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META-ANALYSIS

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The accuracy of an oscillometric ankle-brachial index in the diagnosis of lower limb peripheral arterial disease: A systematic review and meta-analysis

Ángel Herráiz-Adillo[1] | Iván Cavero-Redondo[2] | Celia Álvarez-Bueno[2] | Vicente Martínez-Vizcaíno[2,3] | Diana P. Pozuelo-Carrascosa[2] | Blanca Notario-Pacheco[2]

[1]Department of Primary Care, Health Service of Castilla-La Mancha (SESCAM), Tragacete, Spain

[2]Universidad de Castilla-La Mancha, Health and Social Research Center, Cuenca, Spain

[3]Universidad Autónoma de Chile, Facultad de Ciencias de la Salud, Talca, Chile

Correspondence
Iván Cavero-Redondo, Universidad de Castilla-La Mancha, Health and Social Research Center, Cuenca, Spain.
Email: ivan.cavero@uclm.es

Summary

Introduction: Peripheral arterial disease (PAD) remains underdiagnosed and undertreated, partly because of limitations in the Doppler ankle-brachial index (ABI), the non-invasive gold standard.

Objective: This systematic review and meta-analysis aims to compare the diagnostic accuracy of the oscillometric ABI and the Doppler ABI, and to examine the influence of two approaches to analysis: legs vs subjects and inclusion of oscillometric errors as PAD equivalents vs exclusion.

Methods: Systematic searches in EMBASE, MEDLINE, Web of Science and the Cochrane Library databases were performed, from inception to February 2017. Random-effects models were computed with the Moses-Littenberg constant. Hierarchical summary receiver operating characteristic curves (HSROC) were used to summarise the overall test performance.

Results: Twenty studies (1263 subjects and 3695 legs) were included in the meta-analysis. The pooled diagnostic odds ratio (dOR) for the oscillometric ABI was 32.49 (95% CI: 19.6-53.8), with 65% sensitivity (95% CI: 57-74) and 96% specificity (95%CI: 93-99). In the subgroup analysis, the "per subjects" group showed a better performance than the "per legs" group (dOR 36.44 vs 29.03). Similarly, an analysis considering oscillometric errors as PAD equivalents improved diagnostic performance (dOR 31.48 vs 28.29). The time needed for the oscillometric ABI was significantly shorter than that required for the Doppler ABI (5.90 vs 10.06 minutes, respectively).

Conclusions and relevance: The oscillometric ABI showed an acceptable diagnostic accuracy and feasibility, potentially making it a useful tool for PAD diagnosis. We recommend considering oscillometric errors as PAD equivalents, and a "per subject" instead of a "per leg" approach, in order to improve sensitivity. Borderline oscillometric ABI values in diabetic population should raise concern of PAD.

1 | INTRODUCTION

Peripheral arterial disease (PAD) is an age-dependent manifestation of atherosclerosis, which is highly prevalent in Western countries. Uncommon before the age of 50, its rates increase to about 20% by the age of 80.[1] Moreover, PAD has proved to be an independent risk factor for coronary artery and cerebrovascular disease, and all-cause mortality.[2]

However, this condition remains both underdiagnosed and undertreated, with no consensus regarding on whom and when screening

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should be performed.[3-5] Underdiagnosis can be attributed to the fact that only one out of three patients suffering from PAD are symptomatic,[6] and because invasive catheter digital subtraction angiography, which is considered the gold standard for PAD diagnosis, is an invasive test that requires both iodinated contrast and ionising radiation. Nevertheless, patients with PAD but without claudication are also at increased risk of cardiovascular disease and mortality.[7]

Thus, in an attempt to overcome angiography limitations, the Doppler ankle-brachial index (ABI), because of its simplicity and availability, is considered the non-invasive gold standard for PAD. However, there is a lack of standardisation in ABI measurements. While the American Heart Association suggests using the higher Doppler value between posterior tibial or dorsalis pedis arteries, others recommend the lower value in an attempt to improve sensitivity in PAD diagnosis[8,9] and cardiovascular risk prediction.[10] In addition, although PAD is classically defined as an ABI ≤0.9, the ideal cut-off may be influenced by clinical setting variables such as population characteristics or disease prevalence.[11]

ABI measured by oscillometry is a simple, reproducible and automatic method that is becoming popular, since it surpasses the limitations of the Doppler with regards to equipment, training and time constraints. Both the oscillometric and the Doppler ABI techniques are not fully standardised, in such a way that several procedures have been suggested: simultaneous vs sequential and unique vs multiple measurements. In addition, studies comparing the oscillometric ABI with the Doppler ABI differ in whether they consider calcified members and oscillometric errors as PAD equivalents or not. Moreover, two units of analysis are equally used yielding potentially different results: those analysing legs as independent measurements and those analysing subjects (defining as PAD subjects those with one or two pathological legs).

A previous meta-analysis reported that the oscillometric ABI is a reliable and practical alternative to the conventional Doppler ABI, with 69% sensitivity and 96% specificity.[12] However, although it has been reported that some statistical methods for meta-analyses of diagnostic accuracy might result in misleading summary estimates of sensitivity and specificity, no previous study has comprehensively reviewed and compared the accuracy of both the oscillometric and the Doppler method using Hierarchical Summary Receiver Operating Characteristic (HSROC), which is currently considered the most rigorous multivariate meta-analysis approach.[13]

Thus, the present study aims to identify and evaluate evidence regarding the diagnostic performance of the oscillometric ABI to detect PAD as compared with the Doppler ABI using HSROC meta-analysis procedures, and to examine the influence of two strategies of analysis: (i) subjects vs legs, and (ii) oscillometric errors analysed as PAD equivalents vs exclusion of oscillometric errors.

Review criteria

- Systematic searches in EMBASE, MEDLINE, Web of Science and the Cochrane Library databases were performed through predefined search criteria. Studies reporting a 2 × 2 contingency table comparing Doppler ABI (reference test) and oscillometric ABI (index test) were included.

Message for the clinic

- The oscillometric ankle-brachial index (ABI) has proven good diagnostic performance and excellent feasibility; thus, it might be a useful tool for diagnosing peripheral arterial disease (PAD).
- To detect individuals at high cardiovascular risk, we suggest considering oscillometric errors as PAD equivalents and a "per subject" instead of a "per leg" approach as the unit of analysis.
- Borderline oscillometric ABI values in diabetic population should raise concern of PAD.

2 | METHODS

2.1 | Protocol and registration

The protocol of this study was included in PROSPERO as "The accuracy of oscillometric ankle-brachial index in the diagnosis of lower limb peripheral arterial disease. The influence of two units of analysis and oscillometric errors: a systematic review and meta-analysis" with the registration number: CRD42016051120.

