Diagnostic Accuracy of Ankle-Brachial Pressure Index Compared with Doppler Arterial Waveforms for Detecting Peripheral Arterial Disease: A Systematic Review

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GENERAL PURPOSE: To present the results of a research study evaluating the diagnostic accuracy of the ankle-brachial pressure index (ABPI) compared with that of Doppler arterial waveforms (DAWs) to detect peripheral arterial disease (PAD).

TARGET AUDIENCE: This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES: After completing this continuing education activity, the participant will:

1. Summarize the evidence the authors considered when comparing the diagnostic accuracy of the ABPI with that of Doppler arterial waveforms to detect PAD.
2. Select the characteristics of the participants in the studies the authors analyzed.
3. Identify the results of the authors' study comparing the diagnostic accuracy of the ABPI with that of Doppler arterial waveforms to detect PAD.
4. Distinguish the authors' conclusions about the advantages of using Doppler arterial waveforms to detect PAD.

ABSTRACT

Although the ankle-brachial pressure index (ABPI) is a useful tool for the noninvasive assessment of peripheral arterial disease (PAD), it has several limitations necessitating alternative noninvasive diagnostic tools. This study assesses the diagnostic accuracy of ABPI compared with Doppler arterial waveforms (DAWs) to detect PAD. The authors searched Embase and MEDLINE for original studies that reported sensitivities and specificities for both the ABPI and DAW. Four studies were included representing 657 patients (58.8% men) with a mean age of 63.4 years. The authors detected overall higher sensitivities using DAW compared with ABPI but higher specificities with ABPI compared with DAW. In conclusion, because of the higher sensitivity and lower specificity of DAW compared with ABPI, the authors recommend DAW as a potential screening tool for PAD. To confirm these results, larger sample sizes and comparative trials with homogeneous reference standards and patient populations are required. In addition, DAW is not easily documented for everyday bedside practice in the community. With COVID-19 restrictions, an audible handheld Doppler signal may act as a reproducible equivalent to DAW and thus facilitate timely, safe application of compression therapy at point-of-care.

KEYWORDS: ABPI, ankle-brachial pressure index, assessment, diagnosis, Doppler, peripheral arterial disease, waveform

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INTRODUCTION

Peripheral arterial disease (PAD) is characterized by lower extremity occlusive lesions and includes aortic and branch artery stenotic, occlusive, and aneurysmal diseases.[1] It may cause and complicate lower extremity ulcers from other primary causes, with decreased healing as a result of a decreased blood supply.[1–3] In addition, PAD is associated with increased risk of cardiovascular mortality and morbidity as well as lower leg amputation.[4] With an increasing prevalence of PAD—50% of people over 85 years are affected[4]—appropriate testing for accurate early diagnoses are of utmost importance for timely prevention and management of wounds secondary to PAD.[2,5]

The 2016 *Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease* begins with obtaining the patient's clinical history, followed by review of symptoms and physical examination for clinical signs including obtaining pulses, auscultation for femoral bruits, and lower extremity inspection.[6] The ankle-brachial pressure index (ABPI) is generally used as the initial diagnostic tool to confirm the diagnosis of PAD. Classically, it is measured with a sphygmomanometer and Doppler probe and calculated by dividing the systolic BP measured from the posterior tibialis artery (PTA) or dorsalis pedis artery (DPA) by the highest systolic BP from the right and left brachial arteries.[7,8] A ratio below 0.9 indicates some degree of arterial disease.[6]

Although the ABPI is the primary noninvasive diagnostic tool,[7] it has several limitations; primarily, it is time-consuming, with a mandatory 10-minute rest period before testing.[9] Further, it may not detect mild or moderate disease because occlusion may be masked by a rich collateral vascular network.[10] Increased arterial calcification will artificially increase the ABPI, leading to an underestimation of PAD in those with diabetes mellitus, renal disease, advanced age, or connective tissue disease.[11,12] The ABPI may also have decreased reproducibility and interobserver variability, as well as variations in performance because it can be completed at either or both arms and at the PTA and/or DPA.[13,14] Further, reported sensitivities (17%–100%) and specificities (80%–100%) for the ABPI range widely.[15] These limitations necessitate an alternative noninvasive diagnostic tool for PAD.

