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Audible handheld Doppler ultrasound determines reliable and inexpensive exclusion of significant peripheral arterial disease

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Abstract

Objective: To determine the accuracy of audible arterial foot signals with an audible handheld Doppler ultrasound for identification of significant peripheral arterial disease as a simple, quick, and readily available bedside screening tool.

Methods: Two hundred consecutive patients referred to an interprofessional wound care clinic underwent audible handheld Doppler ultrasound of both legs. As a control and comparator, a formal bilateral lower leg vascular study including the calculation of Ankle Brachial Pressure Index and toe pressure (TP) was performed at the vascular lab. Diagnostic reliability of audible handheld Doppler ultrasound was calculated versus Ankle Brachial Pressure Index as the gold standard test.

Results: A sensitivity of 42.8%, a specificity of 97.5%, negative predictive value of 94.10%, positive predictive value of 65.22%, positive likelihood ratio of 17.52, and negative likelihood ratio of 0.59. The univariable logistic regression model had an area under the curve of 0.78. There was a statistically significant difference at the 5% level between univariable and multivariable area under the curves of the dorsalis pedis and posterior tibial models ($p < 0.001$).

Conclusion: Audible handheld Doppler ultrasound proved to be a reliable, simple, rapid, and inexpensive bedside exclusion test of peripheral arterial disease in diabetic and nondiabetic patients.

Keywords

Peripheral arterial disease, ankle brachial index, leg ulcers, audible Doppler, standard test, compression therapy

Introduction

Lower extremity peripheral arterial disease (PAD) affects about 12% of older general population (age > 65).[1–3] Ankle brachial pressure index (ABPI), the established gold standard PAD screening test, is commonly measured in a vascular lab using a handheld continuous wave (CW) Doppler.[1] However, about 80% of persons with diabetes and 20% of nondiabetic patients have calcified, noncompressible arterial vessels[4] and a direct toe systolic pressure or Toe Brachial Pressure Index (TBPI) measurement is considered a more reliable standard.[5,6] The current PAD detection standard is an ABPI lower than 0.9 or toe pressure (TP) below 55 mmHg.[7] However, vascular lab tests are costly and in some countries and communities, long waiting lists exist and preclude the patients from adequate treatment (e.g., compression therapy for venous ulcers). Accordingly, there is a need for an alternative quick point of care bedside assessment method to exclude PAD. The aim of our study was to determine the accuracy of audible handheld Doppler ultrasound (AHDU) to detect or exclude significant PAD as a simple, quick, and readily available bedside screening tool.

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Methods

Participants

We retrospectively analyzed data from 200 consecutive consenting patients at the Toronto Regional Wound Healing Clinic for foot and lower leg ulcers of different etiologies from July 2012 to July 2013. The institutional ethics review board approved the study.

Diagnostic measurements

All patients underwent a sequential CW Doppler examination of both the left and right legs at the clinic using an AHDU. In addition, a formal bilateral lower leg vascular study was performed at our certified vascular lab including the calculation of ABPI and TP. In the clinic, two nurses and two physicians with at least three years experience in treating patients with chronic wounds determined the quality of the audible arterial signals (monophasic, biphasic, or triphasic) of the dorsalis pedis (DP) and/or posterior tibial (PT) arteries after at least 5 min supine resting position using an AHDU device with 8 MHZ probe (Huntleigh Multi Duplex II Bi-Directional Doppler, HNE Diagnostics, Cardiff, UK). The two clinicians and all of the Doppler technicians were blinded to the results of the alternative assessment.

The exclusion criteria were:

1. inability to measure systolic pressures of both tibial arteries due to occlusion or amputation;
2. inability to determine the AHDU arterial waveform due to an ulcer in the area of interest;
3. patient refusal to give informed consent.