2.2 | Literature search

We systematically searched MEDLINE (via PubMed), EMBASE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews and the Web of Science databases from their inception to February 2017. The search strategy comprises three comprehensive search terms combined with Boolean operators: ("ankle brachial index" OR "ankle brachial indices" OR "ankle-brachial" OR "ankle-arm") AND (oscillomet* OR automat*) AND (usefulness OR accuracy OR sensitivity OR specificity OR comparison OR diagnosis OR diagnostic). The literature search was complemented by reviewing citations of the articles considered eligible for the systematic review. These steps were performed independently by two reviewers (AH and CA) and disagreements were solved by consensus or involving a third researcher (IC).

2.3 | Selection criteria

We aimed to identify original articles analysing the diagnostic performance of the oscillometric ABI (index test) compared with the Doppler ABI (reference standard) used to diagnose PAD. The following inclusion criteria were used: (i) study participants: individuals aged ≥18 years; (ii) the oscillometric ABI as the index test; (iii) the handheld continuous wave Doppler ABI as the reference standard test; (iv) outcome: PAD diagnosis; and (v) study design: cross-sectional and comparative studies with either prospective or retrospective data

collection. The exclusion criteria were: (i) insufficient data to calculate diagnostic odds ratio (dOR); (ii) studies conducted only on patients diagnosed with PAD; and (iii) studies written in a language other than English or Spanish. When the same study reported ABI measurements using two different oscillometers[14] or observers,[15] those maximising dOR were chosen for the meta-analysis. Studies in which a double analysis was possible,[16,17] "per subjects" and "per legs" analysis, an analysis "per legs" was computed for the global meta-analysis because it yielded narrower confident intervals.

2.4 | Data extraction and quality assessment

After analysing original reports, the following data were extracted: (i) author identification, (ii) year of publication, (iii) Doppler ABI calculation, (iv) oscillometric ABI calculation, (v) oscillometric device, (vi) Doppler probe, (vii) average time to perform the Doppler ABI and the oscillometric ABI techniques, (viii) setting, (ix) age, gender and number of participants, (x) prevalence of diabetes mellitus, (xi) prevalence of PAD, (xii) whether or not calcified limbs and oscillometric errors were excluded from analysis, (xiii) unit of analysis (subjects vs legs), (xiv) parameters summarising the accuracy of the test: cut-off, area under the curve (AUC), and a 2 × 2 contingency table (true positives, true negatives, false positives and false negatives) to calculate dOR, sensitivity and specificity. When necessary, we directly contacted the authors for additional data. Studies from which it was not possible to collect a 2 × 2 contingency table were excluded from the meta-analysis.

Quality assessment of studies was performed using the Quality Assessment of Diagnostic Accuracy Studies-2 tool (QUADAS-2) to evaluate four domains in each study: (i) patient selection, (ii) index test, (iii) reference standard and (iv) flow of patients and timing of the tests. All four domains were evaluated regarding the risk of bias and the first three domains were also evaluated in terms of concerns regarding the applicability of results.[18]

Two investigators (AH and CA) assessed each study's methodological quality independently and disagreements were resolved by consensus or with a third investigator (IC).

2.5 | Statistical analysis and data synthesis

This study is reported according to the PRISMA statement[19] and it fulfils the Cochrane Collaboration Handbook recommendations.[20]

The dOR, sensitivity, specificity, positive likelihood ratio (PLR) and negative likelihood ratio (NLR), as well as their corresponding 95% confidence intervals (CIs), were calculated globally and by subgroups. A continuity correction was made by adding 0.5 to all cell counts of the 2 × 2 tables to avoid indeterminate values of dOR, PLR and NLR.[21] PLR and NLR were directly meta-analysed after excluding a significant threshold effect, which was studied through correlation between sensitivity and specificity, and a "shoulder-like" appearance of the HSROC curve.[22]

The dOR is a measure of the effectiveness of a diagnostic test that combines sensitivity and specificity into a single number, which could take values from 0 to infinity.[23] A value of 1 indicates null diagnostic ability of the test, while higher values represent better discriminatory test performance. Moses' constant of linear model was used to compute the dOR. This approach is based on the regression line using the logit of the dOR of each study as a dependent variable and an expression of the positivity threshold of the study as an independent variable.[24]

HSROC curves were used to summarise the overall test performance. They were also used to evaluate the magnitude of heterogeneity, in such a way that wider prediction regions suggest larger heterogeneity.[25,26] Additionally, the I^2 statistic was used to evaluate heterogeneity across studies, with values of <25%, 25%-50% and >50% corresponding to small, medium and large heterogeneity, respectively.[27] Because of large heterogeneity in most cases, dOR estimates were pooled using a random-effects model with the Der Simonian and Laird method.

Subgroup analyses were conducted according to factors potentially causing heterogeneity, such as unit of analysis ("per subjects" vs "per legs"), oscillometric error consideration (inclusion vs exclusion) and the nature of the populations (Primary care, intermediate cardiovascular risk clinics and Vascular services). The "per legs" analysis considered each leg as an independent unit of analysis for comparing the oscillometric and the Doppler measurements. Conversely, in the "per subjects" analysis, individuals rather than legs were the unit of analysis, considering as PAD subjects those with at least one leg with an ABI ≤0.9. In the subgroup analysis, oscillometric errors are defined as the incapacity of the oscillometer to report a value of ankle blood pressure. When oscillometric errors were included into the analysis, they were considered as PAD equivalents.

Random-effects univariate and multivariate meta-regressions were used to separately evaluate the effects of potential covariates in dOR, sensitivity and specificity: (i) unit of analysis (subjects vs legs); (ii) oscillometric errors (inclusion vs exclusion); (iii) calcified legs (inclusion vs exclusion); (iv) timing of oscillometric measurements (simultaneous vs sequential); (v) validation of oscillometric devices (yes vs no); (vi) oscillometric devices specifically designed for ABI (yes vs no); (vii) standard oscillometric and Doppler calculation (yes vs no); (viii) Doppler test blinded to the oscillometric test results (yes vs no); (ix) population recruitment (consecutive vs not) and (x) patients' characteristics: age, gender, sample size, prevalence of diabetes and prevalence of PAD.

Sensitivity analyses were conducted by removing studies one by one in order to assess the robustness of the summary estimates and to detect whether any particular study accounted for a large proportion of heterogeneity.

Finally, publication bias was assessed using both Deeks' statistical test and a funnel plot.[28] Publication bias is suspected when a non-vertical line for the slope of the coefficient is present ($P < .10$), thus proving asymmetry.

Statistical analyses were performed using StataSE software, version 14 (Stata Corp, College Station, TX, USA).

