

COLOR DOPPLER AND ANKLE-BRACHIAL INDEX IN THE DIAGNOSIS OF PERIPHERAL ARTERY DISEASE IN TYPE II DIABETIC SUBJECT

Comment [Z1]: In whole document, there are no uniform spacing

ABSTRACT

Objective: To determine the association of color doppler and ankle-brachial index in the diagnosis of peripheral artery disease in type ii diabetic subject.

Methods: The study was carried out at ultrasound department of, Karachi, Pakistan from January 2020 to December 2020. Patients of diagnosed diabetes mellitus for at least 4 years of either gender between 30-70 years of age were included. All patients were instructed to avoid heavy exercise, smoking and caffeinated beverages before the examination for at the minimum of two hours. All the cases underwent Standard Doppler examination of lower limb peripheral arteries performed by radiologist having experience of more than 10 years. Spectral waveform analysis was evaluated and presence of Biphasic flow or monophasic flow on color Doppler was labelled as peripheral artery disease. Biphasic flow was taken as mild disease while monophasic flow or absence of flow was taken as severe disease. The ABI was computed for each patient by recording systolic blood pressure in the supine position starting with the right arm then proceeding towards right leg, left leg, and finally for the left arm. ABI is a ratio obtained from dividing the higher of the ankle blood pressures for each leg by the highest of the right and left arm's brachial systolic blood pressures. It was labelled as peripheral artery disease if the value was <0.9 . This information along with the demographics was entered in the Performa by the researcher. Data was analyzed by using SPSS Version 26.

Result: Mean age of enrolled participants was 58.21 ± 6.74 year. Of 131 enrolled participants, 103 (78.6%) were male and 28 (21.4%) were female; mean duration of diabetes was 11.24 ± 5.62 years. Kappa statistics of agreement between ABI and Doppler ultrasound in diagnosis of PAD was 0.762 ($P < 0.05$).

Conclusion: This study concludes that Color Doppler ultrasound method is comparable with ankle-brachial index for the detection of peripheral arterial disease.

Keywords: Peripheral arterial disease, Diabetes mellitus type II, ankle-brachial index and color doppler ultrasound.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic disease with a rising global prevalence.¹ It profoundly affects the quality of life and puts major monetary constraints on the patients.² Pakistan ranks at 10 out of 221 countries of the world in having diabetes mellitus between 20–79 years.³ Diabetic patients are two to four times more predisposed to peripheral artery disease (PAD) which is a long-standing, lifestyle-limiting disease caused by atherosclerotic changes in the vessels.^{4, 5} PAD involves partial or complete occlusion of peripheral arteries predominantly of the lower extremities.⁵ Majority of patients are asymptomatic, with the most common presenting complaint is intermittent claudication in symptomatic patients.⁶ There is a slow and insidious progression of disease. It is more frequently present in older individuals, particularly with diabetes mellitus, hypertension, hypercholesterolemia and cigarette smoking.⁷ Moreover, it is an independent risk factor for foot ulcers, amputations, cerebrovascular and cardiovascular ischemic

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events.⁸ PAD can be diagnosed via noninvasive and invasive tests. ABI and ultrasound duplex scanning (USD) are those noninvasive tests which are not only efficiently taken into the account for the diagnosis and confirmation of PAD but these examinations also share important role in follow up of PAD progression.⁹ The ankle-brachial index (ABI) has been considered as a very simple and reliable bedside technique to identify the presence, extent and severity of PAD.¹⁰ It is a ratio of the highest ankle systolic blood pressure obtained in the anterior tibial, dorsalis pedis or posterior tibial artery to that of the highest brachial systolic pressure and is normally between 1.00 and 1.40. An ABI of < 0.9 is regarded as an indication of peripheral artery disease.¹¹ The American Diabetes Association Consensus Statement recommends that a screening ankle-brachial index (ABI) should be conducted in patients with diabetes who have symptoms or signs of PAD.¹² Likewise Color Doppler imaging is also an approved examination in the analysis of PAD. It is widely preferred as it is simple, handy and versatile.¹³ It is a safe and painless investigation as it does not use contrast material or ionizing radiation. It also shares the advantage of being non-invasive and reproducible. It seems to be relatively expensive and broadly accessible as an out-patient basis.¹⁴ The use of Color Doppler assists early diagnosis of critical limb at risk and helps to prevent and reduce the high-rate limb loss.¹⁵ ABI and USD both are valuable tests for PAD. Although ABI is considered an important screening test for PAD with sensitivity of 95% and specificity of 99%, It is however, not sensitive in patients with arterial wall calcification, which is generally present not only with diabetes mellitus but old age, renal failure and hyperparathyroidism are also important associated risk factors. Furthermore, ABI is not sensitive to detect aortic and iliac diseases. In contrast, USD has the advantage in elucidation of the anatomy of arteries which cannot be discerned with ABI and it also has the edge over ABI for recognizing the severity of stenosis. Its importance also lies in the post-surgical follow-up of patients following vascular surgery. The significance of both test for the detection of PAD lies in the identification of agreement of ABI with Color Doppler Ultrasound. Furthermore, good agreement could be substantial to use USD as a screening modality for the detection of PAD.