Doppler arterial waveform (DAW) analysis measures the quality of arterial blood flow as well as the level and severity of occlusion.[16] Healthcare providers can measure DAWs with continuous Doppler or ultrasound probes in pulse-wave Doppler mode. Doppler waveforms are generated in arteries from the aorta down through the lower extremity, and subsequently interpreted by a grading system.[2,7,17] However, limitations of DAW analysis include limited evidence regarding diagnostic accuracy and the feasibility of incorporating it into primary care practice.[7,17]

In this study, the authors compare sensitivities and specificities between the ABPI and DAWs to assess their diagnostic accuracy for the detection of PAD. These results will provide healthcare providers with valuable knowledge regarding an alternative diagnostic tool.

METHODS

The authors conducted a systematic review to examine the performance characteristics of DAWs and the ABPI to evaluate PAD. The systematic review was performed in accordance with the PRISMA (Preferred Reporting Items for Systematic Review and Meta-analyses) guidelines.[18]

Search Strategy and Eligibility Criteria

The authors searched the Embase and MEDLINE in Ovid databases on July 29, 2020 using the search terms ("ankle brachial index" or "ankle brachial pressure index") and ("waveform" or "Doppler arterial waveform or "ultrasonography, Doppler" or "ultrasonography, Doppler, color"). No date or language restrictions were used. References of included studies were manually reviewed for any additional relevant studies.

Eligible and included articles met the following criteria:

1. Studied both DAW and ABPI
2. Were clinical trials, cohort studies, case-control studies, or case series with five or more human participants
3. Study participants were adult patients (>18 years)
4. Reported the proportion of patients (false negatives, false positive, true negatives, true positives), sensitivities, or specificities, for both DAWs and the ABPI
5. Contained English language data

Nonprimary literature (reviews, conference abstracts, letters) and case reports were excluded. Patients were not excluded based on comorbidities.

Data Screening and Extraction

Title and abstract screening and full text review were completed independently by two researchers and conflicts were resolved by discussion with a third. Two independent and blinded researchers completed data extraction, which was then compiled and verified by a third researcher. Conflicts were resolved by discussion with a fourth researcher. Investigators extracted the following data:

–Study and patient characteristics (author, study design, sample size, patient inclusion, exclusion criteria, age, sex, and comorbidities)

–Reference standard and interpretation, ABPI device, operator, location, test interpretation)

–DAW (device, image acquisition, image interpretation, location, and test interpretation terminology)

–PAD prevalence, study key findings, and sensitivities and specificities.

Data Analysis

Studies that applied the ABPI and/or DAW as index tests for the diagnosis of PAD were included. The authors used the terminology ABPI to describe the systolic BP

indices that varied among the studies (ie, ankle-brachial index versus ABPI).

The reference standard was defined as the best available method for establishing the presence or absence of PAD.[19] The criterion standard diagnostic tool for diagnosing PAD is computed tomography angiography (CTA); however, the authors did not exclude studies based on the type of reference standard used.[20]

The level of evidence for included articles was assessed using the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence.[21] Due to heterogeneity of the data, no meta-analysis was conducted. Likelihood ratios were calculated from reported sensitivities and specificities.

Quality Appraisal

The Quality Assessment Tool for Diagnostic Accuracy Studies was used to evaluate the risk of bias and applicability of studies.[22] The risk of bias was assessed for four domains: patient selection, index test(s), reference standard, and flow and timing. Applicability was assessed for three domains: patient selection, index test(s), and reference standard.

