COLLEGE OF HEALTH SCIENCES, SCHOOL OF MEDICINE, DEPARTMENT OF SURGERY

PEVALENCE AND FACTORS OF EARLY ARTERIOVENOUS FISTULA FAILURE IN END STAGE RENAL DISEASE PATIENTS: A SINGLE CENTER RETROSPECTIVE STUDY

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AUGUST, 2024

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A THESIS TO BE SUBMITTED TO VASCULAR AND ENDOVASCULAR SURGERY UNIT, DEPARTMENT OF SURGERY, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCE, ADDIS ABABA UNIVERSITY AS A PARTIAL FULFILLMENT OF SUB-SPECIALITY CERTIFICATE IN VASCULAR AND ENDOVASCULAR SURGERY

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DECLARATION

I, the undersigned, declare that the thesis comprises my own work. In compliance with internationally accepted practices, I have acknowledged and referenced all materials used in this work. I understand that non-adherence to the principles of academic honesty and integrity, misrepresentation/ fabrication of any idea/data/fact/source will constitute sufficient ground for disciplinary action by the college and can also evoke penal action from the sources which have not been properly cited or acknowledged.

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Abbreviations and acronyms

AOR	Adjusted odds ratio
AVF	(Autogenous) Arteriovenous Fistula
AVG	Arteriovenous Graft
CKD	Chronic Kidney Disease
COR	Crude odds ratio
CVC	Central venous catheter
CT	Compute tomography
DASS	Dialysis access associated steal syndrome
DM	Diabetes Mellitus
eGFR	estimated Glomerular filtration rate
ESRD	End Stage Renal Disease
ETB	Ethiopian Birr
HD	Hemodialysis
HTN	Hypertension
IJV	Internal jugular vein
KDOQI	Kidney Disease Outcomes Quality Initiative
PD	Peritoneal Dialysis
RRT	Renal Replacement Therapy
SPHMMC	St. Paul's Hospital Millennium Medical College
TASH	Tikur Anbessa Specialized Hospital
US	Ultrasound
USA	Unites state of America

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Abstract

Background: Hemodialysis the most commonly used renal replacement therapy **(**RRT) in the world. Arteriovenous fistula (AVF) is the preferred method of vascular access for hemodialysis because of its superior long-term patency and better complication profile compared to arteriovenous graft (AVG) or central venous catheter (CVC). But the advantages of AVF are hampered by high rate of early fistula failure. This study aimed to determine prevalence of early AVF failure and evaluate patient factors associated with early AVF failure to improve vascular access selection and outcomes.

Methods: In this cross-sectional study, 79 patients with ESRD for whom autogenous AVF was created from April 2022 up to March 2024 at Menelik II referral hospital were evaluated. Patients' medical records were interrogated for independent variables of age, sex, history of hypertension (HTN) and diabetes mellitus (DM), dialysis status at AVF creation, pre-operative vein diameter and site of AVF creation and the dependent variables of mature fistula and failed fistula. These data were entered to SPSS v26 and study data were analyzed by descriptive statistics (frequency tables) and bivariate and multi-variate logistic regressions were used to assess association of independent variables with early fistula failure.

Results: The mean age of patients was 47.7 ± 14.8 years. Male patients account for 57.3% of study population. 68.1% and 42.7% of patients had history of HTN and DM respectively. 65.2% of patients had started dialysis using CVC at the time of AVF creation. Prevalence of early failure was 31.5%. There was no statistically significant relationship between demographic variables (age, sex), HTN, DM and early fistula failure. Site of fistula creation showed significance in bivariate analysis but the significance disappears during multivariate regression. Factors associated with early AVF failure were dialysis status at AVF creation (AOR 11, 95% CI [1.0 - 74.0], $p = 0.01$) and vein diameter (AOR 0.002, 95% CI [0.001 - 0.05], $p < 0.001$).

Conclusion: Being on hemodialysis and small vein size (<2 mm) are strongly associated with higher odds of early fistula failure. These results have clinical implications for vascular access planning and preoperative patient evaluation.

Key words: End stage renal disease (ESRD), Hemodialysis (HD), Arteriovenous fistula (AVF), Early failure

1. Introduction

1.1 Background

Chronic kidney disease (CKD) is common health problem worldwide. The number of patients with end-stage renal disease (ESRD) has been growing steadily, thus increasing the demand for hemodialysis (HD). Hemodialysis remains the most common form of kidney replacement therapy, with over 2 million people on hemodialysis worldwide (1, 2,3). Arteriovenous fistula (AVF) has been shown to be the best route for delivering HD due to long-term benefits, including less morbidity and mortality, fewer rates of infection and complications, and lower costs compared to other types of vascular accesses (3). However, these long-term benefits are hampered by exceedingly high rates of early AVF failure due to thrombosis and maturation failure. As a result of early thrombosis, neointimal hyperplasia formation and inadequate vasodilation, between 20 and 60% of AVFs fail to mature to an adequate caliber to allow repeat cannulation and provide sufficient blood flow for hemodialysis and thereby prevent timely usability of the AVF for hemodialysis (1,3). Previous studies have identified delayed nephrology care, smaller arterial and venous caliber on sonographic evaluation, and demographic factors, such as older age and female sex, to be associated with AVF failure (14, 16-37).

In Ethiopia, the burden of CKD is rising due to increasing rates of no-communicable diseases like hypertension (HTN) and diabetes mellitus (DM) and limited access to healthcare resources. This often leads to delayed diagnosis and treatment, exacerbating the challenges associated with hemodialysis and vascular access (4). The only currently available renal replacement therapy (RRT) in Ethiopia is HD. There are only limited dialysis centers in the country the majority of which are concentrated in the capital city, Addis Ababa. Maintenance dialysis is available only at private institutions or public-private partnerships in government hospitals. The cost of HD is not affordable for the majority of Ethiopians. If patients don't have functional vascular access, preferably AVF, they will be subjected to additional financial burden and morbidity associated with catheter dialysis. Early AVF failure is significantly associated with mortality in patients with ESRD (4-13)

Regarding factors influencing fistula failure, robust research has been done in the global context. There is significant inconsistency regarding the significance of association some variable have with early fistula failure. Age, gender, HTN, DM and location of AVF formation are some of the variables where the literature happens to be divided on their significance as factors of early AVF failure.

