PREVALENCE OF PERIPHERAL ARTERIAL DISEASE AND ASSOCIATED RISK FACTORS AMONG OLDER DIABETIC PATIENTS ON FOLLOW UP AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA: A CROSS-SECTIONAL STUDY

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A RESEARCH PROPOSAL TO BE SUBMITTED TO ENDOCRINOLOGY AND METABOLISM UNIT, DEPARTMENT OF INTERNAL MEDICINE, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCE FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SUB SPECIALTY IN ENDOCRINOLOGY AND METABOLISM

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ADDISABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCE, SCHOOL OF MEDICINE,DEPARTMENT OF INTERNAL MEDICINE, ENDOCRINOLOGY AND METABOLISM UNIT

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A CROSS-SECTIONAL STUDY

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2024

ADDIS ABABA, ETHIOPIA

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List of Abbreviations and Acronyms

ABI	Ankle Brachial Index
ACE-I/ARBs	Angiotensin Converting Enzyme inhibitors/Angiotensin Receptor Blockers

BMI	Body Mass Index
CAD	Coronary Artery Disease
CVD	Cardio Vascular Disease
DM	Diabetes Mellitus
ESRD	End Stage Renal Disease
GFR	Estimated glomerular filtration rate
CLTI	Critical limb threatening ischemia
ETB	Ethiopian Birr
HDL	High Density Lipoprotein
GC	Gregorian Calendar
LIPAD	Linz Peripheral Arterial Disease Study
LDL	Low Density Lipoprotein
MI	Myocardial Infarction
NCD	Non-Communicable Disease
NHANES	National Health and Nutrition Examination Survey
PAD	Peripheral Artery Disease
PARTNERS	PAD Awareness, Risk, and Treatment: New Resources for Survival Trial
METs	Metabolic Equivalent of Tasks
TASH	Tikur Anbessa Specialized Hospital
TBI	Toe Brachial Index
TC	Total Cholesterol

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Abstract

Background: The burden of non-communicable disease is increasing in low- and middle-income countries. The global prevalence of diabetes has nearly quadrupled, which equates to an annual increase in diabetes prevalence. Peripheral vascular disease is a major macro-vascular complication of diabetes mellitus (DM). A significant number of older Patients with diabetes tend to have no symptoms from PAD putting them at higher risk for diabetic foot ulcer, lower limb amputation. Despite having a targeted screening protocol in the world, Ethiopian diabetic patients are not being assessed unless they develop a complication.

Objective: The aim of this study is to assess the magnitude of peripheral artery diseases using ABI among older diabetes mellitus patients in Tikur Anbessa Specialized Hospital, Ethiopia.

Method: A cross- sectional study done from June 1 to August 31, 2024 GC was employed among 208 diabetes patients age 50 years and above having follow up at Tikur Anbessa Specialized Hospital, endocrine clinic. PAD was diagnosed by an ankle brachial pressure index (ABPI) of </=0.9 on either leg. After the data was collected the completeness and consistency was checked and entered to SPSS version 23 cleaning and analysis. Both binary and multivariable logistic regression analyses were performed to identify risk factors for PAD. The strength of the association of risk factors with PAD was checked using the adjusted odds ratio (AOR) with a 95% confidence interval (CI).

Results: In this study, a total of 208 diabetics were participated and nearly half 110 (51.4%) were females. The mean age of participants was 62.5 ±7.8 years. The prevalence of PAD was 33.7% with 95 % CI. (27.4, 39.9). It was found to be 31.3% and 2.4% for mild and moderate stenosis respectively and 6.7% signifying the presence of poorly compressible arterial calcification or inconclusive (>1.3) results. Age 70 years (AOR: 3.29, 95% CI: 1.56, 6.96), ≥10 years with diabetes (AOR: 1.95, 95% CI, 1.01, 3.79), and Diabetic neuropathy (AOR: 2.90, 95%CI: 1.48,

5.69) were significantly associated with PAD. Sensitivity and Specificity of ABI was 80% and 87% respectively in the moderate and severe PAD patients.

Conclusion and recommendations:

The prevalence of PAD was high. Patients' age, diabetes duration and diabetic neuropathy were significantly associated with PAD. Health professionals better to screen peripheral arterial disease among DM patients, particularly emphasis needed on those having longer duration of diabetes, diabetic neuropathy and elder age particularly starting at age 50 years. ABI demonstrates high sensitivity and specificity especially in the moderate and severe PAD patients. The potential of this simple, cheap, and noninvasive test must be fully utilized especially in recourse constrained countries where, cross-sectional imaging modalities, are not widely available

Key words: Peripheral arterial disease, DM patients, TASH.

1. Introduction

1.1 Background:

Diabetes is a chronic metabolic disease with long-term complications that is characterized by persistently elevated blood glucose levels (1). Worldwide, the prevalence of diabetes has increased within the past few decades. An estimated 537 million individuals worldwide (24 million in the Africa Region) have diabetes in 2021; by 2030, that figure is expected to rise to 643 million, and by 2045, it is predicted to reach 783 million. The greatest increase will occur in areas where economies are transitioning from low- to middle-income status, primarily as a result of these countries' growing populations (3). Furthermore, it is projected that 541 million individuals would have reduced glucose tolerance by 2021. Additionally, it is predicted that in 2021, diabetes-related diseases will claim the lives of almost 6.7 million persons aged 20 to 79 (2). The primary cause of death worldwide is non-communicable diseases (NCD), which include diabetes, cancer, cardiovascular disease (CVD), and chronic respiratory disorders The 2015 National NCDs STEPS survey revealed that 3.2% of Ethiopians had diabetes (5). Around 1.9 million people are estimated to have diabetes as of 2021, according to the IDF (3). According to a 2022 IDF estimate, 19,998 people in Ethiopia have type 1 diabetes (4). The emerging pandemic of obesity is a central factor contributing to the maladaptive elements of insulin resistance, hypertension, dyslipidemia, and chronic inflammation central to the vascular complications (5).

Vascular disease is the most significant cause of morbidity and mortality in people with diabetes. Macro-vascular complications such as CAD, PAD, and CVD, although responsible for the

majority of deaths in patients with diabetes, have a modest relationship to glycaemia (13). Peripheral vascular disease is a major macro-vascular complication of diabetes mellitus. Peripheral artery disease (PAD) is defined as atherosclerotic occlusive disease of lower extremities. PAD is associated with increased risk of lower extremity amputation and is also a marker for atherothrombosis in cardiovascular, cerebrovascular and renovascular beds. Patients with PAD therefore have an increased risk of MI, stroke and death (9). Additionally, PAD causes significant long-term disability in diabetic patients. Because of the unique involvement of distal pattern of vessels and invariable association with neuropathy, peripheral arterial disease in diabetics presents late, having already developed limb threatening ischemia (11). PAD can be clinically identified by intermittent claudication and/or absence of peripheral pulsations in the lower extremities (10). Some degree of PAD can also be present despite palpable dorsalis pedis or posterior tibialis arteries. With the use of Doppler technology and ankle brachial pressure index (ABI) measurement, peripheral artery disease can be identified non-invasively before clinical manifestations. Diabetes is an important risk factor for the development and severity of all forms of atherosclerosis, including peripheral artery disease (PAD), coronary artery disease (CAD), and cerebrovascular disease (CVD). Diabetes also increases the risk of ischemic stroke two to threefold and accounts for 60% of non-traumatic lower limb amputations (7,16).

The vascular evaluation of patients with diabetes is a challenge for providers and requires additional evaluation for a comprehensive assessment, particularly regarding the evaluation of neuropathy, thorough foot examination, and noninvasive physiologic testing (33). Early detection and regular ultrasound check-ups can increase the number of surgical or endovascular interventions, thus reducing the rate of amputations (24).

The examination should focus on inspection of the extremities and feet for signs of skin change, hair loss, ulceration, or increased dryness. Full sensory and motor exam should then be performed with the addition of monofilament testing plus vibration sensation (using 128-Hz tuning fork), pinprick sensation, or ankle reflexes (33).

The presence of neuropathy is an important risk multiplier not seen with other risk factors. Diabetic peripheral neuropathy is characterized by a symmetric sensorimotor distal polyneuropathy (34). Burning, tingling, and shooting pains are frequently described and are typically worse at night (35). Of note, the degree of pain and subjective symptoms are not reliable indicators of sensory

nerve damage. Careful peripheral neurologic examination is recommended annually in patients with diabetes (33).

A study done in Croatia revealed that asymptomatic stage of the disease was found in 12.6%, intermittent claudication in 38.9%, chronic critical ischemia in 25.7%, and foot ulcer or gangrene in 22.8% of patients (24). Intermittent claudication was found to be insensitive in the detection of peripheral arterial disease (1).

The American Podiatric Medical Association and the Society for Vascular Surgery recommend that patients with diabetes have ankle brachial index (ABI) measurements performed when they reach 50 years of age. Furthermore, patients with a prior history of diabetic foot ulcer, known atherosclerotic cardiovascular disease, prior abnormal vascular examination, or prior intervention for PAD should have a clinical examination of the lower extremities and noninvasive physiologic testing (ABI and/or toe pressures) annually (8).

