

FREQUENCY OF PERIPHERAL ARTERIAL DISEASE AMONG PATIENTS WITH DIABETES MELLITUS FOOT SYNDROME IN A TERTIARY HOSPITAL IN LAGOS, NIGERIA.

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ABSTRACT

Diabetes Mellitus Foot Syndrome (DMFS) occurs against a background infection, neuropathy and peripheral arterial disease (PAD). Clinical assessment often under diagnoses PAD. However, the use of a hand held Doppler to calculate the ankle brachial index (ABI) is an inexpensive, non-invasive and quantitative method of determining the presence of PAD. A retrospective analysis of patients with DMFS who had PAD assessment with a hand held Doppler was done. Data retrieved from the doppler report included age, gender, presence of hypertension, smoking status and ankle brachial index (ABI). PAD was defined as ABI of < 0.9 or >1.3. Data was analyzed using Epi info version 3.4.3. A $p < 0.05$ was taken significant. There were 73 patients with DMFS, 28 (38.4%) females and 45 (61.6%) males. Mean (SD) age was 62.4 (11.1) years. Hypertension was present in 30 (41.1%) and 8 (11.0%) were smokers. PAD was present in 39 (53.4%) patients. Of the 39 patients with PAD, 11 (28.2%) had ABI >1.3. Age, gender, smoking status and history of hypertension were not associated with PAD ($p < 0.05$). The frequency of PAD among patients with DMFS was high. Over a quarter had ABI >1.3. Hand held Doppler devices should be made available, at least in tertiary hospitals in resource poor settings so as to improve management of DMFS.

Keywords: Peripheral arterial disease, Ankle brachial index, Diabetes, Foot, Ulcer, Lagos, Nigeria.

INTRODUCTION

Worldwide, foot ulcers are a major cause of morbidity and mortality among people with diabetes (Ekpebegh *et al.*, 2009 and Boulton *et al.*, 2005). Up to 15 to 25% of patients with diabetes will develop a foot ulcer in their lifetime (Singh *et al.*, 2005; Lavery *et al.*, 2003; Reiber, 1996). Peripheral arterial disease (PAD) is one of the most important risk factors for developing diabetes mellitus foot syndrome (DMFS). The presence and severity of PAD impacts negatively on healing rates of DMFS, and is associated with major amputation and mortality amongst these patients (Brechtow *et al.*, 2013). Also, peripheral arterial disease is frequently accompanied by other life threatening complications of diabetes such as cerebrovascular disease and ischemic heart disease (Alzamora *et al.*, 2013; Allison *et al.*, 2008). Thus, identification of and adequate assessment for PAD among patients with DMFS is of utmost importance.

Clinical assessment for PAD includes a history of intermittent claudication and reduced/absent lower limb pulsation on palpation. Hence, PAD is often diagnosed solely by clinical evaluation in such situations (Edo *et al.*, 2013; Nyamu *et al.*, 2003). Clinical assessment for PAD has its own limitations, being subjective and shown to underestimate PAD. The International Working Group on Diabetic Foot (IWGDF) guidelines state that

apart from obtaining a history of PAD symptoms, all patients with diabetic foot ulcers should have evaluation with a hand-held Doppler and ABI measurement (Schaper *et al.*, 2012). The use of a hand held Doppler to derive the ABI is a simple, inexpensive, non-invasive and quantitative method of determining the presence of PAD (Marso and Hiatt, 2006). The ankle brachial index is the ratio of the systolic blood pressure (SBP) at the ankles (posterior tibial and dorsalis pedis arteries) to the SBP at the arm (brachial artery), obtained with the use of the hand held Doppler (2003). According to the IWGDF, poor wound healing in a patient with diabetes foot ulcer necessitates the re-evaluation of perfusion with Duplex ultrasound or angiography of the arteries of the lower limb (Schaper *et al.*, 2012).

Although, duplex ultrasound allows the morphological/functional study of the vascular tree (Collins *et al.*, 2007), some experts advocate the use of further PAD assessment such as magnetic resonance (angio- MR) or CT angiography (angio-CT). The American College of Cardiology/American Heart Association guidelines recommend the use of angio-MR rather than angio- CT as angio-MR allows better definition and leads to fewer technique-related risks. In addition, MRI cannot be used in patients with pacemakers, hearing devices, defibrillators or other implants. Conventional x-ray iodinated digital subtraction angiography (DSA) is the gold standard for evaluating PAD, especially prior to surgical intervention (White, 2007). However, it is invasive as it involves establishing arterial access, and it is associated with hypersensitivity and contrast-induced nephropathy (Parfrey *et al.*, 1989).