Several considerations were established a priori for the quality appraisals. For the index test(s) domain, both the ABPI and DAW were required as an index test for low applicability. For the reference standard, only angiography tests were considered likely to correctly classify PAD and be at low risk of bias. Blinding of index test/reference standard results was considered "unclear" unless explicitly stated or the timeline made it impossible for the assessor of one test to know the results of the other. The interval between index test(s) and reference standard was deemed appropriate if they occurred sequentially on the same day. Agreement was measured using an unweighted Cohen κ calculated using Microsoft Excel (Microsoft Corp, Redmond, Washington).

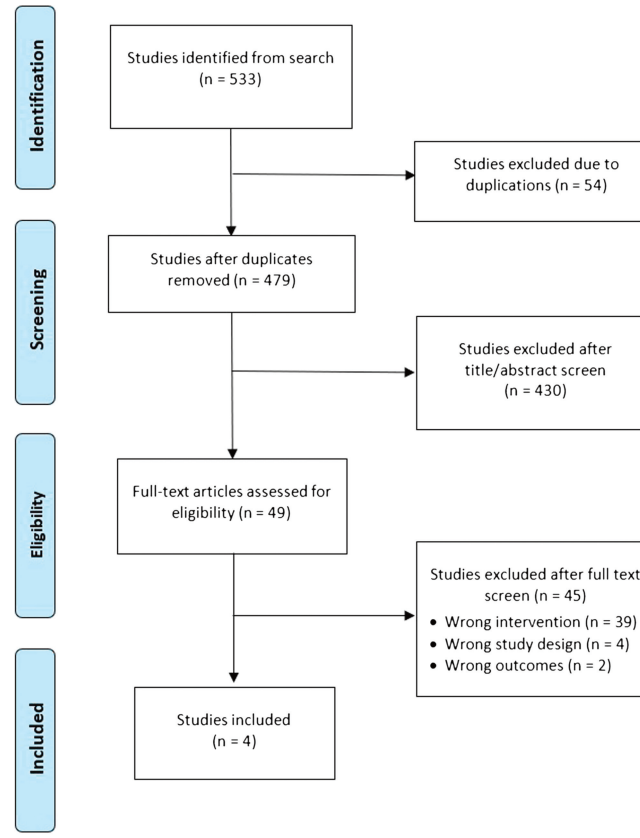
RESULTS

After duplicate removal, the search strategy identified 489 studies, which then underwent title and abstract screening. From this, 49 studies underwent full-text review. Four studies met the eligibility criteria and were included in this synthesis (Figure 1, Table 1):[5,7,17,23] two cross-sectional studies, one retrospective cohort study, and one case-control study. One study had a level of evidence of 2, and three had a level of evidence of 3.

Patient Characteristics

In total, 657 patients were included, with mean age of 63.4 years (range, 22–89 years). Of these, 58.8% (n = 386/657) were men, and 41.2% (n = 271/657) were women (Supplemental Table, http://links.lww.com/NSW/A95). Sample sizes varied across studies ranging from 68[5] to 303 patients.[7] Inclusion and exclusion criteria for patients varied widely resulting in a heterogeneous patient population. The prevalence of PAD ranged from 2.2%[7] to 84.0%.[23] Available identified common comorbidities including diabetes (67.0% of participants, (n = 440/657), hypertension (65.5%, n = 386/589), neuropathy (64.6%, n = 173/371) and smoking history (22.6%, n = 133/589).

Figure 1. SELECTION PROCESS FOR STUDY INCLUSION



Quality Assessment

Interrater reliability was substantial (κ = 0.644; 95% confidence interval [CI], 0.453–0.835) with 86.1% agreement and 61.0% agreement by chance. All conflicts were resolved by consensus and 100% agreement was achieved for the final scores (Table 2 and Figure 2).

Patient Selection. Williams et al[5] was at high risk of bias because they failed to avoid a case-control design. Risk of bias was rated unclear for Babaei et al[7] because the sampling method was not indicated in the methods section. Concerns regarding applicability were also unclear for these two studies[5,7] because they did not report age ranges.

Index Tests. Interpretations of the index test results were conducted without knowledge of the reference standard in two of four studies. Blinding was not specified in Ro et al[23] or Williams et al,[5] resulting in unclear risk of bias. All studies used the ABPI and DAW as index tests, resulting in low concerns regarding applicability.

