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Sensitivity and specificity of the ankle–brachial index to diagnose peripheral artery disease: a structured review

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Abstract

The ankle–brachial index (ABI) is a simple, inexpensive diagnostic test for peripheral artery disease (PAD). However, it has shown variable accuracy for identification of significant stenosis. The authors performed a structured review of the sensitivity and specificity of ABI ≤ 0.90 for the diagnosis of PAD. MEDLINE, EMBASE, Cochrane databases, Science Citation Index database, and Biological Abstracts database were searched for studies of the sensitivity and specificity of using ABI ≤ 0.90 for the diagnosis of PAD. Eight studies comprising 2043 patients (or limbs) met the inclusion criteria. The result indicated that, although strict inclusion criteria on studies were formulated, different reference standards were found in these studies, and methods of ABI determination and characteristics of populations varied greatly. A high level of specificity (83.3–99.0%) and accuracy (72.1–89.2%) was reported for an ABI ≤ 0.90 in detecting ≥ 50% stenosis, but there were different levels of sensitivity (15–79%). Sensitivity was low, especially in elderly individuals and patients with diabetes. In conclusion, the test of ABI ≤ 0.90 can be a simple and useful tool to identify PAD with serious stenosis, and may be substituted for other non-invasive tests in clinical practice.

Keywords

accuracy; ankle–brachial index; peripheral artery disease; sensitivity; specificity

Introduction

Peripheral artery disease (PAD) is a clinical manifestation of the atherosclerotic process. Individuals with PAD have a three- to fourfold increased risk of cardiovascular disease (CVD) morbidity and mortality compared to individuals without PAD. Using the ankle–brachial index (ABI) ≤ 0.90, at least 6.8 million Americans (5.8%) aged 40 years or older had PAD in 2000,[1] which was different from other studies.[2–4] The age-adjusted prevalence of PAD was 12% when ABI was used to diagnose PAD in older adults.[2] An arteriography has been considered a gold standard for assessing PAD severity, location, and extent.[5] However, the general use of arteriography is limited because of the use of ionizing radiation and also because of the risk of local and systemic complications arising from the invasive nature of the procedure and the use of nephrotoxic contrast media. Consequently, several non-invasive tests have been designed for the detection of PAD in clinical practice. These tests include digital subtraction angiography (DSA), computed tomography angiography (CTA), whole body magnetic resonance angiography (WBMRA), Doppler waveform analysis (DWA), color duplex ultrasound (CDU), color duplex imaging (CDI) and ABI. Among these tests, the ABI is the most simple and inexpensive test.[6] Among well-trained technicians, its reliability has been excellent, and the validity of the test for stenosis of ≥ 50% in leg arteries is high (sensitivity ≈ 90% and specificity ≈ 98%).[7]

However, different methods have existed for ABI calculation, and different cutoff values of ABI have been used in the literature. Although an ABI ≤ 0.90 has been recommended by the American Heart Association (AHA),[8] whether the higher or lower of the two ankle arterial systolic

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pressures should be used was not specified, and there has been some disagreement in the literature regarding the measurement of ABI.[9] The higher, the lower, or sometimes the average systolic blood pressures of the dorsal pedal and posterior tibial arteries within the legs have been used to calculate the ABI.[10] Importantly, the ABI was not compared side-by-side with results from arteriography in many studies, thus limiting accurate evaluation of the data.

The accuracy of ABI has been the primary focus of a number of studies on PAD, but to date there has been no structured review of these studies. Thus, the primary objective of the present study is to conduct a structured review to determine the accuracy of the ABI as a diagnostic tool to detect significant stenosis (≥ 50%) in PAD.

Methods

Search strategy and selection criteria

A structured review of original articles analyzing the sensitivity and specificity of ABI for the diagnosis of PAD was performed by searching MEDLINE (January 1966 to December 2008), EMBASE (January 1980 to December 2008), Web of Science – Science Citation Index database, the Cochrane Library and Biological Abstracts database (January 1969 to December 2008).

