Sensitivity and Specificity of Ankle Brachial Index for Diagnosis of Peripheral Arterial Disease in Diabetic Patients Presenting to University Hospital of Nepal

Karmacharya RM, Vaidya S, Yadav B, Sharma S, Bhatt S, Bhandari N, Bhandari S, Maharjan S, Bhusal J

Department of Surgery

Cardio Thoracic and Vascular Surgery Unit,

Dhulikhel Hospital, Kathmandu University Hospital,

Kathmandu University School of Medical Sciences,

Dhulikhel, Kavre, Nepal.

Corresponding Author

Robin Man Karmacharya

Department of Surgery

Cardio Thoracic and Vascular Surgery Unit,

Dhulikhel Hospital, Kathmandu University Hospital,

Kathmandu University School of Medical Sciences,

Dhulikhel, Kavre, Nepal.

E-mail: reachrobin773@gmail.com

Citation

Karmacharya RM, Vaidya S, Yadav B, Sharma S, Bhatt S, Bhandari N, et al. Sensitivity and Specificity of Ankle Brachial Index for Diagnosis of Peripheral Arterial Disease in Diabetic Patients Presenting to University Hospital of Nepal. *Kathmandu Univ Med J.* **Online First**.

ABSTRACT

Background

Diabetes is a significant risk factor for peripheral arterial disease (PAD) that increases morbidity and mortality. Hence, early detection of peripheral arterial disease is necessary. Evidence shows Ankle Brachial Index (ABI) as a promising test to diagnose peripheral arterial disease. However, sensitivity and specificity need to be evaluated before clinical use.

Objective

To determine Ankle Brachial Index sensitivity and specificity for the diagnosis of peripheral arterial disease in diabetic patients.

Method

Diabetic patients were recruited from Dhulikhel Hospital. Doppler ultrasonography (DUS) was done in all the recruited participants and peripheral arterial disease was assessed. Based on Jager's criteria, those with grade III and IV stenosis were diagnosed as peripheral arterial disease and underwent ankle brachial index. Ankle brachial indexscores below 0.9 and above 1.5 were considered abnormal. The diagnosis by ankle brachial index was matched against the gold standard doppler ultrasonography to determine its specificity and sensitivity. Descriptive statistics and independent t-tests were used for statistics. P-value < 0.05 was considered statistically significant.

Result

There were total of 237 diabetic patients of which 31.2% had peripheral arterial disease. We found high sensitivity and specificity of ankle brachial index when tested against doppler ultrasonography with the values ranging from 88.68-89.66% and 86.67-90% respectively.

Conclusion

Ankle brachial index can be used in clinical settings to diagnose peripheral arterial disease in individuals with diabetes mellitus.

KEY WORDS

Ankle brachial index, Diabetes, Peripheral arterial disease, Sensitivity, Specificity

INTRODUCTION

Peripheral arterial disease (PAD) is a disorder caused by decreased perfusion to the extremities as a consequence of atheromatous plaque leading to narrowing or obstruction of arteries.[1] The estimated worldwide prevalence of PAD is 236.62 million; of which 73% is contributed by low and middle-income countries (LMICs).[2] The symptom of PAD is usually seen as calf or thigh pain that worsens with walking termed claudication.[1] In severe cases, the complications of PAD may lead to non-healing ulcers and limb amputation, especially in patients suffering from Diabetes Mellitus (DM).[3] DM is considered the strongest risk factor for PAD after smoking with an odds ratio of 1.82-1.98.[2,4]

In DM, pathological changes such as vascular endothelial injury and hyperglycemia accelerate the atherosclerotic deposition in the vessels worsening the symptoms of PAD eventually increasing morbidity and mortality.[3] Therefore, early detection of PAD in patients with DM is necessary. Digital Subtraction angiography (DSA) is considered the gold standard to detect PAD but is uncommon due to the invasive nature of its procedure.[5] Unlike this, other non-invasive tests include Magnetic resonance angiography (MRA), Computed tomography angiography (CTA), Doppler ultrasound (DUS), and Ankle Brachial Index (ABI).[5] However, except for DUS and ABI, performing other tools require nephrotoxic contrast dye. Hence, DUS is preferred for reference standard in patients with DM taking into account renal protection and its high diagnostic accuracy.[6]