1.2 Statement of the problem

End-stage renal disease (ESRD) is a significant public health concern. However, the burden in Africa is not established due to inadequate registration systems, with the highest registered prevalence is in Tunisia and Egypt, at 713 and 669 per million population, respectively. Although the true burden of ESRD in Sub-Saharan Africa is unknown, it is assumed to be high, with risk factors including both communicable and non-communicable diseases. There is scarcity of studies done on Prevalence and predictors of early AVF failure in Sub-Saharan Africa and particularly Ethiopia (4-8).

With high burden of ESRD, the number of patients who need HD increases annually. AVF is the gold-standard HD access because of higher fistula survival and less complication rates. Unfortunately, AVF also has a high early fistula failure rate. Identifying factors associated with early fistula failure will help devise mechanisms to mitigate the effect of these factors so that patients will have a functional AVF.

This study tried to assess the prevalence of early fistula failure and factors associated with it in the Ethiopian set-up. Having this information will help clinicians to make informed decisions.

1.3 Significance and Rationale of the study

There is inconsistency in the literature regarding the association of some of the factors with early fistula failure. Especially in the Ethiopian scenario, there is significant gap in information (4). There is no quality data on the burden of ESRD, the prevalence of hemodialysis and particularly on prevalence of early fistula failure and factors related to fistula maturation and failure. Therefore, this study aimed to determine the prevalence of failure and identify associated factors. The results of this study will help clinicians make informed decisions, policy makers draft new guidelines or modify existing ones. It also can be used as a springboard for future studies.

1.4 Research question

The purpose of this research was to determine the prevalence of early AVF failure and identify factors related to early AVF failure in ESRD patients for whom autogenous AVF was created

2. Literature Review

2.1 Introduction

Arteriovenous fistula (AVF) is a surgically created communication between an artery and an adjacent vein for the purpose of hemodialysis (HD). Other methods of hemodialysis access include central venous catheters (CVC) and arteriovenous grafts (AVG). HD is the most commonly used renal replacement therapy (RRT) worldwide. Other forms of RRT include peritoneal dialysis (PD) and renal transplantation. RRT will be necessary when a patent's kidneys can't handle their normal excretory functions.

There is abundant evidence in the literature for the preference of AVF to the other vascular access options. Despite their better long-term patency and complication profiles, AVFs are plagued by a high early failure rate. Early fistula failure is defined as an AVF that never matured to be used for dialysis or that fails within the first three months of use. There are different definitions of fistula maturation in the literature. According to The National Kidney Foundation Dialysis Outcome Quality Initiative (NKF-DOQI) 2019 update on Clinical Practice Guidelines, a mature fistula is on that has a flow rate of at least 600ml/min, outflow vein diameter of 6 mm, vein distance from skin less than 6 mm and cannulation length of at least 6 cm (1).

2.1 Burden of Chronic Kidney Disease

Chronic Kidney Disease (CKD) represents a significant global health issue due to its extensive impact on healthcare systems. Clinically, CKD is defined as persistently abnormal kidney function, measured or estimated by a glomerular filtration rate (GFR) consistently below 60 mL/min/1.73m^2 and this condition should be of more than three months duration (2). It is categorized into five stages based on eGFR, with End-Stage Renal Disease (ESRD) corresponding to Stage 5, where renal replacement therapy becomes necessary. The prevalence of CKD and the number of dialysis patients worldwide have been rising over the past thirty years. CKD is a major contributor to mortality, morbidity, diminished quality of life, and high healthcare expenditures. CKD is also considered to be significantly associated with cardiovascular health. It is estimated that, currently, about 850 million people suffer from CKD globally which is far higher than the number of people with DM or human immunodeficiency virus (HIV) (2). Over 10% of the global population is affected by CKD. The prevalence of CKD is different in different geographical areas which can be explained by differences in the risk factors for CKD like difference in prevalence of HTN, DM, obesity and differences in sociodemographic, geographic, genetic and environmental characteristics. The prevalence of CKD increases with advancing age in both sexes (3).

CKD is caused by different etiologies. Some of the causes include: HTN, DM, chronic pyelonephritis, chronic glomerulonephritis, autoimmune diseases, kidney stones, kidney cysts and prolonged acute renal disease. DM is considered to be the most common cause of CKD in the world; HTN takes the second place (2, 3).

In Africa, CKD is prevalent among adults, with the International Society of Nephrology's Global Kidney Health Atlas reporting a prevalence of 6%, ranging from 5% to 18% (2,4). Sub-Saharan Africa sees an estimated 12-23% of adults affected by CKD, raising concerns about ESRD and the need for renal replacement therapy (4). Data specific to Ethiopia is scarce, but existing hospital-based studies suggest CKD is a significant health concern, primarily driven by diabetes, hypertension, and glomerular diseases (4). One review estimated CKD prevalence among patients with chronic illness at approximately 21.7%. the study also reported that HTN is associated with CKD (5), while other studies indicate rates ranging from 14.3% (6) to 21.3% (7). Research in Addis Ababa found that 78.0% of dialysis patients were aged 20 to 60 years, with men constituting 61.9% of ESRD patients receiving dialysis. Hypertension and diabetes mellitus were identified as the leading risk factors (8). Survival patterns for hemodialysis patients in Ethiopia reveal that 45.1% of deaths occur during treatment, with 23.1% of patients dying within the first 90 days of initiating dialysis, and only 42.1% surviving beyond a year. Causes of reduced survival include septicemia (34.1%), cardiovascular disease (29.3%), and the use of catheters for vascular access (9).