Screening for PAD by measuring the ABI, which is the ratio of the tibial systolic artery pressure to brachial systolic artery pressure is preferred to clinical inspection of lower limbs and palpation of the feet pulses. ABI measurement is a non-invasive procedure performed using a Doppler ultrasound useful for diagnosis of PAD, for surveillance, for screening purposes in research studies, and may be used as a marker of the risk of atherosclerosis and of future CV events. The sensitivity and specificity for diagnosing PAD with ABI at rest is reported to be 69 - 89% and 69 - 99%, respectively (49,50,51) with an acceptable intertester and intratester reliability on average of 10%. Some researchers report 95% sensitivity and 100% specificity for diagnosing PAD compared to the gold standard angiography (3). Meaning the sensitivity of ABI for the diagnosis of PAD with >50% stenosis was 95%, and its specificity was 100% (40). An ABI of less than and equal to 0.9 is diagnostic of PAD.

Given its low cost and ease of measurement, ABI deserves further assessment as a screening tool for both PAD and long-term cardiovascular risk amongst diabetics in Africa (22). Also, ABI is the standard for the diagnosis of PAD in clinical treatment or epidemiologic studies and represents a useful resource for the salvage of the lower limb, wound healing and survival prediction of patients (39).

However, one important diagnostic consideration is the increased likelihood of non-compressible pedal vessels and subsequent falsely elevated ABI results in patients with diabetes. Arteries of

the elderly, patients with diabetes or kidney disease may be severely calcified and less compressible leading to falsely high ABI values (1.4). The normal range is between 0.9 and 1.1 while values greater than or equal to 1.3 signify non compressible or calcified peripheral arteries (52). Besides the aforementioned factors, lower limb oedema and wounds may lead to a poor sensitivity and therefore inconclusive results. Additional non-invasive methods can be used in cases of inconclusive results from ABI to confirm or reject the diagnosis of PAD.TBI measurements can be used (The digital arteries are less often affected by incompressibility) which is calculated from the quotient of the systolic toe pressure and brachial pressures. An index of lower than 0.7 is considered to be abnormal. Absolute pressures of lower than 30 mmHg are diagnostic of severe ischemia. Other non-invasive methods that use either segmental pressure characteristics, leading to a more detailed overview about the location of the arterial stenosis or occlusion, or they are able to assess skin perfusion, albeit some methods are especially related to revascularization procedures (e.g., skin perfusion pressure, transcutaneous oxygen measurement (tcpO2, laser Doppler flowmetry, indocyanine green fluorescence angiography) Can be used if ABI and TBI are inconclusive.

Different cutoff values to diagnose PAD have been used, but an index </= 0.9 is the most common and consensual threshold and has been issued by available guidelines. The mode of ABI calculation will greatly affect the estimation of PAD prevalence. When examining bilaterally, by using the lowest ankle pressure, the PAD prevalence will be higher and this will increase the sensitivity for identification of high-risk patients but also lower the specificity and include cases with early disease. More subjects at risk will be identified using the lower ankle blood pressure for ABI calculation and hence should be preferred for risk stratification

1.2. **Statement of the Problem**

The burden of non-communicable diseases (NCD) is increasing, accounting for nearly half the total global burden of disease. Almost 50 percent of the adult disease burden in low- and middle-income countries is now attributable to non-communicable diseases (17). Non-communicable disease is the number one world's killer, causing 60% of all deaths globally (12) and a staggering 35 million people die every year from these silent killers.

In Africa, one in twenty-two (24 million) adults has diabetes. By 2045, there will be 55 million diabetics In Africa, a 129% rise the largest increase of any IDF Region (2). Cardiorenal complications are the primary cause of premature morbidity and mortality in the Africa (AFR) area, where the prevalence of diabetes mellitus is rising (20). The incidence and prevalence of diabetes have increased in Ethiopia too (4).

IN the US, the prevalence rate of PAD is highest for American Indians/Alaska Natives (15.9%), followed by non-Hispanic blacks (13.2%) and Hispanics (12.8%), and lowest for Asian Americans (9%) and non-Hispanic whites (7.6%). An estimated 10 million Americans are affected by PAD, and more than 80,000 are hospitalized each year for the condition (4,5).

The prevalence of PAD varies significantly based on the age of the population studied, from 0.9% in patients between 40 and 49 years old to 14.5% in patients older than 69 years in the National Health and Nutrition Examination Survey (NHANES) (6).

In developing countries, especially in Ethiopia the magnitude of PAD in DM in not known. But PAD accounts for 35.9% of the total vascular surgical diseases that are seen at vascular surgery referral clinic with in a one-year period of 2016/2017(2).

1.3. **Significance of the study**

The findings from this study will provide very important data regarding the use of ABI for earlier screening, identification and diagnosis of PAD among diabetic patients who are 50 years and older. This study will also help narrow the information gap of using the ABI as a screening tool and its performance accuracy when compared to Doppler ultrasound in the diagnosis of PAD.

The results of the study will help develop a module and guideline for people with diabetes locally and in similar low- and middle-income countries regarding performing ABI for earlier screening, identification and diagnosis of PAD among diabetic patients who are 50 years and older.

The findings will be helpful in developing a strategy to address information gaps ranging from hospital level to big community settings, regarding early screening of diabetic patients who are 50 years and older for PAD using ABI for possible early intervention and prevention of complications.

1.4. **Rationale of the Study**

The prevalence and/or magnitude of peripheral arterial disease (PAD) in patients with Diabetes Mellitus is relatively well defined for the Caucasian population. In patients with diabetes the prevalence of PAD may be as high as 40% (8). The risk of PAD is also known to be higher in African Americans and Hispanic Americans with diabetes (7). But when we come to the developing countries especially Ethiopian its magnitude is yet not known despite the higher incidence, morbidity and mortality of the illness.

So, this study will assess the magnitude of PAD in Diabetic patients 50 years and older and will identify a benefit of screening those populations with ABI to help in early diagnosis of PAD and reducing its adverse clinical, economic and human costs of Diabetes Mellitus and its complications particularly PAD. There is a no data regarding PAD and its associated factors in patients with diabetes in Ethiopia and Africa.

1.5 Literature review

Peripheral arterial disease (PAD) is a condition characterized by atherosclerotic occlusive disease of the lower extremities. While PAD is a major risk factor for lower-extremity amputation, it is also accompanied by a high likelihood for symptomatic cardiovascular and cerebrovascular disease. Although much is known regarding PAD in the general population, the assessment and management of PAD in those with diabetes is less clear and poses some special issues. At present, there are no established guidelines regarding the care of patients with both diabetes and PAD.

1.5.1 Epidemiology and Impact of Peripheral Arterial Disease in People with Diabetes

PAD is a manifestation of atherosclerosis characterized by atherosclerotic occlusive disease of the lower extremities and is a marker for atherothrombotic disease in other vascular beds. PAD affects_12 million people in the U.S.; it is uncertain how many of those have diabetes. Data from the Framingham Heart Study (1) revealed that 20% of symptomatic patients with PAD had diabetes, but this probably greatly underestimates the prevalence, given that many more people with PAD are asymptomatic rather than symptomatic. As well, it has been reported that of those with PAD, over one-half are asymptomatic or have atypical symptoms, about one-third have claudication, and the remainder have more severe forms of the disease (2).

The most common symptom of PAD is intermittent claudication, defined as pain, cramping, or aching in the calves, thighs, or buttocks that appears reproducibly with walking exercise and is relieved by rest. More extreme presentations of PAD include rest pain, tissue loss, or gangrene; these limb-threatening manifestations of PAD are collectively termed critical limb ischemia (CLI). PAD is also a major risk factor for lower-extremity amputation, especially in patients with diabetes. Moreover, even for the asymptomatic patient, PAD is a marker for systemic vascular disease involving coronary, cerebral, and renal vessels, leading to an elevated risk of events, such as myocardial infarction (MI), stroke, and death.

1.5.2. Prevalence of Peripheral Artery Disease

The true prevalence of PAD in people with diabetes has been difficult to determine, as most patients are asymptomatic, many do not report their symptoms, screening modalities have not been uniformly agreed upon, and pain perception may be blunted by the presence of peripheral neuropathy. For these reasons, a patient with diabetes and PAD may be more likely to present with an ischemic ulcer or gangrene than a patient without diabetes. While amputation has been used by some as a measure for PAD prevalence, medical care and local indications for amputation versus revascularization of the patient with critical limb ischemia widely vary. The nationwide age-adjusted amputation rate in diabetes is 8/1,000 patient years with a prevalence of 3%. However, regional patterns differ there is nearly a nine-fold variation of major amputations in people with diabetes across the U.S. Therefore, the incidence and prevalence of amputation may be an imprecise measure of PAD.

The reported prevalence of PAD is also affected by the methods by which the diagnosis is sought. Two commonly used tests are the absence of peripheral pulses and the presence of claudication. Both, however, suffer from insensitivity. A more accurate estimation of the prevalence of PAD in diabetes should rely upon a validated and reproducible test. Such a test is the ankle-brachial index (ABI), which involves measuring the systolic blood pressures in the ankles (dorsalis pedis and posterior tibial arteries) and arms (brachial artery) using a hand-held Doppler and then calculating a ratio.