Likewise, the American heart association recommended ABI as the first-line test (Class I; level of evidence A) to detect PAD as it is the most simple, inexpensive, and easy-to-perform test.[7-9] It is measured by calculating the ratio of systolic blood pressure at the ankle (Dorsalis Pedis or posterior tibial artery) to that measured at the arm (brachial artery).[7-9] ABI value ranging from 0.9 to 1.4 is considered normal, less than 0.9 is indicative of narrowing of blood vessels, and greater than 1.4 of vessel stiffening/ calcification.[7-9]

Before using any test in clinical practice, the diagnostic accuracy of the test should be evaluated. A review by Xu et al found high specificity of ABI in diagnosing PAD but the sensitivity of PAD varied, especially in patients with Diabetes.8 It could be because of the variation in the protocol of performing ABI in the included studies which are supported by a study that found inaccuracies in the measurement of ABI in primary care practice.[10] ABI usually underestimates PAD in diabetic patients.[11] Thus clinicians are recommended to follow standard protocol to measure ABI.[10] Therefore, in our study, we aimed to use a standard step-by-step measurement procedure to determine the diagnostic accuracy (sensitivity and specificity) of ABI against reference standard DUS to diagnose PAD in patients with DM. Moreover, our study may as well fill the literature gap by investigating PAD in the Nepali population suffering from DM.

METHODS

This study used a cross-sectional design The study. involved diabetic patients under medication for diabetes visiting medicine OPD of Dhulikhel Hospital from 1st January 2023 to 30th June 2023. Participant recruitment started after the ethical clearance from Kathmandu University School of Medical Sciences, Institutional Review Committee. All the participants provided informed consent and were included in the study if they were diagnosed with Diabetes Mellitus by the medical doctor and excluded if they had a major amputation or were denied participation. Doppler ultrasonography (arterial Doppler) of the bilateral lower limb was done to note the presence of peripheral arterial disease (PAD). The Doppler measured the presence of LEAD along with the severity of the disease. During Doppler ultrasonography, Acuson P300 ultrasound (Siemens) was used with a 7.5-10 MHz linear probe. B mode, color mode, and pulse wave Doppler ultrasonography were used to note waveform, systolic velocity in the femoral artery, popliteal artery, Anterior Tibial Artery (ATA), Posterior Tibial Artery (PTA), and peroneal artery. Jager's criteria from Grade III to Grade IV were taken as significant PAD.6 In Grade III stenosis there is a monophasic waveform with an increase in peak systolic velocity ≥ 100% and marked spectral broadening.[6] there is no forward flow detected with altered flow patterns both proximal and distal to the stenosis for Grade IV stenosis.[6]

If PAD was diagnosed in at least one lower limb, they were also subjected to ABI. ABI was calculated using "Diabetik foot care" ABI machine. ABI was done by a trained nurse under direct supervision by a vascular surgeon. Prior to enrolling the patients, the nurse was trained by a vascular surgeon for two weeks with hands-on experience in at least 50 patients. ABI of the bilateral lower limb was calculated. ABI between 0.9-1.5 was taken as normal and other values as abnormal.

Prevalence of PAD in diabetic patients varies between 12-32%.[6] We expect high sensitivity and specificity of ABI. So, we calculated the sample size based on the study by Akoglu et al using the online calculator https://turkjemergmed.com/calculator.[12] We set the the prevalence at 32%, type I error at 5%, expected sensitivity/specificity at 90%, and marginal error at 10%. The sample sizes obtained for sensitivity and specificity were 108 and 51 respectively.

Data were entered in Microsoft Excel 2016 (Microsoft Corporation) and analyzed using Statistical Package for the Social Sciences version 20.0, SPSS Inc., IBM Corporation, Chicago. For scalar variables, mean, standard deviation and range were calculated. Frequency tables were made for nominal variables. For nonparametric variables, Chi-square test was done. For parametric variables, an independent sample t-test was done. Sensitivity and specificity of ABI taking Doppler ultrasonography as the gold standard was calculated. A p-value less than 0.05 was considered significant.

