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Original Research Article

Ankle Brachial Index Utility: Prevalence of Peripheral Arterial Disease and Risk Factors among Diabetic Patients Attending an Outpatient Clinic in Northwestern Tanzania

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Abstract: ***Background*:** Peripheral arterial disease (PAD) is a disease of public health significance, ranging from asymptomatic to symptomatic presentation. The impact of PAD may be profound in many low to middle income countries (LMICs) where walking a substantial distance is required to obtain the daily basic needs. This study was conducted to determine prevalence of peripheral arterial disease and risk factors among diabetic patients attending an outpatient clinic in Northwestern Tanzania. ***Methods*:** A descriptive cross-sectional study carried out among adult patients attending a Diabetic Outpatient Clinic in Mwanza Tanzania. Demographic data and risk factors for PAD were recorded on a pretested questionnaire. Ultrasound guided ABI was measured using a standard mercury sphygmomanometer. Edinburgh Claudication Questionnaire (ECQ) was compared to the Fontaine Classification in PAD detection. Chi-square test, Fisher's exact test and logistic regression analyses were used to test for significance of association between independent and dependent variables with a p-value (p) <0.05 considered statistically significant. Receiver operator characteristic (ROC) curve analysis was also utilized to determine performance of ABI against clinical grading of PAD. ***Results*:** A total of 386 participants were enrolled in this study with a mean age of 60.0 ± 12.3 years. There was a significant association between an abnormal ABI with HbA1c, family history of cardiovascular diseases, hypertension, cigarette smoking and claudication (p=0.04 to <0.001). Claudication [aOR (95% CI) = 6.30 (3.14-12.64), p<0.001] was independently associated with an abnormal ABI. Prevalence of PAD was slightly lower based on clinical grading of PAD (30.8%) in comparison to an abnormal ABI respectively (34.5%). ABI had a sensitivity of 64.7%, specificity of 79.0%, positive predictive value of 57.9%, negative predictive value of 83.4%, accuracy of 74.6%. Area under the ROC curve of ABI was 0.72 against clinical grading of PAD on performance analysis. ***Conclusions*:** Prevalence of PAD among diabetic patients is relatively high and is significantly associated with claudication symptoms. Ankle brachial index supplemented with linear sonography can be a simple, non-invasive and first-line screening tool for early PAD detection and intervention.

Keywords: Ankle brachial index, peripheral arterial disease, diabetes mellitus.

INTRODUCTION

Globally, there has been a 72% surge in the prevalence of peripheral arterial disease (PAD) mainly attributed to identifiable risk factors such as tobacco use, diabetes, and hypertension [1]. PAD increases the risk of lower-limb complications (e.g. revascularisation procedures and amputations) and cardiovascular complications (e.g. major adverse cardiovascular events), as well as of mortality especially in people with diabetes mellitus (DM) [2]. Diabetic foot and PAD accounted for 41.9% and 8.6% of major limb amputations respectively between 2008 and 2010 at Bugando Medical Centre (BMC) in Mwanza Tanzania [3]. PAD is associated with poorer quality of life and a considerable financial burden in terms of length of hospital stay, admissions, readmissions and direct costs [2]. The impact of PAD may be profound in many low to middle income countries (LMICs) where walking a

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substantial distance is required to obtain the daily life basic needs such as water and food.

Many centers use Doppler ultrasound (DUS) as the initial imaging modality and may be further augmented by other imaging modalities such as computed tomography (CT), magnetic resonance imaging (MRI) and interventional radiology digital subtraction angiography (DSA) [4]. Imaging is useful in providing accurate anatomic location and severity of stenosis in PAD, whereas DSA is indicated for patients with critical limb ischemia (CLI) in whom revascularization is considered [5].

The diagnosis of lower extremity PAD can also established by Ankle Brachial Index (ABI), calculated as the ratio of systolic blood pressure in the ankle and the highest of the two brachial arterial pressures [6]. ABI ≤ 0.90 has pooled estimates for ABI in detecting 50% or greater stenosis were sensitivity = 61% (95% CI: 55–69), specificity = 92% (95% CI: 89–95) [7]. Diabetic patients with an abnormal ABI have an approximately 2-fold higher risk of cardiovascular or all-cause mortality [8]. This study was conducted to determine prevalence of peripheral arterial disease and risk factors among diabetic patients attending an outpatient clinic in Northwestern Tanzania.

MATERIALS AND METHODS

Study Design and Setting

A descriptive cross-sectional prospective study carried out at the diabetic outpatient clinic of BMC, Mwanza Tanzania from May to June 2019.