The prevalence of PAD also varies significantly based on the age of the population studied, from 0.9% in patients between 40 and 49 years old to 14.5% in patients older than 69 years in the National Health and Nutrition Examination Survey (NHANES) (6). An estimated 10 million Americans are affected by PAD, and more than 80,000 are hospitalized each year for the condition (5,14). Targeted screening can more clearly identify a population at risk.

In the PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) trial, nearly 7000 subjects were screened in primary care practices, provided they met one of the following criteria: Age 70 years or older or ages 50 to 69 years with a history of diabetes and/or smoking (23). Using these criteria, 29% of subjects were found to have PAD.

Peripheral arterial disease is common among Ethiopians aged 40 years and above. But, none of the participants with peripheral arterial disease fulfilled the criteria for claudication (1). The overall prevalence of peripheral arterial disease was 10.8%.

1.5.3 Factors associated with PAD:

Diseases related Factors

In patients with diabetes, risk of PAD is increased by duration of diabetes, and presence of peripheral neuropathy. . Peripheral vascular insufficiency was a significant finding in patients having diabetes for an average of 9.8 years, even in the presence of controlled HbA1c (36).In a study which was done in Srilanka showed that history of diabetes mellitus more than 10 years, history of dyslipidemia for more than 10 years, history of hypertension for more than 10 years and smoking, elevated HsCRP and hyperhomocysteinemia were as country specific significant risk factor of PAD (38). Diabetes significantly increases both the incidence and severity of limb ischemia because of several associated factors (25). Insulin resistance is independently associated with PAD, after adjustment for demographic factors and medical co morbidities (26). The distribution of PAD is different in patients with diabetes compared with those without it. Patients with diabetes and PAD tend to have involvement of the more distal arteries, particularly the popliteal and tibial arteries, making limb-salvage revascularization more challenging (7,27). The dorsalis pedis was the commonest site of involvement (36).

Neuropathy that often develops in people with diabetes presents several additional challenges. First, sensory neuropathy reduces the ability to avoid injury by decreasing normal sensation and

withdrawal to pain. In addition, symptoms common to advanced ischemic disease may be less appreciated and may lead to delay in diagnosis (27).

Diabetic peripheral neuropathy also leads to limited joint mobility (due to motor neuropathy), decreased proprioception and pain sensation (due to sensory neuropathy), and decreased sweating (due to autonomic neuropathy). The motor neuropathy fosters the formation of a swan neck foot deformity, resulting in disproportionate increases in pressure points to the metatarsal heads and other parts of the foot, making ulceration more likely (28,29).

As a result, diabetes is the most common cause of non-traumatic lower extremity amputation in the United States, accounting for 55% of amputation-related hospitalizations (30). For people 65 to 74 years old, the risk of amputation is increased more than 20-fold compared with those without PAD and diabetes (31). So, in patients with peripheral arterial disease, diabetic patients have worse arterial disease and a poorer outcome than non-diabetic patients (42). Prevalence of PAD using ABI was 22.0% and 8.0% among diabetic and non-diabetic populations, respectively as stated in Nigerian study (21).

The combination of PAD and diabetes is of additional clinical importance given its association with cardiovascular events. Patients with both diabetes and PAD are at extremely high risk of adverse cardiovascular events. In the Linz Peripheral Arterial Disease (LIPAD) study, the mortality rate from cardiovascular disease over a 10-year period was 5% for people with diabetes, 14% for those with PAD, and 31% for patients with both (32). The mortality for patients with diabetes and PAD who require a lower extremity amputation is 50% at 2 years (8).

Socio-demographic factors

PAD was more prevalent in males and age>40 years and higher with increasing age (37). Female sex was predictor of PAD in Ethiopian population. PAD tends to affect individuals with lower socio-economic status to a greater extent as well as inhabitants of low-income countries compared with high income countries The large prevalence increase between 2000 and 2010 was substantially more pronounced in low-income countries, where two thirds (72.9%, 173 million) of patients with PAD were located. Pande et al. showed a twofold increased risk of PAD among patients with a low income compared with those with a high income. Similar associations have

been reported between PAD and low educational levels. The risk of PAD is also known to be higher in African Americans and Hispanic Americans with diabetes (7). Selvin et al. reported increased crude odds for PAD among individuals of African American ethnicity (OR 2.83, 95% CI 1.48 e 5.42). After adjustment for relevant risk factors, the OR for PAD prevalence in the African American population was still 1.47 (95% CI 1.07 e 2.02), compared with a Caucasian population. Socio-economic factors may prevent access to healthcare and thus timely diagnosis of lower limb PAD, which in turn may lead to later clinical presentation at more severe disease stages.

Behavioral related factors:

Smoking of tobacco is an important risk factor for development and progression of PAD and is associated with an increased need for revascularization, increased risk of CLTI, and amputation (48)

Sedentary behavior (SB) and physical inactivity has been identified as an independent risk factor for cardiovascular diseases (CVDs) including PAD. Mechanistically, sedentary behavior links to the development and worsening of PAD(53)

1.6 Conceptual framework

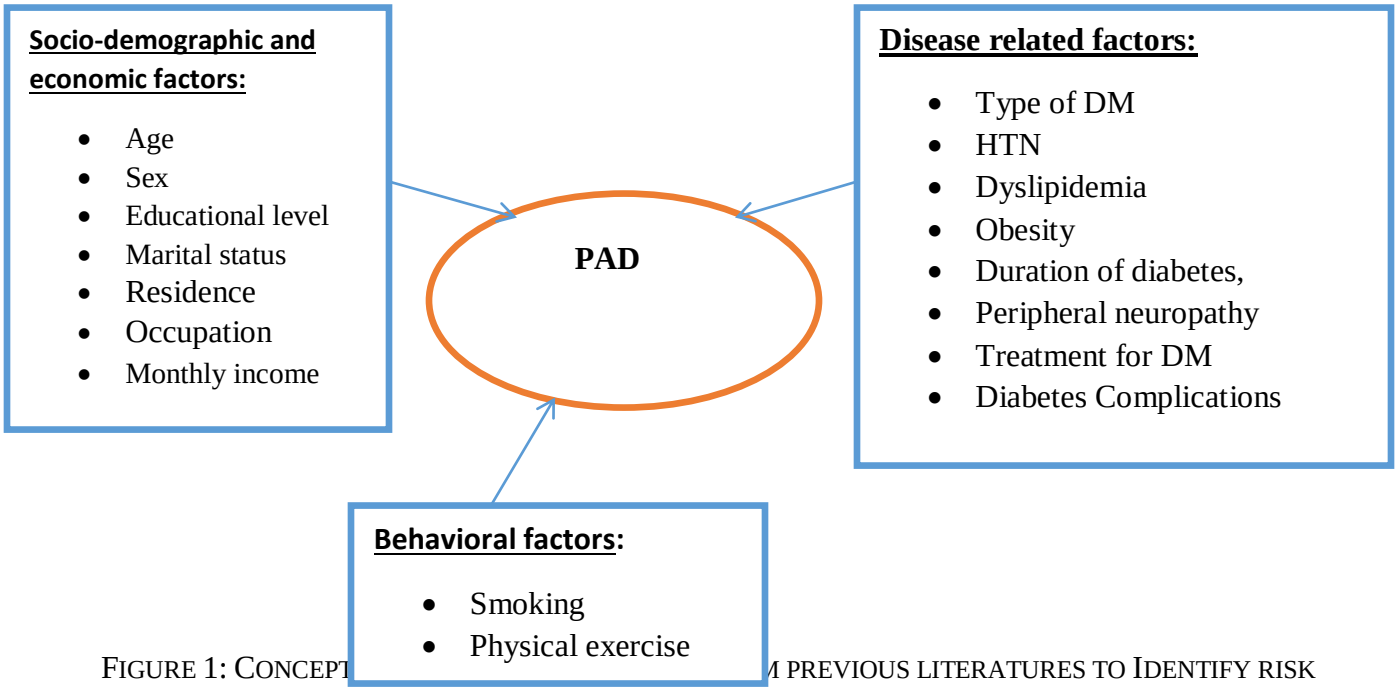

FIGURE 1: CONCEPT[illegible] PREVIOUS LITERATURES TO IDENTIFY RISK FACTORS OF PAD IN TASH, 2024

2. Objectives

2.1 General Objective

To assess the prevalence of peripheral artery diseases and associated factors using ABI among older diabetes mellitus patients in Tikur Anbessa Specialized Hospital, 2024

2.2 Specific Objective

- To determine the prevalence of peripheral artery diseases using ABI among older diabetes mellitus patients in Tikur Anbessa Specialized Hospital
- To identify factors associated with peripheral artery diseases using ABI among older diabetes mellitus patients in Tikur Anbessa Specialized Hospital
- To compare the effectiveness of ABI compared to Doppler ultrasound evaluation in the diagnosis of PAD in older Diabetic patients

3. Methods and materials:

3.1 Study Setting and period:

The study will be conducted from June 1 to August 31, 2023GC at Tikur Anbessa Specialized Hospital. The hospital is found in the capital Addis Ababa, is the largest referral hospital in Ethiopia where specialized clinical services are rendered to the whole nation. The hospital provides sub-specialist level care for patients with diabetes at the diabetes referral clinic. The hospital employs an electronic medical record keeping system where clinical data and laboratory profiles of patients are stored and retrieved when needed. The study will be carried out in the diabetes referral clinic of this hospital.