Although DSA is considered the best method for assessing PAD severity, location, and extent;[5] some studies have shown that WBMRA has good accuracy for grading stenosis with DSA as reference;[11–13] DWA was also a non-invasive method widely used to diagnose PAD;[14,15] moreover, there was excellent agreement between arteriography and CDU findings (the coefficient of correlation was 0.95).[16] Non-invasive and easy methods of detecting PAD were preferred in clinical practice, so an imaging diagnostic technology was often used in many of the studies as a standard reference in defining serious luminal stenosis for the diagnosis of PAD. Studies were eligible if the sensitivity and specificity of ABI ≤ 0.90 for stenosis ≥ 50% in peripheral arteries were clearly reported by comparison with a standard reference such as DSA,[17,18] WBMRA,[19] DWA,[20] CDI,[21] CDU,[16,22] and arteriography.[23] Additionally, relevant references cited within identified publications were reviewed.

The search strategy included the following keywords in various combinations: “ankle brachial index”, “ankle arm index”, “peripheral arterial disease”, “peripheral arterial occlusive disease”, “peripheral vascular disease”, “lower extremity arterial disease”, “sensitivity”, “specificity”, and “accuracy”.

The titles and abstracts of articles retrieved by this search strategy were evaluated against inclusion criteria, and the studies deemed potentially eligible were obtained by requests to authors. When overlapping or duplicate data sets were detected on the same series of patients, only the most recent or most informative study was included in the analysis.

Data extraction

Two investigators independently extracted data from selected articles, which included year of publication, first authors, patient demographics, study objective, study inclusion and exclusion criteria, reported sensitivity and specificity of ABI in PAD and summary statistics on ABI cases, if available. Studies were initially selected according to the following criteria: (i) language: English full text articles; (ii) accuracy of ABI for diagnosis of PAD: based on a reference standard; (iii) study design: cross-sectional or comparative study; and (iv) sample size: at least 50 participants.

Quality assessment

Reporting of a total of seven items was evaluated: (i) the study had a clearly stated aim; (ii) consecutive patients were included; (iii) an appropriate reference standard was used; (iv) a prospective calculation of sample size was reported; (v) a cutoff ABI value was 0.90; (vi) a threshold value of stenosis for PAD was 50%; and (vii) actual numbers of true positive, true negative, false positive and false negative results of the tests or predicted positive and negative values were reported.

Results

The initial search resulted in 256 articles. The title and abstract of each retrieved publication were reviewed to confirm that the sensitivity and specificity of ABI ≤ 0.90 for stenosis was ≥ 50% in peripheral arteries and that results were compared with a standard reference such as arteriography, DSA, CTA, WBMRA, DWA, CDI, or CDU. In the event that this information could not be determined from the abstract, the full article was retrieved and further reviewed. This process resulted in the selection of 33 studies. Of these, 25 articles were further excluded from this analysis: two used a stethoscope and an auscultatory method to determine ABI, respectively;[24,25] one used an automatic blood pressure device to determine ABI;[26] one determined ABI at exercise;[27] two used tissue oxygen saturation and pedal pulse palpation to determine PAD, respectively;[28,29] two used ABI < 0.80 and 1.0 for PAD, respectively;[30,31] one used ABI < 0.90 for the detection of arterial lesions in extremities;[32] one used ABI > 1.3 for PAD;[33] one included patients with stenosis > 70% in leg arteries;[34] 10 articles did not use an appropriate reference standard for PAD;[35–44] one paper had a sample size of only 39 patients;[45] and three were review articles.[46–48] Figure 1 shows the study selection process. Table 1 provides the overall characteristics of 22 excluded articles (not including the three review articles).

Eight studies meeting the inclusion criteria reported on a total of 2043 patients (or limbs): some studies used the number of patients as variables for identification of significant stenosis, whereas others used the number of limbs. Table 2 presents characteristics of the studies selected. Of these, all (100%) underwent a reference test except in one study,[23] where angiograms were available for 53 of these patients. There were some differences in ABI methodology in eight papers.

Because PAD is associated with age, smoking status, type 2 diabetes, hypertension, and dyslipidemia, baseline

