Automated Ankle-Brachial Pressure Index Measurement by Clinical Staff for Peripheral Arterial Disease Diagnosis in Nondiabetic and Diabetic Patients

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OBJECTIVE — Peripheral arterial disease (PAD) is a prognostic marker in cardiovascular disease. The use of Doppler-measured ankle-brachial pressure index (Dop-ABI) for PAD diagnosis is limited because of time, required training, and costs. We assessed automated oscillometric measurement of the ankle-brachial pressure index (Osc-ABI) by nurses and clinical staff.

RESEARCH DESIGN AND METHODS — Clinical staff obtained Osc-ABI with an automated oscillometric device in 146 patients (83 with diabetes) at the time of Dop-ABI measurement and ultrasound evaluation.

RESULTS — Measurements were obtained in most legs (Dop-ABI 98%; Osc-ABI 95.5%). Dop- and Osc-ABI were significantly related in diabetic and nondiabetic patients with good agreement over a wide range of values. When Dop-ABI ≤0.90 was used as the gold standard for PAD, receiver operating characteristic curve analysis showed that PAD was accurately diagnosed with Osc-ABI in diabetic patients. When ultrasound was used to define PAD, Dop-ABI had better diagnostic performance than Osc-ABI in the whole population and in diabetic patients ($P = 0.026$). Both methods gave similar results in nondiabetic patients. The cutoff values for the highest sensitivity and specificity for PAD screening were between 1.0 and 1.1. Estimation of cost with the French medical care system fees showed a potential reduction by three of the screening procedures.

CONCLUSIONS — PAD screening could be improved by using Osc-ABI measured by clinical staff with the benefit of greater cost-effectiveness but at the risk of lower diagnostic performance in diabetic patients.

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Peripheral arterial disease (PAD) is a frequent manifestation of atherosclerosis in the general population and is two to four times more prevalent in diabetic patients (1). A continuous wave Doppler-measured ankle-brachial pressure index (Dop-ABI) ≤0.90 is commonly used for diagnosing PAD (2,3). Ankle-brachial pressure index (ABI) sensitivity is 79% and specificity is 96% for detection of ≥50% reduction in vascular lumina (4). Moreover, Dop-ABI has prognostic value for cardiovascular morbidity and mortality and for coronary heart disease in particular (5). Despite the apparent simplicity of Dop-ABI measurements, they are time consuming and require technical skill and a dedicated device (2,6,7), which preclude routine use of ABI measurements in general practice (6). PAD remains largely underdiagnosed (1), particularly in diabetic patients in whom it is frequently associated with lower limb complications (8).

Automated oscillometric determination of blood pressure is commonly used for screening for hypertension (9). Devices are widely available and reliable (9,10). Several studies reported automated oscillometric ankle-brachial pressure index measurement (Osc-ABI) with good agreement with Dop-ABI results (11,12), suggesting that it might be used for PAD screening.

In this study, we evaluated Osc-ABI and Dop-ABI for PAD screening with ultrasound as a reference diagnostic procedure in diabetic and nondiabetic patients. Furthermore, we assessed the possible utility of involving nurses and clinical staff in PAD screening.

RESEARCH DESIGN AND METHODS

— A total of 146 consecutive patients (292 lower limbs), referred to the physiology department for Doppler ultrasound evaluation of PAD, were prospectively included in the study. A subgroup of 83 patients had known diabetes (56.8%). Risk factors were self reported by the patient, and biological values were found in medical files. The lower limbs were classified as clinically normal when skin was normal and both dorsalis pedis and posterior tibialis pulses were present. The subjects gave informed consent to participate in the study.

Ultrasound examination

Doppler measurement and two-dimensional ultrasound examination were conducted by a single investigator (C.C.), using the Toshiba Powervision 7000 10-MHz linear probe. Two-dimensional images and Doppler interrogation were obtained for iliac to ankle arteries and the abdominal aorta. Stenoses were evaluated with the ratio of the maximal systolic velocity at stenosis to the systolic velocity proximal to the stenosis. Arteries were classified as having no significant stenosis when velocity ratios were <2.