Study Population

All consenting adult patients attending diabetic clinic at BMC from May 2019 to June 2019 were consecutively enrolled into the study. Patients with other sites of PAD other than the lower limb, bilateral lower limbs amputations, difficulty in measuring blood pressures in all four limbs e.g. with oedema, prosthetics, fractures and/or vessel incompressibility (ABI > 1.40) were excluded.

Study Variables

Independent variables included age, sex, body mass index (BMI), hypertension status, family history of cardiovascular diseases (such as cerebral vascular accidents, coronary arterial disease and limb amputation), history of cigarette smoking, level of glycated hemoglobin, claudication and glycated haemoglobin. Dependent variable was the ankle brachial index (ABI) >0.9 is normal suggesting absence of PAD and ≤ 0.90 is abnormal suggesting presence of PAD.

Data Collection

Data for each patient was entered in a pretested coded questionnaire that included; age, sex, body mass index (BMI), hypertensive status, family history of cardiovascular diseases, history of cigarette smoking, level of glycated hemoglobin, claudication and glycated haemoglobin. BMI was calculated and categorized as underweight if BMI was <18.5kg/m^2, normal if 18.5-24.9kg/m^2, overweight if 25-29.9kg/m^2 and obese if ≥30kg/m^2. Lower limb claudication was assessed using Edinburgh Claudication Questionnaire (ECQ) and compared to the Fontaine Classification on clinical grading of PAD [6]. Blood samples were obtained to measure glycated hemoglobin (HbA1c) with levels ≥7% indicating poor glycaemic control. ABI was measured as follows; participant had to rest for about 10 minutes and lie supine to eliminate the effect of gravity, blood pressure was measured in both upper and lower limbs using a mercury sphygmomanometer at the level of the arm and ankle respectively. A ultrasound 7.5Mhz linear probe was used to anatomically localize the arterial vessels before placing the sphygmomanometer cuff. ABI determined by dividing the highest ankle systolic blood pressure by the highest brachial systolic blood pressure. The lowest lower limb ABI value determined presence or absence of PAD.

Data Analysis

Data collected was cleaned and analysed using STATA version 15. Continuous data were summarized into categorical data. Categorical data were then summarized into frequencies and proportions. Chi-square test or Fisher's exact test and logistic regression analyses were used to test for significance of association between independent and dependent variables with a p-value (p) <0.05 considered statistically significant. Receiver operator characteristic (ROC) curve analysis was also applied to determine performance of ABI against clinical grade of PAD.

Ethical Consideration

All were recruited after obtaining a written informed consent form. Participants were assured that their refusal to consent or withdraw from the study would not alter or jeopardize their access to medical care. Ethical clearance to conduct this study was sought from and approved by the Joint CUHAS/BMC Ethics and Review Committee (CREC/365/2019).

RESULTS

A total of 386 participants were enrolled in this study of mean age 60.0 ± 12.3 (range =18 – 95) years and male to female (M:F) ratio = 1:1.3. About 133 out of the 386 participants had an abnormal ABI suggesting a 34.5% prevalence of PAD as shown on **Table 1**.

There was a significant association between an abnormal ABI with glycated hemoglobin (p=0.04), family history of cardiovascular diseases (p=0.02), hypertension (p=0.01), cigarette smoking (p<0.001) and claudication (p<0.001) on Chi-square or Fisher's exact test.

On univariate and multivariate analyses, age [cOR (95% CI) = 1.03 (1.01-1.05), p= 0.001],

hypertension [cOR (95% CI) = 1.94 (1.16-3.22), p= 0.01], family history of cardiovascular diseases [cOR (95% CI) = 1.69 (1.10-2.58), p= 0.02], glycated hemoglobin [cOR (95% CI) = 2.20 (1.04-4.61), p= 0.04], cigarette smoking [cOR (95% CI) = 6.22 (2.56-15.13), p<0.001] and claudication [aOR (95% CI) = 6.30 (3.14-12.64), p<0.001] were significantly associated with an abnormal ABI as shown on **Table 2**.

Prevalence of PAD (**Table 3**) was slightly lower based on clinical grading of PAD (30.8%) in comparison to an abnormal ABI respectively (34.5%). ABI had a sensitivity of 64.7%, specificity of 79.0%, positive predictive value of 57.9%, negative predictive value of 83.4%, accuracy of 74.6%. Area under the ROC curve of ABI was 0.72 against clinical grading of PAD on performance analysis (**Figure 1**).