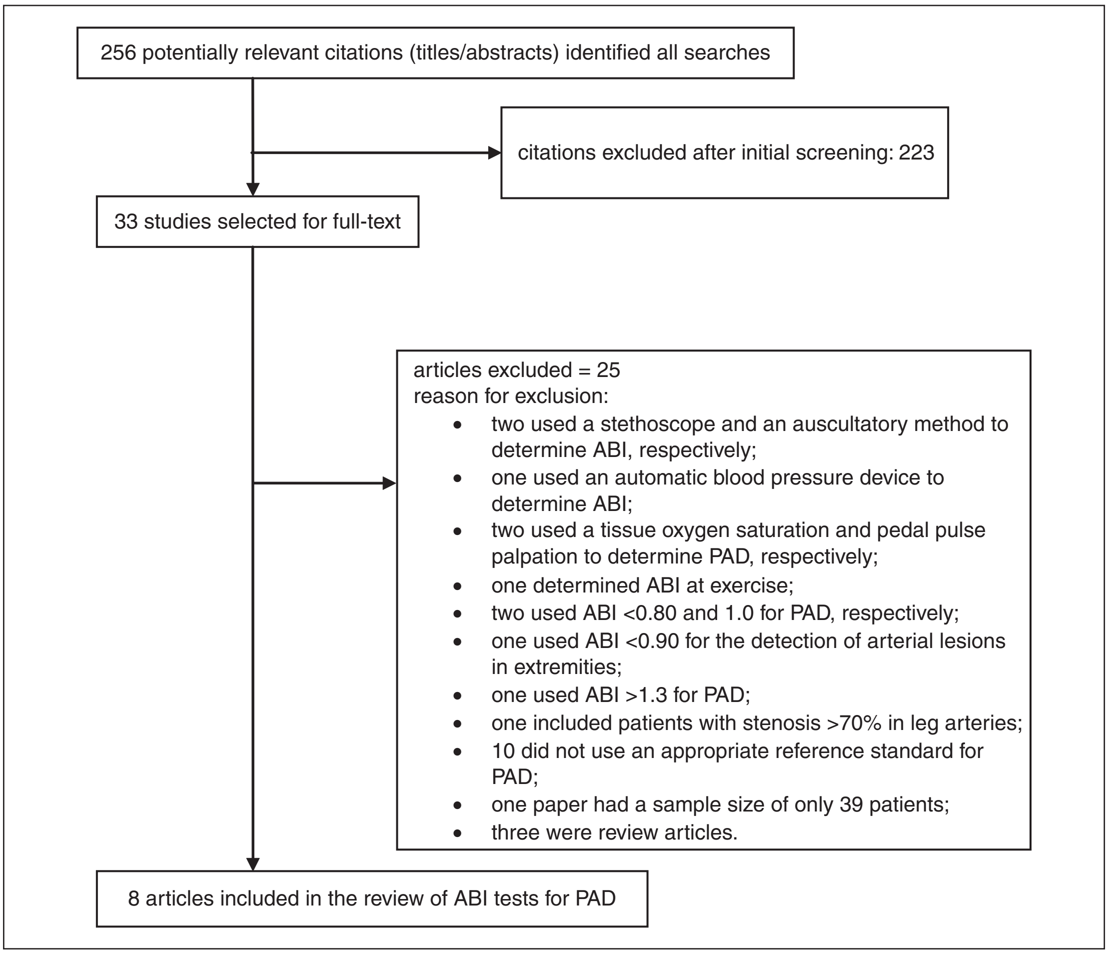

Figure 1. Study selection process and reasons for exclusion.

measures of these variables are obtained through corresponding authors. Table 3 presents baseline demographic characteristics of these patients. A total of 786 limbs were from women and 807 limbs were from men. Age was reported in the studies and ranged from 35 to 94 years old. Table 4 provides detailed data on positive, negative, sensitivity, specificity, accuracy and other selected characteristics. Sensitivity ranged from 15.0% to 79.0%, whereas specificity and accuracy ranged from 83.3% to 99.0% and 72.1% to 89.2%, respectively.

Discussion

The present study represents the first structured review focusing on ABI for the diagnosis of PAD, and indicates that an ABI ≤ 0.90 has a perfect specificity and high accuracy, but its sensitivity varied widely and is lower than the approximately 90% sensitivity reported in previous articles.[7,28,49–51] Furthermore, many imperfect diagnostic methods were found in the studies when compared with the ABI test as standard references, and different methods have existed for ABI calculation in the literature. In addition, eight studies differed in international scope, populations, design, and clinical settings.

According to recent guidelines for the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), the ABI should be considered for patients with PAD who have adverse prognostic features. Both the American Heart Association and American Diabetes Association recommend annual screening for lower extremity arterial disease (LEAD) in patients with type 2 diabetes and those aged over 40 years old.[52] We also found that the test of ABI ≤ 0.90 has an excellent specificity (83.3–99.0%) and high accuracy (72.1–89.2%) in these studies.

However, the sensitivity of the ABI test varied widely among these published studies.