2.2 Renal Replacement Therapy (RRT)

The kidneys are essential for regulating water and electrolytes, excreting metabolic waste, and managing arterial blood pressure, red blood cell production, and vitamin D synthesis. Kidney failure leads to severe, life-threatening complications if not managed through renal replacement therapy (RRT). RRT options include kidney transplantation, hemodialysis (HD), and peritoneal dialysis (PD). Kidney transplantation is the preferred treatment but is not feasible for all patients due to the risks associated with surgery and immunosuppression. Consequently, many patients undergo chronic dialysis, with HD being the most common modality globally (10). The incidence of RRT, including HD and PD, has been increasing annually, with global figures rising from 1.1 million dialysis patients in 2002 to 2.376 million HD patients and 0.289 million PD patients in 2014 (3).

The National Kidney Foundation Dialysis Outcome Quality Initiative (NKF-DOQI) 2019 update on Clinical Practice Guidelines recommend initiating RRT when a patient's weekly renal Kt/V falls below 2 or when symptoms of uremia are present. Non-diabetic patients with an eGFR below 10 mL/min and diabetic patients with an eGFR below 15 mL/min are typically considered for RRT (1).

In Ethiopia, hemodialysis services began in 1980 at Tikur Anbessa Specialized Hospital (TASH). Both hemodialysis and peritoneal dialysis were started with the help of Cuban team of doctors. The first successful maintenance dialysis initiated at a private hospital in 2001 at St. Gabriel Hospital. The first solid organ transplant (kidney transplant) was undertaken in 2015 at St. Paul's Hospital Millennium Medical College (SPHMMC) (11). Between 2015 and 2014, 145 patients received kidney transplant. No transplant has been done since march 2020 (4). Currently, hemodialysis is the only available dialysis modality in Ethiopia, with peritoneal dialysis and kidney transplantation services no more available (4). As of September 2021, Ethiopia had 35 hemodialysis units. Eleven of these units are in government hospitals and the remaining units are found in private hospitals or dedicated dialysis centers. The majority (23 of 35) dialysis units are

found in Addis Ababa. Regional dialysis units are mainly found in university hospitals. A total of 1132 patients were on maintenance hemodialysis which makes the prevalence about ten patients per million population (PMP) (4). The cost of hemodialysis remains exceedingly high for many Ethiopians, with an annual mean cost of approximately $7,739.17 (364,515.10 ETB) (12) (13).

2.3 Hemodialysis Access

Hemodialysis access options include autogenous arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheters (CVC). AVF is created by surgically joining the patient's vein to a nearby artery so that the vein will enlarge and facilitate cannulation during dialysis. AVG, however, uses synthetic material to join the vein to the artery. AVG can be used to join anatomically distant artery and vein unlike autogenous AVF where the artery and vein need to be near to each other (14). AVF is preferred due to its longer patency, fewer complications (fewer thrombotic and infectious complications), and lower cost compared to AVG or CVC. Despite its advantages, primary failure of AVF is a significant issue, often resulting in increased use of CVCs. Shahin et. al. did a systemic review and meta-analysis comparing AVF and AVG and they found out that AVF was associated with significantly higher rate of primary failure but had better primary and assisted primary patency at 1 year, 2 years and 5 years (15). AVFs are usually created in the upper extremity, beginning with the non-dominant hand and beginning as distal as possible to preserve as much vein real state as possible (15). Ideally, patients should start dialysis with a functional AVF, but many begin with CVCs. Studies in Australia, New Zealand, and the USA indicate that a significant proportion of patients initiate dialysis with catheters rather than AVF or AVG (16).

AVGs may be preferrable to AVFs in specific clinical scenarios like when there is paucity of autogenous veins or when a patient has short and fatty extremities. They are also invaluable in patients with increased vascular fragility (like in case of thrombocytopenic purpura) where repeated vein puncture during dialysis may result in bleeding and hematoma formation. AVGs are usually inserted in the upper extremity. There is increased risk of infectious complications when AVGs are used in the lower extremities. There are different configurations of AVG placement. Looped forearm AVGs are said to have better patency rate and need fewer revisions compared to straight grafts. The long-term survival of AVGs is much shorter than AVFs. Thrombosis and infection are the two most common causes of access loss in AVGs (14).

CVCs, while necessary in some cases, are associated with higher risks of infection, increased morbidity, and greater costs. The 2019 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines provide criteria for short-term and long-term CVC use, such as in cases where AVF or AVG is not yet ready or available, or when other conditions necessitate their use (1). CVCs are readily available in most centers, can be inserted in different anatomical areas and since they don't need maturation time, they are ideal for urgent dialysis. Common sites for CVC insertion are internal jugular vein (IJV), femoral vein and subclavian vein. CVCs, however, are prone to complications. Complications include procedure related (arterial injury, pneumothorax, bleeding) and indwelling complications (infection, thrombosis, kinking and blockage) (14). Effective hemodialysis requires suitable access to ensure adequate blood flow, ease of cannulation, cost-

effectiveness, and minimal complications. Although AVF is often ideal, not all patients have suitable veins or achieve successful maturation (14, 15).

A descriptive study at Saint Paul Millennium Medical College (SPMMC) found that 75.7% of patients for whom AVF was created had prior catheter use, with 31.2% had AVF created previously. The majority of procedures involved AVF, with brachiocephalic and brachiobasilic sites being most common. For patients with previous AVF, the causes of failure included infections, limb swelling, and thrombosis (17). Another study found out that AVF was the most common vascular access route used in dialysis patients in Ethiopia (72%). About 16% of patients used temporary catheters, 10% used tunneled hemodialysis catheters and 3% used AVGs (4).

2.4 Risk Factors for early AVF Failure

Maintaining effective vascular access is critical for hemodialysis patients, as access failure is linked to increased mortality, morbidity, and healthcare costs. While AVF is recommended as the first-choice access, it has a higher early failure rate due to factors like immaturity and thrombosis. Clinical factors associated with early AVF failure include diabetes, older age, cardiovascular disease, female sex, obesity, peripheral arterial disease, anemia, and various technical aspects such as vessel size and surgeon experience (14, 18-20)

Diabetes mellitus, female sex, and age are often cited as factors contributing to poor AVF maturation, though their significance may be less when preoperative vessel assessments showed adequate vein diameter. Studies have produced mixed results regarding the impact of these factors on AVF success. Ahmadi et al. noted that diabetes history did not correlate strongly with early AVF failure, while hypertension appeared to be associated with lower odds (21). Both Rezapour et al and Irvinn et al reported that hypertensive patients have significantly lower odds of developing early AVF failure compared to hypertensive patients (22, 23). A meta-analysis on the association of DM with fistula failure done by Yan et al. concluded that diabetic patients have an increased risk of fistula failure (24).