Reference Standard. Only Ro et al[23] used CTA as the reference standard for PAD diagnosis. The three remaining

Table 1. STUDY CHARACTERISTICS, PAD PREVALENCE, REFERENCE STANDARD, SENSITIVITY, SPECIFICITY, AND POSITIVE AND NEGATIVE LRs

Study Authors, Year	Sample Size (n)	PAD Prevalence, % (95% CI)	Reference Standard	ABPI or Doppler waveform	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)
Ro et al,[23] 2012	97 (194 legs)	n = 163/194 84 (NR)	CTA	ABPI	69.3 (61.9–75.9)	96.8 (83.8–99.4)	21.656 (NR)	0.317 (NR)
Ro et al,[23] 2012	97 (194 legs)	n = 163/194 84 (NR)	CTA	Doppler waveform	90.8 (85.3–94.8)	64.5 (45.4–80.8)	2.558 (NR)	0.143 (NR)
Babaei et al,[7] 2020	303 (606 limbs)	n = 13/606 2.2 (NR)	Ultrasound duplex scan	ABPI	72.7 (NR)	95.8 (NR)	17.31 (NR)	0.285 (NR)
Babaei et al,[7] 2020	303 (606 limbs)	n = 13/606 2.2 (NR)	Ultrasound duplex scan	Doppler waveform	81.8 (NR)	93.2 (NR)	12.029 (NR)	0.195 (NR)
Lewis et al,[17] 2016	189	n = 68/189 36 (NR)	Ultrasound duplex scan	ABPI	79 (NR)	91 (NR)	8.778 (NR)	0.216 (NR)
Lewis et al,[17] 2016	189	n = 68/189 36 (NR)	Ultrasound duplex scan	Doppler waveform	97 (NR)	81 (NR)	5.105 (NR)	0.037 (NR)
Williams et al,[5] 2005	68 (130 legs)	n = 37/130 28.5 (NR)	Color duplex imaging	ABPI	Control: 83 (NR); diabetes: 100; diabetic neuropathy: 53 (NR)	Control: 100; diabetes: 88 (NR); diabetic neuropathy: 95 (NR)	Control: 5.882 (NR); diabetes: 8.333 (NR); diabetic neuropathy: 10.6 (NR)	Control: 0.17 (NR); diabetes: 0; diabetic neuropathy: 0.495 (NR)
Williams et al,[5] 2005	68 (130 legs)	n = 37/130 28.5 (NR)	Color duplex imaging	Doppler waveform	Control: 86 (NR); diabetes: 100; diabetic neuropathy: 94 (NR)	Control: 96 (NR); diabetes: 92 (NR); diabetic neuropathy: 66 (NR)	Control: 21.5 (NR); diabetes: 12.5 (NR); diabetic neuropathy: 2.765 (NR)	Control: 0.146 (NR); diabetes: 0; diabetic neuropathy: 0.091 (NR)

Abbreviations: ABPI, Ankle Brachial Pressure Index; CI, confidence interval; CTA, computed tomography angiography; LR, likelihood ratio; NR, not reported; PAD, peripheral arterial disease.

studies used duplex ultrasound[7,17] or color duplex imaging[5] as the reference standard, and these studies were all determined to be at high risk of bias. The presence of blinding to index test results was unclear for Ro et al[23] and Williams et al.[5] All studies had low concern regarding applicability.

Flow and Timing. All studies were found to have low risk of flow and timing bias.

Ankle-Brachial Pressure Index

The ABPI measurements were completed by a technician,[23] nurse,[7] podiatrist, or vascular nurse practitioner;[17] one study[5] did not report who completed the measurements. Available data showed that measurements were obtained at the PTA, DPA, and brachial arteries with a variety of devices, and all studies defined an abnormal ABPI score as less than or equal to 0.9.

