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# Diagnosis of arterial disease of the lower extremities with duplex ultrasonography

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**The development of duplex scanning carries the prospect of an entire non-invasive work-up of patients with peripheral arterial occlusive disease. To obtain the best available estimates of its diagnostic accuracy, a meta-analysis of 71 studies evaluating duplex scanning was performed. Independent methodological judgement left 16 studies for data extraction. Pooled estimates (95 per cent confidence interval of sensitivity and specificity for detection of a stenosis greater than or equal to 50 per cent or occlusion in the aortoiliac tract were 86 (80–91) per cent and 97 (95–99) per cent respectively. The results for the femoropopliteal tract compared well with this, with a sensitivity of 80 (74–85) per cent and a specificity of 96 (94–98) per cent. The accuracy of detection of a stenosis greater than or equal to 50 per cent or an occlusion in the infragenicular arteries was lower with a sensitivity and specificity of 83 (59–96) per cent and 84 (69–93) per cent respectively. Duplex scanning is an accurate tool for assessment of atherosclerotic lesions in the aortoiliac and femoropopliteal tract and can replace routine pre-interventional angiography in a substantial number of patients.**

Duplex scanning is a relatively new diagnostic modality in vascular disease that facilitates non-invasive acquisition of anatomical and physiological information. Changes in a cross-sectional area of the vascular lumen can be determined by means of peak systolic velocity (PSV) at the site of a stenosis, the ratio of PSV at the site of the stenosis and its immediate normal vicinity, end diastolic velocity, and more subjective criteria such as number of phases in the Doppler waveform and degree of spectral broadening. This development carries the prospect of an entire non-invasive work-up of patients with peripheral arterial occlusive disease (PAOD).

Before a new test can be introduced to routine clinical practice and used as a base for clinical decisions it should be evaluated in methodologically sound studies. In order to obtain the best available estimates of the accuracy of this non-invasive tool a systemic literature review was performed and applied methodological criteria were used in the present analysis.

## Materials and methods

*Study selection*

A MEDLINE search was performed between 1976 and June 1994 to retrieve all publications in English, German and Dutch on diagnostic tests in PAOD. The keywords used were arterial occlusive disease, arteriosclerosis, 'claudica*' and vascular disease under the conditions of human and lower extremity. Exclusion criteria were child and adolescence, anaesthesia, neoplasm, wound and injury, and varicose veins. Based on title and abstract all publications on diagnostic tests were selected by one observer. Accuracy of selection was controlled in a random sample of 100 publications yielding interobserver kappas of 0·81, 0·85 and 0·91. Bibliographies from the selected articles were used to complete the search. Publications reporting repeatedly on the same study population were included only once.

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*Qualitative analysis*

All articles on duplex scanning were read by three independent observers and divided into three categories: pilot studies (e.g. case reports, reproducibility studies), formal analysis studies (comparing duplex with angiography as gold standard) and review articles. As, in most studies, angiography was the gold standard it was used as such in the present meta-analysis, without restrictions to angiographic technique or criteria for disease.

The same observers independently graded methodological quality of the gold standard studies according to predefined criteria. Two elements were essential: a clear definition of the study population and a clear description of the duplex scanning technique. Secondary criteria to improve study quality were a series of consecutive patients, a prospective study, predefined test criteria and independent assessment of duplex scanning and angiography. Studies satisfying all criteria were graded level 1, studies satisfying at least the two essential criteria level 2, and the remaining studies level 3. Discrepancies in judgement were discussed in order to arrive at a unanimous decision.

*Quantitative analysis*

Gold standard studies reporting sensitivity and specificity proceeded to quantitative analysis. Raw data were extracted by two observers to summarize diagnostic accuracy according to a modification of the method proposed by Midgette *et al.*[1] A test of homogeneity (Fisher's exact or $\chi^2$ test) was initially applied to determine whether differences in sensitivity and specificity among studies of comparable methodological level were potentially a result of chance alone. When homogeneity could not be rejected, pooled estimates of sensitivity and specificity and 95 per cent confidence interval (c.i.) were calculated according to the DerSimonian and Laird[2] random effects model, to give maximum weight to potential sources of variation. In case of heterogeneity the Spearman correlation between the separate sensitivities and (100-specificities) was determined. Midgette *et al.*[1] proposed fitting of a summary receiver-operating curve to determine optimal test criteria in case of a positive correlation, a procedure described in detail by Littenberg and Moses[3].