Research by Caplin et al. found no significant differences in size of veins between genders. They also didn't find statistically significant difference in fistula maturation and functionality between the two genders (72% and 77% of AV fistulae in female and males respectively were functional) (25). Multiple studies have underlined the importance of adequate vein size for successful maturation of AVF. On their study on factors associated with Fistula failure, Lauvao, et.al. found out that vein diameter is a major predictor of fistula maturation. They found out that posterior radiocephalic, wrist radiocephalic and brachiocphalic fistulae have 54 %, 66% and 81 % maturation rates, respectively. But after multivariate logistic regression analysis, vein diameter was found to be sole independent predictor of fistula functional maturation(26). Dageforde et al and Morwan Bahi also stated that vein diameter has significant association with early fistula failure. The later also studied the association of arterial size and found out that arterial size > 2 mm is associated with better maturation (27, 28). Yan et al. also concluded that vein diameter (together with pre-operative mean arterial pressure) is an independent predictor of early fistula failure (29).

Surgical technique, site selection, and preoperative ultrasound mapping also influence AVF outcomes. Experienced surgeons tend to achieve lower failure rates, and AVFs created at proximal sites generally show better maturation rates compared to distal sites. Regus et.al found out that surgeon's experience is more important for forearm fistulas than arm fistulas (30). In a study done in United Kingdom (UK), Barnes et al. compared fistula failure rate and complications between senior and junior surgeons. They didn't find any difference in fistula failure and complication rates between senior and junior doctors (31). Preoperative ultrasound mapping can improve AVF success, though its superiority over physical examination alone is debated. In their study on the Impact of a preoperative evaluation on the outcomes of an arteriovenous fistula, Kim et al. concluded that routine use doppler vessel mapping is not necessary if physical examination is satisfactory (32)

Several studies showed that patients already on dialysis at the time of AVF creation have a higher risk of fistula failure. Risk of failure increases especially in patients who have their IJV catheters on the same side of upper extremity where AVF is created (33). Azeem et al compared patency and complications of AVF in pre- and post-dialysis settings and found out that early fistula failure was significantly higher in post-dialysis group compared with pre-dialysis group (34)

The mode of anesthesia used for AVF creation was also found to be associated with patency rates. Aitken, et.al reported that patients operated under brachial plexus block has significantly higher 3 months primary patency rates compared to those operated under local anesthesia (84% vs 62%) (35). A systematic review and meta-Analysis done on regional Vs local anesthesia for AVF also concluded that regional anesthesia is associated with lower AVF failure rates when compared with local anesthesia (36)

The effect of systemic heparinization compared to local use of heparin during AVF creation is also studied. Smith, et.al underwent a systematic review and meta-analysis of systemic intraoperative anticoagulation for AVF creation and concluded that systemic heparin use has increased risk of bleeding complications. They reported improvement in patency in AVF but the significance disappears when AVFs and AVGs are studied together (37).

In conclusion, Early AVF failure remains a significant challenge, with various factors influencing its prevalence. While multiple studies have identified factors affecting AVF maturation, there is substantial inconsistency regarding some of the factors including age, sex and comorbid conditions. Furthermore, there is a severe scarcity of studies done in Ethiopia. Understanding and addressing these factors in local settings is crucial for improving AVF outcomes and overall dialysis care.

3. Objectives

3.1 General objective:

The general objective of this study was to assess the prevalence and factors associated with early AVF failure in patients with ESRD for whom AVF was created at Menelik the second hospital, Addis Ababa, Ethiopia

3.2 Specific Objectives:

1.To determine the demographic and clinical profiles of HD patients

2.To assess the prevalence of early AVF failure.

3.To identify factors associated with early AVF failure.

4. Methods

4.1 Study area and period

The study was conducted at Menelik II referral hospital, Addis Ababa. Menelik II referral hospital is one of the public hospitals where AVF creation is practiced. It's affiliated with Tikur Anbessa Specialized Hospital (TASH) and a vascular surgeon and fellows will have a rotation at Menelik II referral hospital at a regular schedule. Vascular surgery has one allocated operation room per week. Most commonly performed vascular procedures at Menelik II referral hospital include AVF creation, venous procedures like stripping and multiple phlebectomies and carotid body tumor excisions. From operating theatre registry, AVF procedures started being documented on late April, 2022. Data collection, analysis and thesis write-up was done in July 2024. Therefore, the study period is from July 01 up to July 30, 2024.

4.2 Study Design

The study designed used is cross-sectional study to determine prevalence and factors related to early AVF failure in ESRD patients. Both descriptive and analytical components of cross-sectional study were used. Descriptive technique was used to determine frequencies and analytical methods were used to assess associations of different factors with early AVF failure.

4.3 Target Population

ESRD patients who underwent AVF creation for HD access.

4.4 Source and study population

All ESRD patients for whom autogenous AVF was created at Menelik II referral hospital from the start of the service (April 2022) up to March 2024 were included. Recently performed AVFs were not included because it was too early to decide whether the fistula had matured or failed.

4.5 Inclusion criteria

All ESRD patients for whom AVF was created at Menelik II hospital from April 2022 up to March 2024 were included.

4.6 Exclusion criteria

Patients with Incomplete or lost medical records were excluded from study

4.7 Sample Size & Sampling procedure

All the AVF procedures done at Menelik II referral hospital in the aforementioned time were included in the study.