3 | RESULTS

3.1 | Baseline characteristics

The search retrieved a total of 472 articles, of which 209 were duplicates. After screening the titles and abstracts of the remaining 263 studies, 155 were excluded on the basis of the previously described criteria, leaving 108 full-text articles to be reviewed. Of those, 77 were excluded, leaving 31 articles for qualitative synthesis and 20 for the final meta-analysis, shown in Figure 1.[19]

The 31 studies comprising this review included 5527 participants: 11 studies (n = 1760) used "per subjects" analysis, 11 studies (n = 1947) used "per legs" analysis and 11 studies (n = 2125) did not clearly describe the strategy of analysis, shown in Table 1. After exclusions, 1538 subjects (11 studies) and 3695 legs (11 studies) were analysed. Reasons for such exclusions were: (i) limb calcification,[16,17,29-34] (ii) oscillometric errors[14,31,33,35-39] and (iii) not all participants had their limbs measured using both the oscillometric and the Doppler.[40] In two studies,[16,17] a double analysis ("per subjects" and "per legs") was performed.

The studies were conducted in 18 countries, with participants ranging in age from 46.9 to 79.6 years. The prevalence of PAD across studies considering subjects (one or two pathological legs) and legs varied from 8.9% to 41.8% and from 1.1% to 56.7%, respectively. Studies which used "per legs" analyses as compared with those using "per subjects" analyses involved younger participants (60.5 vs 64.5 years old), more women (49.1% vs 38%), less prevalence of diabetes (29.8% vs 37.9%), less cardiovascular events (16.5% vs 24.4%), similar mean oscillometric ABI (1.063 vs 1.062) and higher mean Doppler ABI (1.101 vs 1.038).

3.2 | Study quality

Quality assessment of the included studies was performed using the QUADAS-2 tool. Most studies had bias in patient selection (domain 1) and in the reference test (domain 3), see Figure S1. Considering patient selection, six studies (30%) had exclusions that were a potential risk of bias (PAD subjects)[15,29,33,35,40,41] and in two studies (10%),[15,17] there was concern about a case–control design. In eight studies (40%), the reference standard did not fulfil the standard ABI calculation[16,32,35,38-40,42,43] and in four studies (20%),[16,31,39,41] the Doppler test was not blinded from the oscillometric test results. One study (5%)[40] had partial verification bias.

Table S1 provides detailed data on the QUADAS-2 assessment of the studies and the rules used to score each domain.

3.3 | Meta-analysis

Figure 2 depicts the dOR forest plot of the included studies. Heterogeneity across studies comparing oscillometric and Doppler ABI measurements was high in dOR (I^2 = 75.6%), moderate in sensitivity (I^2 = 46.1%) and absent in specificity (I^2 = 0.0%). The pooled estimates for the diagnosis of PAD were 32.49 for dOR, 65% for sensitivity, 96% for specificity, 15.33 for PLR and 0.30 for NLR. Table 2

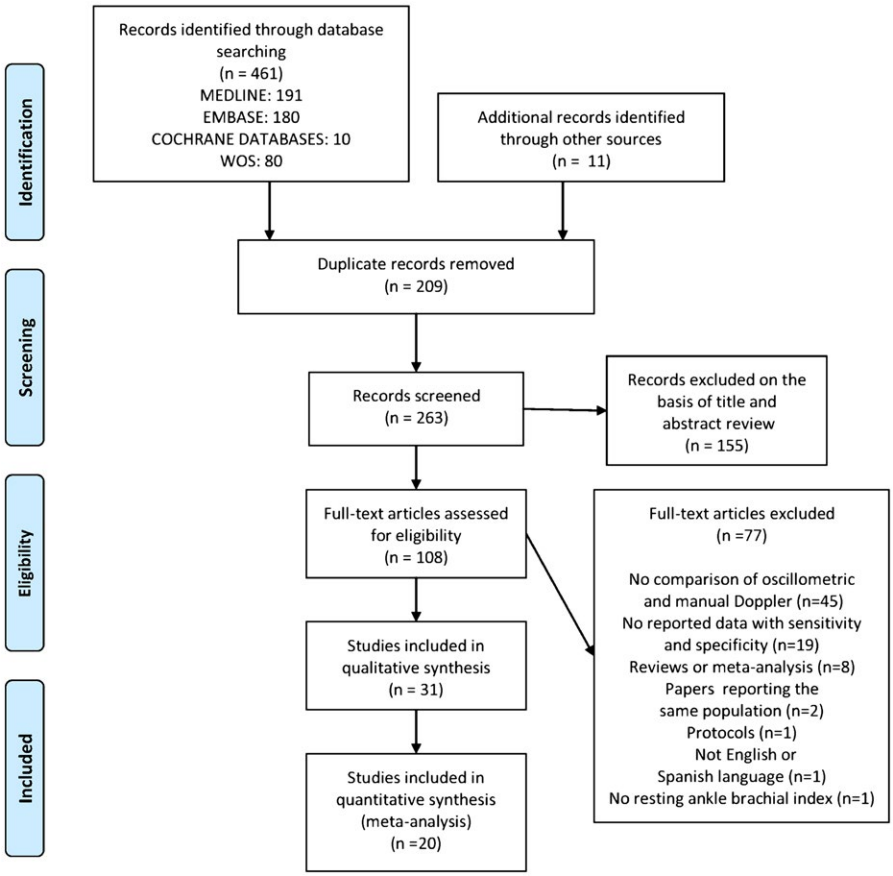

FIGURE 1 Literature search PRISMA flow diagram

TABLE 1 Characteristics of the populations, devices and accuracy outcomes of the studies included in the meta-analysis that conducted: "per subjects" (not legs) analysis, "per legs" (not subjects) analysis and with not well defined unit of analysis