Statistical analysis

Our primary analysis evaluated the diagnostic reliability of AHDU versus the ABPI gold standard test for measurements taken on the DP and PT arteries, separately, while combining the diagnostic measurements on the left and right limb. Because of the dependent nature of the data (i.e., partially based on the same data, data from both legs of each subject), standard statistical testing methods were inappropriate; thus, our estimates and corresponding 95% confidence intervals (CIs) were determined from a bootstrap procedure with 1000 replications.[8]

ABPI was categorized into two groups, normal ABPI (>0.9 and <1.3) and abnormal ABPI (<0.9).[9] Under the hypothesis that triphasic signal indicated adequate blood supply for healing (i.e., normal), biphasic compromised blood supply while monophasic indicated PAD (i.e., abnormal), we calculated specificity, the proportion of individuals without the PAD that are correctly identified by ADHU; sensitivity, the proportion of individuals with PAD that are correctly identified by ADHU; positive predictive value (PPV), the proportion of individuals with an abnormal ADHU reading who actually have PAD; and negative predictive value (NPV), the proportion of individuals with a normal ADHU reading who actually do not have PAD; positive likelihood ratio (LR), the probability of a person who has the disease testing positive divided by the probability of a person who does not have the disease testing positive; and negative LR, the probability of a person who has the disease testing negative divided by the probability of a person who does not have the disease testing negative, along with their corresponding 95% CIs.

Receiver operating characteristic (ROC) analyses was performed to describe the relationship between sensitivity and specificity of ABPI and AHDU at various cutoff values. ROC curves were smoothed using a univariable logistic regression model. An optimum cutoff value was estimated that maximized the sensitivity and specificity. The area under the curve (AUC) was calculated as a measure of overall diagnostic performance along with 95% CIs. A truly uninformative test with no discriminatory power (one no better at identifying true positives than flipping a coin) has an area of 0.5, while a perfect (theoretical) test (one that has zero false positives and zero false negatives) has an area of 1.00. In general, AUCs of 0.5–0.7 represent no to low discriminatory power; 0.7–0.9 represents moderate discriminatory power; and >0.9 represents high discriminatory power.[10]

A subgroup analysis was performed to evaluate the diagnostic reliability of AHDU versus the ABPI for persons with diabetes versus nondiabetics, males versus females, age ≤ 65 versus age > 65, and lower leg ulcers versus foot ulcers.

As previously mentioned, diabetes status is an important predictor of the overall diagnostic performance of ADHU. Thus, a multivariable logistic regression was used to model the association between AHDU and diabetes status with the dichotomized ABPI measurement. The remaining signs or symptoms were investigated using a forward selection procedure using a significance level of 0.15, where a sign or symptom common to both the PT and DP regression models was kept in the models. The AUC was calculated for the final multivariable logistic regression models along with 95% CIs.

The difference in AUC between the univariable models and the multivariable models was compared using the methods described in Hanley and McNeil.[11]

Our secondary analysis included an evaluation of the diagnostic reliability of AHDU versus TP. Here, TP measurements were categorized into two groups, normal (>55 mmHg) and abnormal (<55 mmHg), with the methods from the primary univariable analysis applied in the same way.

Since AHDU is an audible and therefore operator dependent test, interrater reliability (percentage agreement and Cohen's Kappa) was evaluated by selecting 20 consecutive patients to undergo AHDU for both legs (40 legs in total) by two independent operators: a nurse and a physician. The physician and the nurse were blinded to each other's assessment.

All analyses were performed using Stata 13.

Results

A total of 400 possible legs were included in this analysis. A total of 379 ABPI measurements were taken on PT and 394 measurements taken on DP, with 37 and 38 observations excluded with ABPI measurements greater than 1.3, respectively. TP was measured in 364 legs. AHDU detected 28 monophasic, 235 biphasic, and 136 triphasic audible arterial signals among the 400 legs. Detailed patient characteristics are presented in Table 1.

The interrater reliability test demonstrated 87.5% agreement between the physician and the nurse performing AHDU (Cohen's kappa = 0.76).

Tables 2 and 3 show the results of sensitivity, specificity, NPV, PPV, positive and negative likelihoods for AHDU measurements taken on PT and DP. In particular, we report a specificity of 98.6% (95% CI: 96.96, 99.67) and 97.8% (95% CI: 95.27, 99.64); a sensitivity of 37.5% (95% CI: 25.00, 50.98) and 30.19% (95% CI: 18.52, 43.10); PPV of 81.82% (95% CI: 61.90, 94.74) and 72.73% (95% CI: 54.55, 89.47); NPV of 90.91% (95% CI: 87.02, 93.94) and 88.10% (95% CI: 82.04, 92.36); positive LR of 28.50 (95% CI: 11.81, 118.17) and 14.09 (95% CI: 6.20, 58.30); and negative LR of 0.63 (95% CI: 0.50, 0.76) and 0.71 (95% CI: 0.58, 0.82) for measurements on DP and PT, respectively. These results show a similar consistency across subgroups.