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Table 1—*Population characteristics*

	No diabetes	Diabetes	*P*
n	63	83	
Sex (% male)	65	71	
Age (years)	61.3 ± 18.1 (19–92)	62.5 ± 10.9 (35–91)	0.62
BMI (kg/m²)	25.1 ± 5.1 (16–42)	28.6 ± 5.6 (17.3–44.9)*	0.002
Overweight (BMI ≥25)	33 (50.8%)	58 (71.6%)*	0.03
Obesity (BMI ≥30)	12 (18.5%)	33 (40.7%)*	0.007
Systolic blood pressure (mmHg)	138.5 ± 20.3 (78–211)	147 ± 22.9 (103–197)*	0.02
Diastolic blood pressure (mmHg)	73.2 ± 12.3 (39–100)	76.3 ± 15.3 (48–139)	0.20
Pulse pressure (mmHg)	65.2 ± 15.2 (39–112)	70.5 ± 15.5 (43–105)*	0.04
Normal clinical limb examination	29 (46)	50 (60.2)	0.11
Dyslipidemia	22 (34.9)	37 (44.6)*	0.01
Hypertension	29 (46)	63 (75.9)*	0.0002
Smoking	28 (44.4)	22 (26.5)*	0.03
Coronary artery disease	20 (31.7)	22 (26.5)	0.58
Stroke	6 (9.5)	5 (6)	0.63
Clinical peripheral artery disease	9 (14.3)	25 (30.1)*	0.0016
Family history of cardiovascular disease	8 (12.7)	6 (7.2)	0.25
Diabetes duration (years)	—	11.7 ± 10.9 (0.5–57)	
A1C (%)	NA	8.44 ± 2.06 (5–13.7)	
Total cholesterol (mg/dl)	196 ± 39 (124–260)	183 ± 42 (50–206)	0.32
LDL cholesterol (mg/dl)	117 ± 33 (67–184)	104 ± 37 (50–206)	0.19
HDL cholesterol (mg/dl)	52 ± 15 (24–76)	49 ± 14 (25–83)	0.48
Triglycerides (mg/dl)	136 ± 56 (56–255)	146 ± 74 (29–377)	0.37
Creatinine (μM)	120 ± 93 (50–470)	109 ± 63 (56–450)	0.50

Data are means ± SD (range) or *n* (%). *$P < 0.05$ with *t* test comparison of means or χ^2 test comparison of frequencies.

ABI measurement

ABI was measured in all patients at the time of Doppler ultrasound examination. Osc-ABI was measured with an automatic device (Dynamap 8100, Critikon, Little Chalfont, Buckinghamshire, U.K.) by nurses or clinical staff. Systolic blood pressure was measured with the cuff placed above the ankles for both legs and both arms. Nurses or clinical staff were taught to measure Osc-ABI, i.e., to install the cuff with the sampling area facing the ankle artery, namely posterior, and anterior tibial artery for ankle measurement and brachial artery. This instruction was achieved in a single training session. Dop-ABI was measured by a single investigator (C.C.) with a continuous wave Doppler device (MD2, 8-MHz probe, Huntleigh, Luton, U.K.). Measurement was obtained at the posterior and anterior tibial arteries and both brachial arteries. ABI was computed as the ratio of ankle blood pressure to the highest brachial systolic blood pressure for both Osc-ABI and Dop-ABI.

Evaluation of costs

Costs of procedures were derived from the French medical care system fees for Doppler ultrasound examination or ABI measurement, combined with a visit with a cardiologist, a general practitioner, or a nurse.

Statistical analysis

The data were analyzed with SAS software (version 9.1; SAS Institute). Qualitative and quantitative variables were compared using χ^2 and Student's *t* tests, respectively. The level of agreement between Osc-ABI and Dop-ABI was assessed both by correlation analysis using Pearson's correlation coefficient and by a Bland-Altman plot (13). Receiver operating characteristic (ROC) curves were computed as well as areas under ROC curves using PROC LOGISTIC; curve areas were compared using a nonparametric approach (14) implemented in an SAS macro for correlated data or a Wald test (15).

Positive predictive value (PPV) and negative predictive value (NPV) were computed. The positive likelihood ratio was computed as the probability of true positive over the probability of false positive, and the negative likelihood ratio was computed as the probability of false negative over the probability of true negative. The MacNemar test was used to compare sensitivity and specificity. $P < 0.05$ was considered as significant. Data are shown as means ± SD.

