The results were presented to Moi University School of medicine and also to the MTRH board.

3.8 Ethical Considerations

Before commencement of the study, the research proposal was vetted and approved by the department of medicine of Moi university afterwads, approval to conduct this study was sought from the Institutional research and ethics committee and permission was obtained from the MTRH management. Written informed consent was also sought directly from the respondents undergoing the catheter insertion procedure. This followed a detailed explanation to the patients on the purpose of the study. No form of inducement or bribing was given to the study participants to participate in the study

Information gathered was maintained confidential where all the data collection forms were kept under lock and key and information entered into the computer software was stored in a password protected computer..

Patient names or other identifying characteristics were not used in the study to maintain anonymity. Respondents were free to withdraw from the study anytime without need to seek prior authorization or consequence for doing so.

CHAPTER FOUR

4.0 RESULTS

A total of 92 patients were screened in the study and 85 patients were eventually included in the study.

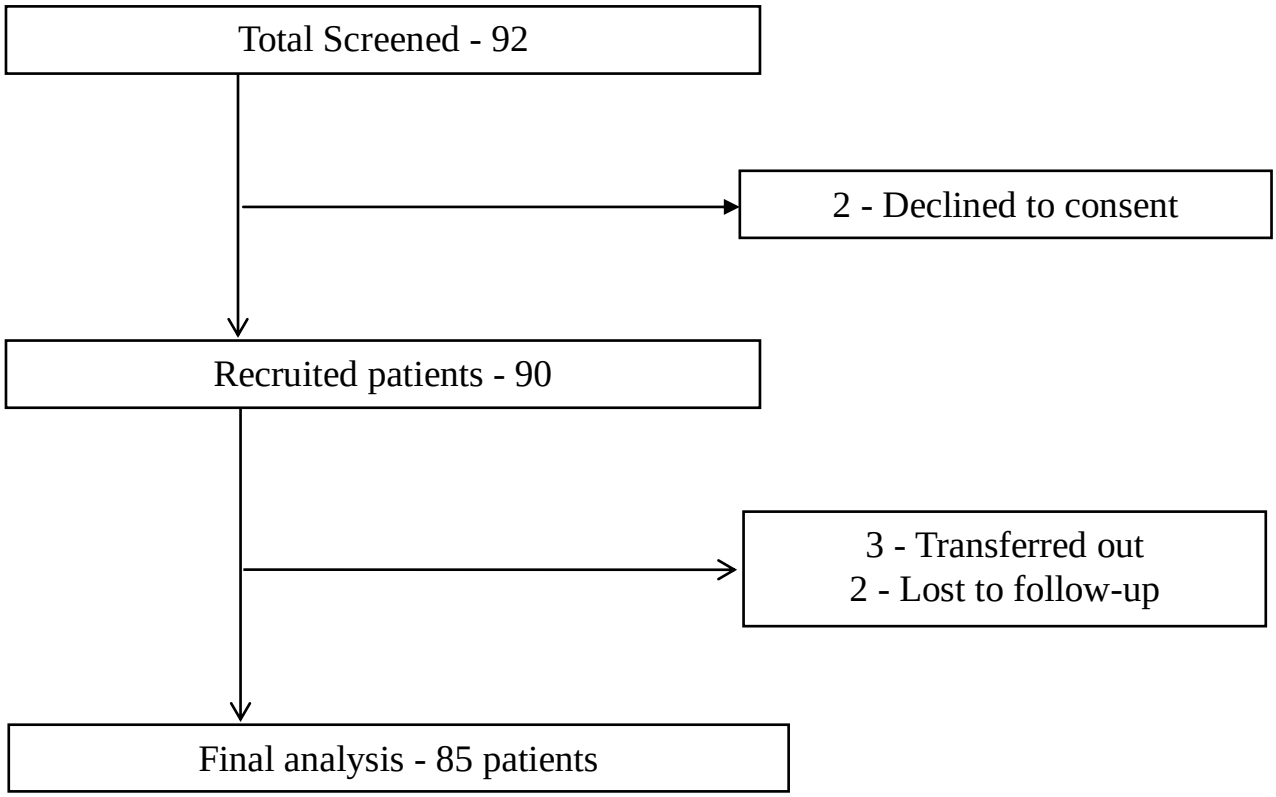


Figure 5: Flow diagram of screening and recruitment.

4.1 Objective One - To determine the frequency and types of complications related to vascular access in patients with hemodialysis catheters.

A total of 85 patients were recruited for the study. Out of 85 sampled, a proportion of 49.4% (42) were male and 50.6% (43) were female.

The results show that most respondents were above 45 years of age representing a proportion of 49.4% (42/85), followed by those between 30 to 45 year being 31.8% (27/85) and the least age was less than 30 years at 18.8% (16/85). The mean age of the study population was 44.3±17.4 years.

The most common vascular access site was internal jugular vein with a proportion of 88.2% (75/85) , and followed by femoral vein access site with 10.6%.(9/85). The mean temperature was 36.6±0.4 degrees centigrade in the study while the mean systolic pressure was 135.5±28.5 mmHg. The mean diastolic Blood pressure was 78.5±15.8 mmHg. The Mean pulse rate was 88.9±15 beats per minute.

The mean BMI was 20.8+/- 2.2. Most patients were within the normal BMI category at 75.3%. Those who were underweight were 9.4% and overweight patients were 5.9%

Most patients recruited for catheter insertions had chronic kidney disease (CKD) accounting for 91.8% which was (78/85) of the total number of patients while acute kidney injury patients were 8.2% of the total being (7/85) patients.