4.8 Study variables

Independent variables

Socio-demographic

- Age
- Sex

Clinical variables

- Comorbidities: HTN, DM
- Pre-operative doppler Ultrasound - vein size
- Dialysis status at the time of AVF creation – not on dialysis or started dialysis

Surgical variables

- Anatomic area of AVF creation
    - Distal radiocephalic

- Proximal radiocephalic
- Brachiocephalic
- Brachiobasilic

Dependent variables (outcome variables)

Fistula maturation

Early fistula failure

AVF complications

- Pseudoaneurysm
- Infection
- Dialysis access–associated steal syndrome (DASS)
- Venous hypertension

Death

Some variables which are thought to be associated with early fistula failure from literature review are removed because either there is no sufficient data (medication, calcium and phosphorous level, peripheral arterial disease) or the variables are constant for all cases (surgical expertise, heparin use and anesthesia)

4.9 Operational definitions

1. **Autogenous Arteriovenous fistula (AVF)** - A surgical connection of an artery and vein, usually, in patient's upper extremity, which allows for easy access for hemodialysis treatments (KDOQI)
2. **AVF primary patency** - A duration of time measuring intra-access patency that starts from the date of AVF creation to the date of one of the following events (whichever one comes first): thrombosis or any intervention to facilitate, maintain, or re-establish patency (e.g. angioplasty). (KDOQI)
3. **Dialysis access–associated steal syndrome (DASS) -** Compromised perfusion and ischemia of tissue after construction of an AV access due to diversion of arterial blood flow into the AV access away from the peripheral system, leading to a range of signs and symptoms. (KDOQI)
4. **Early AVF failure or primary AVF failure** - AVF never maturing to support dialysis or that fails within three months of use (KDOQI). A fistula was considered failed if it is written so in the follow-up notes or if post-op doppler showed thrombosis or a fistula which failed to mature.
5. **End stage renal disease (ESRD)** - The final, permanent stage of chronic kidney disease (CKD), where kidney function has declined to the point that the kidneys can no longer function on their own and patients need renal replacement therapy (RRT). (Filipska et al)
6. **Failure to mature** - An AV access that, despite radiologic or surgical intervention (i.e. endovascular or open procedural management), cannot be used successfully for dialysis by 3 months after its creation (KDOQI)
7. **Functional AVF** - A fistula that was being used successfully for dialysis with dialysis duration of 3-5 hours depending on the centers' protocol
8. **Hemodialysis (HD)** – A procedure to remove fluid and waste products from the blood and to correct electrolyte imbalances using a machine (dialysis machine). HD access may be central catheters, AVF or AVG (KDOQI)
9. **Mature AVF** - A fistula was considered mature if the patient was using it for dialysis successfully (functional AVF) or if the hemodynamic parameters are met from maturation studies (flow rate of at least 600ml/min, vein size of 6 mm and 6mm distance from skin level - KDOQI), or if the fistula was deemed 'mature' on the follow-up notes
10. **Pseudoaneurysm:** A collection of blood outside the vessel (walled off by surrounding tissue), communicating with the fistula or prosthetic graft through a defect (KDOQI).
11. **Renal replacement therapy (RRT)** - Modalities of treatment that are used to replace the waste filtering functions of a normal kidneys. Include renal transplantation, peritoneal dialysis and hemodialysis (GP – 10)
12. **Venous hypertension** – upper extremity edema after AVF creation. It is usually secondary to central vein stenosis or occlusion

4.10 Data collection procedure

Menelik II referral hospital operation theater log book was used to identify AVF procedures done starting from the start of recording (April, 2022) up to March 2024. The medical record numbers listed on the log book were then used to retrieve the medical records of the patients from the medical records storage room. Menelik II referral hospital started using electronic medical record keeping since 2023. Those records were collected from the electronic archive.

The necessary data from the medical records were entered in the prepared questionnaire by the principal investigator. The demographic variables (age, sex) and clinical variables (co-morbidities, dialysis status) were from patient histories and follow-up notes. Pre-AVF doppler ultrasound vessel mapping data were also collected from patient records and entered in to the questionnaire. Operative details like the type of anesthesia, heparin use, side (right or left) and site of fistula (radiocephalic, brachiobasilic or brachiocephalic) were gathered from operation notes. AVF status (mature, failed or complicated) was gleaned from patient follow-up notes in the vascular and renal clinics and post-AVF doppler ultrasound reports. An AVF was deemed mature if it was so labeled in the follow-up notes or if the patient had been using it successfully for dialysis and that is recorded in the follow-up notes or if post-AVF maturation studies showed maturation. A fistula was considered failed if clinical evaluation during follow-up identified failure (absence of trill) or surveillance doppler ultrasound identified thrombosis or a fistula failed to mature even if it's patent.

4.11 Data analysis

The following variables were identified for investigation regarding early AVF failure prior to data collection: age, sex, history of hypertension, history of peripheral vascular disease, history of DM, dialysis status at AVF creation, vein diameter, surgeon experience, type of anesthesia, site of AVF creation (distal forearm, proximal forearm or cubital area) and intra-op heparin use. Data on history of peripheral vascular disease was almost inexistent. Almost all AVFs were done by vascular surgery fellows and all were done under local anesthesia. Only local heparinized saline was used – no record of systemic heparin administration. Therefore, these variables were considered constant and the remaining variables (age, sex, history of HTN and DM, dialysis status, vein diameter and site of AVF creation) were investigated. Continuous variables like age and vein size were changed in to categorical variables to make statistical analysis easier. Statistical analysis was performed using SPSS version 26 (IBM, Armonk, NY, USA).

Descriptive analysis was done initially for frequency assessment of independent variables. Prevalence of failure was also calculated and charted. Bivariate regression was then employed to test association of individual variables with outcome variables. Finally, variables that showed strong association (dialysis status, site of AVF creation and vein size) were included in

multivariate logistic regression. A p-value < 0.05 was considered significant. Chi- square test and adjusted R-squared were used to measure model fitness.

4.12 Ethical Consideration

Ethical clearance was obtained from School of Medicine, Collage of Health Sciences, Addis Ababa University Institutional Review Board. Support letter was also obtained from department of surgery, School of Medicine, Collage of Health Sciences, Addis Ababa University addressed to Menelik II referral hospital. Variables were coded and no name or medical record number was used during data entry.