Reference	Study population	n	Age (years)	Gender (% men)	PAD prevalence	Doppler ABI	Oscillometric ABI	Oscillometric device	Sensitivity (%)	Specificity (%)	dOR	AUC
"Per subjects" analysis[d]												
Benchimol[29]	Cardiology consultants	219[a] 212[b]	55.0	62	29.7	↑DPA or PTA/↑BA	Ankle/↑BA	OMRON M4[g]	76	95	52.1	
Benchimol[40]	Preventive medicine consultants	354[a] 196[b]	50.5	74	13.3	PTA/↑BA	Ankle/↑BA[j]	OMRON HM 722[g]	92	98	362.6	
Ena[31]	Diabetic patients from Internal Medicine office	110[a] 93[b]	71.0	65	32.3	↑DPA or PTA/↑BA	Ankle/↑BA[j]	OMRON M6[g]	67	87	12.7	0.870
Novo-García[16]	Primary care subjects with type 2 diabetics	215[a] 193[b]	69.5	56	19.7	DPA or PTA/BA same side	Ankle/BA same side	OMRON M6[g]	37	92	6.8	0.764
Arévalo-Manso[41]	Ictus or transient isquemic attack subjects	30[a]	67.8	66	26.7	↑DPA or PTA/↑BA	Ankle (PTA)/↑BA	OMRON HEM-907[g]	100	100	765.0	1.000
Nelson[39]	High cardiovascular risk patients	250[a] 242[b]	71.2	69	21.5	DPA or PTA/↑BA AUSC	NR	OMRON HEM-907[g]	62	92	16.8	0.870
Takahashi[32]	Atomic bomb survivors	115[a] 113[b]	72.3	41	8.8	PTA/R BA	Ankle/↑BA[i]	OMRON VP2000[f, g]	50	100	207.0	
Umuerri[42]	Hypertension clinic consultants	153[a]	57.5	67	41.8	Louder DPA or PTA/↑BA	Ankle/↑BA	OMRON M3[g]	61	90	13.1	0.787
Forés, 2014[14]	Primary care subjects	88[a]	72.7	48	13.6	NR	Ankle/↑BA[j]	OMRON M6[g]	33	97	15.8	
Forés, 2014	Primary care subjects	88[a]	72.7	48	13.6	NR	Ankle/↑BA[i]	Microlife Watch BP Office[f,g]	8	97	3.9	
Špan, 2016[33]	General practitioner's office	136[a]	68.2	NR	10.3	↑DPA or PTA/↑BA	NR[i]	MESI ABPI MD[f,h]	57	99	105.9	
Herráiz-Adillo, 2016[17]	Primary care and vascular consultants	90[a] 82[b]	70.4	56	30.5	↑DPA or PTA/↑BA	Ankle/↑BA[i]	OMRON M3[g]	84	100	549.4	0.970
"Per legs" analysis[e]												
Beckman, 2006[30]	Vascular clinic consultants	201[a] 345[c]	66.0	47	27.8	↑DPA or PTA/↑BA	Ankle/↑BA[j]	CasMed740[h]	R: 73 L: 88	R: 95 L: 85	32.9	
Vinyoles[35]	Hypertensive primary care subjects	100[a] 157[c]	66.4	39	11.5	PTA or DPA if PTA undetected/↑BA	Ankle/↑BA	OMRON HEM 705CP[g]	R: 37 L: 20	R: 93 L: 97	7.2	

(Continues)

TABLE 1 (Continued)

Reference	Study population	n	Age (years)	Gender (% men)	PAD prevalence	Doppler ABI	Oscillometric ABI	Oscillometric device	Sensitivity (%)	Specificity (%)	dOR	AUC
MacDougall[36]	Vascular clinic consultants	57[a] 62[c]	65.0	84	32.3	↑DPA or PTA/ average (L+R) BA or ↑BA	Mid-calf/ average (L+R) BA	OMRON HEM 711C[g]	71	89	19.1	
Aboyans[15]	Vascular clinic consultants	54[a] 108[c]	58.2	52	23.1	↑DPA or PTA/ average (L+R) BA or ↑BA	Ankle/average (L+R) BA[j]	Spengler ProM[g]	76	96	69.0	
Korno[34]	Vascular clinic consultants	61[a] 120[c]	67.0	NR	56.7	↑DPA or PTA/↑BA same side	Ankle/↑BA[j]	CasMed 740[h]	71	92	27.4	0.920
Wohlfahrt[44]	General population	839[a] 1678[c]	54.3	47	1.1	↑DPA or PTA/R BA	NR[i]	Boso ABI system 100[f,h]	78	98	147.5	
Kollias[37]	Cardiovascular clinic consultants	93[a] 183[c]	62.5	62	13.1	↑DPA or PTA/↑BA	NR[i]	Microlife Watch BP Office[f,g]	83	97	128.0	0.981
Rosenbaum[43]	Cardiovascular risk factors (≥2)	157[a] 314[c]	59.1	51	17.8	OSC ↓DPA or PTA/ OSC R BA	Ankle/↑BA[i]	SCVL[f,g]	57	89	10.3	
Novo-García[16]	Type 2 diabetics	215[a] 403[c]	69.5	56	14.4	DPA or PTA/BA same side	Ankle/BA same side	OMRON M6[g]	24	94	4.9	0.724
Sinski[38]	Coronary artery disease patients	80[a] 158[c]	70.1	66	35.4	PTA/↑ BA	NR[i]	Microlife Watch BP Office[f,g]	46	98	34.9	
Herráiz-Adillo[17]	Primary care and vascular consultants	90[a] 167[c]	70.4	56	25.1	↑DPA or PTA/↑ BA	Ankle/↑BA[i]	OMRON M3[g]	79	96	77.3	0.958
Not well defined unit of analysis												
Di Yacovo[51]	Internal medicine department	145	70.0	47	NR	NR	NR	NR	66	87	13.0	
Fröhlich[52]	Outpatient clinic	100	NR	NR	40.0	NR	NR	Angio Experience[h]	56	92	14.6	0.740
Fröhlich[52]	Outpatient clinic	100	NR	NR	40.0	NR	NR	Boso ABI system 100[f,h]	86	87	41.1	0.920
Hamel[53]	Hospitalised patients ≥ 65 years	287	79.6	48	13.3	↑DPA or PTA/↑BA	Ankle/↑BA	OMRON M6[g]	34	96	12.4	

(Continues)

TABLE 1 (Continued)

Reference	Study population	n	Age (years)	Gender (% men)	PAD prevalence	Doppler ABI	Oscillometric ABI	Oscillometric device	Sensitivity (%)	Specificity (%)	dOR	AUC
Khukhua[54]	No PAD symptoms	104	57.9	57	9.6	NR	NR	OMRON 705 IT[g]	90	100	–	
Bakalakou[55]	NR	130	67.0	66	30.4	NR	NR	OMRON M4[g]	80	95	76.0	0.900
Campens[56]	Cardiology department	99	NR	NR	22.0	NR	NR	Datascope Acutorr Plus[g]	80	97	129.3	
Rantamaula[57]	Diabetic patients	100	NR	NR	18.5	NR	NR	OMRON M3[g]	43	94	11.8	
Balkanay[58]	Cardiovascular clinic	53	46.9	66	17.0	NR	NR	Microlife Watch BP Office[f,g]	6	97	2.1	
Laroche[59]	>55 years old with any ischaemic event	505	69.0	63	NR	NR	NR	SCVL[f,g]	64	67	3.6	
Gerald Seinost[60]	NR	372	NR	NR	NR	NR	NR	NR	R: 81 L: 74	R: 83 L: 84	R: 20.8 L: 14.9	
Liu[61]	Diabetic patients	230	NR	NR	NR	NR	NR	OMRON VP1000[f,g]	R: 94 L: 96	R: 95 L: 97	R: 297.7 L: 776.0	

ABI, ankle brachial index; AUC, area under curve; AUSC, auscultatory technique; BA, brachial artery; DOR, diagnostic odds ratio; DPA, dorsalis pedis artery; L, left; NR, not reported; OSC, oscillometric; PAD, peripheral arterial disease; PTA, posterior tibial artery; R, right.

n, sample size: a: subjects; b: number of subjects really analysed, after excluding those with calcified limbs, oscillometric errors and those without both Doppler and oscillometric measurements; c: number of legs really analysed, after excluding calcified limbs and oscillometric errors. PAD prevalence (according to Doppler ABI): d: considering subjects (1 or 2 pathological legs); e: considering legs. Ankle brachial index formulas: ↑: highest value is considered; ↓: lowest value is considered. Characteristics of oscillometers: f: specifically designed for ABI measurements; g: validated for arm BP measurement; h: not validated; i: simultaneous oscillometric measurements; j: not simultaneous oscillometric measurements.