Overall ABPI sensitivities ranged from 53% to 100% and specificities ranged from 88% to 100%.[5] More specifically, the one study that used CTA as the reference standard had sensitivities of 69.3% (95% CI, 61.9–75.9) and specificities of 96.8% (95% CI, 83.8–99.4).[23] For the two studies that used ultrasound duplex scan as the reference standard sensitivities ranged from 72.7%[7] to 79%[17] and specificities from 91%[17] to 95.8%.[7] For the study that used color duplex imaging as the reference standard,[5] sensitivities ranged from 53% to 100% and specificities from 88% to 100%.

Similarly, in studies with diabetes prevalence of 100%, sensitivities ranged from 53%[7] to 100%[5] and specificities ranged from 88%[5] to 95.8%.[7]

Doppler Arterial Waveform

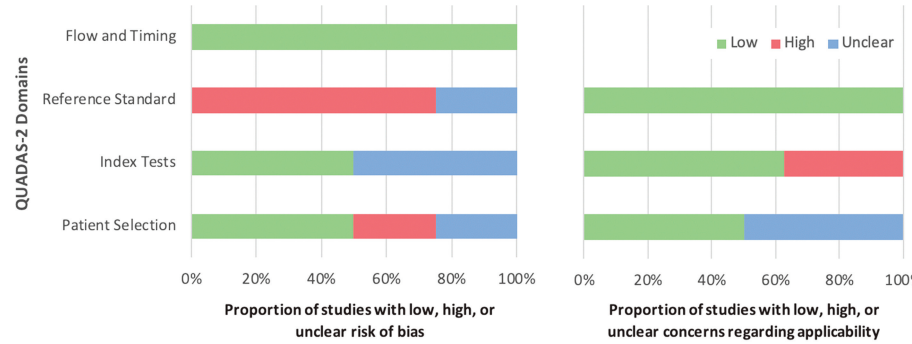
The DAW measurements were acquired by a technician,[23] podiatrist, or vascular nurse[17] and the recorded occupation was NR in the other two studies. Image interpretation was completed by an experienced clinician[7] or physician[23] in two studies, and was NR in the other two studies.[5,17] Three of the four studies reported measurement locations: the common femoral arteries;[17] DPA and PTA;[5] and common femoral, popliteal, PTA, and DPA.[23] One study[7] did not report this information. Measurements

Table 2. QUADAS-2 ASSESSMENT FOR RISK OF BIAS AND CONCERNS REGARDING APPLICABILITY

	Risk of Bias				Concerns Regarding Applicability		
Study	Patient Selection	Index Tests	Reference Standard	Flow and Timing	Patient Selection	Index Tests	Reference Standard
Ro et al,[23] 2012	Low	Unclear	Unclear	Low	Low	Low	Low
Lewis et al,[17] 2016	Low	Low	High	Low	Low	Low	Low
Williams et al,[5] 2005	High	Unclear	High	Low	Unclear	Low	Low
Babaei et al,[7] 2020	Unclear	Low	High	Low	Unclear	Low	Low

Abbreviation: QUADAS, Quality Assessment Tool for Diagnostic Accuracy Studies.

Figure 2. QUADAS-2 ASSESSMENT FOR RISK OF BIAS AND CONCERNS REGARDING APPLICABILITY



Abbreviation: QUADAS, Quality Assessment Tool for Diagnostic Accuracy Studies.

were taken with a variety of devices and categorization of waveforms for interpretation varied among studies, with normal defined as triphasic[5,23] in half of the studies and grade A (sharp systolic peak, prominent dicrotic notch)[7,17] in the other half. Abnormal waveforms were defined as loss of triphasic pattern or loss of reverse flow component in two studies[5,23] and as grade B (sharp peak, absent dicrotic notch, downslope bowed away from baseline), grade C (absent dicrotic notch, flattened systolic peak, amplitude reduction, pulse elongation), or grade D (severe amplitude reduction and pulse elongation) in the other two.[7,17]

Overall, sensitivities ranged from 81.8[7] to 100%[5] and specificities ranged from 64.5%[23] to 96%.[5] Moreover, the only study that used CTA as their reference standard[23] reported a sensitivity of 90.8% (95% CI, 85.3–94.8) and specificity of 64.5% (95% CI, 45.4–80.8). For the two studies that used ultrasound duplex scan for the reference standard, sensitivities ranged from 81.8%[7] to 97%[17] and specificities from 81%[17] to 93.2%.[7] In the study that documented color duplex imaging as the reference standard,[5] sensitivities ranged from 86% to 100% and specificities from 66% to 96%.