Hypertension was the most common comorbid condition recorded in the study with 30.6% and malignancy was the least recorded comorbidity at 5.9%

Table 1 : Socio-demographic characteristics of the participants

Variables	**Total**
	N(%) or Mean±SD N= 85
Gender	
Female	43(50.6)
Male	42(49.4)
Age Categories	
<30	16(18.8)
30 to 45	27(31.8)
>45	42(49.4)
Age (Years)	46.3±17.4
Level of expertise	
Experienced	78 (91.7)
In training	7 (9.3)

Table 2: Baseline Clinical characteristics of patients

Vascular Site	
Femoral Vein	9(10.6)
Internal Jugular Vein	75(88.2)
Category of indication	
Emergency insertion	81 (95.3)
Elective Insertion	4 (4.7)
Systolic BP (mmHg)	135.5±28.5
Diastolic BP (mmHg)	78.5±15.8
Pulse Rate (per min)	88.9±15
BMI(kg/m2)	20.8±2.2
BMI Category	
Healthy weight	64(75.3)
Below 18.5	8(9.4)
Overweight	5(5.9)
Kidney disease Stage	
AKI	7(8.2)
CKD	78(91.8)
Comorbidities	
Diabetes	6(7.1)
Hypertension	26(30.6)
Diabetes & Hypertension	18(21.2)
Malignancy	5(5.9)
Others (CGN, Vasculitides, SLE, AIN, Hep B, Hep C, RVD, Heart disease, Urethral strictures)	30(35.3)

Table 3: Summary of Mechanical complications of Vascular access.

Mechanical Complications	**N(%)**
Absent	72(84.7)
Recorded	13(15.2)
Summary of Mech. Complications	**N(%)**
Difficult Cannulation	7(8.2)
Major Bleeding Episode	1(1.2)
Hematoma	2(2.4)
Catheter dysfunction	2(2,4)
Arterial Puncture	1(1.2)

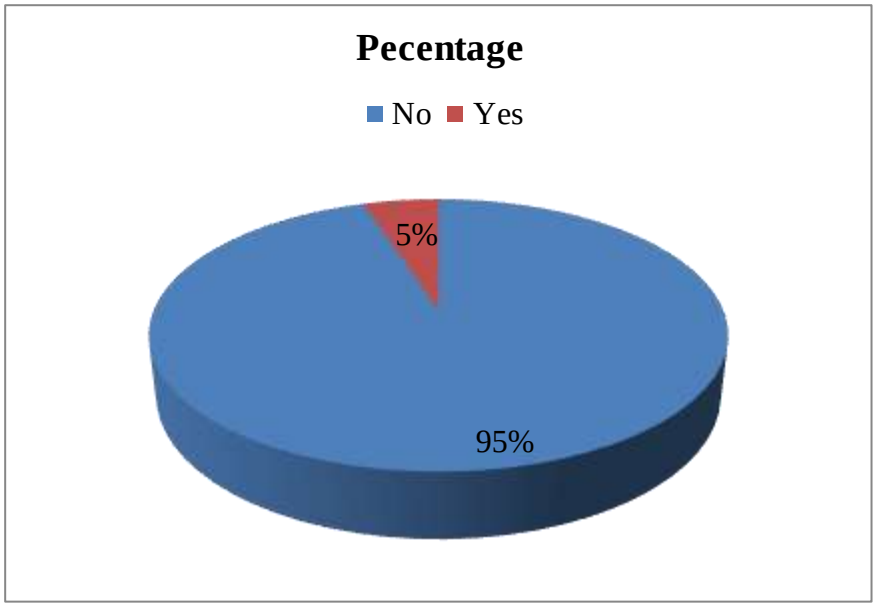


Figure 6: Summary of Exit site infection results

Table 4: Summary of the Blood and catheter tip culture results

Results of blood cultures done	**Results of catheter tip cultures done**
Sample1 *Coagulase negative Staphylococcal spp*	Catheter tip1 *Coagulase negative Staphylococcal spp*
Sample 2 *Staphylococcus epidermidis* isolated	Catheter tip2 *Staphylococcus epidermidis* isolated
Sample 3 *Escherichia coli* isolated	Catheter tip3 *Escherichia coli* isolated
Sample 4 No bacterial growth cultured.	Catheter tip4 *Coagulase negative Staphylococcal spp* isolated

95.3% (81/85)of catheters were inserted as emergency procedures while 4.7% (4/85) of the catheters were inserted as elective procedures.

91.7% being (78/85) of renal catheters assessed were inserted by trained medical officers attached in the renal department. They were considered experienced since they had inserted more than 50 catheters by the time of this study, while 9.3% or (7/85) of catheter insertions were conducted by medical registrars rotating in the renal unit in the period under study These were doctors who had inserted less than 50 catheters prior to this study.

Summary of Mechanical complications.

A total of 13 mechanical complications were noted This represents a incidence proportion of 15.3%. The commonest complication was difficult cannulation 7(8.2%), others included, Major bleeding episode 1(1.2%), Hematoma 2(2.4%), Catheter dysfunction 2(2.4%) and arterial puncture 1(1.2%).

Regarding Catheter related infections, The proportion of infection complications was 4/85 representing (4.7%). All 4 episodes occurred on the internal jugular site. The bacterial organisms isolated on both the blood and catheter tip cultures included 2/4 coagulase negative staphylococcus spp, 1/4 had Staphylococcus epidermidis , and ¼ grew Escherichia coli.