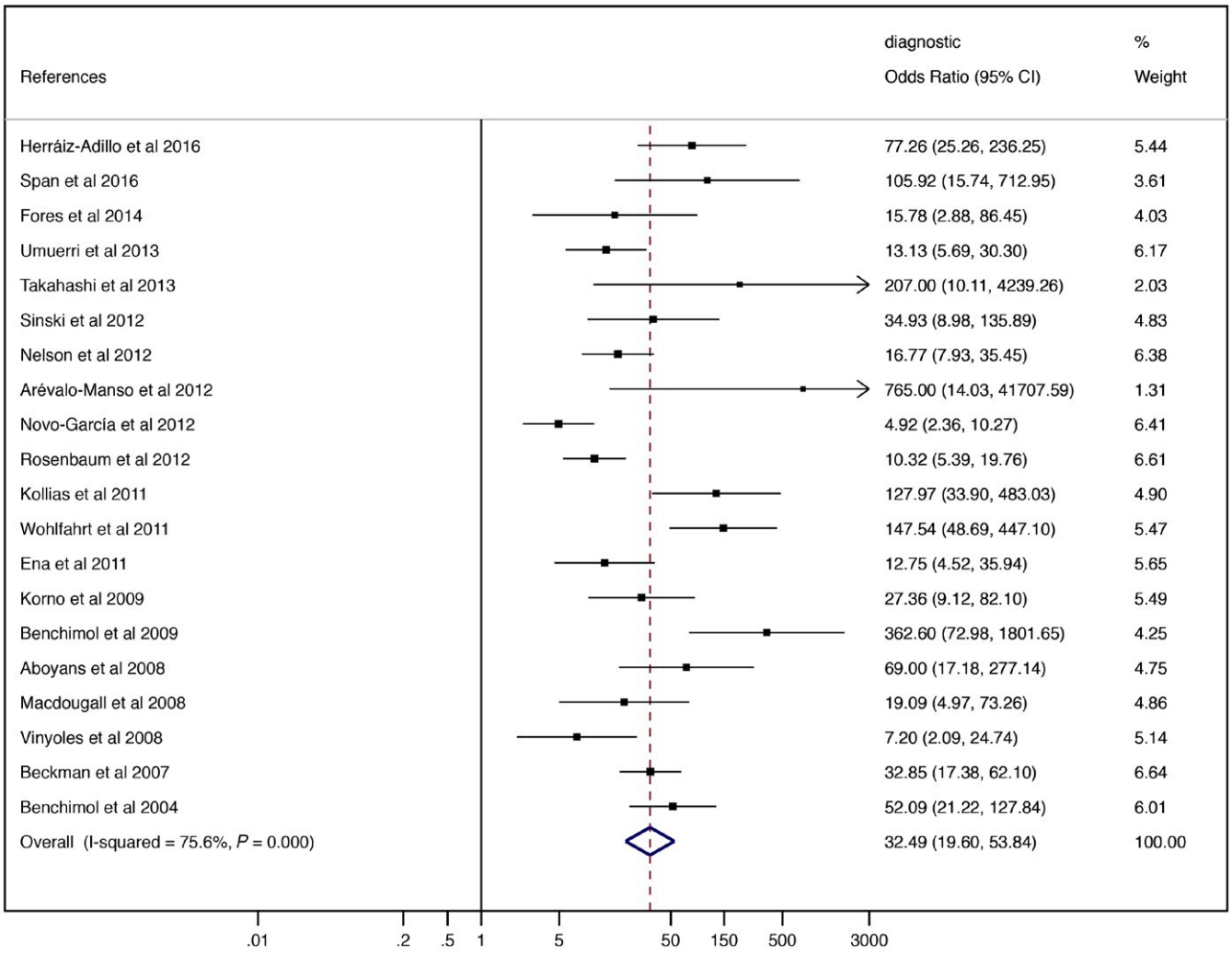

FIGURE 2 Forest plot of the diagnostic odds ratio of the oscillometric ankle brachial index in comparison to the Doppler ankle brachial index to detect peripheral arterial disease

TABLE 2 Pooled estimations of accuracy parameters in the diagnosis of peripheral arterial disease: global, by unit of analysis ("per subjects" vs "per legs") and regarding oscillometric errors (included vs excluded)

Type of analysis	No. of studies	Sensitivity (%)	Specificity (%)	PLR	NLR	dOR
Global	20	65 (57-74)	96 (93-99)	15.33 (8.8-26.8)	0.30 (0.18-0.50)	32.49 (19.6-53.8)
"Per subjects"	11	67 (57-78)	95 (90-100)	21.79 (10.3-46.0)	0.27 (0.13-0.54)	36.44 (16.7-79.3)
"Per legs"	11	62 (51-76)	96 (92-99)	12.50 (5.8-26.8)	0.33 (0.16-0.67)	29.03 (14.6-57.9)
OSC errors included as PAD equivalents	11	63 (50-78)	94 (89-99)	15.25 (7.2-32.3)	0.26 (0.13-0.51)	31.48 (13.6-72.9)
OSC errors not included	11	58 (46-74)	95 (90-100)	15.57 (7.2-33.8)	0.31 (0.15-0.62)	28.29 (13.2-60.6)

dOR, diagnostic Odds Ratio; OSC, oscillometric; NLR, negative likelihood ratio; PAD, peripheral arterial disease; PLR, positive likelihood ratio. Values in parentheses are 95% confidence intervals.

depicts the global estimates of accuracy in the diagnosis of PAD. Figure 3 shows the global HSROC curve estimating the discriminating accuracy of the oscillometric ABI for identifying PAD.

Figures 4 and 5 depict the global forest plots of sensitivity and specificity in the meta-analysis.