Table 1: Baseline Characteristics According To ABI* (N=386)

Variable	Categories	Normal ABI n=253 n (%)	Abnormal* ABI n=133 n (%)	Chi	p
Age, years**	-	58.5 (12.9)	62.9 (10.4)	-	-
Sex	Male	101 (61.2)	64 (38.8)	2.40	0.12
	Female	152 (68.8)	69 (31.2)		
BMI, kg/m^2***	<18.5	6 (85.7)	1 (14.3)	-	0.433$^{\#}$
	18.5-24.9	72 (69.2)	34 (30.8)		
	25.0-29.9	75 (66.4)	38 (33.6)		
	≥ 30.0	100 (61.7)	62 (38.3)		
Hypertension	No	78 (75.7)	25 (24.3)	6.56	0.01
	Yes	174 (61.7)	108 (38.3)		
History of CVD***	No	165 (70.2)	70 (29.8)	5.80	0.02
	Yes	88 (58.3)	63 (41.7)		
HbA1c, %****	< 7.0	24 (64.9)	13 (35.1)	4.44	0.04
	≥ 7.0	74 (45.7)	88 (54.3)		
Cigarette smoking/ exposure	No	246 (68.5)	113 (31.5)	20.18	<0.001
	Yes	7 (25.9)	20 (74.1)		
Claudication by ECQ***	No	209 (80.4)	51 (19.6)	79.81	<0.001
	Atypical	29 (40.3)	43 (59.7)		
	Typical	15 (27.8)	39 (72.2)		
Clinical grade of PAD***	Asymptomatic	211 (79.0)	56 (21.0)	-	<0.001$^{\#}$
	Mild claudication	23 (53.5)	20 (46.5)		
	Moderate to severe claudication	5 (22.7)	17 (77.3)		
	Rest pain	13 (30.2)	30 (69.8)		
	Necrosis or gangrene	1 (9.1)	10 (90.9)		

*Abnormal ABI ≤0.90 suggests presence of PAD. **Mean (standard deviation). ***BMI=Body mass index; CVD=cardiovascular diseases; ECQ= Edinburgh Claudication Questionnaire; PAD=peripheral arterial disease. ****Glycated haemoglobin (n= 199). $^{\#}$Fisher's exact test.

Table 2: Risk Factors Associated with ABI (N=386)

Variable	Univariate*			Multivariate*		
	cOR	95% CI	p	aOR	95% CI	p
Age, years	1.03	1.01-1.05	0.001	1.00	0.97-1.03	0.820
Female	0.72	0.47-1.09	0.12	-	-	-
BMI ≥25 kg/m2	1.35	0.84-2.17	0.22	-	-	-
Hypertensive	1.94	1.16-3.22	0.01	1.15	050-2.64	0.75
Positive family history of CVD*	1.69	1.10-2.58	0.02	1.57	0.81-3.03	0.18
HbA1c ≥ 7.0%**	2.20	1.04-4.61	0.04	1.69	0.72-3.93	0.23
Positive cigarette smoking/ exposure	6.22	2.56-15.13	<0.001	6.75	0.76-60.10	0.09
Presence of claudication by ECQ	7.63	4.73-12.31	<0.001	6.30	3.14-12.64	<0.001

*cOR = crude Odds Ratio; CI = Confidence Interval; aOR = adjusted Odds Ratio; BMI=Body mass index; CVD= cardiovascular diseases. **Glycated haemoglobin (n= 199).

Table 3: Performance of ABI Against Clinical Grading of PAD

Test (ABI)	Disease (Clinical Grade of PAD)		Total
	Asymptomatic	Symptomatic	
Normal	211 (TN)	42 (FN)	253 (65.5)
Abnormal	56 (FP)	77 (TP)	133 (34.5)
Total	267 (69.2)	119 (30.8)	386 (100.0)
Statistic		**Value**	**95% CI**
Sensitivity		64.7%	55.4% to 73.2%
Specificity		79.0%	73.7% to 83.8%
Positive Likelihood Ratio		3.09	2.36 to 4.03
Negative Likelihood Ratio		0.45	0.35 to 0.57
Disease prevalence		30.8%	26.3% to 35.7%
Positive Predictive Value		57.9%	51.3% to 64.3%
Negative Predictive Value		83.4%	79.6% to 86.6%
Accuracy		74.6%	70.0% to 78.9

TN=True Negatives; FN=False negatives; FP=False positives; CI = Confidence Interval