3.2 Study Design:

A cross-sectional study design was conducted

3.3 Source and study population:

The source of population comprises all patients diagnosed with diabetes mellitus and age ≥50 years having follow-up in Tikur Anbessa Specialized Hospital. The study of population comprises all patients diagnosed with diabetes mellitus and age ≥50 years who visit the diabetes clinics of Tikur Anbessa Specialized Hospital from June 1 to August 31, 2023GC, for follow up.

3.4 Eligibility Criteria:

Inclusion Criteria

- All patients with diabetes mellitus and age ≥50 years who had at least one prior visit to the respective diabetes clinic.

Exclusion Criteria

- Incomplete medical records.
- Seriously ill for interview.

3.5 Sample size determination

The least sample size (n) required for the study was calculated using the formula to estimate a single population proportion.

$$n = \frac{Z_{\frac{\alpha}{2}}^{2} P (1 - P)}{d^{2}}$$

Where;

n = required sample size

$Z_{\alpha/2}$ = critical value for normal distribution at 95% confidence interval= 1.96 ($\alpha = 0.05$).

P = Proportion = 30.7 taken from similar study Debre Tabor (47)

d = margin of error= 2%

$$n = \frac{(1.96)^2 * (0.307)(.693)}{(0.02)^2} = 204$$

Taking 5% non-response rate, the total sample size will be **224**.

3.6 Study Variables

Dependent/Outcome Variables

Peripheral Artery Disease

Independent Variables: Socio-demographic and economic factors (age**,** sex**,** educational level**,** marital status**,** residence**,** occupation, monthly income), disease related factors (type of DM**,** HTN**,** Dyslipidemia**,** Obesity**,** Duration of diabetes, Peripheral neuropathy**,** Treatment and Diabetes Complications) and behavioral related factors (physical activity and smoking).

3.7. Data Collection tool and Procedure:

Data was collected between June 1 to August 31 / 2024 through self-administered and interviewer-guided structured questionnaire. Three-day training was given for data collectors (Clinic Physicians) about ABI measurement. Doppler U/S was done by radiologists in the hospital. Information was gathered by using structured questionnaires detailing socio-demographic (age, sex, residence, marital status and occupation and income), clinical data and ABI measurement by using hand-held Doppler and Doppler U/S from system documentation. Data on clinical and laboratory profiles of the participants was obtained through review of electronic medical records or patient charts. The questionnaire was prepared in English and translated to Amharic. Finally, it was translated back to English to check its consistency. Data was collected by trained nurses.

3.8 Data Quality Management

To ensure the quality of data, before data collection, a three-day onsite theoretical and practical training was given for the data collectors on ABI measurement and measurement of variables, so as to ensure consistency and reduce intra- and inter-observation difference on the measurement of variables. The collected data was checked for completeness and consistency on each day of data collection. Supervision and monitoring were made every day by the assigned supervisors and principal investigator. The questionnaire was prepared in English to keep the consistency of the questions. During data collection the principal investigator was supervise all activities during the data collection. Data completeness and consistency was checked on spot questionnaires with missed variables were turned back to the data collectors for correction by revisit. Measuring equipment was tested regularly during data collection.

3.9 Data management and Analysis:

After the data collected, the completeness and consistency of the questionnaire was checked. Then the variables will be coded. After this, SPSS version 23 will be used to enter, clean and analyze the collected data. For continuous data by the mean ± standard deviation was computed and categorical variable presented with frequency and percentages. The Chi-squared test was used, after checking its assumption. Both bivariable and multivariable binary logistic regression analyses

were performed to identify risk factors for PAD. Variables in bivariable analysis with P < 0:3 were entered into multivariable logistic regression. In multivariable logistic regression, variables with P ≤ 0:05 were declared statistically significant. Goodness of fit of the statistical model was checked by the Hosmer-Lemeshow test (P = 0.87). The strength of the association of risk factors with PAD was demonstrated by computing the crude odds ratio (COR) and the adjusted odds ratio (AOR) with a 95% confidence interval (CI)

3.10 Operational definition:

- PAD was defined as Grade III (50% to 99% stenosis) or IV stenosis (100% stenosis) by color Doppler ultrasonography.
- The ankle-brachial index (ABI) is the ratio of the ankle and the brachial systolic blood pressure and is used to assess individuals with PAD. An ankle-brachial index </= 0.90 suggests the presence of PAD and is a marker of cardiovascular risk (46)
- Intermittent claudication (IC) is defined as exertional leg pain that does not begin at rest and involves the calf, thigh and or buttock causing the patient to reduce their walking speed or stop walking and resolves within 10 minutes of rest.

3.11. Ethical Considerations

The study will be done in conformity with ethical guidelines. The purposes and importance of the study will be explained and informed written consent will be obtained from each study participant. Confidentiality will be maintained at all levels of the study. All results will be communicated to the treating physicians. All study participants will be informed that participation in this study will have neither incentives nor direct benefits. Participants who are unwilling to participate in the study and those who wish to quit their participation at any stage will be informed to do so without any restriction. The project will be evaluated by the Department of Internal Medicine IRB and ethical clearance will be obtained.

4. Results

4.1: Socio-demographic Characteristics of study participants:

In this study, a total of 208 diabetics were participated and nearly half 110 (51.4%) were females. The mean age of participants was 62.5 ±7.8 years and the majority age (78.8%) were 50-69 years old. More than half (57.7%) were diagnosed as diabetics during age of 41-59 years. Almost all 198(95.2%) of the participants were urban residents and nearly one-third (65.9%) were married (**Table 1**):

TABLE 1: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS, IN TASH, 2024

Variable		Frequency	Percent
Age	50-59	71	34.1
	60-69	93	44.7
	70-79	38	18.3
	>=80	6	2.9
Gender	Male	101	48.6
	Female	107	51.4
Residence	Urban	198	95.2
	Rural	10	4.8
Marital Status	Single	21	10.1
	Married	137	65.9
	Divorced	16	7.7
	Widowed	34	16.3
Educational status	No formal education	23	11.1
	Primary school	53	25.5
	Secondary school	59	28.4
	Higher education	73	35.1
Occupation	Government	23	11.1
	Private	35	16.8
	House wife	71	34.1
	Retired	63	30.3
	Others*	16	7.7
Age during diagnosis	≤30	14	6.7
	31-40	40	19.2
	41-59	120	57.7
	≥60	34	16.3

4.2: Behavioral-related factors:

Nearly half, 103(49.5%) reported as performed regular moderate intensity level of physical activity, 16.8% had sedentary behavior. The majority 177(85.1%) did not have history of smoking and only 1.9% were active smokers. (**Table 2**).

TABLE 2: BEHAVIORAL CHARACTERISTICS OF STUDY PARTICIPANTS IN TASH, 2024

Variable		Frequency	Percent
Level of physical activity	High intensity	38	18.3
	Moderate intensity	103	49.5
	Low intensity	32	15.4
	Sedentary	35	16.8
Smoking status	Never smoked	177	85.1
	Former smoker	27	13.0
	active smoker	4	1.9

4.3: Treatment related characteristics:

In this study nearly three-fourth (76.4%) and nearly 2/3- (63%) were taking Metformin and Insulin respectively. The type of insulin they took were NPH only, NPH with prandial insulin, Glargine with prandial insulin and pre-mixed insulin (Mixtard) in 42.3%, 16.8%, 1.4% and 2.4% respectively. The mean total daily dose of insulin was 50.89±29.64 with 10 and 158 as a minimum and a maximum dose respectively. Nearly half (49.5%) were taking statins (**Table: 3**)

TABLE 3: MEDICAL TREATMENT RELATED CHARACTERISTICS OF THE STUDY PARTICIPANTS, IN TASH, 2024

Variable		Frequency	Percent
SGLT2 inhibitor	Yes	21	10.1
	No	187	89.9
Metformin	Yes	159	76.4
	No	49	23.6
Sulfonylurea	Yes	5	2.4
	No	203	97.6
Insulin	Yes	131	63.0
	No	77	37.0
Type of Insulin	NPH only	88	42.3

	NPH with prandial insulin	35	16.8
	Glargine with prandial insulin	3	1.4
	Pre-mixed insulin (Mixtard)	5	2.4
Range of insulin dose	10-20	3	1.4
	21-40	19	9.1
	41-70	27	13.0
	71-100	44	21.2
	>100	31	14.9
Duration of Insulin treatment	< 1 year	12	5.8
	1-3 years	19	9.1
	4-5 years	15	7.2
	6-10 years	27	13.0
	> 10 years	39	18.8
Aspirin	Yes	64	30.8
	No	144	69.2
Statins	Yes	103	49.5
	No	105	50.5
ACE-i or ARBs	Yes	63	30.3
	No	145	69.7
Diuretics	Yes	25	12.0
	No	183	88.0
Calcium channel blockers	Yes	34	16.3
	No	174	83.7
Beta blockers	Yes	4	1.9
	No	204	98.1