RESULTS — Population characteristics for diabetic and nondiabetic patients are shown in Table 1. Diabetic patients had microvascular disease with nephropathy (34.6%), retinopathy (35.8%), and neuropathy (48.1%) or macrovascular disease (40.7%) including coronary artery disease, PAD, stroke, or carotid stenosis. PAD was clinically suspected because of the absence of distal artery pulses in 54% of nondiabetic patients and 40% of diabetic patients. PAD was diagnosed with Dop-ABI in 33% of nondiabetic patients and 27% of diabetic patients. Doppler ultrasound examination showed at least one arterial stenosis in 41.7% of the legs in diabetic patients and in 50.8% of the legs in nondiabetic patients. A proximal localization (i.e., iliac or femoral artery) was more frequent in nondiabetic than in diabetic patients (37.7 and 5.2% of the localizations, respectively, $P < 0.0001$), who had more distal localization (72.0 vs. 20.8% of the localizations in nondiabetic patients, $P = 0.0004$).

Both techniques of ABI measurement were highly correlated

Dop-ABI was measurable in 98% of the total population studied (97% of diabetic and 99.2% of nondiabetic patients), whereas Osc-ABI was obtained in 95.5%

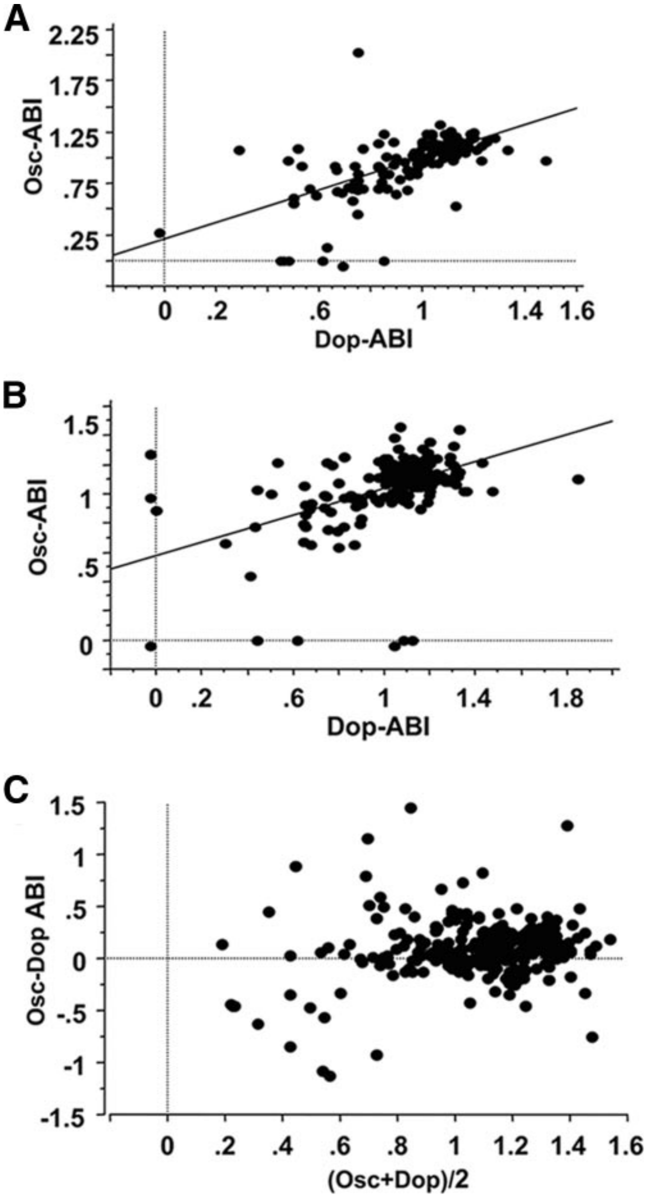

Figure 1—*Relationship between Dop-ABI and Osc-ABI in nondiabetic* (A) (r = *0.60;* P $<$ *0.0001) and diabetic* (B) (r = *0.49;* P $<$ *0.0001) patients. C: Bland-Altman representation of Doppler and oscillometric measurement of ABI in the whole population and the 95% limit of agreement to the mean difference.*

of the legs in the whole population (P = 0.16 for comparison of techniques), in 95.8% of diabetic patients, and in 95.3% of nondiabetic patients. When Osc-ABI was not measurable, Dop-ABI was either not measurable or <0.90 in most patients (9 of 13 legs).