3.4 | Time of measurements in Doppler ABI and oscillometric ABI

Six and seven studies reported time of measurements in the Doppler ABI and the oscillometric ABI, respectively. The Doppler ABI time

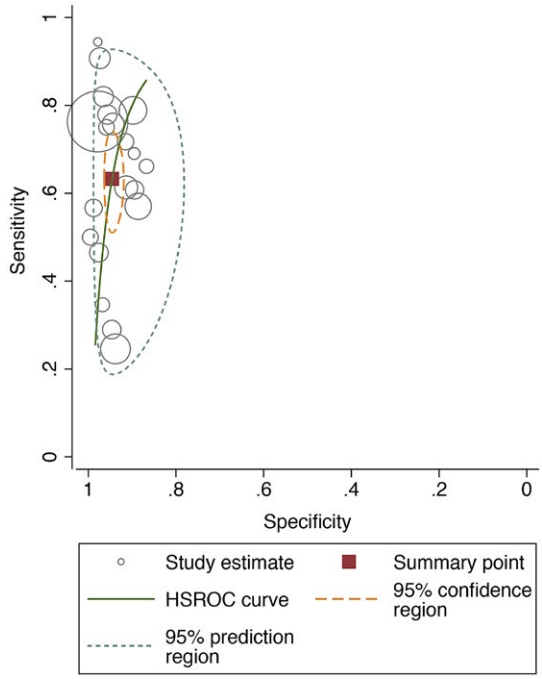

FIGURE 3 Hierarchical summary receiver operating characteristic curve summarising the ability of the oscillometric ankle brachial index to detect peripheral arterial disease in comparison to the Doppler ankle brachial index

measurements ranged from 6.65 to 14.00 minutes, while those of the oscillometric ABI ranged from 2.0 to 8.1 minutes. The time needed for the Doppler ABI was significantly longer (10.06 minutes, 95% CI: 6.76-13.35) than that required for the oscillometric ABI (5.90 minutes, 95% CI: 5.08-6.73), also showing higher intra and inter study variability, see Figure S2.

3.5 | Subgroup analysis

3.5.1 | Unit of analysis ("per subjects" vs "per legs")

"Per subjects" analyses showed higher dOR than "per legs" analyses: 36.4 (I^2 = 73.5%) vs 29.0 (I^2 = 80.7%), see Figure S3. Pooled estimates of accuracy parameters in this subgroup analysis (sensitivity, specificity, PLR and NLR) are depicted in Table 2. Figures S4 and S5 show the HSROC curves by unit of analysis.

3.5.2 | Inclusion or not of oscillometric errors

When oscillometric errors were analysed as PAD equivalents, dOR and sensitivity increased from 28.29 to 31.48 and from 58% to 63%, respectively. Specificity did not change substantially (95% vs 94%), see Table 2.

3.5.3 | Nature of the populations

Eight studies[14,16,17,32,33,35,40,44] included populations from Primary care services (mostly patients without symptoms of PAD), eight studies[29,31,37-39,41-43] included populations from intermediate cardiovascular risk services and five studies[15,17,30,34,36] included populations from Vascular services (mostly patients with symptoms of PAD). Weighted prevalence of PAD was 6.0% for Primary care, 25.5% for intermediate cardiovascular risk and 35.0% for Vascular services. Regarding dOR, these estimates were 44.68, 24.91 and 31.84, respectively. Estimates for sensitivity and specificity for each of the populations abovementioned, and in order of appearance, were as follow: 50%, 65% and 77% for sensitivity and 97%, 92% and 91% for specificity. See Figures S6-S8.

3.6 | Sensitivity analysis for the effect of individual studies

The influence of each study in the overall dOR was estimated by performing meta-analyses after removing one study at a time. No study significantly affected the pooled dOR, which indicates that the overall dOR estimation can be considered robust.

3.7 | Meta-regression

We performed univariate and multivariate meta-regressions to estimate the contribution of the abovementioned potential covarying factors that could explain heterogeneity, see "Statistical analysis and data synthesis". In the univariate model, regarding dOR, only the Doppler ABI calculation based in standard formulas or not (β [SE] = 1.51 [0.43], P = .003, I^2 = 56.3%) and diabetes (β [SE] = −0.02 (0.00), P = .025, I^2 = 71.4%) achieved statistical significance, see Table S2. According to sensitivity, a Doppler ABI calculation based or not in standard formulas also achieved statistical significance (β [SE] = 0.40 [0.09], P = .001, I^2 = 0.0%), while no difference across studies with regards to specificity was observed. Similarly, in multivariate analysis, both Doppler ABI calculations based in standard formulas or not and diabetes achieved statistical significance regarding dOR. There was a trend towards higher dORs in studies with a standard Doppler ABI calculation and in studies with a low prevalence of diabetes. Such covariates accounted for 86.7% of the total variance, see Table S3.

3.8 | Publication bias

Using Deeks' method, the asymmetry test did not suggest the existence of a large publication bias (intercept 1.68, 95% CI: −0.13 to 3.49, P = .051), tending studies with less diagnostic accuracy towards higher values of dOR, see Figure S9.

4 | DISCUSSION

PAD is a common vascular disorder that is very often underdiagnosed and undertreated, in part because of limitations of the Doppler ABI. Although a previous meta-analysis dating back to 2012 reported an acceptable performance of the oscillometric method, no previous study has comprehensively reviewed and compared the accuracy of the oscillometric and the Doppler ABI using the HSROC model.