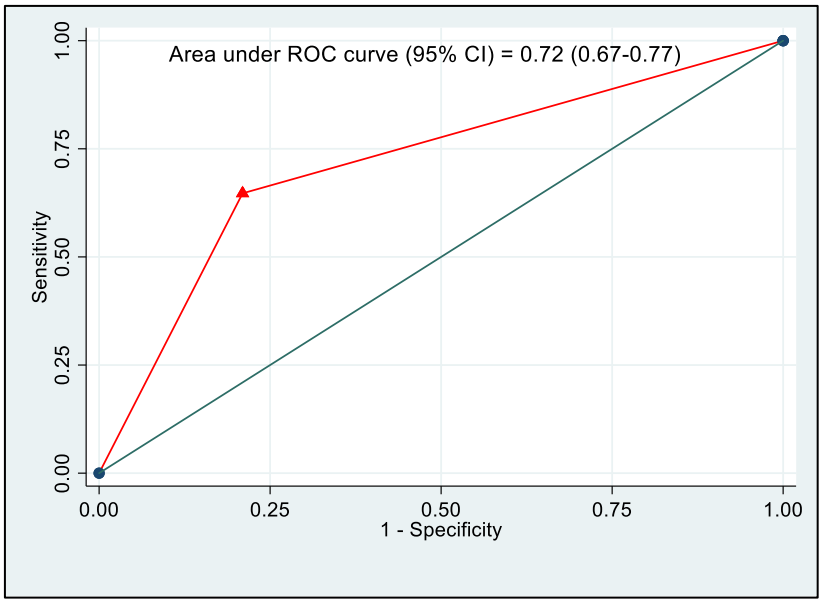

Figure 1: Receiver Operator Characteristic Curve Showing Performance of ABI Against Clinical Grading of PAD

DISCUSSION

PAD prevalence of 30.8% (95% CI = 26.3-35.7) in the current study by clinical grading of PAD and an abnormal ABI is similar and comparable to a pooled prevalence of peripheral artery disease among patients with DM in sub-Saharan Africa of 33.0% (95% CI = 29.7-36.2) [9]. We established almost similar findings to a previous structured review where ABI had a lower sensitivity (64.7% vs. 15-79%), higher specificity (79.0% vs. 83.3-99.0%) and accuracy (74.6% vs. 72.1-89.2%) [10]. Sensitivity of ABI is well known to be low, especially in elderly individuals and patients with diabetes [11]. A recent systematic review was unable to determine the reliability of the ABI due to reviewed studies' inconsistencies. Therefore, advised ABI results should be interpreted in the context of other findings [12]. It was also worth noting that intra-rater and inter-rater variability tests were not included in our study and urge they should be considered in future studies.

The mean age of participants with an abnormal ABI was slightly higher compared to those with normal ABI. A slight frequency preponderance of an abnormal ABI towards females was also observed. The prevalence of PAD increases with age, above 40 years and above [13]. PAD has been shown to be higher in women due to differences in response to stressors including a sex-specific predisposition for endothelial dysfunction and disease in age-related estrogen deficiency [14].

Our study did not demonstrate any significant association between obesity and an abnormal ABI, even though obesity was previously shown to have a causal association with PAD after controlling for the potential intermediate factors such as hypertension, dyslipidemia and hyperglycemia by Mendelian randomization analysis [15]. Recent studies have on the contrary reported that, overweight individuals have a lower PAD prevalence and mortality unlike underweight individuals [16, 17]. PAD has been documented to have a significant association in subjects with DM and hypertension [18] analogous to the present study where hypertensive

participants had a 2-fold risk if with an abnormal ABI. This study provides further support to the positive association between an abnormal ABI and HbA1c level. Patients with poor glycemic control as indicated by high levels of HbA1c, have a greater incidence of PAD as has been highlighted in a case control study [19].

Overall, presence of claudication symptoms in our study was the most independent risk factor associated with an abnormal ABI suggesting underlying PAD. Screening of the asymptomatic population is still emphasized in literature, for early preventive measures such as lifestyle modification, exercise and medical treatment of PAD before critical limb ischemia sets in and associated cardiovascular risk [20, 21].

CONCLUSIONS

Prevalence of PAD among diabetic patients is relatively high and is significantly associated with claudication symptoms. Ankle brachial index supplemented with linear sonography can be a simple, non-invasive and first-line screening tool for early PAD detection and intervention.

Authors' Contribution

FK, VK, PSN were involved concept and design, acquisition of data or analysis and interpretation of data, article drafting, revision & editing. PM was involved in acquisition of data and article revision. All authors approved the final article version for publication.

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Declaration of Conflict of Interest

The authors declare that they have no conflict of interest.

Data Availability

The data will be available from the corresponding author upon request.

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