Osc-ABI was related to Dop-ABI (r = 0.53, $P < 0.0001$) in the total population, as well as in nondiabetic patients and in diabetic patients (Fig. 1*A*). Bland-Altman representation showed that Dop-ABI and Osc-ABI were in good agreement in a wide range of values, and the difference did not vary with the average values in any significant way (Fig. 1*B*). The mean difference between the two methods was 0.0207 ± 0.27 in the total population, 0.028 ± 0.25 in diabetic patients, and 0.0098 ± 0.28 in nondiabetic patients.

Osc-ABI performance for diagnosis of PAD, as defined by Dop-ABI ≤0.90

ROC curves constructed for Osc-ABI with Dop-ABI ≤0.90 defining PAD (Fig. 2*A*) showed a high diagnostic accuracy. Areas under the curve (AUCs) of ROC curves were not different in diabetic and nondiabetic patients (AUC 0.83 and 0.844, respectively, P = 0.66). The best cutoff value for optimal sensitivity and specificity was 1.02 in the whole population, 1.04 in diabetic patients, and 1.0 in nondiabetic patients (Fig. 2*B*).

Osc-ABI and Dop-ABI performance for diagnosis of peripheral artery stenosis

ROC curves were constructed for Dop-ABI and Osc-ABI with stenosis at ultrasound as the criterion for diagnosis of PAD (Fig. 3*A*). The ROC curve analyses showed that Dop-ABI was better than Osc-ABI for correctly classifying patients for PAD ($AUC_{Dop\text{-}ABI}$ 0.873, $AUC_{Osc\text{-}ABI}$ 0.806, P = 0.026). Dop-ABI performance was equivalent in nondiabetic and diabetic patients (P = 0.068 for AUCs of ROC curves), whereas Osc-ABI did not perform as well as Dop-ABI in diabetic patients (P = 0.026 for ROC AUC comparison).

The diagnostic accuracy for selected ABI thresholds (Table 2) showed that the commonly used value of 0.90 has a high specificity but a medium sensitivity in the whole population. The sensitivity of Dop-ABI and Osc-ABI was greater in the nondiabetic population compared with that in diabetic patients. Thus, a threshold value of 0.90 defined a highly specific test at the expense of sensitivity for both Dop-ABI and Osc-ABI. Dop-ABI and Osc-ABI presented high PPVs in the total population (95.3 and 88.1%, respectively) but also in diabetic patients (92.5 and 83.3%, respectively). Conversely, NPVs were medium in both the whole population (76.1 and 65.9%, respectively) and diabetic patients (74.7 and 66.2%, respectively). To optimize the threshold values of ABI for screening and diagnosis, respectively, ROC curves were further analyzed. Figure 3*B* and *C* shows that the highest sensitivity and specificity were achieved at cutoff values between 1 and 1.1 for both Dop-ABI and Osc-ABI in patients with or without diabetes.

Evaluation of costs of the screening procedure

According to the French medical care system, the costs of PAD screening would be 121€ (162 US dollars [USD]) with a vascular ultrasound study only or 66€ (88 USD) with ABI only by a cardiologist, 43€ (58 USD) with ABI only by a general practitioner, and 33€ (44 USD) with ABI only by a nurse.