MATERIAL AND METHODS

The study was carried out at ultrasound department of our institute, Karachi, Pakistan from January 2020 to December 2020. In this cross-sectional study, 131 patients of diagnosed diabetes mellitus for at least 4 years of either gender between 30-70 years of age were included. Patients not consenting were excluded from the study. Those patients with chronic diseases like atrial fibrillation, congestive heart failure, asthma, chronic obstructive pulmonary disease, and chronic kidney disease, history of deep venous thrombosis, malignancy, angioplasty or history of previous bypass surgery were also excluded. Patients with amputations of the lower or upper limbs and extensive gangrene (which can hinder performing color Doppler ultrasound) and marked edema of one or both feet and fracture were also excluded from the study. History and physical examination were performed by the researcher including palpation of dorsalis pedis artery and posterior tibial artery pulses in both the lower limbs. All patients were instructed to avoid heavy exercise, smoking and caffeinated beverages before the examination for at the minimum of two hours. Blood pressures of the patients were monitored by mercury

sphygmomanometer using standard method in a sitting position. Body mass index (BMI) was measured as the ratio of weight in kg to height in m². Blood samples were sent to laboratory for glycated haemoglobin A1c and lipid profile. All adult type II diabetic patients referred to Doppler ultrasound of lower limbs and fulfilling the inclusion and exclusion criteria underwent Standard Doppler examination of lower limb peripheral arteries performed by radiologist having experience of more than 10 years on Standard Ultrasound machine Toshiba Aplio or Toshiba Xario with an ultrasound transducer of more than 10 MHz. Spectral waveform analysis was evaluated and presence of Biphasic flow or monophasic flow on color Doppler was labelled as peripheral artery disease. Biphasic flow was taken as mild disease while monophasic flow or absence of flow was taken as severe disease. The ABI was computed for each patient by recording systolic blood pressure in the supine position starting with the right arm then proceeding towards right leg, left leg, and finally for the left arm. ABI is a ratio obtained from dividing the higher of the ankle blood pressures for each leg by the highest of the right and left arm's brachial systolic blood pressures. It was labelled as peripheral artery disease if the value was <0.9. This information along with the demographics was entered in the Performa by the researcher. Data was analyzed by using SPSS Version 26.

RESULTS

Comment [Z4]: Not a good presentation. It is just like medical report

A total of 131 patients with diabetes mellitus type II were enrolled in the study. The mean age and duration of disease of patients was 58.21±6.74 years and 11.24±5.62 years. 103 (78.6%) were male and 28 (21.4%) were female. Mean height, weight and BMI was 154.17±9.22 cm, 71.44±13.87 kg and 29.94±5.34 kg/ m². Mean systolic/diastolic blood pressure was 138.47±18.14 mmHg and 84.23±9.84 mmHg. Majority of the patients at presentation had poor glycemic control with a mean HbA1c of 9.14±3.11%. Lipid profiles analysis showed mean values of total cholesterol (132.55±37.59 mg/dl), triglycerides (156.69±89.59 mg/dl), HDL (31.21±7.28 mg/dl) and LDL (74.25±32.51mg/dl). Table 1

Kappa statistics of agreement between ABI and Doppler ultrasound in diagnosis of PAD was statistically significant 0.762 (P<0.05). Table 2

The Kappa statistics of agreement between ABI and Doppler ultrasound in diagnosis of PAD was statistically significant both for age <50 years and > 50 years i.e. it was 0.744 (P<0.05) for age <50 years and 0.784 (P<0.05) for age ≥50 years. Among both male and female patients, the Kappa statistics of agreement between ABI and Doppler ultrasound in diagnosis of PAD was statistically significant i.e. (P <0.05), however there is strong agreement for females i.e. kappa 0.837 and moderate for males i.e. kappa 0.729. Table 3

TABLE 1: BASELINE CHARACTERISTICS OF PATIENTS (n=131)

VARIABLE		Statistics	
Gender	Male	103	78.6%
	Female	28	21.4%

Age (years)	58.21±6.74
Duration of diabetes mellitus (years)	11.24±5.62
Systolic blood pressure (mmhg)	138.47±18.14
Diastolic blood pressure (mmhg)	84.23±9.84
Height (cm)	154.17±9.22
Weight (kg)	71.44±13.87
BMI (kg/m2)	29.94±5.34
hba1c (%)	9.14±3.11
Total cholesterol (mg/dl)	132.55±37.59
Triglyceride (mg/dl)	156.69±89.45
High density lipoproteins (mg/dl)	31.21±7.28
Low density lipoproteins (mg/dl)	74.25±32.51

TABLE 2: Agreement between ABI and doppler ultrasound in diagnosis of pad (n=131)