ABI detection in type 2 diabetes and the elderly yielded lower sensitivity, 15–20%,[19] 63%,[20] 68%,[16] 69.3%[17] and 70.6%,[22] suggesting that the test may be affected by diabetes status and aging. Many elements may contribute to the sensitivity of ABI detection, including patients' age, ethnicity, and health status, as well as other factors. Our review includes patients with a wide age range (35–94 years old), and thus arterial wall calcinosis in elderly individuals might have led to overestimation of artery pressure. Additionally, both genetic and environmental factors may lead to a lower ABI and greater prevalence of PAD in African Americans,[53] who had approximately 1.5 times as much aortic surface involvement of fatty streaks as did non-Hispanic white individuals.[54] However, the difference in ABI is trivial in that Aboyans et al. reported an ABI 0.02 difference between

Table 1. Overall characteristics of 22 excluded articles

First author	Size	Mean age (years)	Male	Population	ABI	Reference	Objective	Characteristic	Results
Carmo[24]	81	18–?	52	Outpatients	Stethoscope-ABI	Doppler-ABI	Assess the accuracy of stethoscope-ABI for the diagnosis of PAD	Most patients were elderly (> 70 years old) and had hypertension	Stethoscope-ABI was a useful method to detect PAD
Takahashi[25]	119	74.8	60	Outpatients	Auscultatory-ABI	Doppler-ABI	Assess the accuracy of auscultatory-ABI for the diagnosis of PAD	General population	Auscultatory-ABI could be useful in excluding PAD, but not enough to confirm the presence of PAD
Aboyans[26]	54	58.2	28	Outpatients	p-ABI; Auto-ABI	Doppler-ABI	Assess the validity and reliability of pulse palpation-ABI and auto-ABI	Healthy volunteers, suspected arterial intermittent claudication and subclinical PAD	Pulse palpation-ABI and auto-ABI cannot be recommended for diagnosis of PAD
Tellier[27]	105	61	76	Multiple population	Exercise ABI	No reference	Compare exercise WBTI and rest/exercise in the detection of asymptomatic PAD	Most of patients had coronary artery disease	WBTI contributes to the detection of PAD
Comerota[28]	49	43 67	13 8	Control and PAD	StO_2	Documented PAD	Determine the accuracy of StO_2 for PAD	35 normal and 14 PAD	StO_2 can potentially detect PAD
Collins[29]	403	63.8	195	Primary care clinics	Pedal pulse palpation	ABI < 0.9	Determine the accuracy of pulse palpation for PAD	Most patients had hypertension and hyperlipidemia	Pulse palpation is not sensitive for PAD
Feigelson[30]	284	66	Not clearly indicated	Control and PAD	ABI < 0.8	Documented PAD	Determine the accuracy of ABI for PAD	Half of patients had hyperlipidemia	ABI < 0.8 can detect PAD
Baxter[31]	20	62	12	No detail	ABI < 1.0	Arteriography	Assess the accuracy of both ABI and color Doppler imaging for stenosis of lower limb artery	No detail	Both ABI and color Doppler imaging were helpful to detect stenosis of lower limb artery prior to arteriography
Nassoura[32]	298	27.3	256	Trauma center	ABI < 0.9	Angiography	Assess the role of ABI in the evaluation for PET	Occult arterial injury from penetrating proximity extremity trauma	ABI < 0.9 can screen patients with PET
Suominen[33]	1762	69.5	1041	Vascular clinic	ABI > 1.3	DSA	Assess accuracy of elevated ABI in PAD	Most of patients had hypertension and diabetes	ABI > 1.3 had a good specificity, but lower sensitivity for diagnosis of PAD
Okamoto[34]	160	67	94	Hemodialysis patients	ABI < 0.9	Multidetector-row computed tomography	Compare the validity of non-invasive tests in hemodialysis patients	Hemodialysis patients	ABI test had a lower sensitivity on PAOD with more than 70% stenosis

(*Continued*)

Table 1. (Continued)