RESULTS

There were a total of 237 Diabetic patients who were screened for PAD among which 74 (31.2%) had PAD in at least one of the limbs. Of them, PAD was present in the bilateral lower limb in 47 patients (63.5%), only on the right lower limb in 16 patients (21.6%), and only on the left lower limb in 10 patients (13.5%). Of them, ABI was done in 68 patients. ABI was not done in six patients as they deferred for the test. Of the 68 patients in which ABI was done, PAD was present in the bilateral lower limb in 43 patients (63.2%), only on the right lower limb in 15 patients (22.1%), and only on the left lower limb in 10 patients (14.7%). The sensitivity and specificity of ABI (taking Doppler ultrasonography as the gold standard) were calculated for the right side, left side, and bilateral lower limb as shown in table 1-3. Maximum sensitivity was 89.66 and maximum specificity was 90%.

Table 1. Cross tabulation between ABI and Doppler finding on the right side

Cross tabulation between ABI and PAD present/absent		PAD present as confirmed by doppler ultrasonography	
		Yes	No
ABI detecting PAD	Yes	52	1
	No	6	9
Sensitivity 89.66%, Specificity 90%.			

Table 2. Cross-tabulation between ABI and Doppler finding on the left side

Cross tabulation between ABI and PAD present/absent		PAD present as confirmed by Doppler ultrasonography	
		Yes	No
ABI detecting PAD	Yes	47	2
	No	6	13
Sensitivity 88.68%, Specificity 86.67%.			

Table 3. Cross-tabulation between ABI and Doppler finding on both sides (n=136)

Cross tabulation between ABI and PAD present/absent		PAD present as confirmed by Doppler ultrasonography	
		Yes	No
ABI detecting PAD	Yes	99	3
	No	12	22
Sensitivity 89.19%, Specificity 88%.			

DISCUSSIONS

The objective of our study was to determine the diagnostic accuracy (sensitivity and specificity) of ABI against reference standard DUS. PAD was present in 31.2% of total participants with DM and we found high specificity and sensitivity of ABI in diagnosing PAD.

Our finding of having high specificity is in line with a study by Kashetsky et al that demonstrated the specificity ranging from 83-99%.[13] High specificity of ABI meant if ABI is less than 0.9, it is suggestive of arterial narrowing of more than 50%. In contrast, another study found low specificity of only 56% for arteries at the ankle which according to the authors was because the pulse could not be detected and ABI could not be reported.[14] But in our study, we didn't find any such issue, hence, our results differed from that study. Additionally, we found high sensitivity of ABI similar to a study that found a sensitivity of 95% using manual Doppler.[14] However, few other studies contradicted our findings showing low sensitivity of ABI.[14-16] The explanation authors provided for low sensitivity was the potential false readings due to artificial elevation of the pressure as a consequence of already calcified vessels. Unlike those studies, the high sensitivity in our study could be because we considered both ABI readings that showed calcification as well as narrowing as abnormal while the previous studies considered only narrowing as abnormal. Additionally, we followed the standard protocol for ABI in all patients.

This study compared the ABI findings with the reference standard, DUS. We used DUS in this study instead of other imaging techniques such as CTA, MRA, DSA, etc. because it is a non-invasive, safe, and accurate vascular imaging tool that provides location, extent of the disease, and hemodynamic details.[5,6] Collins et al. demonstrated 88% sensitivity and 96% specificity of DUS to diagnose PAD.[17] Moreover, DUS is relatively cheaper and does not require nephrotoxic contrast compared to CTA, MRA, and DSA.[5] When assessing the diagnostic accuracy of ABI against the diagnosis of PAD by DUS, a study done in the South Asian population found high sensitivity and specificity consistent with our results.[18] Another study found high specificity of ABI compared to DUS and recommended ABI as a diagnostic tool for PAD.[13]