The ABI has been validated against angiographically confirmed disease and found to be 95% sensitive and almost 100% specific. (Bernstein and Fronek, 1982) Peripheral arterial disease has been traditionally defined as an ABI < 0.9. However, studies show that abnormally high ABI (>1.3), which occurs from non-compressibility of the foot arteries, is associated with diabetes, (Aboyans *et al.*, 2008) major amputation, (Everhart *et al.*, 1988; Silvestro *et al.*, 2006) cardiovascular and cerebrovascular disease (Alzamora *et al.*, 2013; Allison *et al.*, 2008) as well as mortality (O'Hare *et al.*, 2006; Resnick *et al.*, 2004). Hence, some workers have used a range of <0.9 -1.3 to define normal ABI (Aboyans *et al.*, 2008).

Numerous studies have determined the frequency/prevalence of PAD among patients with diabetes (Marso and Hiatt, 2006; Aboyans *et al.*, 2008; Hiatt *et al.*, 1995; Umuerrri and Obasohan, 2013; Rheeder *et al.*, 2004; Prompers *et al.*, 2007; Jude *et al.*, 2010). In a 2010 review, the prevalence of PAD among DM patients was reported as 8% to 33% (Jude *et al.*, 2010). The Eurodiale study, a prospective study, which recruited a large cohort of European patients with newly presenting diabetic foot ulcers found a prevalence of 49.0% of PAD (Prompers *et al.*, 2007). The wide variation in its prevalence can be attributed to differences in the methods used to define PAD, as previously described by Hiatt *et al.*, (Hiatt *et al.*, 1995).

In Nigeria (Edo *et al.*, 2013; Adeleye, 2005), and other developing countries (Ahmad *et al.*, 2013; Chalya *et al.*, 2011; Nyamu *et al.*, 2003), most workers have used clinical methods as the only means for assessing PAD in patients with DMFS. In a Nigerian study, 27(44.3%) of the 61 patients with DMFS were diagnosed with PAD using reduced/absent lower limb arterial pulsation (Edo *et al.*, 2013). Other studies in Nigeria have documented the use of ABI <0.9 alone in PAD diagnosis among patients with DMFS (Ikem *et al.*; Umuerrri and Obasohan, 2013; Ogbera *et al.*, 2008) or a combination of clinical methods and ABI <0.9 to define PAD among patients with DMFS (Ekpebegh *et al.*, 2009). There is limited data on the frequency or prevalence of PAD defined as ABI <0.9 and >1.3.

We hypothesized that the frequency of PAD using ABI of < 0.9 or >1.3 among patients with DMFS would be higher than previous reports. Our aim was therefore to determine the frequency of peripheral arterial disease among patients with DMFS in a tertiary health care centre using ABI cut off values of <0.9 or >1.3 to define PAD. We also set out to determine the pattern of abnormal ABI among our study participants.

METHODS

A retrospective study of the hand held Doppler report of patients with DMFS referred to the Diabetes, Endocrinology and Metabolism Unit of the Lagos University Teaching Hospital over a 1 year period was conducted. The Lagos University Teaching Hospital is the largest tertiary hospital in Lagos State, and serves as a referral centre for other peripheral hospitals from within and outside the state.

Approval for the study was obtained from the Health Research and Ethics Committee of the Lagos University Teaching Hospital, Idi- Araba, Lagos State.

Procedure for ABI Measurement

A hand held Doppler (Lifedop 150 Basic by Summit technologies) which used a 8Hz probe was used to measure the systolic blood pressure of the brachial, the dorsalis pedis and posterior tibial arteries (Aboyans *et al.*, 2012).

The procedure was done with the patient in the supine position, having rested for at least 10 minutes. Doppler gel was applied over the probe which was placed at 45⁰ to 60⁰ to the surface of the skin. The probe was moved around the surface landmark of the artery until the clearest signal was heard. The cuff was then inflated about 20 mmHg above the level at which the signal was no longer heard and subsequently deflated slowly to detect the signal reappearance. The signal disappearance corresponds to the SBP. The brachial pressure on one arm was first determined, followed by the ankle pressures of the dorsalis pedis and posterior tibial arteries bilaterally and then the brachial pressure on the other arm. The higher values of the brachial and ankle pressures were used to calculate the ABI.