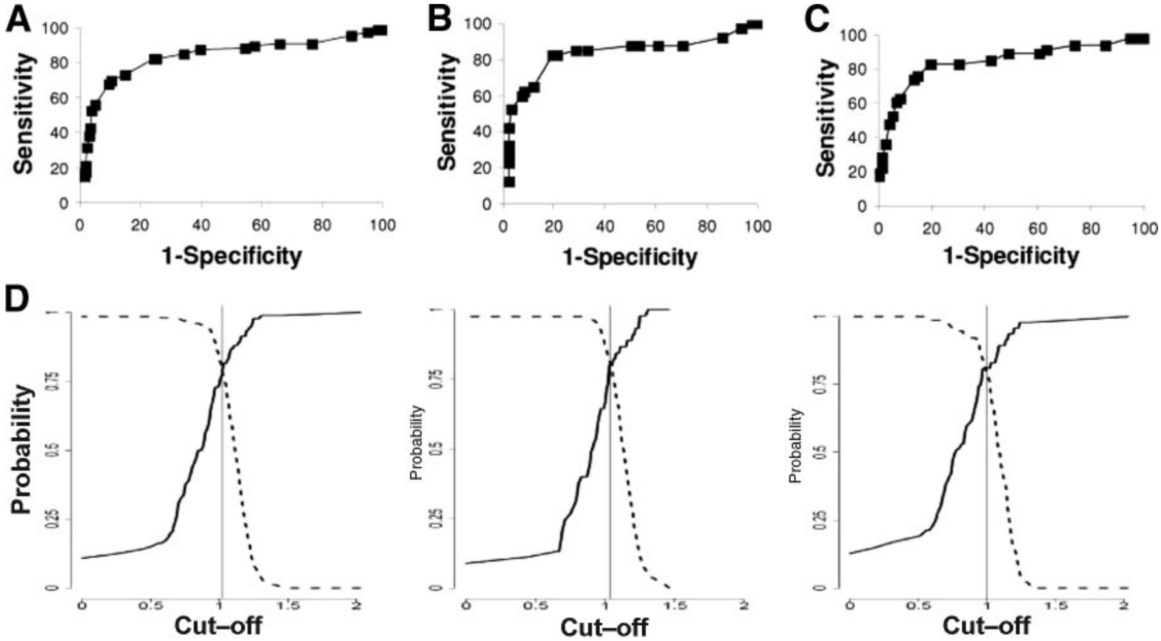

Figure 2—*ROC Curves for Osc-ABI for diagnosis of PAD, as defined with Dop-ABI <0.90 in the whole population* (A)*, diabetic patients* (B)*, and nondiabetic patients* (C)*.* D*: Best cutoff determination for maximizing both the sensitivity and the specificity in the whole population, diabetic and nondiabetic patients. ——, sensitivity; – – –, specificity.*

CONCLUSIONS— Automated oscillometric ABI measurement by clinical assistants with little formal training was shown to be feasible in most patients, including diabetic patients. The diagnostic efficiency was close to that of Dop-ABI in nondiabetic as well as in diabetic patients, as validated against ultrasound. Furthermore, we defined threshold values for Osc-ABI measurement as a screening or diagnostic test for PAD in nondiabetic and diabetic patients.

Our study showed that Dop-ABI and Osc-ABI were significantly related, as previously reported in several studies (11,12,16). Both methods were limited in some patients (0.6% of the legs in our population) when lower limb arteries were not compressible. We also described, for the first time, evaluation of the use of the oscillometric method in diabetic patients. Indeed, we showed that Osc-ABI was obtained in most diabetic patients and related to Dop-ABI. Furthermore, the low rate of failure for Osc-ABI (1.3% of diabetic patients) showed that most arteries could be evaluated with this method. The availability of an automated oscillometric method in diabetic subjects is of particular interest because PAD is frequently associated with few clinical symptoms (10). Indeed, we validated both Dop-ABI and Osc-ABI against ultrasound as a reference and Osc-ABI against Dop-ABI as a reference in diabetic patients and established threshold values for detection of artery stenosis. The analysis of ROC curves showed that Dop-ABI was slightly better than Osc-ABI in diabetic patients. Despite this difference, Osc-ABI could represent an alternative method for ABI measurement, even in diabetic patients, with the benefit that this method is more readily available than Doppler measurement.

Our study further extended the evaluation of Dop-ABI and Osc-ABI as a diagnostic or a screening test. Setting the threshold at 0.90 led to a PPV >95% and a threshold of 1.1 led to an NPV >99% (17–19). In our study, Dop-ABI showed a similar PPV (95%) at a threshold of 0.90 but a lower NPV (76%) with a threshold of 1.1. This result may be related to differences in the populations studied: the relatively smaller size of our population and higher-risk patients. We demonstrated similar results with Osc-ABI and Dop-ABI in the same patients, with PPV and NPV that were 10% lower in the diabetic subpopulation. Despite this difference, the diagnostic accuracy of Osc-ABI remained high enough to conclude that it could help in PAD assessment in diabetic patients. Indeed, PAD is frequent in diabetic patients, despite missing or confounding clinical symptoms, because of its coexistence with neuropathy (10). Thus, the use of Osc-ABI as a routine test could improve PAD diagnosis and management of lower limb complications in diabetes (8).