5. Results

Sociodemographic characteristics

Eighty-nine procedures done from April 2022 up to March 2024 were reviewed for this study. The procedures were done on 79 patients – ten patients had two procedures. Four patient cards from pre-electronic era couldn't be found. The age of study population ranged from 17 years to 76 years. The mean age was 47.7 ± 14.8 years. The majority of patients were within the age group of 30-44 years (36.0%). Around 45% of participants were younger than 45 years. The majority (57.3%) of patients are males. One patient died of sepsis of chest focus: all others were alive at the time of data collection (*Table 1*).

Table 1. Sociodemographic characteristics (n=89)

Characteristics	**Frequency**	**Percent**
Age		
17-29	8	8.9
30-44	32	36
45-59	29	32.6
60-76	20	22.5
Sex		
Male	51	57.3
Female	38	42.7

Clinical profile

Majority of patients have a history of hypertension (61.8%). History of diabetes was found in 42.7% of patients. Almost two-thirds (65.2%) of patients had already started dialysis before AVF creation. Most patients received hemodialysis through central venous catheter (mostly placed in the IJV) opposite to the limb where AVF was created (43 patients - 74% of those on dialysis). Two patients had CVC in the lower extremity (both at right femoral vein) and two patients had their AVF done on the same side of neck CVC. Fourteen patients had previous failed AVF and were having dialysis through CVC eleven of which were on the same side of AVF (*Table 2*). Data regarding the cause of ESRD was sparse. From the reported causes, HTN and DM are the most common. One patient was mentioned to have adult polycystic kidney disease.

Table 2. Clinical profile of the study participants (n=89)

Characteristics	Frequency	Percent
History of hypertension		
Yes	55	61.8
No	34	38.2
History of Diabetes Mellitus		
Yes	38	42.7
No	51	57.3
Dialysis status at the time of AVF creation		
Not on dialysis	31	34.8
On dialysis	58	65.2

Preop doppler vein mapping

All patients had preoperative doppler ultrasound vein mapping. Most patients had veins (veins that are used for the AVF) between 2 and 3 mm in diameter – 42.7% of patients had vein diameter larger than 2.5 mm but less than 3 mm. All arterial sizes were more than 2 mm and no occlusive disease in the arteries nor central venous stenosis or occlusion was reported.

Surgical and procedural characteristics

All AVF creations were done under local anesthesia – regional blocks were given used for secondary procedures like superficialization or transposition of brachiobasilic fistulae. Local heparinization was used in all patients – no report of systemic heparin administration. Most procedures are done by vascular fellows.

The most common fistula type was brachiocephalic (76.4%). Seventy-four AVFs (83.1%) were created in the left upper extremity (*Table 3*).

Table 3. AVF related variables (n=89)

Characteristics	Frequency	Percent
Site of AVF creation		
Brachiocephalic	68	76.4
Brachiobasilic	15	16.9
Distal radiocephalic	6	6.7
Position of the AVF		
Right upper extremity	15	16.9
Left upper extremity	74	83.1
Vein size (mm)		
<2	10	11.2
2-2.5	32	36
2.6-3	38	42.7
>3	9	10.1
Status of fistula		
Mature and functional	58	65.2
Mature with complications	3	3.4
Early failure	28	31.5

Fistula status

Fifty-eight (68.5 %) AVFs were mature. Roughly one in three AVFs had early fistula failure. Three patients had mature fistulae but there were complications (3.4%):

1. One patient had mild (stage 2) Dialysis access-associated steal syndrome. She had mild pain and coldness in the hand during dialysis sessions.
2. One patient had venous hypertension. Swelling of the upper extremity on the side of AVF. Doppler US showed no DVT or central venous occlusion. Computed tomography (CT) venography couldn't be done because of elevated creatinine.
3. One patient had anastomotic Pseudoaneurysm which resulted in ligation of fistula.

Thrombosis was incriminated as the cause of early fistula failure in 18 (64.3%) patients. One patient had fistula failure due to infection. In the rest of the fistula failure cases, there was no documentation of the cause of failure or there was no post-operative doppler ultrasound (US) (Table 4).

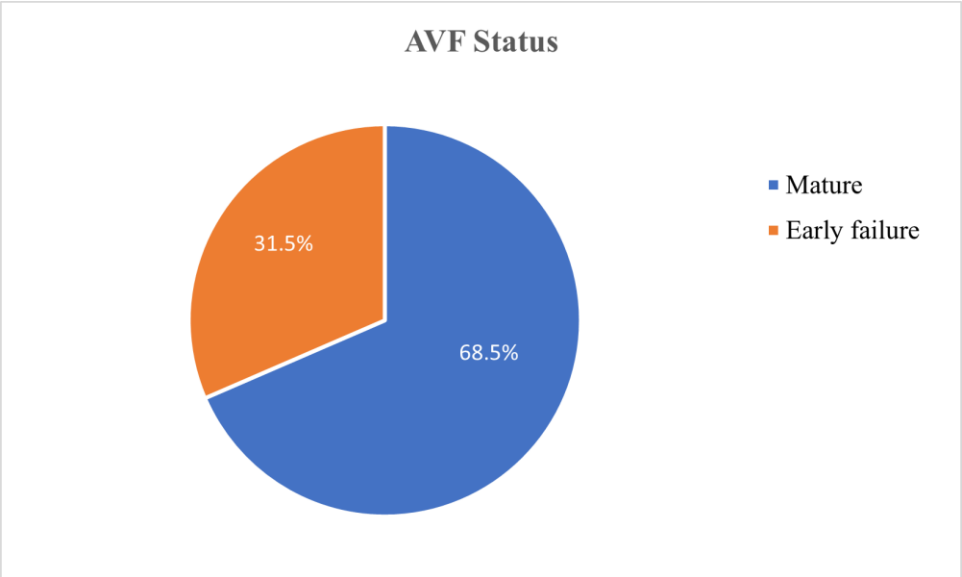

Figure 1. AVF Status

Table 4. Causes of early failure (n=28)

Causes of early failure	Frequency	Percent
Thrombosis	18	64.3
Infection	1	3.6
Unknown	9	32.1

Factors associated with early AVF failure

There was no statistically significant association between age, sex, history of HTN or DM and site of AVF creation and early AVF failure. Brachiobasilic site had significantly lower odds of early fistula failure compared to brachiocephalic fistula but this association faded during multivariate analysis (Table 5). Dialysis status during AVF creation and vein diameter have significant association during multivariate logistic regression. Patients who were on dialysis at the time of AVF creation had 11 times higher odds of experiencing early fistula failure compared to those who were not on dialysis (AOR 11, 95% CI [1.0 - 74.0], p = 0.01).