Figures 1 and 2 show the results for the ROC analysis for the univariable and multivariable logistic regression models, which only includes diabetes status as a predictor. The theoretical optimum cutoff value was 0.90 for both the PT and DP univariable models, which correctly classified patients with 87.0% and 90.3% accuracy, respectively.

Table 1. Patient characteristics.

		AHDU, right			AHDU, left		
	Overall population ($n = 200$)	Monophasic ($n = 13$)	Biphasic ($n = 119$)	Triphasic ($n = 67$)	Monophasic ($n = 15$)	Biphasic ($n = 116$)	Triphasic ($n = 69$)
Male (%)	117 (58.5)	10 (76.9)	71 (59.7)	36 (53.7)	10 (66.7)	73 (62.9)	34 (49.3)
Diabetics (%)	88 (44)	7 (53.8)	55 (46.2)	25 (37.3)	8 (53.3)	58 (50.0)	22 (31.9)
Mean age (*SD*)	67.6 (12.0)	75.1 (12.5)	69.0 (11.6)	63.4 (11.6)	75.7 (13.0)	68.5 (11.5)	64.2 (11.6)
ABPI							
Mean ABPI, DP right (*SD*)	1.07 (0.21)	0.92 (0.40)	1.05 (0.19)	1.14 (0.15)	0.84 (0.40)	1.06 (0.18)	1.13 (0.15)
Mean ABPI, DP left (*SD*)	1.06 (0.23)	0.78 (0.43)	1.07 (0.21)	1.12 (0.14)	0.80 (0.48)	1.07 (0.20)	1.12 (0.14)
Mean ABPI, PT right (*SD*)	1.07 (0.24)	0.88 (0.44)	1.06 (0.24)	1.13 (0.14)	0.93 (0.62)	1.05 (0.19)	1.13 (0.13)
Mean ABPI, PT left (*SD*)	1.08 (0.25)	0.83 (0.46)	1.07 (0.24)	1.14 (0.14)	0.81 (0.49)	1.08 (0.23)	1.13 (0.14)
Toe pressure							
Toe pressure, right (*SD*)	95.4 (32.2)	47.6 (27.4)	97.3 (31.2)	102.2 (24.9)	48.0 (34.3)	97.9 (31.2)	100.3 (26.0)
Toe pressure, left (*SD*)	96.9 (30.7)	51.7 (31.6)	97.4 (29.3)	105.0 (25.2)	48.6 (28.8)	98.3 (28.9)	103.8 (26.0)
Ulcer location							
Lower leg (%)	134 (67.0)	5 (38.5)	81 (68.1)	47 (70.1)	7 (46.7)	77 (66.4)	50 (72.5)
Foot (%)	66 (33.0)	8 (61.5)	38 (11.9)	20 (29.9)	8 (53.3)	39 (33.6)	19 (27.5)

Note: DP, dorsalis pedis; PT, posterior tibial; ABPI, Ankle Brachial Pressure Index; AHDU, audible handheld Doppler ultrasound.

Table 2. Primary analysis: sensitivity, specificity, NPV, PPV, positive and negative likelihoods for AHDU measurements taken on dorsalis pedis artery.