4.2 Objective Two

- To determine the factors associated with vascular access site complications.

Table 5: Factors associated with mechanical complications.

Variable	**Unadjusted OR (95% C.I)**	**P-Value**	**Adjusted OR (95% C.I)**	**P-Value**
Vascular site FV : IJV	**0.08(0.02,0.38)**	**0.001**	**0.03(0,0.2)**	**0.001**
Age Category				
<30	Ref		Ref	
30 to 45	0.98(0.21,5.44)	0.985	0.63(0.07,5.09)	0.656
>45	0.46(0.09,2.57)	0.343	0.2(0.01,1.92)	0.177
Elevated BP	0.96(0.24,3.37)	0.951	1.69(0.25,11.65)	0.579
BMI	0.84(0.55,1.16)	0.336	1(0.58,1.58)	0.986
Sex: Male	0.69(0.19,2.38)	0.564	0.89(0.14,5.76)	0.899

In the logistic regression analysis fit at baseline (week 1), The risk of mechanical complication reduced by 92% for those in the internal jugular group compared with femoral group. (OR 0.08, 95% CI 0.02, 0.38). In the adjusted OR the risk reduced by 97% in the IJV group compared to the femoral group (OR 0.03 (95% CI 0, 0.28) P= 0.001).

The risk of mechanical complications was not associated with the patients age, presence of hypertension, sex and BMI.

CHAPTER FIVE

DISCUSSION

To determine the frequency and types of complications related to vascular access in patients with hemodialysis catheters.

A proportion of 50.6% (43) were male and 49.4% (42) were female in this study. This compares well with another study done at Kenyatta National hospital (KNH) which looked at level of preparedness for hemodialysis (Kabinga et al., 2019) which found a male to female ratio of 1:1 among 82 patients studied. A study done in Nigeria by *Edaigbini et al* on 77 renal patients found a higher figure of 61% of males with renal disease (Edaigbini et al., 2019). In another Nigerian study of 147 patients with kidney disease the males were 63% (Raji et al., 2018). The higher male prevalence in west Africa is unclear and could suggest higher renal disease in males than female patients overall.

This study found that most patients fall above 45 years of age with a mean age of 44.2±16.8 years. The findings compare with the KNH study which found a mean age of 45.39 ± 15.96 years (Kabinga et al., 2019). Raji et al in Nigeria found the man age of 46.3 ± 17.2 years (Raji et al., 2018) again similar to this study. These findings confirm that chronic kidney disease is a disease that affects the older age group and tends to be prevalent as you age due to a rise in other comorbid conditions like diabetes and hypertension.

95.3% of catheters were inserted as emergency procedures while 4.7% of the catheters were inserted as elective procedures. This contrasts to findings by Lewis et al in USA who also found that 30% of the catheters were inserted as emergency procedures. The difference could be attributed to early detection and anticipation of RRT in the USA coupled with better referral systems compared to ours. A study in KNH by Kabinga et

al got similar findings with my study where 74.4% of catheters were inserted as emergent procedures. The similar findings can be explained by the fact that when most renal failure patients are admitted they present late with acute indications like metabolic acidosis, electrolyte derangements e.g hyperkalemia, oliguria or uremic symptoms.

91.7% being (78/85) of renal catheters assessed were inserted by trained medical officers attached in the renal department. They were considered experienced since they had inserted more than 50 catheters by the time of this study, while 9.3% or (7/85) of catheter insertions were conducted by medical registrars rotating in the renal unit in the period under study These were doctors who had inserted less than 50 catheters prior to this study. The higher number of experienced doctors could be attributed to the fact that they cover the renal unit on full time basis while registrars are only attatched to the renal unit for 6 weeks before moving to a different department during their training period. The low number of mechanical complications recorded in this study could also be explained by the fact that most catheter insertions are done by trained and experienced doctors in the renal department of MTRH.

The commonest site for catheter insertion is the internal jugular vein with 88.2% of the patients receiving hemodialysis catheters on this site. The femoral vein is the other site used but only 10.6% of the patients used it. These findings are similar to (Clark et al., 2016) which demonstrated the preference of the right internal jugular site followed by the left internal jugular and then the femoral vein access points. The preference for the jugular site is attributed to prior literature which has demonstrated a lower rate of infection on that site compared to the femoral veins. The IJV is also less prone to stenosis which is more prevalent with the subclavian route seen from previous studies in literature.

A total of 13 mechanical complications were noted This represents an incidence proportion of 15.3%. The commonest complication was difficult cannulation 7(8.2%), others included, Major bleeding episode 1(1.2%), Hematoma 2(2.4%), Catheter dysfunction 2(2.4%) and arterial puncture 1(1.2%). All the 85 post insertion chest x rays were reported as normal. The catheter tips were in the right atrium and no hemothorax or pneumothorax was reported.

similarly the study by (Raji et al., 2018) in Nigeria found a total incidence proportion of 12.9%. It went further to show the observed immediate complications of tunneled catheters were difficult cannulation at 7(4.7%), reactionary hemorrhage 5(3.4%), arrhythmia 3(2.0%), hemothorax 2(1.4%) while death during catheter placement was recorded in 2(1.4%) cases (Müller-Ortiz et al., 2019) found that of 18% rate of mechanical complications, Ninety five percent of recorded complications were arterial puncture, followed by hematomas in 10% and pneumothorax in 5%. This was on 100 patients who had catheter insertion using anatomic method. In yet another Nigerian study the rate of complications recorded was 16.9%. This study was on 77 catheter sites 73 permanent and 4 temporary (Edaigbini et al., 2019). In a systematic review by (Ruesch et al., 2002) in Geneva which looked at 17 prospective studies comparing complication rates between internal jugular and subclavian vessels, 6 studies showed more arterial punctures in IJV compared to SCV. (3.0 – 0.5% (RR 4.7 95% CI 2.07 – 10.77)). The review however did not include femoral vein catheters. The review reported a higher rate of infectious complication on the internal jugular than the subclavian site. In 3 trials 8.6% versus 4.0% .