Table 5. Site of AVF creation

Variable	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for Exp(B)
Site=Brachiobasilic	-1.716	0.824	4.338	1	0.037	0.180	0.036 to 0.904
Site=Distal radiocephalic	0.685	0.962	0.507	1	0.477	1.984	0.301 to 13.075
Dialysis_Status_duringAVFCreation=On dialysis	2.223	0.678	10.737	1	0.001	9.236	2.443 to 34.915
Constant	-2.234	0.619	13.015	1	0.000	0.107	-

Patients with vein diameter between 2.5 and 3mm had 99.8% reduced risk of early fistula failure compared to patients with vein diameter less than 2 mm (AOR 0.002, 95% CI [0.001 - 0.05], p < 0.001). Patients with larger vein diameter than 3mm have also less chance of failure but it doesn't reach statistical significance. (Table 6).

Table 6. Multivariable logistic regression of factors associated with early AVF failure

Characteristics	**COR (95% CI)**	**AOR (95% CI)**	**P-value**
Site of AVF			
Brachiocephalic	1	1	1
Brachiobasilic	0.1 (0.1-1.3)	0.1 (0.2-1.3)	0.08
Distal radiocephalic	0.5 (0.9-2.7)	2 (0.1-21)	0.5
Dialysis status at the time of AVF creation			
Not on dialysis	1	1	1
On dialysis	7 (1.9-26)	11 (1-74)*	**0.01**
Vein size (in mm)			
<2	1	1	1
2-2.5	0.14 (0.02-1.2)	0.1 (0.01 -1.1)	0.6
2.6-3	0.003 (0.001-0.05)	0.002 (0.001-0.05)*	**<0.001**
>3	0.00 (0.000-.)	0 (0.000-.)	0.99

In summary, dialysis status and vein size are found to be critical factors in predicting early fistula failure. Even though site of AVF creation had strong association with early fistula failure, it didn't reach statistical significance. The other studied variables, viz. age, sex, HTN and DM were not found to be significantly associated with early AVF failure.

6. Discussion

This study showed early AVF failure rate of 31.5% and a statistically significant association between dialysis status at the time of AVF creation ($p = 0.01$) and vein size with early AVF failure ($p < 0.001$). no significant association was observed between age, sex, history of HTN, history of DM and site of AVF creatin.

The prevalence of early AVF failure identified in this study is within a range of prevalence reported by other studies. Twenty to sixty percent of AVFs created fail to mature successfully for dialysis use according to studies done previously (1,2, 16-37).

In this study there was no significant association between age, sex, HTN, DM and site of fistula creation with early fistula failure. The association of age, sex, history of hypertension and diabetes with early fistula failure in the literature is inconsistent. Ahmadi, et.al reported that they didn't find association of DM and hypertension and early fistula failure (21). Conversely, Yan, et.al performed a metanalysis on the association of DM and fistula failure and they reported significantly higher risk of fistula failure in diabetic patients (24). Rezapour et al. also found less fistula failure in hypertensive patients (22). Female sex was associated with higher rates of fistula failure in studies conducted by See, YP, et al, Bashar et al and several others (16,18). Caplin, et.al, on the other hand didn't find such association in their study of vein size and fistula functionality between the two genders (25).

Even though it faded during multivariate analysis, AVF created at Brachiobasilic site had significantly lower rate of early AVF failure (OR= 0.18, 95% CI [0.036 - 0.904], $p = 0.037$) compared to brachiocephalic site in this study. Santoro, et. al and Regus et.al, reported that proximal fistulas have lower odds of early fistula failure compared to distal ones. Santoro et.al, also mentioned there is higher risk of steal syndrome in proximal fistulae (14, 30). See, YP et.al didn't identify significant association between location of AVF and early fistula failure. They noted, however, brachiobasilic fistulae have a higher risk of cannulation failure (16).

The two variables with significant association with early AVF failure in this study were dialysis status at the time of fistula creation and vein diameter. Patients who were already on dialysis (all of them through central venous catheters) at the time of fistula creation had an adjusted odds ratio of 11 compared to those who haven't started dialysis ($p = 0.01$). This result is in agreement with existing research highlighting that patients on dialysis at the time of AVF creation are at higher risk of early failure. Azeem et.al studied 'Patency and Complications of Arterio-venous Fistula Created in Pre- and Post-dialysis Settings' and reported that patients in the post-dialysis group had significantly higher odds of having early AVF failure (34). According to Ozpak et.al, fistula failure was more common when the central venous catheter was inserted ipsilateral to the AVF than contralateral catheter (33). Lauvao et al, reported that dialysis status was not significant predictor of fistula failure (26).

Vein diameter was found to have the strongest association with early fistula failure in this study. Patients with vein diameter 2.6 – 3mm had 99.8% lower odds having early fistula failure when

compared to patients with veins with diameter less than 2 mm. Veins with more than 3 mm size also showed better maturation profile than those <2mm. But due to the small number of patients with veins larger than 3 mm (9 patients in this study), the p value doesn't reach statistical significance (P=0.99). The effect of vein size in early fistula failure is well documented in the literature and the results of this study are in line with consensus of the literature albeit the small sample size especially on the fringes of vein size spectrum. The literature is quite consistent on this issue that veins of larger diameter have a better chance of maturation. Lauvao et al asserted that vein diameter was the sole independent predictor of functional fistula maturation (24). Bashar et al, See, YP et al and Abreu et al are all in agreement that vein size is a significant predictor of fistula maturation (16, 18, 20).