	PPV (%) (95% CI)	NPV (%) (95% CI)	Specificity (%) (95% CI)	Sensitivity (%) (95% CI)	LR+ (95% CI)	LR− (95% CI)
Overall population	81.82 (61.90, 94.74)	90.91 (87.02, 93.94)	98.68 (96.96, 99.67)	37.50 (25.00, 50.98)	28.50 (11.81, 118.17)	0.63 (0.50, 0.76)
Diabetics	80.00 (60.00, 92.31)	86.13 (79.41, 91.67)	98.33 (96.08, 99.25)	29.63 (15.38, 50.00)	17.78 (6.72, 52.73)	0.72 (0.52, 0.85)
Nondiabetics	83.33 (58.33, 93.33)	94.30 (90.59, 97.50)	98.91 (97.34, 99.50)	47.62 (27.78, 70.59)	43.81 (14.78, 122)	0.53 (0.30, 0.73)
Males	86.67 (69.23, 95.24)	91.62 (87.70, 95.45)	98.80 (96.88, 99.45)	46.43 (28.00, 67.74)	38.54 (13.28, 100.94)	0.54 (0.33, 0.73)
Females	71.43 (50.87.50)	90.07 (84.94, 94.56)	98.55 (96.55, 99.33)	25.00 (10.52, 45.00)	17.25 (7.14, 53.21)	0.76 (0.58, 0.92)
Age ≤ 65	75.00 (60.00, 90.00)	91.67 (86.71, 95.36)	99.31 (98.46, 99.42)	18.75 (5.56, 36.36)	27.00 (9.19, 69.00)	0.82 (0.64, 0.95)
Age > 65	83.33 (62.50, 95.00)	90.23 (85.34, 94.38)	98.13 (95.91, 99.41)	46.88 (30.43, 65.57)	25.00 (10.11, 94.71)	0.54 (0.35, 0.71)
Lower leg ulcer	77.78 (50.00, 90.91)	93.45 (90.22, 96.52)	99.07 (97.66, 99.56)	31.82 (14.29, 53.33)	34.36 (11.20, 97.68)	0.69 (0.46, 0.86)
Foot ulcer	84.62 (63.64, 94.44)	85.15 (76.92, 91.58)	97.73 (94.57, 99.03)	42.31 (25.00, 62.50)	18.62 (6.16, 54.63)	0.59 (0.36, 0.77)

Note: NPV, negative predictive value; PPV, positive predictive value; LR+, positive likelihood ratio; LR−, negative likelihood ratio; CI, confidence interval; AHDU, audible handheld Doppler ultrasound.

Table 3. Primary analysis: sensitivity, specificity, NPV, PPV, positive and negative likelihoods for AHDU measurements taken on posterior tibial artery.

	PPV (%) (95% CI)	NPV (%) (95% CI)	Specificity (%) (95% CI)	Sensitivity (%) (95% CI)	LR+ (95% CI)	LR− (95% CI)
Overall population	72.73 (54.55, 89.47)	88.10 (82.04, 92.36)	97.86 (95.27, 99.64)	30.19 (18.52, 43.10)	14.09 (6.20, 58.30)	0.71 (0.58, 0.82)
Diabetics	88.89 (80.00, 94.12)	82.71 (76.03, 88.71)	99.10 (98.13, 99.26)	25.81 (12.00, 43.75)	28.65 (12.01, 55.50)	0.75 (0.57, 0.89)
Nondiabetics	61.54 (50.00, 81.82)	92.13 (88.27, 96.15)	97.04 (93.37, 98.81)	36.36 (18.18, 53.85)	12.29 (6.49, 31.40)	0.66 (0.48, 0.84)
Males	78.57 (57.14, 93.33)	88.10 (82.17, 92.18)	98.01 (95.36, 99.36)	35.48 (20.00, 50.00)	17.86 (7.22, 63.39)	0.66 (0.50, 0.81)
Females	62.50 (50.00, 84.62)	88.11 (81.94, 92.81)	97.67 (95.73, 99.28)	22.73 (7.41, 38.89)	9.77 (4.30, 25.60)	0.79 (0.65, 0.94)
Age ≤ 65	50.00 (50.00, 75.00)	91.89 (87.41, 95.92)	98.55 (96.30, 99.29)	14.29 (5.00, 26.67)	9.89 (6.35, 16.75)	0.87 (0.78, 0.96)
Age > 65	77.78 (54.55, 93.33)	84.66 (78.48, 89.44)	97.18 (93.29, 99.27)	35.90 (22.45, 52.27)	12.74 (4.82, 51.56)	0.66 (0.49, 0.81)
Lower leg ulcer	77.78 (53.33, 91.67)	91.08 (87.27, 94.61)	98.98 (97.52, 99.52)	26.92 (12.00, 45.00)	26.38 (9.15, 76.70)	0.74 (0.56, 0.89)
Foot ulcer	69.23 (50.00, 90.91)	81.63 (74.47, 89.11)	95.24 (90.12, 98.73)	33.33 (20.00, 53.85)	7.00 (3.00, 26.48)	0.70 (0.50, 0.86)

Note: AHDU, audible handheld Doppler ultrasound; NPV, negative predictive value; PPV, positive predictive value; LR+, positive likelihood ratio; LR−, negative likelihood ratio; CI, confidence interval.