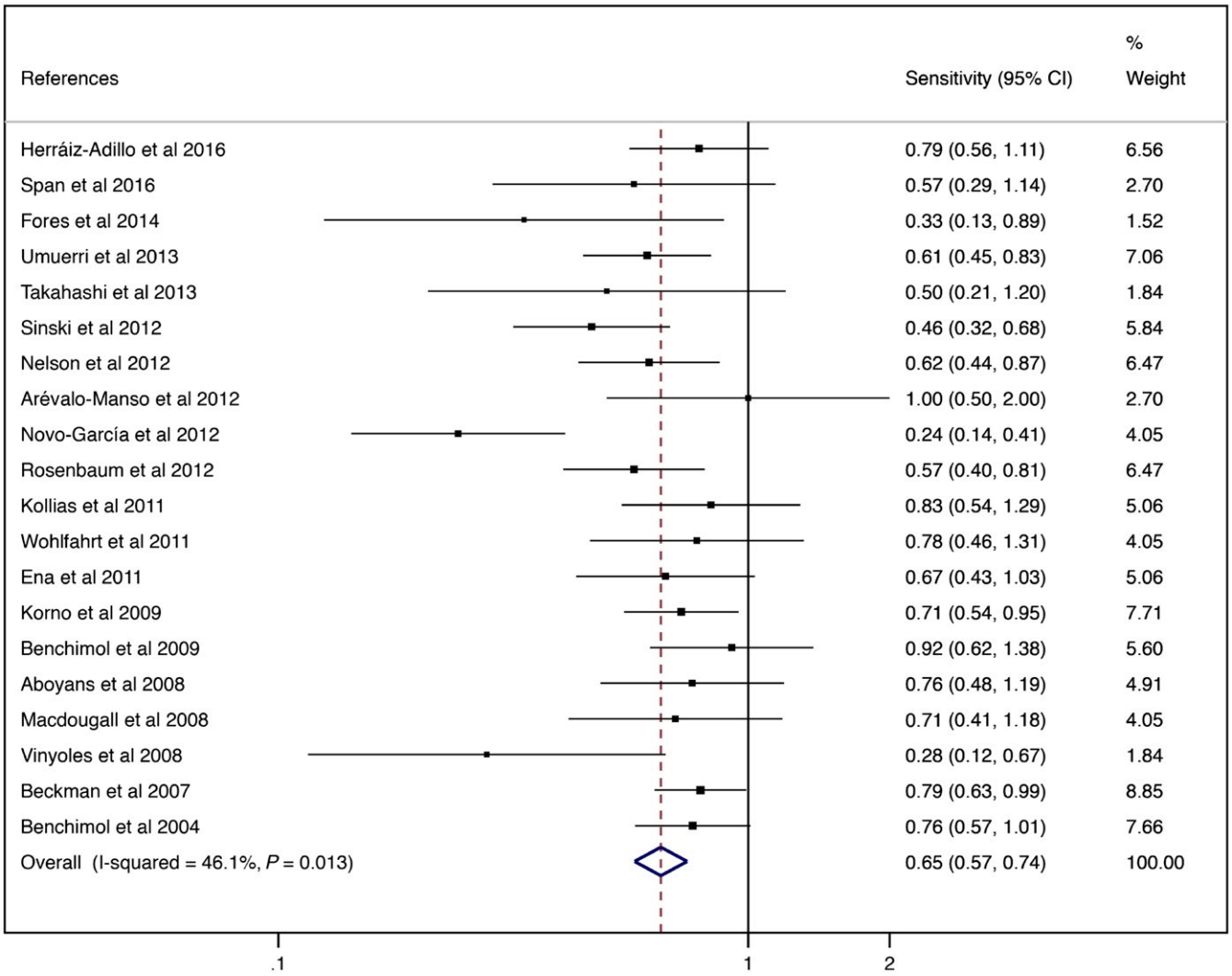

FIGURE 4 Forest plot of the sensitivity of the oscillometric ankle brachial index in comparison to the Doppler ankle brachial index to detect peripheral arterial disease

This meta-analysis includes 20 studies, which altogether involved 1263 subjects (3695 legs). Samples were mostly from Vascular clinics (mainly patients with symptoms of PAD), intermediate cardiovascular risk clinics (Internal Medicine, Cardiology, Ictus and Hypertensive) and Primary care settings (mainly asymptomatic patients for PAD).

In our meta-analysis, the pooled dOR (a single indicator of test accuracy that combines sensitivity and specificity) was 32.5. This means that for the oscillometric ABI, the odds for a positive test among subjects with PAD would be 32 times higher than the odds for a positive test among subjects without PAD. Although a specific cut-off for dOR has not been established in diagnostic tests, as it depends on many additional considerations, the value exhibited by the oscillometric ABI is in line with other useful diagnostic tests (for example, dOR in faecal immunochemical test for colorectal cancer in symptomatic patients is around 24[45]).

Our estimates slightly modify those previously reported in a smaller sample[12] and use a more theoretically based multivariate meta-analysis approach (HSROC). Specifically, our data revealed a high specificity value (96%). This along with a high PLR (15.33), which is considered the best parameter to diagnose a disease,[46] indicates an excellent theoretical capacity of the test to ascertain PAD. However, a modest sensitivity (65%) and NLR (0.30) suggest only a moderate ability of the oscillometer ABI to rule out the disease, potentially leading to shortcomings in a screening program because of a high prevalence of false negatives. Despite the abovementioned flaws in diagnostic accuracy, feasibility has been proved to be a key advantage of the oscillometric ABI. With a mean of 5.9 minutes, the oscillometric ABI was performed almost two times faster than the Doppler ABI, and had less intra and inter study variability. In addition, the learning curve for the oscillometric ABI is much shorter than that for the Doppler ABI, as it is mainly an automated technique. In fact, the oscillometric ABI can be even more accurate than the Doppler ABI, when both techniques are performed by physicians with little experience.[47] This may be the case in screening.

Thus, a good diagnostic performance, along with its great feasibility, low cost and inherent harmlessness show that the oscillometric ABI could prove useful in diagnosing PAD in clinical practice.

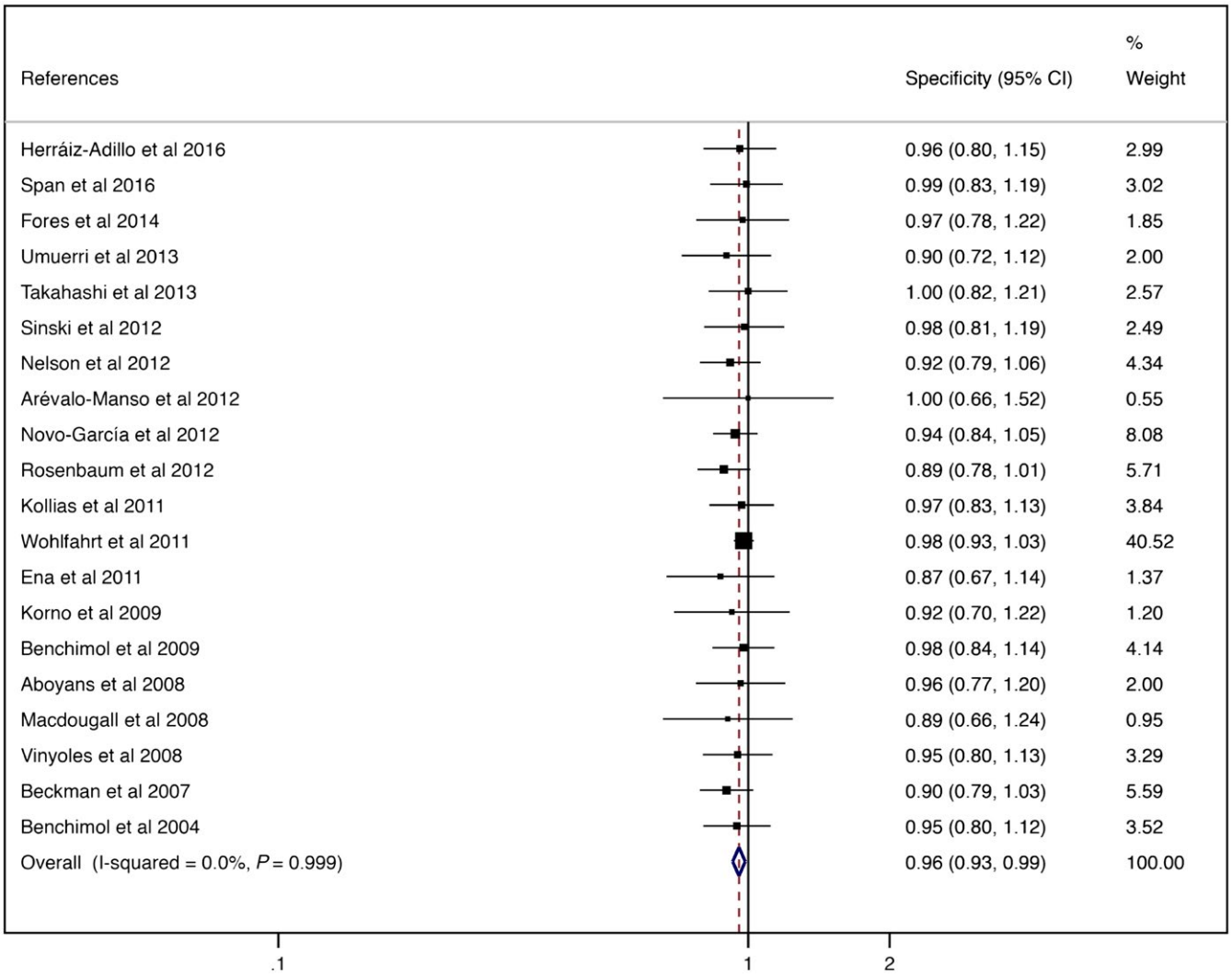

FIGURE 5 Forest plot of the specificity of the oscillometric ankle brachial index in comparison to the Doppler ankle brachial index to detect peripheral arterial disease