Conclusion

In summary, early failure of arteriovenous fistulas is a significant issue affecting patients on hemodialysis. The study's findings highlight critical factors influencing early AVF failure like dialysis status at the time of AVF creation and vein diameter. These results underline the importance of preoperative evaluation and early referral of patients so that they can have their AVF created a head of time before they start HD with CVC. Therefore, individual patient approach and tailoring the ESRD care to the specific anatomic and clinical characteristic of an individual patient could reduce the incidence of early failure and enhance patient outcomes. Future research should continue to explore these factors in larger, more diverse populations to further refine strategies for optimizing AVF success.

Limitations of the study

The study was conducted in a single center and with limited sample size. The homogeneity of some of the variables also made it difficult to assess more variables than the mentioned ones.

Recommendations

Further studies including multiple centers and multiple variables and a larger sample size should be conducted to appropriately assess variables that may have been deemed to be not associated. Case control studies or prospective cohort studies incorporating multiple centers may have a better chance of fleshing out the subtle associations.

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8. Annex I: Informed Consent Form (English version)

Addis Ababa University, College of Health Science, School of Medicine, Department of Surgery, Vascular Surgery Unit

Hello, my name is ——————————————— I am here on behalf of Oumer Ahmed, Vascular and Endovascular Subspecialty Fellow in Addis Ababa University Department of Surgery. He is conducting research on "Prevalence and factors of early arteriovenous fistula failure in end stage renal disease patients: a single center retrospective study". He has received permission from Addis Ababa University College of Health Sciences and Addis Ababa health Bureau. Your participation on this study will only be on based on your willingness. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time.

If you agree to participate in the study, you will be interviewed and your clinical data will be collected from your medical records. You can stop at any time if you don't feel comfortable during an interview or/and data collection process. The data collection and filling the questionnaire will take about 10 minutes.

The information that you provide will be kept confidential by using only code numbers and locking the data. Your name will not be written on the questionnaire. No one will have access to the non-coded data except the principal investigator and the data will not be used for purposes other than the study. Your willingness and active participation are very important for the success of this study.

Based on the understanding of the above information, are you willing to participate in this study?
A) Yes

B) No

If no, reasons of refusal ——————————————————————————————

Respondent Signature _____Date_____

Data collector: Name_____ Signature_____

Date of data collected_____

Checked by Supervisor: Name _____Signature_____

For further explanation, use the Principal Investigator's Address;

Name: Dr. Oumer Ahmed

Email: osinbad@gmail.com

Phone Number: +251920188982

9. Annex II: English Version Questionnaire

Code …….

Part 1. Socio-demographic data

No	Questions	Responses	Remark
101	Age	……. years	
102	Sex	1. Male 2. Female	
103	Handedness	1. Right-handed 2. Left-handed 3. Ambidextrous	

Part II – Clinical data

No	Questions	Responses	Remark
201	Cause of ESRD	1. Diabetic nephropathy 2. Hypertensive kidney disease 3. Chronic Glomerulonephritis 4. Obstructive Uropathy 5. If Others, Specify_____ 7. Unknown	
202	Duration of 1. CKD 2. ESRD	 1……in years/months 2…… in years/months	
203	Current medications	1. Antiplatelets A. Aspirin_____ B. Clopidogrel_____ 3. Statins _____ 4. Anticoagulants A. Warfarin _____ B. Rivaroxaban 5. Antihypertensive A. Calcium channel blockers___ B. ACE inhibitors_____ C. Beta-blockers_____ 6. If Others, specify _____	
204	History of hypertension	1. Yes If yes, duration……. 2.No	
205	History of Peripheral Arterial Disease (PAD)	1.Yes If yes, duration…… 2.No	

206	History of DM	1.Yes If yes, Specify the type & duration_____ 2.No	
207	Dialysis status at the time Of AVF creation	1.Not on dialysis If no, skip questions 208 & 209 2.On central venous catheter (CVC) 3.Failed previous permanent HD access	
208	If you answer '2' for question 207	1. Location A. Ipsilateral internal jugular vein (IJV)- same side of AVF creation B. Ipsilateral subclavian vein C. Contralateral IJV D. contralateral subclavian vein E. Lower extremity 2. Duration …….	
209	If you answer '3' for question 207	1.Site of previous AVF A. Same limb to current AVF I. wrist and snuff box II. distal forearm III. proximal forearm IV. cubital fossa V. Mid arm B. Opposite limb I, II, III, IV, V – Location is like above 2.Cause of failure……. 3. duration of use before failure…… 4. More than one failed AVF A. Which limb/site ---------- (use the list in '1' e.g. A-III) B. Duration of use……. C. cause of failure 5.Failed AVG Mention which limb, site and type……	
210	Pre-op ultrasound vessel mapping	1. Not done 2. Arterial size…….mm	

		3. Arterial stenotic or occlusive disease A. absent B. Present If present, specify…. 4. Vein size…….mm 5. presence of central vein stenosis or occlusion A. Absent B. Present If present, specify……	

Part III – Surgical and procedural data

No	Questions	Responses	Remark
301	Surgical expertise	1. Vascular surgeon 2. Senior vascular Fellow 3. Junior vascular Fellow	
302	Type of anesthesia	1. Local anesthesia 2. Regional anesthesia 3. General anesthesia	
303	Site and type of AVF	1. Upper extremity A. Left B. Right 2. Site A. Posterior radiocephalic – snuff box B. Wrist radiocephalic C. Distal radiocephalic D. Proximal Radiocephalic E. Brachiocephalic F. Brachiobasilic	
304	Intra-op heparin use	1. Systemic Dose…… 2 Local Dose…….	

Part IV – Outcome data

No	Questions	Responses	remark
401	Maturation assessment	1. Physical examination 2. Ultrasound A. Access flow rate…….ml/min B. Outflow vein size……mm C. Vein distance from skin……mm	
402	AVF status	1. Mature 2. Early failure A. failed before being ever used B. failed within 3 months of use 3. Patent but complicated A. pseudoaneurysm B. Infection C. Steal syndrome D. Ischemic monomelic neuropathy (IMN)	
403	Reason for AVF failure	1. Thrombosis 2. Failure to mature – accessory vein, small vein…. 3. Infection 4. Other, specify…… 5. Unknown	
404	Patient status	1. Alive 2. Dead Cause of death……	