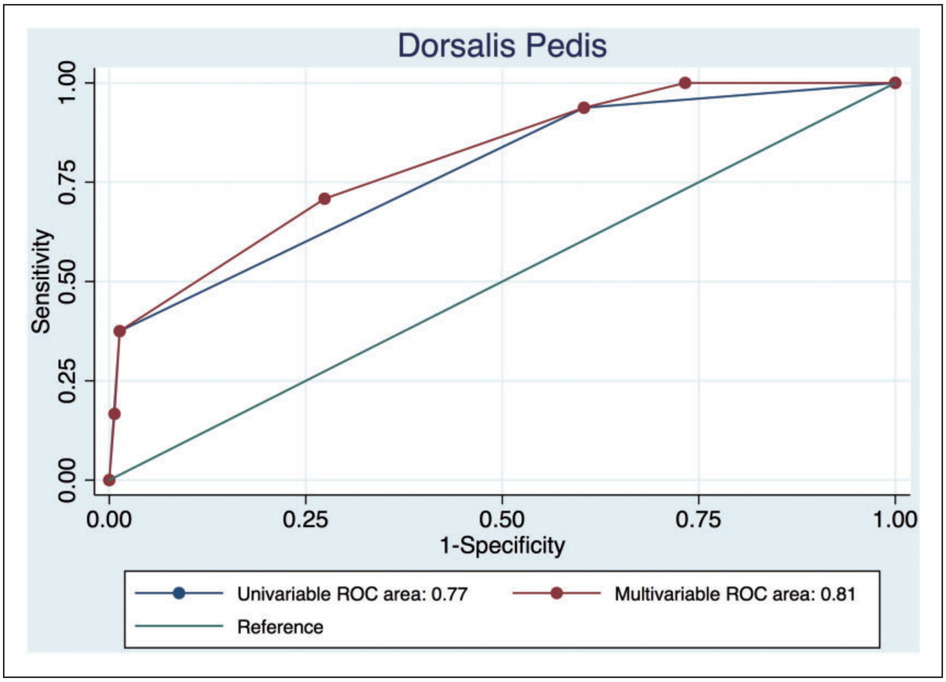

Figure 1. ROC curves of dorsalis pedis. *Note*: ROC, Receiver operating characteristic.