Diagnostic meta-analyses usually show great variability across individual studies. In ours, only the Doppler ABI calculation based in standard formulas or not and diabetes achieved statistical significance in dOR to explain heterogeneity, in such a way that those studies with a standard Doppler calculation and those with a low prevalence of diabetes exhibited higher values of dOR. These findings emphasise the lack of accuracy of the oscillometric ABI in diabetic patients, as has been previously reported in studies using both ultrasound and angiographic confirmation.[48,49] As meta-regression analyses suggested, this lack of accuracy especially occurs at the expense of sensitivity, which emphasises the use of cut-off values greater than 0.9 for diabetic patients (values between 1.0 and 1.1 have been suggested).[48] The physiological explanation seems to be calcification, which turns the artery wall rigid and poorly compressible, making ABI less reliable, especially for the oscillometric method. Although it was not possible in this meta-analysis (only two studies focused specifically on diabetic population[16,31]), it would be interesting to perform a subgroup analysis of diabetic patients as part of an individual patient-based meta-analysis, to examine overall estimates of sensitivity and specificity in such population.

Although oscillometric errors (inclusion or not) and the unit of analysis (subjects vs legs) did not achieve statistical significance in the meta-regression, we observed a trend towards better performance when analysing oscillometric errors as PAD equivalents and subjects rather than legs, especially at the expense of sensitivity. The reason for better performance in the "per subjects" group is that only one pathological leg is necessary to diagnose a PAD subject, thus increasing the likelihood of achieving perfect agreement. Since the presence of one pathological leg in a subject implies a high cardiovascular risk, and taking into account that one half of the studies used a "per legs" analysis, the sensitivity of the oscillometric ABI to detect individuals at high cardiovascular risk may have been undervalued. As a consequence, to detect individuals at high cardiovascular risk, we suggest a "per subject" approach and an analysis of oscillometric errors as PAD equivalents. Both considerations, along with an increase in the oscillometric cut-off, as Verberk et al suggested in a previous meta-analysis[12] (oscillometers did tend to report higher ABI values than the Doppler), could improve sensitivity, which is, as has been proved, the main limitation of the oscillometric ABI.

In our study, inclusion or not of calcified limbs does not seem to account for heterogeneity, probably because of a low prevalence of calcification. However, as calcification increases with age, diabetes and chronic kidney disease, a bias in overall performance can be expected in these cohorts. Therefore, standardisation in the analysis of calcified limbs seems desirable. In that sense, we proved in a previous work[17] that when calcified limbs are considered as PAD equivalents, oscillometric ABI maintains its diagnostic accuracy to detect PAD.

Similarly, our meta-analysis did not find significant differences regarding the oscillometric technique (simultaneous vs sequential, validated or not and devices specifically designed for ABI or not). This suggests that oscillometric devices, which are conventionally used for blood pressure readings on the arm, can be more useful and cheaper to diagnose PAD.

In our meta-analysis, we proved a spectrum effect across different populations. This is defined as a variation in sensitivity, specificity or both across different subgroups because of pathologic, clinical or comorbid features or different care settings.[50] In general, we found that populations receiving Vascular services showed higher rates in sensitivity while populations in Primary care rated higher in specificity. Theoretically, higher sensitivities (but lower specificities) may be expected in those cohorts including patients with high cardiovascular risk or with PAD symptoms; however, the opposite is expected in Primary care settings. Thus, generalisations of estimates from specific subgroups to general population, and vice versa, should be cautiously taken, particularly when heterogeneity is present.

This meta-analysis has some inherent limitations related to systematic reviews and meta-analyses. First, heterogeneity was high in dOR and moderate in sensitivity, limiting the possibility of giving specific guidelines for the clinical use of the oscillometric ABI. Second, the analysis showed certain publication bias. In theory, studies with low test performance might be less (or more) likely to be published. Third, the reliability of pooled estimates is contingent upon the quality of the studies in the meta-analysis, the quality assessment of studies with QUADAS-2 showed some deficiencies across the studies, especially the patient selection and reference test domains, see Figure S1 and Table S1. Fourth, although Doppler ABI is considered the non-invasive gold standard, it has some flaws, especially when measurements are performed by poorly skilled technicians.[47] Four studies[29,30,40,42] did not report the staff performing the Doppler technique, therefore accuracy of the Doppler technique cannot be warranted in all the studies. Although it would be desirable to compare oscillometric ABI against the reference standard angiography, such comparison seems to be unjustified, especially in low cardiovascular risk populations where revascularisation is not planned. Finally, to avoid indeterminate values in dORs, PLRs and NLRs, a continuity correction was made by adding 0.5 to all cell counts in the 2 × 2 tables. This may be considered a manipulation of data.

5 | CONCLUSION

The resting oscillometric ABI showed good diagnostic performance and high capacity to diagnose PAD in clinical practice. It also exhibited excellent feasibility, potentially making it a useful tool in mass screening programs for PAD, despite only moderate sensitivity. To detect individuals at high cardiovascular risk, we suggest considering oscillometric errors as PAD equivalents and a "per subject" approach as the unit of analysis. This could improve sensitivity, which is, along with the yield in diabetics, the main limitation of the test.

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DISCLOSURES

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Ángel Herráiz-Adillo: concept/design, data collection, data analysis/interpretation, critical revision, writing (original draft), approval of article. Iván Cavero-Redondo: data analysis/interpretation, statistics, critical revision, writing (original draft), approval of article. Celia Álvarez-Bueno: data collection, critical revision, writing (original draft), approval of article. Vicente Martínez-Vizcaíno: concept/design, statistics, critical revision, writing (review), approval of article. Diana P. Pozuelo-Carrascosa: critical revision, writing (original draft), approval of article. Blanca Notario-Pacheco: concept/design, critical revision, writing (review), approval of article.

ORCID

Ángel Herráiz-Adillo http://orcid.org/0000-0002-2691-0315

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