Further, we established threshold values of ABI optimized for a screening purpose. The ROC curves showed that both Dop-ABI and Osc-ABI could be used for screening for arterial stenosis with a cutoff set at 1.0 to 1.1, which identified >80% of the patients with PAD whatever the technique used and the presence or absence of diabetes. These results were in agreement with those reported for Dop-ABI with a normal value between 1 and 1.2 (2,5,17,20).

Obstacles to adopting ABI measurement for PAD diagnosis in primary care were identified previously as time, cost, and the need for a dedicated device and operator skill (6,7,12). In contrast, we have demonstrated that Osc-ABI can be easily performed by clinical assistants, i.e., nurses or others, after minimal training and with commonly available devices (2,7). The 1 to 1.1 threshold value would identify most patients with PAD. This approach represents substantial savings of costs and time, with a significant improvement in the diagnosis and management of PAD in the general population and particularly in diabetic patients. Our study was not designed for cost-effectiveness evaluation; however, we showed that the use of Osc-ABI, as first-line screening for PAD, would reduce by 61 and 75% the use of vascular studies for PAD diagnosis (25 of

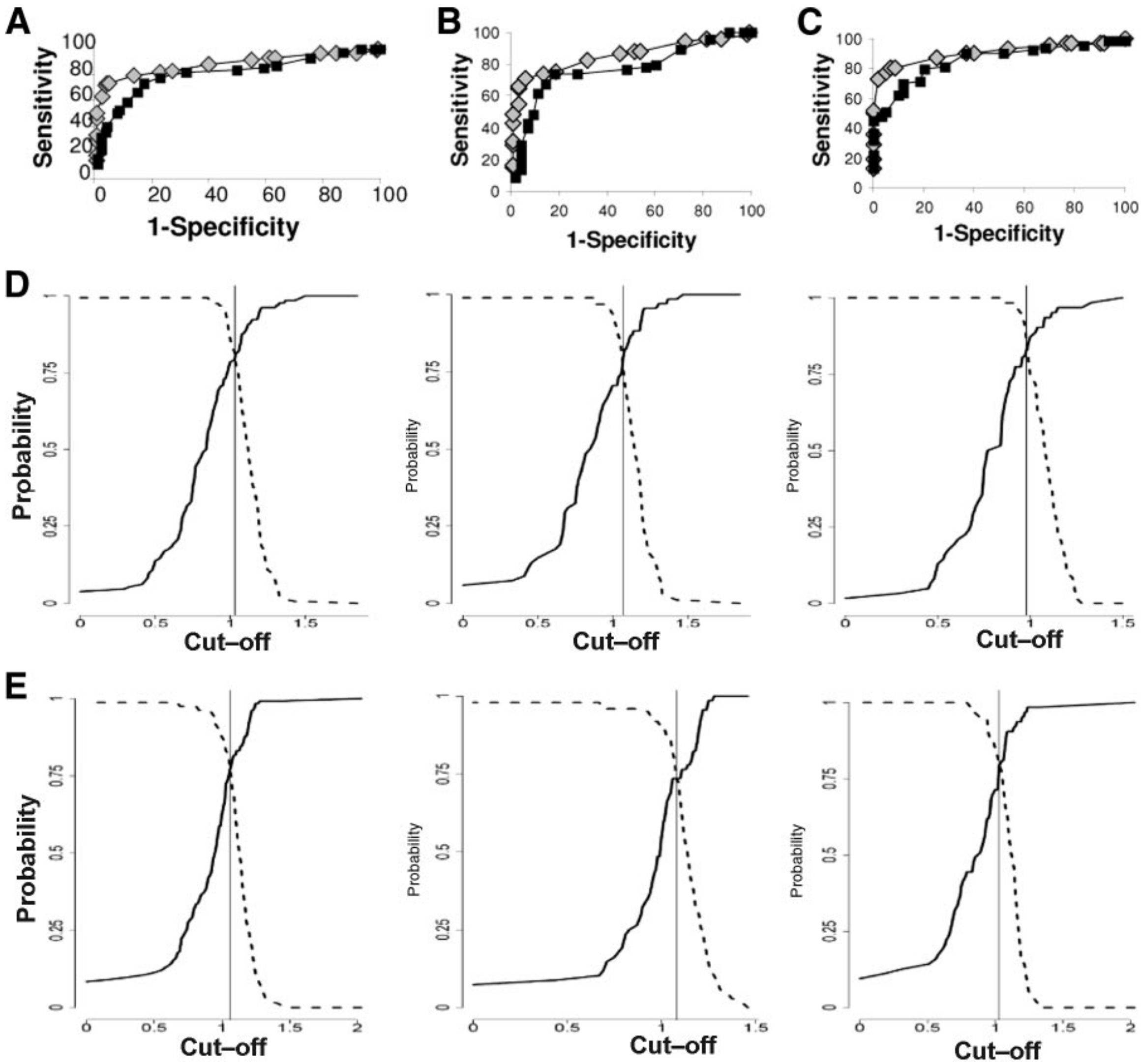

Figure 3—*ROC curves for Dop-ABI and Osc-ABI for diagnosis of ultrasound-identified arterial stenosis in the whole population (*A*), diabetic patients (*B*), and nondiabetic patients (*C*). Black square, Osc-ABI; gray diamond, Dop-ABI.* D*: Osc-ABI.* E*: Dop-ABI best cutoff determination for maximizing both the sensitivity and the specificity in the whole population, diabetic and nondiabetic patients. ——, sensitivity; – – –, specificity.*

Table 2—*Diagnostic performance of Dop-ABI and Osc-ABI for diagnosis of ultrasound-identified arterial stenosis in the total population and in nondiabetic and diabetic patients*

	Sensitivity (%)		Specificity (%)		NPV (%)		NLR		PPV (%)		PLR	