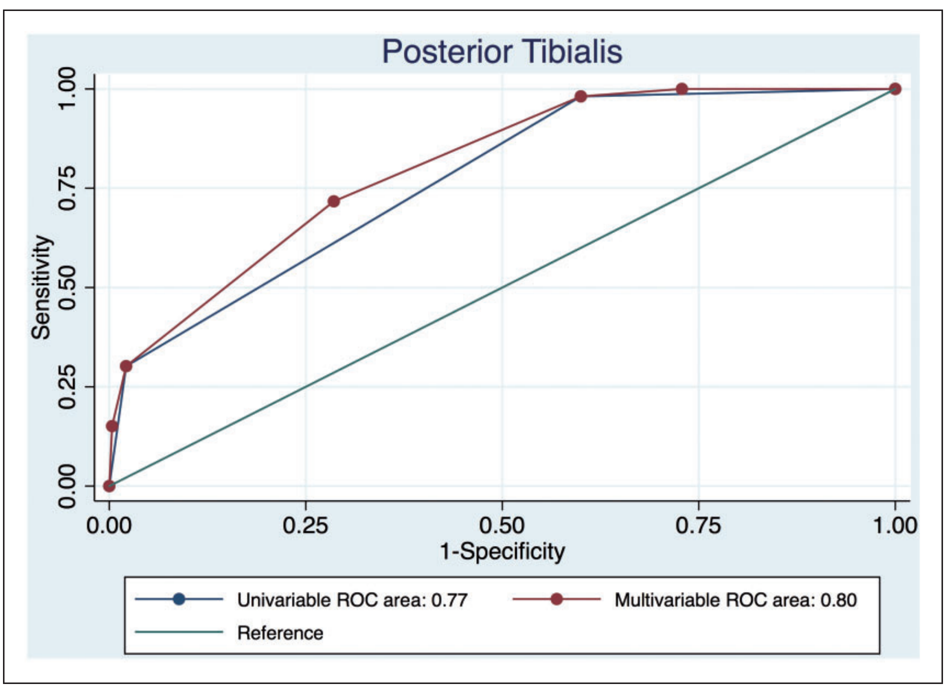

Figure 2. ROC curves of posterior tibialis. *Note*: ROC, Receiver operating characteristic.

Under a univariable and multivariable logistic regression model, the AUC for measurements on DP was 0.77 (95% CI: 0.70, 0.84) and 0.81 (95% CI: 0.73, 0.87), respectively. These results were consistent measurements taken on PT, where AUC for the univariable model was 0.77 (95% CI: 0.66, 0.84) and 0.80 (95% CI: 0.70, 0.87) for the multivariable model. There was a statistically significant difference at the 5% level

Table 4. Evaluation the diagnostic reliability of AHDU versus toe pressure.

	PPV (%) (95% CI)	NPV (%) (95% CI)	Specificity (%) (95% CI)	Sensitivity (%) (95% CI)	LR+ (95% CI)	LR− (95% CI)
Overall population	65.22 (50.00, 82.61)	94.10 (90.56, 96.61)	97.55 (95.12, 99.08)	42.86 (25.64, 56.76)	17.52 (8.90, 46.89)	0.59 (0.43, 0.75)

Note: AHDU, audible handheld Doppler ultrasound; NPV, negative predictive value; PPV, positive predictive value; LR+, positive likelihood ratio; LR−, negative likelihood ratio.

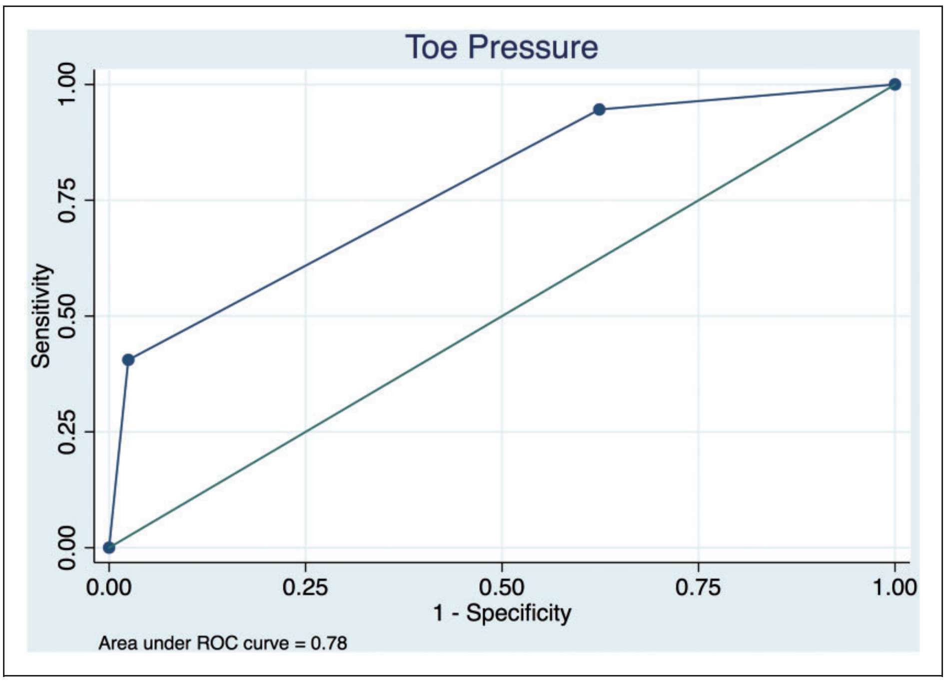

Figure 3. ROC curves of toe pressures. *Note*: ROC, Receiver operating characteristic.

between univariable and multivariable AUCs of the DP and PT models ($p < 0.001$).