The assessment of ABI was carried out by the endocrinology unit senior registrars and unit consultant.

Data Collection

The hand held Doppler report was used to retrieve patients' data on demographic variables, hypertension, smoking and foot affected by DMFS. In the report, hypertension was categorized as "yes" or "no", smoking status as "yes", "no" and "past" and laterality of foot affected as "right", "left" and "both".

Outcome

Peripheral arterial disease (PAD) was the main outcome of the study. It was defined as an ABI of <0.9 or >1.3 .

Statistical Analysis

Statistical analysis was done with Epi info 3.5.3 software. Continuous variables are presented as means and standard deviations and categorical variables are expressed as frequencies with accompanying percentages. The differences between the groups were compared using the Student's test for continuous variables and chi square test for categorical variables. For the chi-square test, where the expected value of a cell was <5 , the Fisher's exact test results was used. Statistical significance was set at $\leq p 0.05$.

RESULTS

Demographic and Clinical Characteristics

Seventy-three (73) patients' hand held doppler ultrasound reports for DMFS were available for analysis. This comprised of 28 (38.4%) females and 45 (61.6%) males. Their age ranged from 26 to 79 years. Female and male patients with DMFS had similar demographic and clinical characteristics. The demographic and clinical characteristics of the patients are shown in Table 1.

The ABI range of the patients was 0.2-2.5. The median (IQR) ABI was 1.0 (0.5)

Frequency of Peripheral Arterial Disease (PAD)

The proportions of DMFS patients with ABI <0.9 , 0.9-1.3 and >1.3 were 34(46.6%), 28(38.3%) and 11(15.1%) respectively. Thus, peripheral arterial disease (PAD) was present among 39(53.4%) of the 72 patients with DMFS.

Among the 39 persons with PAD, 11 (28.2%) had ABI >1.3 .

Association of Peripheral Arterial Disease (PAD) with Demographic and Clinical Characteristics

Among these patients with DMFS, there was no significant difference in the age, gender distribution, smoking status, laterality or presence of hypertension in patients who had peripheral arterial disease compared to those who did not have PAD (Table 2).

DISCUSSION

Diabetic foot ulcers occur against a background of the triad of infection, neuropathy and peripheral arterial disease. The aim of our study was to determine the frequency of PAD among patients with DMFSs using the criteria of ABI of <0.9 or >1.3 , derived from a hand-held Doppler.

In this study, the frequency of PAD was high (53.4%) and was not significantly associated with age, gender, history of hypertension, smoking or laterality of foot affected by the ulcer. While some studies (Ekpebegeh *et al.*, 2009; Edo *et al.*, 2013) on DMFS have reported a lower rate of PAD compared to the present study, others have described the contrary (Adeleye, 2005; Ahmad *et al.*, 2013; Ikem *et al.*, 2010). The reason for this can be ascribed to differences in the patients' characteristics such as age, sex, presence of other risk factors for PAD, criteria used in determining the presence of PAD as well as the study design. (prospective vs retrospective). For instance Ikem *et al.* (2010) defined PAD as ABI <0.9 while Adeleye *et al.* (2005) defined the presence of PAD clinically.

Previous studies (Adeleye, 2005; Edo *et al.*, 2013; Nyamu *et al.*, 2003; Otu *et al.*, 2013) from Africa except a few (Ekpebegeh *et al.*, 2009; Ikem *et al.*, 2010) have used clinical methods as the sole criterion in diagnosing PAD among patients with DMFS. Some of the studies (Adeleye, 2005; Edo *et al.*, 2013) varying from 31% to 44.3% have reported lower frequency of PAD compared to that found in this study. Ekpebegeh *et al.* (2009) reported a lower frequency (31%) of PAD in the study of 42 patients with DMFS compared to this study. A combination of reduced/absent pedal pulsations or ABI <0.8 or >1 was used to diagnose PAD. The difference in PAD frequency could be explained by the younger age of their patients (56.1 years in the study by Ekpebegeh *et al.* (2009) vs 62.4 years in this study) and the use of clinical methods in addition to ABI by Ekpebegeh *et al.* (2009) which have been shown to underestimate PAD.