In this study, the prevalence of PAD in DM was 31.2% which is higher than in other Asian countries. A Korean study found PAD in 25.2% of the population with DM.[6] Similarly, other studies done in the UK, and Asian countries found the prevalence of 20-29%, and 12-32%, respectively.[6,19,20] Higher prevalence in our settings could be because of the heterogeneity of the participants and another reason could be, we used both DUS and ABI to assess PAD while the above-noted studies only used ABI which might have underestimated PAD. Also, patients in our setting seek medical care only when the disease condition is severe which might also be the potential cause for high prevalence. Recent studies have used photoplethysmography, ABI and DUS for screening of peripheral arterial disease.[21] They have found photoplethysmography to have more sensitivity and specificity to diagnose peripheral arterial disease compared to ABI. However, ABI in conjuction to DUS has a very good sensitivity and specificity.

There are a few limitations of this study. The study design used does not show cause and effect relationship. Only participants with DM were included in the study and other risk factors that have been shown to be significantly associated with PAD such as smoking, hypertension were not studied. Therefore, future studies may be done in the general population exploring various risk factors contributing to PAD to know the burden of PAD which may increase the generalizability of the study.

CONCLUSION

In resource-limited settings like Nepal, ABI can be an acceptable vascular imaging tool with high specificity and sensitivity to diagnose PAD in patients with DM.