First author	Size	Mean age (years)	Male	Population	ABI	Reference	Objective	Characteristic	Results
Benchimol[35]	219	55	136	Cardiology clinic	ABI < 0.9	Known PAD	Compare automatic ABI with Doppler ABI	General population	Automatic ABI is feasible and precise to detect PAD by comparison with Doppler ABI
Stoffers[36]	117	62.5	51	Primary health care	ABI	Ultrasound instruments	Evaluate the use of ABI as supplementary test for diagnosing PAOD through receiver operating characteristic	General population	ABI measurement is useful supplementary test for diagnosis of PAD in primary health care
Mehlsen[37]	80	72	33	Possible PAD	ABI	No reference	Compare oscillometric with plethysmography ABI	Patients with possible PAD	Oscillometric ABI is reliable in the exclusion of PAD
Migliacci[38]	205	64.5	99	Primary care	Palpation-ABI	Doppler-ABI	Assess the accuracy of palpation-ABI in a setting of primary care	Patients with intermediate cardiovascular risk	Palpation-ABI is a sensitive method for exclusion of PAD
Allen[39]	111	69	62	Vascular surgical unit	Photoplethysmography toe pulse	ABI	Assess the accuracy of photoplethysmography toe pulse for diagnosis of PAD	63 normal and 48 PAD	Photoplethysmography toe pulse technique had a high accuracy for PAD
Vinyoles[40]	100	66.4	39	Hypertensive patients	Oscillometry-ABI	Doppler-ABI	Assess the accuracy of oscillometry-ABI for diagnosis of PAD	Hypertensive patients	Oscillometry-ABI does not seem useful in detection of PAD
Flanigan[41]	585	62	244	Vascular institute	ABI	SFA-duplex ultrasound	Compare the accuracy of SFA-duplex ultrasound with ABI	Most patients had past smoking, hypertension and hyperlipidemic	SFA-duplex ultrasound identifies more patients with early lower extremity atherosclerosis than ABI
Beckman[42]	201	66	95	Outpatients	Oscillometry-ABI	Doppler-ABI	Assess the accuracy of oscillometry-ABI for diagnosis of PAD	A third of patients had diabetes	Automatic oscillometry is an accurate method of ABI measurement for diagnosis of PAD in outpatients population
MacDougall[43]	94	24–91	73	Multiple population	Oscillometry-ABI	Doppler-ABI	Assess the accuracy of oscillometry-ABI for diagnosis of PAD	Control patients, patients with significant cardiac risk profiles and possible PAD	Oscillometry-ABI had a reasonable correlation with Doppler-ABI
Espeland[44]	5140	45–75	2078	Type 2 diabetes	ABI	No reference	Determine measurement characteristics of ABI	Obese patients with type 2 diabetes	The average leg ABI had slightly greater precision for cardiovascular disease risk
Alnaeb[45]	39	70 66	15 11	Diabetes and controls	Photoplethysmography	Duplex angiography	Investigate the performance of photoplethysmography for diagnosis of diabetic PAD	24 diabetic patients and 15 controls	Photoplethysmography correlated significantly with duplex angiography and ABI in diabetes

ABI, ankle–brachial index; PAD, peripheral artery disease; p-ABI, pulse palpation-ABI; Auto-ABI, automatic oscillometric devices ABI; WBTI, whole body thallium imaging; StO_2, tissue oxygen saturation; PET, proximity extremity trauma; DSA, digital subtraction angiography; PAOD, peripheral artery occlusive disease; SFA, superficial femoral artery

Table 2. Overall scope and dimension of the studies

First author	Country	Population	Design	Objective	Methods of ABI	Sample size	Mean age	Male	Reference	Characteristic	Results
Schroder, 2006[16]	Germany	Outpatient	Comparative study	Compare the accuracy of LAP-ABI with HAP-ABI on PAD	HAP-ABI was used	216 (limbs)	64.4	139	CDU	Half of patients have hypertension or hyperlipidemia; a third have claudication	LAP-ABI was superior to HAP-ABI in sensitivity
Niazi, 2006[17]	USA	A major academic center	Comparative study	Compare accuracy of LAP-ABI with HAP-ABI on PAD	HAP-ABI was used	208 (limbs)	69	54	DSA	Most patients have hypertension or hyperlipidemia	LAP-ABI was superior to HAP-ABI in sensitivity
Guo, 2008[18]	China	Community population	Community-based cohort study	Evaluate accuracy and cut-off of ABI for diagnosis of PAD	The lowest ABI of both legs was used	298 (patients)	64.9	199	DSA	Half of patients have coronary artery disease and received statins	ABI is reliable, but 0.95 is suitable for Chinese patients
Wikstrom, 2008[19]	Sweden	Elderly population	Population-based cohort study	Assess the relation between ABI and PAD	Only posterior tibial artery pressure was used	268 (limbs)	76	162	WBMRA	45% of patients take a cardiovascular drug	ABI < 0.9 underestimated the prevalence of PAD in elderly population
Parameswaran, 2005[20]	USA	Type 2 diabetes	Cross-sectional study	Compare the accuracy of pulse oximetry and ABI to diagnose PAD	Only posterior tibial artery pressure was used	114 (limbs)	63	27	DWA	Outpatient	Two methods alike
Williams, 2005[21]	UK	Most type 2 diabetes	Comparative study	Evaluate the efficacy of screening methods in different populations	The higher value was used	130 (limbs)	63–69	50	CDI	Outpatient, diabetes and neuropathy	ABI was less efficacious in diabetes
Premalatha, 2002[22]	India	Type 2 diabetes	Comparative study	Compare Se and Sp of ABI with CDU on diagnosis of PAD	The mean of dorsalis pedis and posterior tibial artery pressure was used	94 (patients)	59.5	No detail	CDU	Inpatient, foot infection	ABI was a good initial screening tool, but had a low Se in diabetes
Lijmer, 1996[23]	The Netherlands	Suspected PAD	Retrospective study	Evaluate the diagnostic accuracy of ABI	The ratio of the maximum ankle pressure and the maximum brachial pressure was used	441/94 (patients/limbs)	63	292	Angiogram	No detail	The cutoff of 0.91 was justified of non-invasive test for PAD