Threshold value ABI	Dop	Osc	Dop	Osc	Dop	Osc	Dop	Osc	Dop	Osc	Dop	Osc
Total population												
0.90	63.1	39.7	97.5	95.6	76.1	65.9	0.38	0.63	95.3	88.1	24.3	9.0
1	73.1	58.8	94.9	88.7	81.0	72.4	0.28	0.46	92.2	81.0	14.3	5.2
1.1	87.7	81.7	59.8	68.1	85.5	82.0	0.2	0.27	64.4	67.7	2.19	2.6
No diabetes												
0.90	72.6	50.7	98.3	95.0	77.6	65.5	0.47	0.71	97.8	91.6	42.7	10.5
1	80.6	69.8	91.6	88.3	82.1	73.6	0.35	0.57	90.9	86.2	9.7	6.0
1.1	93.5	90.5	46.6	63.3	87.5	86.3	0.26	0.37	64.4	72.1	1.75	2.5
Diabetes												
0.90	54.4	29.4	96.8	95.9	74.7	66.2	0.28	0.50	92.5	83.3	17.0	7.9
1	66.2	48.5	96.8	90.8	80	71.8	0.21	0.34	93.7	78.6	20.7	5.3
1.1	82.4	73.5	68.4	72.4	84.4	79.8	0.14	0.15	65.1	64.9	2.60	2.7

NLR, negative likelihood ratio; PLR, positive likelihood ratio.

63 nondiabetic patients and 21 of 83 diabetic patients). In patients in whom distal artery pulses were not palpable, vascular studies would have been reduced by 24 and 36% in nondiabetic and diabetic patients, respectively. The reduction of costs (roughly divided by a factor of 3) clearly supports the hypothesis of cost saving in PAD diagnosis with the use of Osc-ABI, as measured by nurses and clinical staff. Moreover, the early recognition of PAD would improve the management of lower limb complications and cardiovascular risk factors in the general population, with a further reduction in costs because of early intervention for modifiable cardiovascular risk factors (10,21). Nevertheless, the cost-effectiveness of Osc-ABI needs to be assessed in a study specifically design for that purpose.

In summary, our study showed that Osc-ABI measurement was feasible for clinical assistants using an automatic blood pressure monitoring device. This may be a low-cost and effective procedure to improve PAD management in at-risk patients, including subjects with diabetes, with early recognition and appropriate counseling for the control of modifiable cardiovascular risk factors.

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