Another study by Eisen et al in 2006 conducted in the USA got an incidence proportion of 14% of these mechanical complications. These findings were

comparable to our study. The most common complication was failure to place occurring in 22% (86/385) of all attempts. Other complications included arterial punctures in 4.6% (18/385)), 3.6% with catheter malpositioning and 0.7% with hematoma formation. While the findings on difficult cannulation were consistent with ours, the higher incidence proportion reported could be attributed to the difference in description of what constituted difficult cannulation. They considered it to be more than one needle pass as opposed to our study where the criteria needed to be met with more than two needle passes when attempting to establish vascular access. The difference could also be attributed to the difference in sample size and the fact that they did this study among critically ill patients (Eisen et al., 2006)

In contrast to our study on rate of catheter dysfunction being 2.4%, a study in Poland by (Hryszko et al., 2004) found catheter malfunction at 31.51%. It further concluded that the catheterization of the internal jugular vein is associated with longer catheter survival when compared to the femoral vein. It recommended placement in the internal jugular vein due to minimal chances of getting catheter dysfunction. The higher rate of catheter dysfunction in the study are attributed to the low threshold set to determine catheter dysfunction as blood flow rates of < 150ml/min while we used a cutoff of 200ml/min to conclude catheter dysfunction. It could also be attributed to the fact that in this study, only NTHC were analysed as opposed to our study where both TDC and NTHC were analysed.

In another unpublished study by F. Oduor in KNH assessing the adequacy of dialysis dose among CKD patients, it noted the high dependence rate on the temporary catheters. It further reported the high rate of poor performance of the non-tunneled catheters due to poor flow rates < 300ml/min. This finding concurs with our study where 2.4% of mechanical complications are due to catheter dysfunction. The higher

rate of catheter dysfunction could also be due to the fact that they used 300ml/min as the cutoff flow rates for determining catheter dysfunction.

Our study found 4(4.7%) of patients with catheter related infection out of the 85 patients followed up. It further showed that all the 4 infective complications occurred on the internal jugular vascular access point. No infection was reported in the femoral vein. From literature review, the femoral site is more prone to infection compared to the internal jugular veins. Our study only had the IJVs recording ESI and this can be explained by the low numbers of femoral catheters in our study or due to random chance. The low incidence of catheter ESIs in our study could also be attributed to the stict infection prevention measurers observed by doctors and nurses working in the renal unit and by extension the adherence to these protocols by clinical staff working at the Moi Teaching and Referral Hospital. Out of the 4 CRIs events recorded, 1 was both catheter site and tunnel infection. The other 3 were ESI which demonstrated growth of organisms namely *staphylococcus epidermidis*, coagulase negative *staphylococcus* spp. and *Escherichia Coli* spp on blood and catheter tip cultures taken. There was no bacterial isolate on one of the catheter tips collected but Blood cultures showed coagulase negative S*taphylococcus spp*. Similar findings were demonstrated by a study by (Kairaitis & Gottlieb, 1999) had similar findings on the rate of catheter related infections. It found a rate of 8% with catheter site infections. The higher in incidence proportion however was likely due to the fact that his study focused only on NTDCs while in our study both TDC and NTDC were under evaluation. The TDC have a lower rate of infective complications due to the subcutaneous component and cuff that reduce likelihood of infections. The cuff also forms a subcutaneous fibrous mechanical barrier which reduces risk of ESI. The study had sought to assess the catheter and patient factors on incidence of infective complications. It was a

prospective study with 105 patients as a sample size in the study. It further concluded that both gram positive and gram negative isolates were responsible for ESI which was similar to our study. In another study by Shamira et al in 2021, They found an overall incidence rate of 4.8% for catheter related infections. The finding were similar to the findings in my study.

In Nigeria, a study by Akwa et al found a lower incidence rate of 0.4% as infection complications. This figures are much lower than those in our study and the difference in findings could be attributed to the difference in the methodology adopted. He used a retrospective approach on 60 patient files and this may have led to missing of some of the ESI if they were not properly documented in the patient files before the study was conducted.. (Akwa, 2010)

In the study by Raji et al in the same setting however showed catheter related infection was the commonest long-term complications and occurred in 15 cases (10.1%) while being diabetic increased the risk of developing catheter related complications. The higher rate of ESI in this study could be attributed to the longer period of study He sought to do the study over a period of 5 years while my study lasted for on year. The study further concluded that being diabetic was associated with an increased risk of infective complications. In our study we were unable to make these association since our infective complications were low and limited only to the internal jugular site.

In another study by (L.A. et al., 2006) on 1319 CVCs, rate of infection was 9.7% in the IJV route while the rate of infections among the femoral vein vascular site group was higher at 15% the difference in findings could be because of .high numbers of FV in the study and again emphasizing the sterile surgical conditions and good catheter

care practices like routine handwashing and wearing of gloves and face masks when handling catheters during RRT.