4.4 Biochemical and diseases related characteristics:

Almost all 206 (99%) of the study participants had type 2 diabetes mellitus. The mean Hemoglobin A1C was 8.50±2.389 and fifty-seven (27.4%) had ≤7% of HgA1C and hundred ten (52.9%) had poor glycemic control >7% HgA1C.21 Nearly half 99(47.6%) of participants had 130-250mg/dl fasting blood sugar.26(12.4%) of participants had a GFR of <60/ml/min/1.73m2, and4(1.9%) had ESRD. Lipid profiles of the participants were as follows, TC >200 in 30(14.1%), LDL>/=70 in 90(43.3%), TG >150 in 46(22.1%), HDL in 108(51.9%). Microproteinuria occurred in 44(22.1%) and Macroproteinuria occurred in 25(12%) of the participants on the 24-hr. urinary protein measurement. One hundred-seven (70.7%) participants have hypertension and 82(39.4%) of them had uncontrolled blood pressure. Nearly half 100 (48.1%) of the participants had history of dyslipidemia.75(35.9%), 61(29,2%) of participants were overweight and obese respectively.

5(2.4%) participants were morbidly obese. Only one third 71(34.1%) of participants were symptomatic and pedal pulses were palpable in the majority of the participants and only 17(8,2%) were having non palpable or reduced pedal pulses. Participants developed different diabetic related complications. Microvascular complication occurs in 81.7%, in which 31.3%, 20.2%, 30.3% of participants had diabetic neuropathy, diabetic retinopathy, diabetic kidney disease respectively. Macrovascular complication occurs in 25% of participants, of whom, 17.8%. 5.3% and 1.9% had HF, MI and Stroke respectively. 41.7% of participants had hypoglycemia (**Table 4)**

TABLE 4: DISEASES AND LABORATORY FINDING RELATED CHARACTERISTICS OF THE STUDY PARTICIPANTS, IN TASH, 2024

Variable		Frequency	Percent
Type of diabetes	Type 2	206	99
	Type 1	2	1
Hemoglobin A1C %	≤7	57	27.4
	7-9	44	21.2
	>9	66	31.7
	Missing	41	19.7
Fasting blood sugar	70-130	79	37.9
	130-250	99	47.6
	>250	11	5.3
	Missing	19	9.1
24-hour urinary protein	</+150	59	28.4
	150-500	44	21.2
	500-999	17	8.2
	≥1000	8	3.8
	Missing	80	38.5
Total cholesterol	≤200	136	65.4
	>201	30	14.4
	Missing	42	20.2
LDL	<70	90	43.3
	>/=70	90	43.3
	Missing	28	13.5
TG	<150	125	60.1
	150-299	34	16.3
	≥300	12	5.8
	Missing	37	17.8
HDL	<50	108	51.9
	50-60	54	26.0
	>60	12	5.8
	Missing	34	16.3

Estimated Glomerular Filtration rate	>90	108	51.9
	60-90	37	17.8
	<60	26	12.4
	Missing	37	17.8
Intermittent claudication	Yes	71	34.1
	No	137	65.9
Dorsalis Pedis pulse	Palpable	191	91.8
	Not palpable	17	8.2
History of hypertension	Yes	147	70.7
	No	61	29.3
Blood pressure control	Controlled	114	54.8
	Uncontrolled	82	39.4
	Missing	12	5.8
History of dyslipidemia	Yes	100	48.1
	No	108	51.9
Obesity or metabolic syndrome	Yes	98	47.1
	No	110	52.9
History of Diabetic Neuropathy	Yes	65	31.3
	No	143	68.7
History of Diabetic Retinopathy	Yes	42	20.2
	No	166	79.8
History of glaucoma or cataract	None	182	87.5
	Cataract	17	8.2
	Glaucoma	9	4.3
History of diabetic kidney disease	Yes	63	30.3
	No	145	69.7
History of known PAD	Yes	5	2.4
	No	203	97.6
History of stroke	Yes	4	1.9
	No	204	98.1
CAD history	Yes	11	5.3
	No	197	94.7
Heart failure history	Yes	37	17.8
	No	171	82.2
Recent Hypoglycemia	Level 1	52	25.0
	Level 2	31	14.9
	Level 3	3	1.4
	No hypoglycemia history	122	58.7

4.5 Prevalence of PAD and Degree of Stenosis:

PAD was diagnosed by an ankle brachial pressure index of </=0.9 on either leg. The peripheral arterial disease was found to be 31.3% and 2.4% for mild and moderate stenosis respectively using

the lowest ankle pressure. But using the highest ankle pressure for calculating the ABI, it was found to be 8.2%, 1% and 0.5% for mild, moderate, and sever stenosis respectively. About 13.9% and 6.7% signifying the presence of poorly compressible calcified arteries or inconclusive (>1.3) using the highest and the lowest ankle pressures respectively, which is also a common finding in older diabetic patients (**figure 2**):

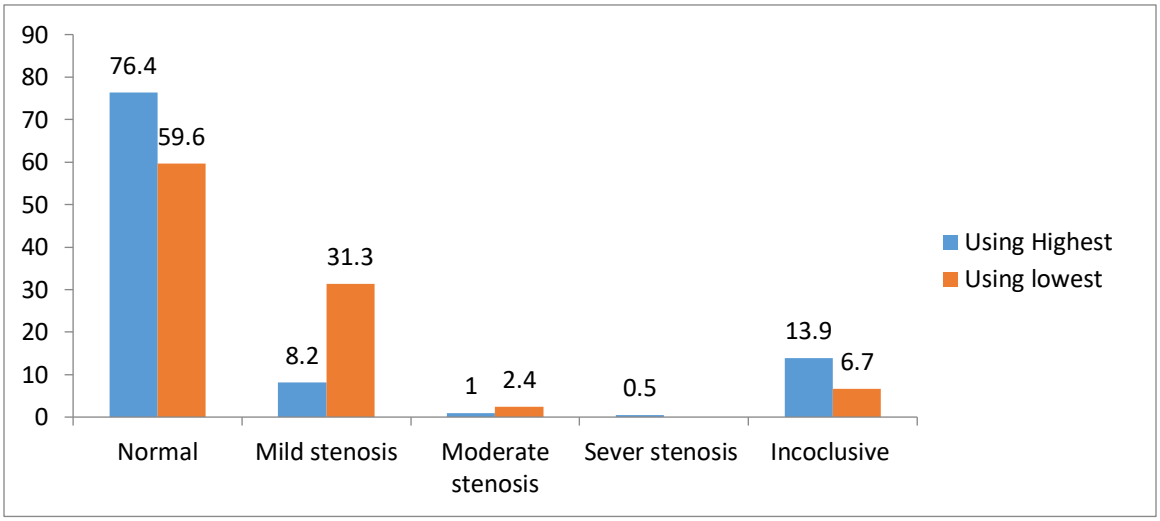

FIGURE 2: SCHEMATIC PRESENTATION TO PAD USING ABI (USING THE HIGHEST AND LOWEST ANKLE PRESSURE) MEASUREMENTS, IN TASH, 2024.

In addition to ABI, Doppler Ultrasound findings were computed to diagnose peripheral arterial disease. About 25%, 13.8%, and 8.6% had only atherosclerotic wall change, Wall change with mild stenosis, and wall change with moderate to severe stenosis respectively. Overall, the prevalence of PAD using Doppler ultra sound was 22.4% (**figure 3**).

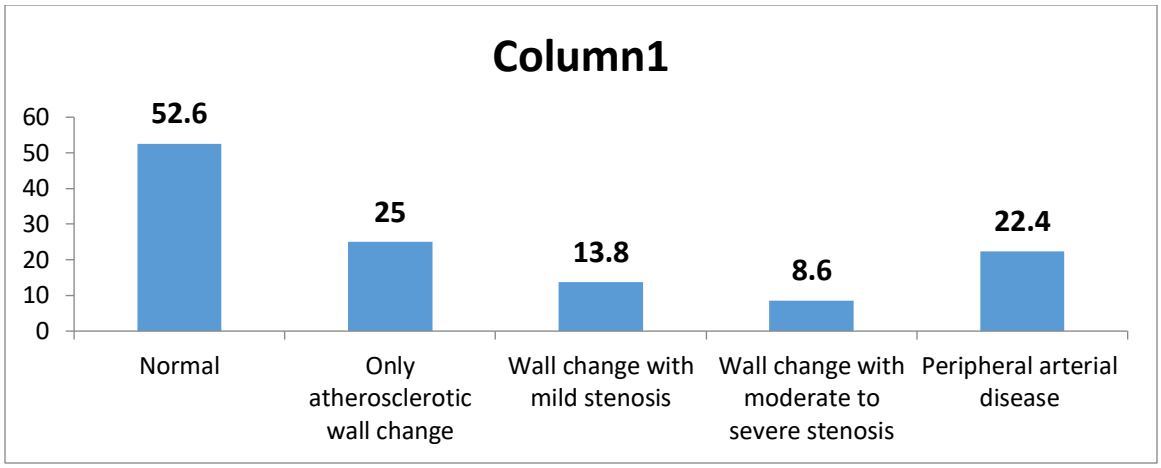

Figure 3: The Doppler Ultrasound findings study participants among DM patients in TASH, 2024.