LAP-ABI, lower of DP and PT/higher of the two brachial systolic pressures; HAP-ABI, higher of DP and PT/higher of the two brachial systolic pressures; DSA, digital subtraction angiography; ABI, ankle–brachial index; WBMRA, whole body magnetic resonance angiography; PAD, peripheral artery disease; DWA, Doppler waveform analysis; CDU, color duplex ultrasound; CDI, Color duplex imaging; Se, sensitivity; Sp, specificity.

Table 3. Baseline characteristics and medical conditions

Variables	Value or frequency (statistical estimate)
Age, years	35–94
Men, *n* (%)	807 (50.7)
Diabetes, *n* (%)	570 (35.8)
Dyslipidemia, *n* (%)	982 (61.6)
Hypertension, *n* (%)	1142 (71.7)
Smoking history, *n* (%)	415 (26.1)

African Americans and non-Hispanic white individuals.[55] Furthermore, arterial wall calcinosis in diabetes might lead to an overestimation of the lower limb pressure which leads to a low sensitivity. This may be attributable to increased incidence of arterial calcification, which can cause increased vascular rigidity and spuriously elevate the ABI in diabetes and in elderly individuals. Moreover, the reason for elevated ABI values in spite of stenosis could be due to collateral circulation, which maintains blood flow to the lower limb beyond the obstruction.

Wikstrom et al.[19] reported a poor sensitivity of 20% (right leg) and 15% (left leg) on the ABI test. We carefully reviewed this study. In addition to arterial wall calcinosis in elderly individuals (average age was 76 years in this study), WBMRA used in this study had a lower spatial resolution which could result in over- and under-grading of stenosis, especially on the smaller caliber vessels of the lower legs. Furthermore, the ABI was calculated for each leg by only posterior tibial artery pressure with the brachial artery pressure, which was measured unilaterally by a mercury sphygmomanometer instead of the Doppler method. Moreover, the study was imperfect because of the interval (range 3–24 months) between the ABI and WBMRA test; the development of stenosis in some cases during this time frame could not be excluded. All these could contribute to a low sensitivity of ABI for stenosis detection in this study.

The previous articles stated that the ABI test had a sensitivity of > 90% and a specificity of > 95% in diagnosing > 50% stenosis of lower limb arteries. We carefully reviewed these studies and found important differences, which include the following: (i) the populations in these studies were composed of surgical patients and young healthy controls,[7,49,50] whereas most of patients had cardiovascular risk factors in our review such as being older, smoking, and having diabetes, hypertension and dyslipidemia; (ii) Ouriel et al.[7] used ABI < 0.97 for diagnosis of PAD and failed to describe the diseased limbs included in their analysis; (iii) Yao et al.,[49] Criqui et al.[50] and Carter et al.[51] reported that the ABI was a sensitive test for PAD, but did not report any sensitivity or specificity for the ABI and included less than 50% stenosis in their analysis;[49,50] (iv) Feigelson et al.[30] reported that a combination of ABI ≤ 0.8 and a posterior tibial peak forward flow ≤ 3 cm/s had a sensitivity of 89% and a specificity of 95% in diagnosing PAD.