Variable		Peripheral Arterial disease (Ultrasound)		Kappa
		Yes	No	
Peripheral arterial disease (ABI)	Yes	117 (96.7%)	01 (10%)	0.649
	No	04 (3.3%)	09 (90%)	

TABLE 3: Stratification of agreement between ABI and doppler ultrasound in diagnosis of PAD by age, gender and duration of diabetes (n=131)

Variables		Peripheral arterial disease (ABI)	Peripheral Arterial disease (Ultrasound)		Kappa
			Yes	No	
Age groups	<50 years	Yes	58	1	0.744
		No	2	5	
	>50 years	Yes	59	0	0.784
		No	2	4	
Gender	Male	Yes	93	1	0.729
		No	3	6	
	Female	Yes	24	0	0.762
		No	1	3	
Duration of diabetes	<8 years	Yes	56	1	0.649
		No	1	2	
	>8 years	Yes	61	0	0.762
		No	3	7	

DISCUSSION

Radiological diagnosis of peripheral arterial disease (PAD) is demanding. Secondary to its high incidence, prevalence and threatening consequences, PAD has attained an important place in health care. A large number of clinical and epidemiological studies have identified the interrelation of PAD frequency with patient's age and duration of diabetes.¹⁶ Due to non-standardized diagnostic procedures, there is reported differences in incidence and prevalence of PAD in several studies.¹⁷ Of 131 enrolled participants, 103 (78.6%) were male and 28 (21.4%) were female with female to male ratio of 1: 3.7. Mean duration of diabetes was 11.24 ± 5.62 years. Of 131 patients, 50 were presented with intermittent claudication, 55 with numbness, 35 with discoloration of skin (Gangrene) and 32 were presented with ulceration. ABI measurement (ankle systolic pressure/upper arm systolic pressure) is considered a diagnostic standard in the early diagnosis of PAD. It should be assessed in every diabetic patient presenting with foot ulcers, myalgias of unknown cause and decreased posterior tibial artery pulsations. ABI of > 1.0 is considered as normal. Patients having moderate and severe arterial disease i.e. ABI of 0.50 and below should be examined once in 3 months, and those having mild arterial disease with ABI values above 0.90 should be tested every one or two years. These authors have further recommended that in type II diabetic patients older than 35 years having diabetes of more than 20 years, as well as in type II diabetic patients older than 40, ABI should be evaluated once a year.¹⁸ The ABI is a more approachable and convenient method for screening PAD in the clinical setting than is color Doppler ultrasonography. However, it has the limitation of underestimating the presence of arterial disease, which may hinder proper management.¹⁹ Color doppler ultrasonography is a promising imaging technology for evaluation of vascular diseases. Its non-invasiveness, safety, and accuracy had led to its wide spread use. It has the advantage of providing substantial information regarding anatomical localization and the degree of stenosis. Furthermore, it also has the supremacy to demonstrate real time imaging which can further assess in determining the hemodynamic of arteries.²⁰ In contrast to our study, Sadr SM et al reported the sensitivity of USD for the diagnosis of PAD was calculated to be 100% and the overall agreement between ABI and USD was poor (Kappa=0.28).²¹ He further assessed that USD can be used for the confirmation of the diagnosis of PAD with 96.9% sensitivity and 96.2% specificity.²¹ However in our study we found that the agreement between ABI and Doppler ultrasound in diagnosis of PAD was 0.762 ($P < 0.05$) showing good agreement. The sensitivity of ABI with regards to Doppler was 90% and specificity of 96.7%. Another study showed the sensitivity and specificity between two modalities was found to be different in both feet i.e. 60% and 93.90% for right foot, meanwhile, 60% and 97.40% for left foot.²² Agreement between ABI and USD in the detection of arterial obstruction was evaluated by Ugwu et al and showed good agreement with DUS (kappa=0.65).²³ This study should be comprehended after taking into account the limitations. First, there are small numbers of patients and patients. Another type I diabetes mellitus was not included.

CONCLUSION

This study concludes that there is good agreement between color Doppler and ABI for the detection of peripheral artery disease. Color Doppler ultrasound is however having the advantage of displaying proper anatomy, arterial wall, localization and degree of stenosis. It is cost effective, convenient, and easily available and with its real time capabilities, hemodynamic status of the vessel can also be well demonstrated. However in financially constraint environment

Comment [Z5]: Is 0.762 a P Val? It is more than 0.05 ($P > 0.05$) not $P < 0.05$. statistically it shows that there is no significant relation between ABI and Doppler

Comment [Z6]: What is the relation between color doppler and ABI as the objective of the research

where there is limited access to color Doppler ultrasound, ABI can serve as an acceptable alternate to help in detection and improving PAD management in at-risk patients. .

Ethics approval and consent to participate: Ethical approval was obtained from the Ethical Review Board of our Advanced Radiology Clinic (ARC), Karachi, Pakistan, regarding data collection and use for research purposes. Written informed consent was obtained from all the patients for assigning them to sample and using their data in research.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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