In a study conducted in Pakistan on 104 patients aged between 5 and 15 years, the frequency of exit site infection was higher at 16.3% and *Staphyloccocus aureus*, *E. coli* and *Klebsiella pneumonia* were the common aetiologic pathogens on blood cultures., while *S. aureus*, *P. aeruginosa* and *E. coli* were the commonest catheter tip culture organisms. The findings are similar in terms of aetiologic pathogens causing ESI (Children & Hospital, 2019) The higher incidence proportion however could be attributed to the difference in socio demographic characteristics of the patients. The study focused mainly on a pediatric population which may not have had the adequate information on good catheter care practices.

No study has been done in Kenya to look at the burden of these complications. In Kenyatta National Hospital, *Kabinga et al* only assessed for the level of preparedness for RRT and noted the high rate of dependence on the temporary catheters among hemodialysis patients at KNH (Kabinga et al., 2019)

To describe the factors associated with vascular access complications in my study, I analyzed a number of factors from literature that have been associated with mechanical complications. These factors include the vascular access site, age of the patient, BMI status of the patient, comorbid condition of hypertension and the gender of the patient.

Using a logistic regression model, only one factor under study i.e. the vascular access site was seen to be significantly associated with occurrence of mechanical complications. The risk of a mechanical complication occurring was increased by 92% and 97% on unadjusted and adjusted odds ratios respectively in the femoral vein

compared to the internal jugular vein with a p value = 0.001. These findings were similar to a study that was done in USA by Lewis et al who found a difference of 33% versus 24% for femoral and internal jugular veins respectively. This difference was statistically significant with a p value of 0.022. In yet another study in Poland by Hryszko et al, 40 IJV and 33 FV catheter insertions were studied. The study showed fewer catheter dysfunctions occurred in the IJV compared to the FV (51% versus 14% respectively) group by the end of the 3rd week of catheter use with the difference showing statistical a significant p value of 0.0002 (Hryszko et al., 2004).

The higher number of catheter dysfunction reported in the study could be because they only studied NTHCs which were followed up for varied periods of time and were only removed if they showed dysfunction. The higher number of femoral catheters which are prone to dysfunction due to kinking and hence higher failure rates is also a likely explanation to these differences. Catheters in the femoral vein have also been found to be prone to catheter related thrombosis, this is because they are more likely to be preffered for critically ill patients who are more likely to be bed ridden even after catheter insertion sisnce they remain immobile. The IJV route is preferred for those patients who are ambulant and hence these group of patients have lower rates of catheter related thrombosis. Lower cutoffs for blood flowrates of 150ml/min compared to our study where a cutoff of 200ml/min used to define catheter dysfunctions could further explain these differences in findings.

Similar findings were noted in a study the study by Raji et al which had sought to describe outcomes of tunneled dialysis catheters (TDCs) on 147 patients. While difficult cannulation and bleeding episodes were reported as the common mechanical complications, it concluded that the IJV remains a good and safe route for vascular access. Diabetes was found to be associated with increased risk of infection. We could

not assess this association since all the infection complications reported in our study occurred only on the IJV route. The difference in findings could also be attributed to the fact that study only looked at catheters on the IJV site and it was also done using a retrospective study design (Raji et al., 2018)

In my study a low or high BMI was not associated with occurrence of mechanical complications. The findings compare to a study by Eisen et al done in 2006 on 385 patient which did not demonstrate any association between high or low BMI with occurrence of these mechanical complications.

The findings contrast a study done by Heideman et al in Michigan, USA in 2017. The p-value reported was 0.001. The difference in findings between these two studies could be due to the difference in socio demographic characteristics of the two populations where the developed countries have a population with higher BMI and possibly due to the larger sample size used in the USA study.

In my study I did not find an association between age and the occurrence of mechanical complications. These findings compared with the study by Eisen et al where age was not linked to mechanical complications. The findings however were however different to a study by Lefrant et al in 2002 in Australia who found age above 77 associated with the occurrence of mechanical complications. The difference in findings however could be attributed to the fact that he compareded the subclavian access to the femoral access and he also had a higher sample size of 289 patients. Using the subclavian vein is now discouraged due to the high rate of other mechanical complications like central stenosis with subsequent loss of the whole ipsilateral arm for future vascular access.

The sex/gender of the patient was not associated with occurrence of mechanical complications. The findings were in contrast to a study by Schummer et al which showed that the male patients had a lower risk of catheter failure at 2.1% (mechanical complication) compared with female patients who had a rate of 3.8% giving a significant p value of 0.028. The difference could be attributed to the longer study period, and the larger sample size used in their study.

The findings also contrasted the study by Eisen et al which interestingly had a contrary result to the study by Schummer et al. The study concluded that the male gender is associated with a higher rate of mechanical complications than the female gender p value of 0.04. Although the sample size used was much smaller in this study, it was still larger than our study population giving a possible explanation to the difference in findings witnessed. Gender does not have anay known scientific explanation to directly contribute to occurrence of mechanical complications except for anatomical varriations in males and females.

The last factor studied was elevated blood pressure which similarly did not show an association with occurrence of mechanical complications from our study. While studies in literature link diabetes and hypertension to infective complications more than mechanical complications, The studies by Eisen et al and the one by Shummer et al did not find any association with comorbidities. Similarly, the study by Raji et al did not associate high blood pressure with occurrence mechanical complications.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusions

The most frequent mechanical complications is difficult cannulation in Moi Teaching and Referral Hospital.

The incidence proportion of catheter-related infections is low at MTRH.

Vascular access site was associated with occurrence of mechanical complications whereas advanced age, male gender, low or high BMI, diabetes and hypertension had no effect.