On the other hand, Ikem *et al.* (2010) in their study among patients with DMFS in Ife, Nigeria, found 31(76.4%) of the 46 patients with diabetic foot ulcers to have ABI <0.9 . Although, the age and gender composition for both studies were similar, the difference in rate of PAD can be explained by the higher proportion of other established risk factors for PAD in their patient population. This includes a history of tobacco use which was observed in 26.1% of the patients in their study and comparatively higher than the present study (13.8%). Furthermore, 73.9% of the DMFS patients in the Ife study had hypertension, which is much higher than ours (49.2%). Other risk factors for PAD that have been identified in DM patients include hypertension, (Carbayo *et al.*, 2007; Adler *et al.*, 2002; Umuerrri and Obasohan, 2013) smoking, (Carbayo *et al.*, 2007; Adler *et al.*, 2002) older age, (Adler *et al.*, 2002; Marso and Hiatt, 2006; Umuerrri and Obasohan, 2013) male gender, (Dormandy and Rutherford, 2000) and hypercholesterolaemia (Carbayo *et al.*, 2007; Adler *et al.*, 2002), duration of diabetes (Adler *et al.*, 2002; Marso and Hiatt, 2006; Umuerrri and Obasohan, 2013) and glycaemic control (Adler *et al.*, 2002; Marso and Hiatt, 2006).

In this study, 11(28.2%) patients had an ABI > 1.3, indicative of medial arterial calcification. Although occlusive vascular disease cannot be assessed when arteries are poorly compressible, it has been demonstrated that with the use of alternative tests such as the toe-brachial index, 62.2% to 80% of such patients would have occlusive peripheral arterial disease (Suominen *et al.*, 2008; Aboyans *et al.*, 2008). Thus, some workers have proposed that ABI>1.3 should be considered PAD-equivalent among persons with diabetes (Aboyans *et al.*, 2008). An ABI >1.3 has been associated with excess mortality, cerebrovascular disease (Alzamora *et al.*, 2013; Allison *et al.*, 2008), heart failure, (Allison *et al.*, 2008) and lower quality of life (Allison *et al.*, 2008). It is noteworthy that a significant proportion of our study participants who had high ABI, and consequently increased risk of cardiovascular events and mortality independent of other cardiovascular risk factors would have been missed if ABI <0.9 was solely used to diagnose PAD.

The strength of this study was the use of an objective means to assess peripheral arterial disease. Our limitations include the possibility that not all patients in our institution with DMFS during the study period were assessed with the hand-held Doppler. It is also plausible that patients with lower grades of DMFS were not referred for PAD assessment; this may affect the generalizability of our results to the DMFS population. The retrospective nature of the study is also a limitation. The relationship between ABI and parameters such as glucose control, presence of other DM complications, and DMFS outcome in Nigerians is a thrust for further research.

CONCLUSION AND RECOMMENDATION

The frequency of PAD using the hand held Doppler to calculate ABI among these patients with DMFS was high. Over a quarter of these patients had an abnormally high ABI which impacts negatively on cardiovascular risk and ulcer outcome. Such simple devices should be made more readily available, at least in major hospitals in resource poor settings for better management of patients with DMFS.

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Table 1: Demographic and clinical characteristics of the study population

Variable	n (%)
Age (years)	
Mean (SD)	62.4 (11.1)
ABI	
Range	0.2-2.5
Median (IQR)	1.0 (0.5)
Hypertension	
Yes	29(39.7)
No	30(41.1)
Not indicated	14(19.2)
Smoking	
Yes	8(11.0)
No	50(68.5)
Not indicated	15(20.5)
Laterality	
Right	21(28.8)
Left	20(27.4)
Bilateral	6(8.2)
Not indicated	26(35.6)

*ABI- Ankle brachial index

Table 2: Association of peripheral arterial disease with demographic and clinical characteristics

Variable	PAD Present n=39	PAD Absent n=34	P value
Age (years)	64.2(9.6)	60.3(12.3)	0.143
Gender			
Females	17(43.6)	11(32.4)	0.457
Males	22(56.4)	23(67.6)	
Hypertension ^a			
Yes	14/29(48.3)	15/30(50.0)	0.898
No	15/29(51.7)	15/30(50.0)	
Smoking ^a			
Yes	4/27(14.8)	4/31(12.9)	0.607*
No	23/27(85.2)	27/31(87.1)	
Laterality ^a			
Right	11/22(50.0)	10/25(40.0)	0.781*
Left	9/22(40.9)	11/25(44.0)	
Bilateral	2/22(9.1)	4/25(16.0)	

*fishers exact