The prevalence of PAD was 33.7% with 95 % CI. (27.4, 39.9). Its' prevalence was relatively high for men (17.7%) than women (15.8%) using ABI. But its' prevalence was relatively low (22.4%) using Doppler U/S. (**Figure: 4**).

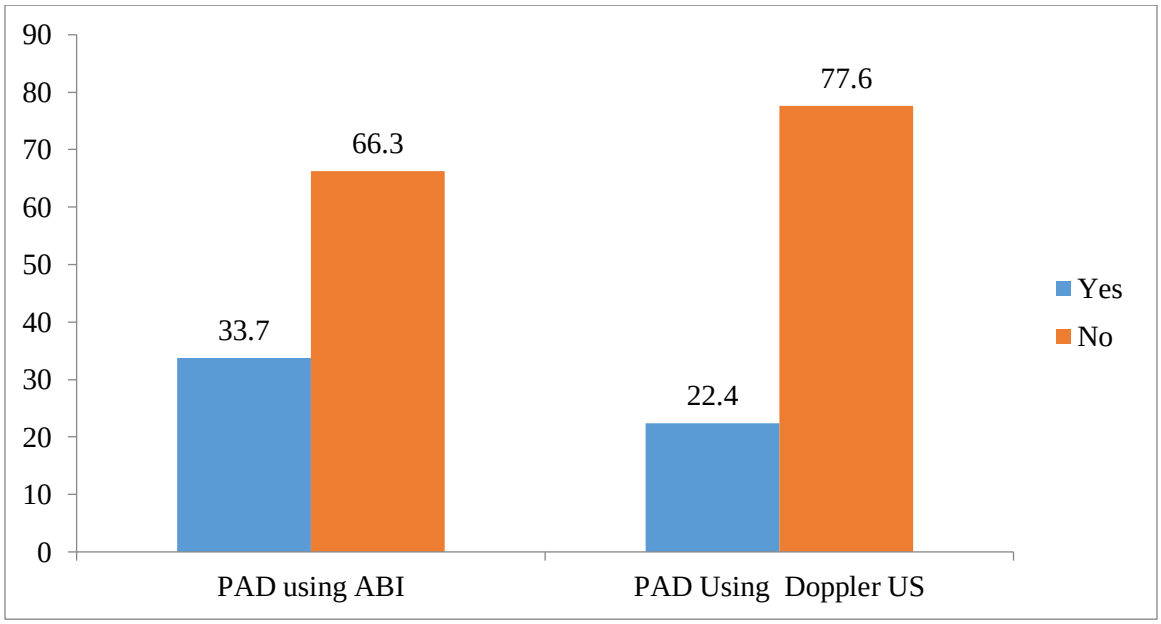

FIGURE 4 : COMPARISON OF PAD USING ABI AND DOPPLER ULTRA-SOUND AMONG DIABETES PATIENTS IN TASH, 2024

ABI * Doppler ultrasound Crosstabulation

Count

		Doppler ultrasound				
		Nomal	Only atherosclerotic wall changes	Wall changes with Mild stenosis/narrowing	Wall changes with moderate to severe stenosis/narrowing	Total
ABI	normal	54	25	10	2	91
	mild stenosis	2	2	3	3	10
	moderate stenosis	1	0	0	1	2
	severe stenosis	0	0	0	1	1
	inconclusive	5	2	3	3	13
Total		62	29	16	10	117

Mild stenosis

Sensitivity	38%
Specificity	87%
PPV	33%
NPV	89%

Sensitivity	80%
Specificity	87%
PPV	40%
NPV	98%

Moderate to severe stenosis

In our study dense calcifications with ABI >1.3 were excluded from final analysis while calculating sensitivity and specificity of ABI. Of the 54 limbs diagnosed as PAD on DUS, only 26 were categorized as PAD by ABI, yielding a sensitivity of 54%. Out of the 91 limbs classified as normal on DUS, 81 limbs were correctly categorized as normal based on ABI yielding a specificity of 87%. The overall sensitivity and specificity of ABI compared to doppler ultrasound is 54% and 87% respectively. In the present study, out of the 65 patients who had an ABI range of 0.9–0.7, 41 (64%) were completely asymptomatic with no clinical or examination findings of PAD. The ABI value <0.40 showed 98% agreement with DUS, ABI of 0.40-0.69 showed 87% agreement and ABI of 0.70–0.90 also showed 87% agreement. ABPI of >0.9 (negative for PAD) showed 60% agreement with DUS. Overall agreement was 78.1% (κ =0.65; good agreement)

4.6 Factors Associated with PAD:

In the bivariable analysis, gender, age, diabetes duration, smoking history, SGLT2I taking, neuropathy, hypertension, dyslipidemia and BMI were candidate variables for multivariable analysis. However, only age, diabetes duration and diabetic neuropathy were statistically significant factors of PAD. Participants with age 70 years old or more were more than triple (AOR: 3.29, 95% CI: 1.56, 6.96) more likely risk for PAD compared with those 50-69 years old. Similarly, Patients having 10 years or more after diagnosis of DM had nearly double burden (AOR:1.95, 95% CI, 1.01, 3.79) to develop PAD compared with patients having less than 10 years diabetes duration. The odds of developing PAD were nearly three times (AOR: 2.90, 95%CI: 1.48, 5.69) higher for patients having diabetic neuropathy compared with the counterparts **(Table 5).**

TABLE 5: FACTORS ASSOCIATED WITH PAD STUDY PARTICIPANTS AMONG DM PATIENTS IN TASH, 2024

Variable		PAD		COR (95%CI)	AOR (95% C.I)	P
		No	Yes			
Gender	Male	64	37	1.29 (.72, 2.30)	1.12(.54, 2.34)	.753
	Female	74	33	1	1	
Age in year	50-69	118	44	1	1	
	≥70	20	26	3.48 (1.77, 6.86)	3.29(1.56,6.96)	.002
DM duration in	<10	68	22	1	1	
year	≥10	70	48	2.11 (1.15, 3.88)	1.95(1.01, 3.79)	.048

Smoking	No	120	57	1	1	
history	Yes	18	13	1.52 (.69, 3.31)	1.1(.43, 2.78)	.841
SGLT2I taking	Yes	10	11	.41(.16,1.04)	2.55(.93, 6.98)	.068
	No	128	59	1	1	
Neuropathy	Yes	30	34	.29 (.15,.54)	2.90(1.48, 5.69)	.002
	No	108	36		1	
Hypertension	Yes	97	50	.94(.50,1.78)	.68 (.32, 1.47)	.336
	No	41	20	1	1	
Dyslipidemia	Yes	65	35	.89(.50, 1.58)	1.17(.59, 2.30)	.639
	No	73	35	1	1	
BMI in Kg/m^2	<30	99	47	1	1	
	≥30	38	23	1.27 (.68, 2.37)	1.54 (.72, 3.29)	.256

5. Discussion:

The prevalence of PAD was 33.7% with 95 % CI. (27.4, 39.9) using ABI. For this study we took the finding using the lowest ankle pressure to calculate ABI for discussion due to its' higher prevalence in agreement with the European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Asymptomatic Lower Limb Peripheral Arterial Disease and Intermittent Claudication. The severity of PAD was (31.3%) and (2.4%) for mild and moderate stenosis respectively. This implies the nearly one-third of older diabetes patients develop Peripheral arterial disease. This finding was in line with previous studies conducted in Debre Tabor Hospital (30.7%) (47) South India (36%) (37), and United states (29%) (23). But our finding was higher than the previous literatures done Jimma (10.8%), and Nigeria (22%) (21). This

could be explained by the differences in the characteristics of study population. In Jimma, community-based survey was done among general population with age above 40 years and ABI was calculated using the higher values of ankle and brachial systolic blood pressure measurements. Our study was conducted in a clinical setting with DM patients older than 50 years may have contributed to this higher prevalence. In Nigeria ABI was measured using LifeDop handheld Doppler with 8 Hz probe which might result this difference. The prevalence of PAD found in this study was quite high compared to some other studies. This could be attributable to the fact that the majority of diabetes patients in our setting present late, often with complications when the progression of PAD had probably gone unchecked. It should be noted that tight control of blood glucose leads to delay in and sometime prevention of some long-term complications like atherosclerosis and nerve damage and should be attended to by physicians.

This high prevalence is a result of hyperglycemia, dyslipidemia, and insulin resistance, secondary to DM, which all induce development and progression atherosclerosis by disrupting the vessel wall through promotion of vascular inflammation and endothelial cell dysfunction, derangements of various cell types like platelets within the vascular wall, promotion of coagulation, and inhibition of fibrinolysis (44). However, our finding was lower than studies conducted in south west Nigeria (52.5%) and India (40%). This discrepancy could be explained by the variation in the socioeconomic factors, lifestyle, and duration of diabetes of study participants.