6.2 Recommendations.

The rate of vascular access complications are acceptably low but further comparative studies with ultrasound guided insertion need to be done. Preferential insertion of dialysis catheters into the internal jugular vein should be considered.

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APPENDICES

Appendix I: Data Collection Sheet

TITLE: SHORTTERM COMPLICATIONS OF VASCULAR ACCESS FOR HEMODIALYSIS PATIENTS IN MTRH.

Consent form

A. ENGLISH

My name is Dr. Dancun Bosire. I am a qualified doctor, registered by the Kenya Medical Pactitioners and Dentists Board. I am currently persuing a masters degree in Internal medicine at Moi university.. I would like to recruit you into my research which is assessing ***the incidence of short term complications from hemodialysis catheter insertion and dwell in.*** This study takes 4 weeks and weekly examination will be done to check for the complications.

ABOUT VASCUAR ACCESS COMPLICATIONS.

There are three anatomical sites for venous access with temporary dialysis catheters; they are subclavian, internal jugular and femoral veins.

Insertion at each site has a potential for major complications. These complications range from mechanical, throbotic and infection. I will be observing for emergence of these complications during your first month sessions of dialysis. Chest x rays, Doppler ultrasound, and blood samples will be taken for evaluation where necessary and proper channels to communicate in case complications arise will be followed to ensure prompmt intervention. We will keep all your test results in private. Treatment does not depend on your participation in this study. This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/ Moi Teaching and Referral Hospital.

If you need further clarification, please contact IREC using the address below.

The Chairman IREC

Moi Teaching and Referral Hospital,

PO Box 3, Eldoret. My mobile phone number is 0726048425

YOUR CONSENT:

For Adults above 18 years of Age.

I have been adequately informed that I am being recruited in a research study to assess complications of hemodialysis vascular access in MTRH. The investigator has also informed me that my participation in this study, is voluntary and will not exclude me from my routine care even if I were to opt out. He has also informed me that I will not be required to pay for the tests done for the purpose of this study.

Sign ……..

ILANI

Jina langu ni Dr. Dancun Bosire Momanyi, Daktari aliyehitimu na kusajiliwa na Bodi ya madaktari kwa mujibu wa sharia za humu nchini Kenya. Sasa hivi ninaendeza masomo yangu katika kiwango cha shahada ya pili (Masters) kwenye chuo kikuu cha Moi University.

Ningependa kukujumuisha katika utafiti ninaofanya wenye maada *" UCHUNGUZI WA MATATIZO YANAYOTOKANA NA KUWEKA NA KUTUMIA CATHETERS ZA DIALYSIS KWENYE MISHIPA YA DAMU MIONGONI MWA WANGONJWA WA FIGO KATIKA HOSPITALI YA RUFAA YA MOI , ELDORET."*

KUHUSU MATATIZO YA CATHETER ZA DIALYSIS

Kuna sehemu tatu kwenye mwili ambapo hizi catheter zinaweza kuwekwa kwa mishipa ya damu ili kutumika kuosha damu. Sehemu hizi ni kwenye mishipa ya shingo (internal jugular na subclavian veins) na kwenye miguu (Femoral vein.)

Vinapowekwa vifaa hivi vya dialysis vinaweza kusababisha madhara ikiwemo kuvuja damu, kusababisha kuganda kwa damu kwenye mishipa, na kufanya vidonda kutokana na viini vya *bacteria* vinavyoweza kuingia katika sehemu hio.

Langu litakua kuona kama matatizo haya yatakuwepo na kuwafahamisha madaktari husika ili upate matibabu ya dharura kusitisha haya matatizo. Picha za x ray na Doppler zitaweza kutumika ili kutafiti haya na damu kupelekwa katika maabara ikiwa itahitajika kutolewa.

Matokeo ya utafiti huu yatawekwa kwa siri na daktari na mgonjwa muhusika ndio wataelezwa iwapo kuna swala ibuka. Matibabu yako ya kawaida hayatategemea

kuhusika kwa utafiti huu na pia mgonjwa yeyote atakua huru kujiondoa kwenye utafiti huu wakati wowote.

Shughuli hii imeidhinishwa na kamati ya utafiti ya IREC (Institutional research and Ethics Committee.) ya hospitali ya Moi.

Iwapo utahitaji maelezo Zaidi kuhusu utafiti huu, uko huru kuwasiliana na Ofisi ya IREC katika anwani ifuatayo.

Kwa mwenyekiti wa IREC,

Moi Teaching and Referral Hospital

P.O Box 3 Eldoret.

Nambari yangu ya simu ni 0726048425

UITHINISHO.

Kwa wagonjwa wa umri wa 18 na kuendelea

Nimeridhika na maelezo ya kwamba ninajumuishwa kwenye utafiti huu unaolenga kubaini matatizo yatokanayo na kuwekewa dialysis catheter, Kujihusisha huku ni kwa hiari yangu binafsi na hakutanizuia kupata matibabu yangu inavyotakikana hata nikiamua kujiondoa baadae. Amenihakikishia ya kwamba sitahitaji kutoa malipo yoyote katika utafiti huu.

Sahihi……

Appendix II: Questionnaire

DATA COLLECTION SHEET.