Table 4 shows the results of our secondary analysis, which evaluated the diagnostic reliability of AHDU versus TP. Here, we show a sensitivity of 42.8% (95% CI: 25.64, 56.76), a specificity of 97.55% (95% CI: 95.12, 99.08), NPV of 94.10% (95% CI: 90.56, 96.61), PPV of 65.22% (95% CI: 50.00, 82.61), positive LR of 17.52 (95% CI: 8.90, 46.89), and negative LR of 0.59 (95% CI: 0.43, 0.75). The univariable logistic regression model had an AUC of 0.78 (95% CI: 0.69, 0.85) (Figure 3). The theoretical optimum cutoff value was 55 mmHg, which correctly classified patients with 92.3% accuracy (Figure 4).

Discussion

To date, ABPI (usually measured in a specialized vascular lab) is the accepted gold standard for the detection or exclusion of PAD.[10] Carter demonstrated that ABPI < 0.9 has 95% sensitivity and 90% specificity as compared to angiography-documented PAD.[11,12] Most of the recent studies consider ABPI of 0.9–1.3 as normal. Therefore, this cutoff point for detection of PAD was benchmarked for this study.[9]

ABPI, although not a complicated testing procedure, often requires considerable time due to the presence of lower extremity wounds, local pain, edema, woody fibrosis, confused or handicapped patients. Furthermore, depending on country and health care system, there may be long waiting list for duplex Doppler test. Therefore, the combination of a physical examination and simple nonexpensive bedside AHDU alternative test can improve the quality and speed up the process of PAD ulcer patient assessment.

The current study demonstrated that audible waveform analysis using AHDU produced comparable results to an ABPI with cutoff point of 0.9 (Figure 5). AHDU had an overall sensitivity of 42.8% and specificity

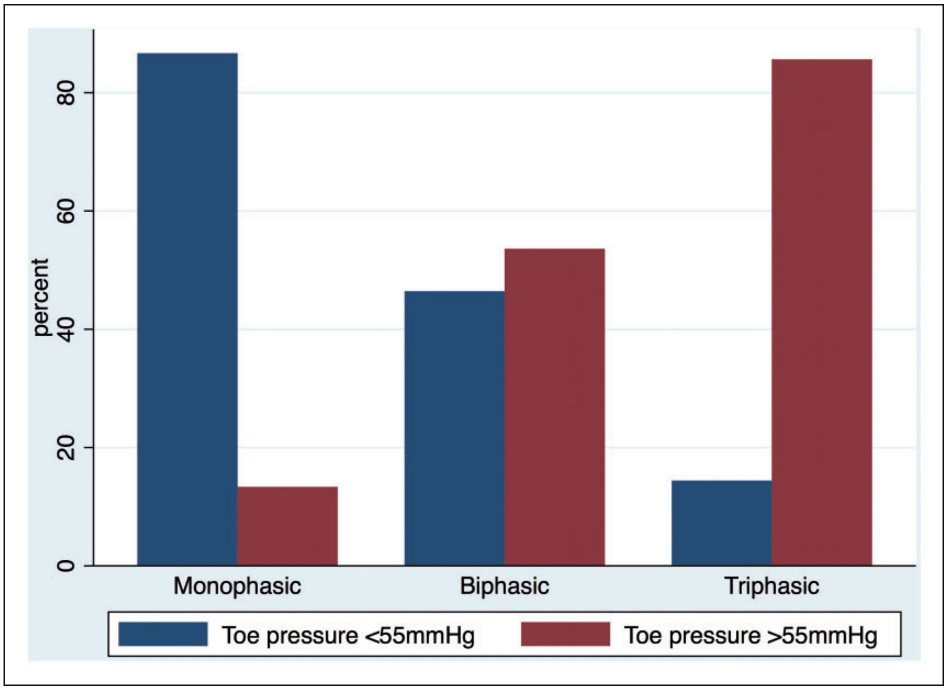

Figure 4. Toe pressure distribution based on AHDU wave forms.