In the current study, age, diabetes duration and diabetic neuropathy were significantly associated with PAD. Elderly participants with age 70 years old or more had more than triple risk for PAD compared with those 50-69 years old. This finding is in-agreement with similar studies in Debre Tabor (47), Srilanka (38), United States (23), and India (40). This could be due to the fact that thickening of the intima due to aging compromises endothelium integrity and decreases the availability of nitric oxide, a known vasodilator. Stiffening of the arterial walls disturbs the normal blood flow that makes it easier for calcium and fatty deposits to build upon the inside of arteries which leads to further fatty build-up and narrowing of the vessel resulting in PAD (45).

Patients having longer duration with DM had nearly double to develop PAD compared with the counterparts. Our finding is consistent with previous study findings in Srilanka (38) and India (41). This could be due to the fact that as duration of diabetes increased, vascular complications can be aggravated including PAD. Thus, it is noted that screening programs of PAD should be perform

regularly for diabetic patients. Similarly, the odds of developing PAD were nearly three times higher for patients having diabetic neuropathy compared with the counterparts. This is consistent with previous studies (28, 29). The presence of peripheral neuropathy might increase the risk of foot complications like Diabetic foot ulcer. Therefore, early detection is important to take preventive measures.

The prevalence of PAD was relatively low (22.4%) using Doppler U/S. The results of the present study demonstrate the reliability of ABI as a diagnostic tool in the evaluation of patients suspected of having PAD. ABI demonstrated a good sensitivity and specificity especially in the moderate and severe PAD patients. However, owing to a relatively low sensitivity in the mild PAD, ABI could potentially miss some patients of PAD when used as a screening test. So, this calls for caution in the mild PAD patients where if the clinical suspicion of PAD is high a second confirmatory test like DUS should be undertaken. However, when a patient is labelled as PAD on ABI it is almost certain that he will have PAD on DUS and also ABI has a higher NPV for the presence of severe stenosis. As per the updated guidelines of National Institute for Health and Care Excellence the diagnosis of PAD should not be ruled out solely based on a normal ABI especially in diabetic population who are at a higher risk of vascular calcification and may have spuriously high ankle pressures [58]. However, the findings of the present study do not necessarily conform to this view especially in moderate-severe PAD where ABI has a good sensitivity. Our findings corroborate other data which has reported a reasonably high accuracy of ABI in the diagnosis of PAD, Alnaeb et al. 2007 [57] demonstrated the accuracy of ABI in diabetic patients and reported a high sensitivity of 80% and specificity of 93% compared to Doppler. Another study by Ugwu et al. 2021 [54] in diabetic people recorded a high diagnostic accuracy of over 90% for ABI.

Strength and limitations

This study had limitations that should be considered. Since the study participants were taken only from a single diabetes center, the findings may not represent that of the general diabetes population. Additionally, since some records of the participants were incomplete, we are unable to check association of some biochemical profiles with PAD. However, it is the first study in the study area which can be baseline for future studies.

Conclusion:

The prevalence of PAD was high. Prevalence of PAD was higher using ABI compared with Doppler Ultrasound. The ABI has a high sensitivity and specificity for PAD diagnosis. Patients' age, diabetes duration and diabetic neuropathy were significantly associated with PAD.

Recommendations:

Health professionals better to screen peripheral arterial disease using ABI among DM patients, particularly emphasis needed on those having longer duration of diabetes, diabetic neuropathy and older patients starting at age 50 years for the early detection and secondary prevention of this complex chronic condition before any disease related adverse events occurs.

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Annexes

Annex 1: Information sheet

I, the undersigned, want to do a study on the prevalence of PAD and its associated factors among older patients with diabetes mellitus. The high risk of this patient group and unknown magnitude of this problem in our setup gave rise to the research concern. The clinical data will be collected using a structured questionnaire.

I agree to accept responsibilities for:

- The scientific, ethical and technical conduct of the research project,

- Requesting amendment for ANY change on the protocol that might need to happen during execution of the project, and obtain written approval for the request from Department of Internal Medicine-IRB,
- Submitting scientific publications that emanate from the project, and
- Reporting any unprecedented protocol violation within seven days of event ifthe project is approved as a result of this application.

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Email: abdisameherete@gmail.com
Signature: …….
Date of Submission: May 7, 2024
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Email: abdurezakahmed1977@gmail.com
Signature: …….
Date: …….
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College of Health Sciences, Addis Ababa University,
Phone: +251 115 510 653
Email: imed.som@aau.edu.et
Addis Ababa, Ethiopia.

Annex 2: Informed consent form

You are invited to take part in this research because you are over 50 years old and living with diabetes. There will be 306 individuals taking part in this research. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read through the following information carefully and feel free to ask if it is not clear or to discuss it with anyone you wish. Please take time to decide whether or not you want to take part in this research. We would like to stress that taking part in this study is entirely voluntary, you can refuse

to take part in this study or you can withdraw your participation from the study at any time without any consequences to you.

The research will be conducted from June 1 to August 31, 2023GC. Data will be collected through structured questionnaires.

If you decide to take part in this study, you will be asked to complete the questionnaire administered at your respective clinic. your weight, height, Ankle Brachial Index will be measured and Doppler U/S of your lower extremities will be done. You will also be interviewed about socio-demographic status and base line clinical data. You can stop at any time if you don't feel comfortable during an interview and measurement process. The measurement and filling the questionnaire will take about 15 minutes.

All data collected from the study will be kept confidential. Presentations of the study's results at meetings/conferences or their publication in a scientific journal will not include your name.

There will be no payment for participation in this study.

If you have any questions related to the study before/during participation in the study, you can consult the contact person listed below.

1. Abdissa Meherete(MD, Internist, Endocrinology Fellow)

   Phone: +251 913557186

   Email: abdisameherategmail.com

Certificate of Consent	

I have read the foregoing information. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily consent to participate in this research study. _____ Initials of the participant _____ Signature of the participant Date _____ day/month/year	I confirm that the participant was given an opportunity to ask questions about the study and all the questions have been answered correctly. I confirm that consent has been given voluntarily. _____ Printed name of the person taking the consent _____ Signature of the person taking the consent Date _____ day/month/year

አባሪ 2፡በመረጃየተደገፈየፈቃድ ቅጽ

ከ 50 አመት በላይ የሆናችሁ እና የስኪር ህመም ጋር የሚኖሩ ስለሆኑበዚህ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል።በዚህ ጥናት ውስጥ 306 ግለሰቦች ይሳተፋሉ:: ከመወሰንዎ በፊት ጥናቱ ለምን እንደሚደረግ እና ምን እንደሚያካትት መረዳት ለእርስዎ አስፈላጊ ነው።እባክዎ የሚከተለውን መረጃ በጥንቃቄ ያንብቡ እና ግልጽ ካልሆነ ለመጠየቅ ወይም ከሚፈልጉት ሰው ጋር ለመወያየት ነፃነት ይሰማዎ።በዚህ ጥናት ውስጥ ለመሳተፍም ወይም ላለመሳተፍ ም መወሰን ጊዜ ይውሰዱ።በዚህ ጥናት ውስጥ መሳተፍ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ መሆኑን ልናሳስብ

እንወዳለን፣ በዚህ ጥናት ላይ አለመሳተፍም ትችላላችሁ ወይም በማንኛውም ጊዜ ተሳትፎዎን ከጥናቱ ማንሳት ይችላሉ ።ይህ በእናንተ ላይ የሚያመጣው ምንም አይነት ችግር አይኖርም$

›ÆGý¿#¬ú »ð p>ú የስኳር በሽታ ያለባቸው ታካሚዎች የእግር ደም ስT መጥበብ ወይም መዘጋ|>ü**ሞ**R#¬ú Á…?@$ ይህም ከጤናማ ሰዎች ጋር ሲነፃፀሩ በ6 እጥፍ ከፍ ያለ የ›ÐT aY>| ›ÐT FfOÕ ›«Äü/úH o>þ? ¡ð@ ¿>ú ÃHYU… (>HX>þ o@q o»ú?>ü| o™«Ñ@) FÕop#¬ú« >üÓaH Á…?@$ በኢትዮጵያ በአፍሪካ እና በሌሎች ዝቅተኛ እና መካከለኛ ገቢ ባላቸው አገሮች ውስጥ የስኳር በሽታ ላለባቸው ታካሚዎች የÃH YT FÕoq ¬ÁH F±Ï| እና ተያያዥ ምክንያቶች ላይ የመረጃ እጥረት አለ እነዚህ ምልከታዎች እና የዚህ ችግር መጠን ያልታወቀ መሆኑ በእኛ መዋቅር ውስጥ እነዚህን የምርምር ጥያቄዎችን አስነስቷል።