A.) DEMOGRAPHIC DATA

Patient code:

Age:

Gender:

Weight:

Height:

BMI:

B.) PATIENTS DIAGNOSIS

1. AKI
2. CKD

OTHER CORMOBIDITY Diabetes Hypertension

Malignancy

Other (Specify) ……

C.) Type of vascular access used

Internal Jugular ☐

Femoral vein ☐

Subclavian vein ☐

Insertion done by

Consultant ☐

Registrar ☐

☐

Medical officer

SHORT TERM COMPLICATIONS NOTED

MECHANICAL COMPLICATIONS (During insertion)

1.Difficult cannulation ☐

2. Major bleeding episode (Bleeding requiring prolonged digital compression) ☐

Hematoma ☐

Kinked catheer ☐

Hemothorax ☐

Pneumothorax ☐

Arterial puncture (pulsatile /Bright red blood) ☐

Catheter dislodged ☐

Vessel occlusion (Stenosis/ Thrombosis) ☐

WEEK 1 FOLLOWUP

Vital signs

1. Temperature
2. Blood pressure
3. Pulse rate

Catheter infections.

Inspection of catheter site for infection

Pain	YES ☐	NO ☐
Induration > 2cm	☐	☐
Pus from exit site	☐	☐

CATHETER MALFUNCTION (Reduced blood flowrate <200ml/min) YES ☐

NO ☐

WEEK 2 FOLLOWUP

Vital signs

4. Temperature
5. Blood pressure
6. Pulse rate

Catheter infections.

Inspection of catheter site for infection

Pain	YES	☐	NO	☐
Induration > 2cm		☐		☐
Pus from ext site		☐		☐

CATHETER MALFUNCTION (Reduced blood flowrate <200ml/min) YES ☐

NO ☐

WEEK 3 FOLLOWUP

Vital signs

7. Temperature
8. Blood pressure
9. Pulse rate

Catheter infections.

Inspection of catheter site for infection

Pain	YES	☐	NO	☐
Induration > 2cm		☐		☐
		☐		☐

Pus from exit site

CATHETER MALFUNCTION (Reduced blood flowrate <200ml/min) YES ☐

NO ☐

WEEK 4 FOLLOWUP

Vital signs

10. Temperature

11. Blood pressure

12. Pulse rate

Catheter infections.

Inspection of catheter site for infection

Pain	YES ☐	NO ☐
Induration > 2cm	☐	☐
Pus from exit site	☐	☐

CATHETER MALFUNCTION (Reduced blood flowrate <200ml/min) YES ☐

NO ☐

Appendix II: Sterile technique for catheter insertion

After obtaining informed consent, The patients were wheeled into a minor there and placed in a supine position with adequate exposure of the preferred site for catheter insertion.

The catheter was inserted by a qualified medical officer, or registrar in the department.

Sterile surgical technique included hand scrubbing, gown, gloves, a mask and surgical drape.

Skin was disinfected with 10% povidone or 70% isopropyl alcohol

Anatomic landmarks were established and a needle advanced before attaching the catheter through the modified seldinger technique and secured on the skin with nylon 2.0 suture. Once good flows were established.

Afterwards, the insertion the exit site was dressed with a transparent dressing

All patients were observed for mechanical complications. For internal jugular catheters, all patients routinely had a chest radiograph that was read by a radiologist blinded to the clinical status of the patient to assess for catheter position, pneumothorax, hydrothorax, and mediastinal hematoma. All complications are managed as clinically indicated.

And patients were monitored until the first dialysis session was complete.

Appendix III: Technique for Catheterization at the Internal Jugular

In the central approach for internal jugular venous catheterization (figure 1), the apex of the triangle formed by the two heads of the sternocleidomastoid muscle and the clavicle serves as the landmark. The internal jugular vein runs deep to the sternocleidomastoid muscle and then through this triangle before it joins the subclavian vein to become the brachiocephalic vein. After the landmarks have been identified, sterile barriers approaches are used, and the local anesthesia is been administered, Afterwards the patient is placed in Trendelenburg's position with the head rotated at 45 degrees away from the site of cannulation. The doctor places the index and middle finger of his or her non dominant hand on the carotid artery and inserts a 22-gauge "finder" needle through the skin, immediately lateral to the carotid pulse and slightly superior to the apex of the triangle. The needle is advanced past the apex of the triangle, in the direction of the ipsilateral nipple, at an angle of 20 degrees above the plane of the skin. The vein is usually located near the surface of the skin and is often encountered after less than 1.3 cm of the needle has been inserted. If the first pass is unsuccessful, the needle should be directed slightly more medially on the next insertion attempt. With the finder needle in place, an 18-gauge introducer needle is then inserted alongside it and into the vein. A J - shaped guidewire is then advanced gently checking to not force it against resistance into the introducer needle and advanced to a maximum of 15 cm and secured by the nondominant hand as the introducer needle is removed over the guide wire. A catheter is then introduced over the guidewire after serial dilatation with 2 dilaters. Once the CVC is inserted, it is sutured into place and covered with a sterile dressing. Catheter position is preliminarily confirmed by return of blood and free flow of fluid through all ports.

Appendix IV: **Procedure for collection of catheter tip and blood for Culture in suspected CRI**

Once catheter-related infections were suspected, all catheter sites were examined carefully. If there was any purulence or erythema, an exit-site infection was considered likely and the catheter removed.

Two samples of blood were drawn from peripheral sites for culture to evaluate the possibility of bacteremia.

This was done because it is difficult to determine whether a positive culture of blood from a CVC indicates contamination of the hub, catheter colonization or a catheter-related bloodstream infection.

Due to this difficulty in establishing the possibility of bacteremia from a CVC, besides the peripheral blood sampling, all suspected CRI catheters were removed and the tips sent for culture along with the blood.