REFERENCES

1. Zemaitis MR, Boll JM, Dreyer MA. Peripheral Arterial Disease. 2023 May 23. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan–. PMID: 28613496.
2. Song P, Rudan D, Zhu Y, Fowkes FJI, Rahimi K, Fowkes FGR, et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. *Lancet Glob Health.* 2019 Aug;7(8):e1020-e1030. doi: 10.1016/S2214-109X(19)30255-4. PMID: 31303293.
3. Soyoye DO, Abiodun OO, Ikem RT, Kolawole BA, Akintomide AO. Diabetes and peripheral artery disease: A review. *World J Diabetes.* 2021 Jun 15;12(6):827-838. doi: 10.4239/wjd.v12.i6.827. PMID: 34168731; PMCID: PMC8192257.
4. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet.* 2013 Oct 19;382(9901):1329-40. doi: 10.1016/S0140-6736(13)61249-0. Epub 2013 Aug 1. PMID: 23915883.
5. Tran B. Assessment and management of peripheral arterial disease: what every cardiologist should know. *Heart.* 2021 Nov;107(22):1835-1843. doi: 10.1136/heartjnl-2019-316164. Epub 2021 May 13. PMID: 33985986; PMCID: PMC8562307.
6. Hur KY, Jun JE, Choi YJ, Lee YH, Kim DJ, Park SW, et al. Color Doppler Ultrasonography Is a Useful Tool for Diagnosis of Peripheral Artery Disease in Type 2 Diabetes Mellitus Patients with Ankle-Brachial Index 0.91 to 1.40. *Diabetes Metab J*. 2018 Feb;42(1):63-73. doi: 10.4093/dmj.2018.42.1.63. PMID: 29504306; PMCID: PMC5842302.
7. Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al. Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. *Circulation*. 2012 Dec 11;126(24):2890-909. doi: 10.1161/CIR.0b013e318276fbcb. Epub 2012 Nov 16. Erratum in: Circulation. 2013 Jan 1;127(1):e264. PMID: 23159553.
8. Dachun Xu, Jue Li, Liling Zou, Yawei Xu, Dayi Hu, Pagoto SL, et al. Sensitivity and specificity of the ankle--brachial index to diagnose peripheral artery disease: a structured review. *Vasc Med*. 2010 Oct;15(5):361-9. doi: 10.1177/1358863X10378376. PMID: 20926495.
9. McClary KN, Massey P. Ankle Brachial Index. 2023 Jan 16. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan–. PMID: 31334946.
10. Nicolaï SP, Kruidenier LM, Rouwet EV, Bartelink ML, Prins MH, Teijink JA. Ankle brachial index measurement in primary care: are we doing it right? *Br J Gen Pract*. 2009 Jun;59(563):422-7. doi: 10.3399/bjgp09X420932. PMID: 19520025; PMCID: PMC2688044.
11. Aerden D, Massaad D, von Kemp K, van Tussenbroek F, Debing E, Keymeulen B, et al. The ankle--brachial index and the diabetic foot: a troublesome marriage. *Ann Vasc Surg*. 2011 Aug;25(6):770-7. doi: 10.1016/j.avsg.2010.12.025. Epub 2011 Apr 21. PMID: 21514102.
12. Akoglu H. User's guide to sample size estimation in diagnostic accuracy studies. *Turk J Emerg Med*. 2022 Sep 30;22(4):177-185. doi: 10.4103/2452-2473.357348. PMID: 36353389; PMCID: PMC9639742.
13. Kashetsky N, Sachdeva M, Lu JD, Mufti A, Kim P, Bagit A, et al. Diagnostic Accuracy of Ankle-Brachial Pressure Index Compared with Doppler Arterial Waveforms for Detecting Peripheral Arterial Disease: A Systematic Review. Adv Skin Wound Care. 2022 Apr 1;35(4):195-201. doi: 10.1097/01.ASW.0000822628.82131.1d. PMID: 35311767.
14. Crawford F, Welch K, Andras A, Chappell FM. Ankle brachial index for the diagnosis of lower limb peripheral arterial disease. *Cochrane Database Syst Rev.* 2016 Sep 14;9(9):CD010680. doi: 10.1002/14651858.CD010680.pub2. PMID: 27623758; PMCID: PMC6457627.
15. Chuter VH, Searle A, Barwick A, Golledge J, Leigh L, Oldmeadow C, et al. Estimating the diagnostic accuracy of the ankle-brachial pressure index for detecting peripheral arterial disease in people with diabetes: A systematic review and meta-analysis. *Diabet Med.* 2021 Feb;38(2):e14379. doi: 10.1111/dme.14379. Epub 2020 Sep 22. PMID: 32740980.
16. Guirguis-Blake JM, Evans CV, Redmond N, Lin JS. Screening for Peripheral Artery Disease Using the Ankle-Brachial Index: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*. 2018 Jul 10;320(2):184-196. doi: 10.1001/jama.2018.4250. PMID: 29998343.
17. Collins R, Burch J, Cranny G, Aguiar-Ibáñez R, Craig D, Wright K, et al. Duplex ultrasonography, magnetic resonance angiography, and computed tomography angiography for diagnosis and assessment of symptomatic, lower limb peripheral arterial disease: systematic review. *BMJ*. 2007 Jun 16;334(7606):1257. doi: 10.1136/bmj.39217.473275.55. Epub 2007 Jun 4. PMID: 17548364; PMCID: PMC1892528.
18. Weragoda J, Seneviratne R, Weerasinghe MC, Wijeyaratne SM. ABPI against Colour Duplex Scan: A Screening Tool for Detection of Peripheral Arterial Disease in Low Resource Setting Approach to Validation. *Int J Vasc Med*. 2016;2016:1390475. doi: 10.1155/2016/1390475. Epub 2016 Mar 10. PMID: 27034837; PMCID: PMC4806287.
19. Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA. 2001 Sep 19;286(11):1317-24. doi: 10.1001/jama.286.11.1317. PMID: 11560536.
20. Rhee SY, Guan H, Liu ZM, Cheng SW, Waspadji S, Palmes P, et al. Multi-country study on the prevalence and clinical features of peripheral arterial disease in Asian type 2 diabetes patients at high risk of atherosclerosis. Diabetes Res Clin Pract. 2007 Apr;76(1):82-92. doi: 10.1016/j.diabres.2006.07.029. Epub 2006 Sep 6. PMID: 16950543.
21. Huang HL, Chang CH, Lo MT, Lin C. Diagnostic Potential of Combined Photoplethysmography and Ankle-Brachial Index in Peripheral Arterial Disease: A Duplex Ultrasonography-Based Comparative Study. *J Am Heart Assoc*. 2024 Oct;13(19):e034625. doi: 10.1161/JAHA.124.034625. Epub 2024 Sep 30. PMID: 39344605; PMCID: PMC11681468.