የዚህ ጥናት ዓላማዎች ›ÆGý¿#¬ú »ð p>úየስኳርበሽታባለባቸውታካሚዎችላይየÃH YT FÕoq ¬ÁH F±Ï| እናተያያዥምክንያቶችንለGÕና|እንዲሁም ™þoü™Á owp>¬ú FXT¿ Á; …ÐT F»Wx« ™Y`ÆI >G¬` ¿>¬ú« Ó`Gýz >FFTFT Œ¬ú$

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Annex 3: Questionnaire on the Magnitude of PAD and its associated factors among older patients with diabetes mellitus

Code _____

I-care number _____ Date of interview _____/2023

Section 1: Demographics

1. Age? _____years
2. Gender?
    a. Male
    b. Female
3. Residence?

a. Urban
b. Rural

4. Current marital status?
    a. Single
    b. Married
    c. Divorced
    d. Widowed
5. What is your level of education?
    a. No formal education
    b. Primary school
    c. Secondary school
    d. Higher education
6. What is the occupation you practiced, over the past 12 months?
    a. Government employee
    b. Self-employed
    c. Housewife
    d. Farmer
    e. Pensioner
    f. Unemployed
7. What is your average household monthly income? _____Birr

Section 2: Diabetes History

8. How long have you had diabetes? ____ years
9. How old were you when you were diagnosed with diabetes? _____years
10. What type of treatment are you currently taking for your diabetes? Choose all that apply.
    a. Insulin (_____years)10
    b. SGLT2i (_____years)
    c. Metformin
    d. Sulfonylureas
    e. DPP4 inhibiters
    f. GLP1 RA
    g. Other, specify _____
11. Which type of insulin do you use?
    a. NPH only
    b. NPH with Regular insulin
    c. Glargine insulin with Regular insulin
    d. Mixed insulin
    e. Other, specify_____
12. What is your total daily dose of insulin? _____IU

Section 3: Physical Examination & Laboratory Results

13. Weight _____Kg
14. Height _____cm
15. BMI _____kg/m^2
16. SBP _____mmHg
17. DBP _____mmHg

18. Recent hemoglobin A1C _____%
19. Recent FBS_____mg/dl
20. Total serum cholesterol _____mg/dl
21. Serum HDL cholesterol _____mg/dl
22. Serum LDL cholesterol _____mg/dl
23. Serum triglycerides _____mg/dl
24. Serum creatinine _____mg/dl
25. 24-hour urine protein excretion _____mg
26. ABI
27. Doppler ultrasound

Section 4: PAD Risk Factors

28. Physical activity level
    a. Vigorous (75 minutes a week eg. running)
    b. Moderate (150 minutes a week eg. Walking at a fast pace)
    c. How much time do you spend sitting on a usual day? (home, work, transportation) _____hours
29. Smoking status?
    d. Never
    e. Ex-smoker. Smoked _____ cigarettes daily, for _____years
    f. Currentsmoker. Smoke _____ cigarettes daily, for _____years
30. Self-reported history of medical conditions (ever), Choose all that apply.
    a. Hypertension
    b. Dyslipidemia
    c. Obesity
    d. None of the above
31. Current medications (Use of medication within the past year), Choose all that apply.
    a. Asprin
    b. Metformine
    c. Sulfonylurias
    d. DPP4 inhibitirs
    e. GLP1 RA
    f. SGLT2 inhibitors
    g. Statins
    h. Rivaroxaban
    i. ACEI/ARBs
    j. diuretics

Section 5: Acute & Chronic Diabetes Complications

32. Any neuropathy?
    a. Yes, review chart _____
    b. No
33. If no previous assessment, do Monofilament test – assess 10 sites/foot & if no response at 4 sites Positive)
    a. Positive
    b. Negative

34. Any visual impairment?
    a. Yes
    b. No
35. Any diabetic eye complications?
    a. Yes, specify 1. Diabetic retinopathy 2. Cataracts 3. Glaucoma
    b. No
36. Any nephropathy?
    a. Yes, review chart _____
    b. No
37. Any PAD?
    a. Yes, review chart _____
    b. No
38. Any Coronary Heart Disease?
    a. Yes, review chart _____
    b. No
39. Any Cerebrovascular Disease?
    a. Yes, review chart _____
    b. No
40. Any recent hypoglycemia?
    a. Level 1 (mild)- between 54 – 69mg/dl or shaking, sweating, rapid heartbeat, increased hunger
    b. Level 2 (moderate)- less than 54mg/dl or confusion, irritability, sleepiness
    c. Level 3 (severe)- loss of consciousness, seizure, coma or requiring help from others
41. ABI----------
42. US----------

Thank you for your time.

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10. □□? (□□□□□□□□□□□□□□□)
    1. □□□□□ (____ □□□)
    2. SGLT2 ኢንሂቢተር (____ □□□)
    3. Metformine
    4. Sulfonylurias
    5. DPP4 inhibitirs
    6. GLP1-RA
    7. ሌላ፣ይግለጹ_____
11. □□□□□□□□□□□□□□□□□□□□□ሚ□□ሙት?
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14. □□□ _____ □ንቲ □□□
15. ቢኤምአይ ____ □□/□^{2}(ይዘለል)
16. የደም ግፊት _____/_____mmHg
17. □□□□□□□□□□□□□□1ሲ (HgA1C) _____%
18. □□□□□□FBS_____mg/dl
19. □□□□□□□ም□□□□□□ (Total cholesterol) _____ mg/dl
20. □ችዲ□ል□□□□□□ (HDL-C) _____ mg/dl
21. □ልዲ□ል□□□□□□ (LDL-C)_____ mg/dl
22. □□ም□□ይ□□□□ይድ (TG)_____ mg/dl
23. □□ምክሪ□ቲኒን (Cr) _____ mg/dl
24. 24-□□□□□□□□□□□□□□ን_____ mg

□□□ **4**□ **የሚዳርጉ ምክንያቶች**

25. □□□□□□□□□□□□□□□□□ (አንዱን ይምረጡ)
    1. □□□□ (በድምር 75 ደቂቃ በሳምንት ለምሳሌ በፍጥነት መሮጥ)
    2. □□□□ ((በድምር 150 ደቂቃ በሳምንትለምሳሌ ፈጣን የእግር ጉዞ)
    3. □□□□□□□□□□□□□□□□□□□□□□□□□□ (በቤት፣ በስራ ቦታ፣ ትራንስፖርት ላይ) _____ሰዓት

26. ሲ□□ ይጠቀማሉ?
    1. □□□□
    2. አቁሜአለሁ:: በቀን_____ሲጋራለ_____አመት
    3. እጠቀማለሁ:: በቀን_____ሲጋራለ_____አመት

28. □□□□□በሽታዎች□□□□ (□□□□□□□ የነበሩ) □□□□□□□□□□□□□□□

    1. □□□□□□
    2. □□□□□□□ (የኮሌስትሮል መጨመር)
    3.
    4. የለም

29. □□□ኑ ጊዜ □ሚ□□ሙት□□□□□□ (□□□□□1 □□□□□□□ተ□□ሙትም) □□□□□□□□□□□□□□□

    1.
    2. SGLT2 ኢንሂቢተር□□□□ት□ርሚን
    3. የለም

□□□ **5**□ □□□□□□□□□□□**ዱ**□□□□□□□**ጉ**□□□

30.□□□□□በስኳሩ ምክንያት የመጣ □□□□□□□?

1. □ለ□□ታካሚውን ፋይል □□□□□ _____
2. □□ም

31. ምርመራ ተደርጎ የማያውቅ ከሆነ: የሞኖፊላመንት ምርመራ ውጤት (ከ10 ቦታ በአንድ እግር 4ቱ ከጎደለ)

1. ጉድ□ት □ለ
2. ጉድ□ት □□ም

32. □□□□□□□□□□?

1. □ለ
2. □□ም

33. □□□□□በስኳሩ ምክንያት የመጣ □ዓይን□□□?

1. □ለ□□□□□ 1.□□□□□□□□□□□□□2. □□□□□□□□□□3. □□□□
2. □□ም

34. □□□□□በስኳሩ ምክንያት የመጣ □ኩ□ሊት□□□?

1. □ለ□□ታካሚውን ፋይል □□□□□ _____
2. □□ም

35. □□□□□□እግር ደም ስር□□□?

1. □ለ□□ታካሚውን ፋይል □□□□□ _____
2. □□ም

36. □□□□□□□□□□□?

1. □ለ□□ታካሚውን ፋይል □□□□□ _____
2. □□ም

37. □□□□□□ስት□ክ □□□?

1. □ለ□□ታካሚውን ፋይል □□□□□ _____
2. □□ም

38. በቅርብ ጊዜ የተከሰተ የስኳር መውረድ?

1. □□□ 1 (□□□□□) - □54-69mg/dl □□□□እጅ □□□□□□□□□□□ □□□□□መፍጠ□□□□□
2. □□□ 2 (□□□□□) - □54mg/dl □□□□□□□□□□□□□ □□□□□□ □□□□□□□□
3. □□□ 3 (□□□) - □ስን መሳ□□ ሙሉ ሰውነትን ማን□□□□ □□□□□□□□□ን□□□□□□□□□ግ ከሆነ

የድምር ውጤት _____

□□□□□□□□□□□::