The ABI is performed by measuring the systolic blood pressure from both brachial arteries and from the dorsal pedal (DP) or posterior tibial (PT) arteries after the patient has been at rest in the supine position for 10 minutes. Optimal recordings are obtained with blood pressure cuffs that are appropriately sized to the patient's lower calf (immediately above the ankle), and systolic pressures are recorded with a handheld Doppler instrument[16,17,19,20–23] or oscillometric method.[18] Since ankle arterial pressures are normally greater than 90% of the brachial arterial pressure, an ABI ≤ 0.90 has been used in the diagnosis of PAD.[2,18,23] Nevertheless, the three most common methods were used to calculate the ABI: HAP-ABI = higher of DP and PT/higher of the two brachial systolic pressures; LAP-ABI = lower of DP and PT/higher of the two brachial systolic pressures; ABI = mean of DP and PT/mean of both arms.[16,17,56] Furthermore, Tables 1, 2 and 4 show that other methods were also used, which led to different sensitivity and specificity, as well as prevalence of PAD.[10] The LAP-ABI method was superior to HAP-ABI in sensitivity within each leg, which studied significant stenosis of limbs instead of patients.[16,17] The authors confused the lower of the two ipsilateral ankle pressures with the lower of the right and left leg ABIs; the LAP-ABI method was more sensitive (83.7%,[17] 89%[16] vs 69.3%,[17] 68%[16]), but with a less specific and positive predictive value than HAP-ABI (64.3%[17], 93%[16] vs 83.3%[17], 99%[16]).

Table 4. Performance of ABI ≤ 0.90 in detecting ≥ 50% stenosis in PAD

First author	Tp	Fp	Fn	Tn	Se	Sp	+Pv	–Pv	A	*n*
Schroder[16]	77	1	36	102	68.0	99.0	99.0	74.0	82.9	216
Niazi[17]	115	7	51	35	69.3	83.3	94.3	40.7	72.1	208
Guo[18]	16	28	5	249	76.0	90.0	36.4	98.0	88.9	298
Wikstrom (right leg)[19]	10	2	41	215	20.0	99.0	83.0	84.0	84.0	268
Wikstrom (left leg)[19]	9	2	52	202	15.0	99.0	82.0	80.0	79.6	265
Parameswaran[20]	22	2	13	77	63.0	97.0	91.7	85.6	86.8	114
Williams[21]	28	5	9	88	76.0	95.0	84.8	90.7	89.2	130
Premalatha[22]	48	3	20	23	70.6	88.5	94.1	53.5	75.5	94
Lijmer[23]	63	1	17	13	79	96	98.4	43.3	80.9	94

Tp, true positive; Fp, false positive; Fn, false negative; Tn, true negative; Se, sensitivity; Sp, specificity; +Pv, positive predictive value; –Pv, negative predictive value; A, accuracy.

An important theme that emerges from these studies is imperfect diagnostic accuracy of these imaging diagnostic techniques such as WBMRA, CDI, DWA and CDU, which preclude a formal meta-analysis. Therefore, blood pressure has been similarly affected by physical and psychological conditions, the Doppler device, setting circumstances, and technicians' experience. All these lead to variance in accuracy of the ABI test.

A true quantitative meta-analysis is not possible because of the variety in study designs, populations and methods of ABI. Moreover, the comparison of a diagnostic test against imperfect standard references may result in underestimation of the test accuracy. Therefore, a limitation of the present review is that it constituted a qualitative analysis and hence could be considered a subjective appraisal. We chose to include a varied selection of studies to provide a perspective as balanced as possible. The studies originated in many different countries and were conducted by different sponsors. More studies are needed of the sensitivity and specificity of an exact ABI test (≤ 0.90) controlling for as many of the variables mentioned above as possible, with a well-designed and properly controlled protocol, especially by comparison with arteriography in general populations, as well as in elderly individuals and in those with diabetes. Nevertheless, we believe that some important and consistent messages have emerged that should influence the use of ABI in the future.

In conclusion, high specificity and accuracy were reported in these articles indicating that ABI ≤ 0.90 could reliably identify patients with serious stenosis $\geq 50\%$. Our findings suggest that in populations aged between 40 and 75 years old with at least one vascular risk factor (i.e. hypertension, diabetes, dyslipidemia, tobacco), the ABI should be used for a preliminary diagnosis of PAD because of its simplicity, convenience, high specificity and high degree of accuracy in clinical practice.

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