Similarly, in studies with diabetes prevalence of 100%,[5,7] identification of sensitivities ranged from 81.8%[7] to 100%[5] and specificities ranged from 66%[5] to 93.2%.[7] In addition, measurement of the common femoral artery had sensitivity of 97% and 81% specificity. Data were not available for other locations.

Comparing ABPI and DAW

In patients with PAD and peripheral diabetic neuropathy, all studies reported higher sensitivities of DAW compared with ABPI (Table 1). Patients with diabetes without neuropathy had a sensitivity of 100% for both DAW and ABPI. In patients without diabetes, the sensitivity of DAW was 86% whereas the sensitivity of ABPI was 83%.

Persons without diabetes had higher specificity for the ABPI detection of PAD in all studies compared with DAW (Table 1). The higher specificity of PAD detection using ABPI in patients without diabetes was 95% versus 66% in patients with diabetic neuropathy. However, William et al[5] found that DAW had slightly higher specificity (92%) compared with ABPI (88%) in detecting PAD in patients with diabetes without neuropathy.

DISCUSSION

These results suggest that DAW has higher sensitivity for detecting PAD compared with ABPI, and ABPI has higher specificity for detecting PAD compared to DAW. That is, results demonstrated a higher DAW sensitivity (fewer false negative results) compared with ABPI in all patients, including persons with diabetes. Thus, DAW has better potential value as a screening tool for PAD compared with ABPI because it is less likely to miss individuals with the disease.[24] The diagnostic accuracy of ABPI has been extensively studied, with previous reviews finding excellent specificity of an ABPI 0.90 or less (range, 83.3%–99.0%) but varying sensitivities. Lower sensitivities ranging from 15 to 70.6% have been documented in older patients and persons with diabetes,[25] partly because both populations are more likely to have calcified arteries.[7] Such diabetes-related arterial calcification could result from oxidative stress, inflammation, adiposity, insulin resistance, advanced end-products of glycation, and hyperphosphatemia.[26] Calcified arteries lead to increased stiffness and eventual noncompressible vessels with potential artificial elevation in ABPI[7,17,26] and an underestimation of PAD.[7,17] Because the majority of participants in the reviewed studies had diabetes, these review findings may reflect a high presence of arterial calcification and thus potentially decreased ABPI sensitivity in detecting PAD.

Data on DAW are sparse; however, DAW may have better sensitivity because arterial calcification and lower extremity edema do not affect its measurements.[27] Because DAW denotes total blood flow, patients with significant arterial stenosis that also have good collateral blood flow will record normal values.[17,27] This provides useful arterial blood supply information to establish healing capacity.[17]

In addition, DAW has a lower specificity, or greater number of false positive results, compared with ABPI for detecting PAD overall, including in patients with diabetes. Thus, ABPI may be a better diagnostic test because it provides fewer false positive errors.[24] The lower specificity of DAWs may be attributable to a combination of factors, including different classifications of abnormal waveforms[16,28,29] and operator variability.[17,30]

A previously published review highlighted inadequate definitions to characterize DAWs and a lack of consensus leading to decreased standardization of DAWs and inappropriate testing.[29] In addition, continuous Doppler provides a better waveform classification as compared to pulse-wave Doppler.[31] Obtaining DAWs requires operator skill and experience: Incorrect placement of the Doppler probe may provide inaccurate results.[32] Several additional factors can alter the Doppler waveforms and decrease specificity, including the potential for vasodilation secondary to heat leading to a decrease in early diastolic reversal of flow,[30] uncompensated congestive heart failure dampening waveforms following exercise,[30] and sympathetic nerve system signals influencing postexercise blood flow and DAWs.[17] It is recommended that patients rest supine for 5 to 10 minutes before waveforms measurements are taken.[16]