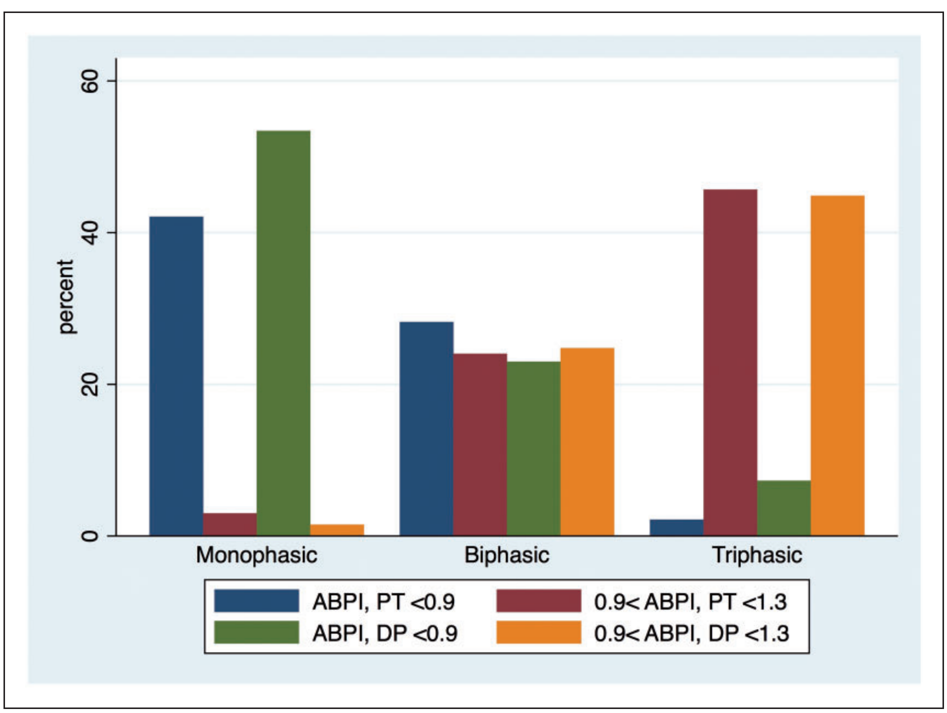

Figure 5. ABPI distribution based on AHDU waveforms. *Note*: ABPI, Ankle Brachial Pressure Index.

97.5% with a positive LR+ = 17.52 in the population studied. The LR is a better tool to judge whether a test result usefully changes the probability that a condition exists because LR assesses the value for performing a diagnostic test. LR of greater than 1 indicates the test result is associated with the disease. In this study, the LR+ = 17.52 is a proof for the usefulness of the test. The high NPV (94.10%) is consistent with our hypothesis that triphasic and biphasic waves in AHDU are useful indicators for exclusion of PAD. Furthermore, the high specificity (97.55%) of AHDU in study population for PAD should allow considering it as a primary screening test.

Referral to a vascular specialist or vascular laboratory formalized duplex segmental exam is recommended for patients with monophasic AHDU waves. The marginal PPV (65.22%) does not allow the use of an AHDU as a conclusive diagnostic test or facilitate mapping of arterial segments for further investigations and possible arterial interventions (angioplasty or bypass).[12,13]

The limitations of our study include a medium-sized sample and relatively small number of subjects assessed for interrater reliability. However, the high positive LR shows that results are consistent and reproducible. Additionally, there are some publications that are skeptical about distinguishing three types of audible Doppler signals, but would prefer to state if the signal is present or absent. On the contrary, Young et al.[14] determined the reliability of AHDU waves comparing students with registered podiatrists and demonstrated the accuracy of audible output interpretation by podiatrists. The strength of our study includes the high interrater reliability test of 87.5% agreement between the physician and the nurse performing AHDU, the wide availability of portable handheld Doppler ultrasound device along with the ability to perform the test in a shorter time frame.

Conclusions

AHDU with its very high specificity, positive LR and NPV for general populations and other subgroups can be utilized as a simple, fast, and accurate test for exclusion of PAD in diabetic and nondiabetic patients. The low cost and the inexpensive equipment required for the AHDU may be of special interest considering the high prevalence of PAD in aging population. We suggest AHDU is suitable alternative to the ABPI for a screening tool as a reliable and quick test before commencing therapy (e.g., compression therapy) or referring the patient. Further studies are needed to confirm the important conclusions from this analysis.

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Conflict of interest

None declared.

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