Appendix V: Procedure for managing Prolonged Exit-Site Bleeding Following Catheter Insertion.

Minor, self-limited oozing at the exit site following insertion of a tunneled catheter is a frequent occurrence; however, some patients experience prolonged oozing or overt bleeding that may necessitate a transfusion or other intervention.

When prolonged oozing or bleeding occurs in the absence of hypotension or other contraindications, the patient should be maintained in an upright position to reduce central venous pressure. While coagulopathies should be corrected, It is standard procedure to first check the platelet count and perform an INR to rule out these abnormalities.

If application of pressure dressings and/or direct digital pressure remains ineffective at controlling oozing or bleeding, placement of a purse-string suture at the exit site can often achieve hemostasis. This should be performed while observing aseptic technique, taking special care to avoid nicking the catheter. If uremic bleeding is suspected, administration of desmopressin (DDAVP) or other agents may be considered.

Appendix VI: Letters of Approval for the study.

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/204
Approval Number: 0001750

26th September, 2016

Dr. Dancun Bosire Momanyi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
26 SEP 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Momanyi,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Short Term Complications of Vascular Access for Hemodialysis at Moi Teaching and Referral Hospital".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1750*** on 26th September, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 25th September, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix VII: Hospital Approvals (MTRH)

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

30th September, 2016

Dr. Dancun Bosire Momanyi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Short Term Complications of Vascular Access for Hemodialysis at Moi Teaching and Referral Hospital".

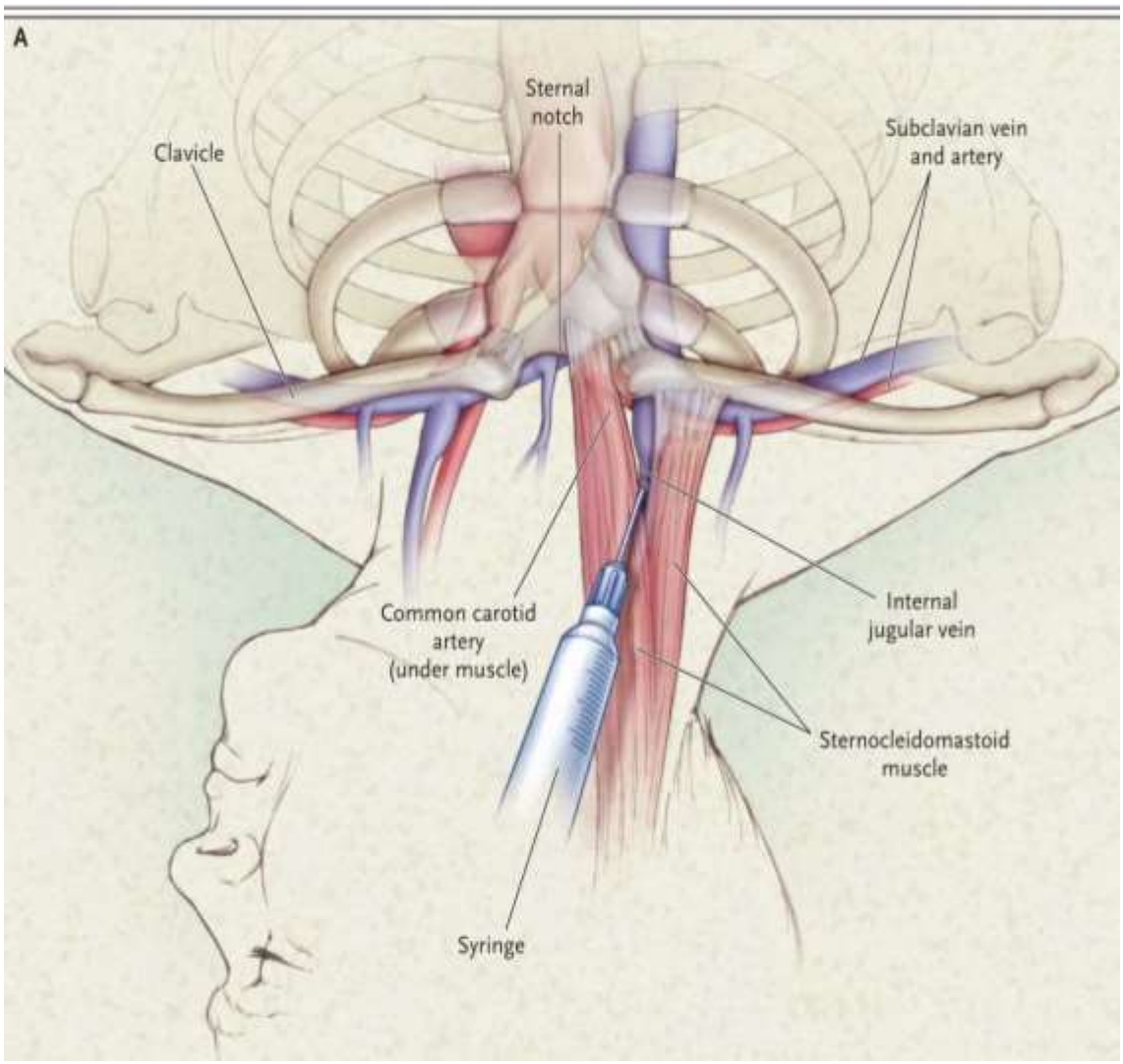
You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

30/09/2016

DR. WILSON ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Appendix VIII: Technique of catheter placement at the right internal jugular vein



Appendix IX: Images of observed catheter insertions from my study.