There are several limitations to this systematic review. First, patient population heterogeneity with a large prevalence of PAD may limit accuracy of results. Second, the heterogeneity of reference standards, devices, operators, and location for measurements may limit the study result comparisons. Third, the small sample size may affect the quality and generalizability of the results. Until reference standards for DAWs are completely standardized, the authors recommend CTA as the reference standard.

Audible Handheld Doppler Waveform versus DAW

The COVID-19 pandemic has dramatically changed the delivery of wound care. Clinicians are challenged by the need to provide wound care and there is often a delay in preforming virtual vascular assessments. Whereas palpation of a pulse translates into a large margin of error and is not reproducible, recorded Doppler sounds can be communicated to the interprofessional team to quickly initiate appropriate treatment (eg, compression therapy for venous edema or referral to a vascular lab for formalized studies).

In 2015, Alavi et al[33] evaluated Doppler wave forms using audible signals (absent, monophasic, biphasic, triphasic). The authors determined the accuracy of audible arterial foot signals with a handheld Doppler ultrasound from the DPA or PTA of 200 consecutive patients. As a control and comparison, a formal bilateral lower leg duplex Doppler segmental lower limb vascular study including the calculation of ABPI and toe pressure was performed at a certified vascular lab. The diagnostic reliability of audible handheld Doppler ultrasound (AHDU) was compared with ABPI as the reference standard. Alavi et al[33] calculated a specificity of 97.5% and sensitivity of 42.8% with a negative predictive value of 94.10% and positive predictive value of 65.22%. The AHDU proved to be a reliable, simple, rapid, and inexpensive bedside exclusion test of PAD in patients with or without diabetes (no significant difference).

After publication of this study and the advent of the COVID-19 pandemic, transporting patients to vascular laboratories or receiving health care services outside of the home is difficult. The use of audible Doppler signals can differentiate an absence of arterial pulse (not palpable and not recordable) from a recorded signal. The audible signal can be recorded in an MP3 format using a smartphone and included in a patient's medical record.

The advantages of audible Doppler signal testing are numerous. For example, the patient does not need to lie flat for 10 minutes prior to the test; is not required to have a BP cuff on the lower calf, which often causes pain; the result is not influenced by arterial calcification, edema, or woody fibrosis; and the patient can sit during the procedure, which can usually be performed in less than 5 minutes.

Despite the AHDU utilizing Doppler waveforms as with DAW, the findings of Alavi et al[33] contrast with the performance of DAW in this review. The discrepancy may be due to differences in waveform interpretation. The studies in this review defined any waveform that was not triphasic or grade A as abnormal, whereas Alavi et al defined only monophasic waveforms as abnormal. This difference in diagnostic threshold may explain the high sensitivity and low specificity of DAW in this review versus the high specificity and low sensitivity of AHDU in the study by Alavi et al. The authors encourage further studies comparing the audible handheld Doppler signal with ABPI and DAWs.

CONCLUSIONS

Despite the review limitations, the authors recommend DAW over ABPI as a screening test for PAD because of its higher sensitivity. In addition, ABPI is recommended as a diagnostic test for PAD because of its higher specificity compared with DAW. To confirm these results, clinical studies with larger sample sizes and scientific rigor with homogeneous reference standards are required. Future studies should also consider the audible handheld Doppler at the bedside as an alternative method to document DAWs. ●

PRACTICE PEARLS

- ABPI has several limitations for the noninvasive assessment of PAD
- DAWs had a higher sensitivity but lower specificity compared with ABPI
- Doppler waveforms for PAD can be detected with an audible signal that can be recorded on a smart phone
- Audible handheld doppler ABPI is less likely to miss persons with significant disease, especially with calcified vessels

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