Three different vascular segments were analysed: the aortoiliac tract extending from the infrarenal abdominal aorta to the common femoral artery; the femoropopliteal tract from the



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common femoral artery to the trifurcation; and the infragenicular arteries from the trifurcation to the pedal arteries. Some authors subdivided these segments into smaller parts but their reported diagnostic accuracy would be too optimistic because a false-negative or false-positive result was compensated for by the large number of accurate results. Moreover, when data of such studies are pooled, confidence intervals of the estimated sensitivity and specificity will be artificially narrow. In these studies, therefore, the results were transformed by dividing the raw data for the respective vascular segments by the number of subdivisions made to approximate the actual number of segments examined. If possible, accuracy for detection of a stenosis greater than or equal to 50 per cent, an occlusion, or both separately was determined because the findings will lead to different treatment strategies.

## Results

### *Study selection and qualitative analysis*

From a total of 6993 studies, 636 reported on the evaluation of diagnostic tests in PAOD, including 15 pilot studies, 16 review articles and 40 gold standard studies[4–43] on duplex ultrasonography*. None of the review articles provided original data and reviews were only used to complete the search. Six gold standard studies were excluded because they were double reports[4–9]. The remaining 34 studies are listed in *Table 1*. Six studies satisfied all methodological criteria[10–15], 15 met at least the two essential criteria[16–30], and 13 publications were of lower methodological quality[31–43].

### *Quantitative analysis*

Four level 2 studies were excluded from quantitative analysis because of unspecified cut-off criteria[25], study population[26], unspecified investigated segment[27] or unclear angiographic criteria[29]. All level 3 studies were excluded because, owing to methodological shortcomings, no inference could be drawn from the results. Duplex scanning results extracted from the 16 remaining level 1

*A complete reference list is available from the authors on request

**Table 1** Results of qualitative analysis

| Reference | Year | Criteria satisfied | Population | Scanning technique |
|---|---|---|---|---|
| *Level 1* | | | | |
| Koennecke *et al.*[10] | 1989 | All | Chronic PAOD | Colour coded |
| Polak *et al.*[11] | 1990 | All | Claudication, critical ischaemia | Colour coded |
| Whelan *et al.*[12] | 1992 | All | Investigation of PAOD | Colour coded |
| Moneta *et al.*[13] | 1992 | All | Claudication, critical ischaemia | Colour coded |
| Hatsukami *et al.*[14] | 1992 | All | Severe claudication, critical ischaemia | Colour Doppler |
| Baxter and Polak[15] | 1993 | All | Claudication, critical ischaemia, cellulitis | Colour Doppler |
| *Level 2* | | | | |
| Jager *et al.*[16] | 1985 | 1, 3, 4, 5, 6 | Claudication, rest pain, gangrene | B/W coded |
| Kohler *et al.*[17] | 1987 | 1, 3, 4, 5, 6 | Symptomatic PAOD | B/W coded |
| Langsfeld *et al.*[18] | 1988 | 1, 4, 5 | Claudication, critical ischaemia | B/W coded |
| Collier *et al.*[19] | 1990 | 1, 2, 4, 5 | Normal femoral, week/absent distal pulses | Colour Doppler |
| Legemate *et al.*[20] | 1991 | 1, 3, 4, 5, 6 | Claudication, critical ischaemia | B/W coded |
| Legemate *et al.*[21] | 1991 | 1, 3, 4, 5, 6 | Claudication, critical ischaemia | B/W coded |
| Whyman *et al.*[22] | 1992 | 1, 3, 4, 5, 6 | Calf claudication, referred for PTA | Colour Doppler |
| Davies *et al.*[23] | 1992 | 1, 3, 4, 5 | Claudication, referred for PTA | Colour coded |
| Vashist *et al.*[24] | 1992 | 1, 3, 4, 5, 6 | Claudication | Colour coded |
| Sacks *et al.*[25] | 1992 | 1, 3, 4 | Claudication, critical ischaemia | B/W coded |
| Fowkes *et al.*[26] | 1992 | 1, 2, 4, 5, 6 | Duplex for screening in general population | B/W coded |
| Ebner *et al.*[27] | 1992 | 1, 4, 5 | Claudication | Colour coded |
| Karasch *et al.*[28] | 1993 | 1, 3, 4, 5, 6 | Claudication, clinically suspected AOD | Colour coded |
| Langholz *et al.*[29] | 1993 | 1, 4, 5, 6 | Fontaine I–IV | Colour coded |
| Allard *et al.*[30] | 1994 | 1, 3, 4, 5, 6 | Claudication, rest pain, gangrene, other | B/W coded |
| *Level 3* | | | | |
| Mergelsberg *et al.*[31] | 1986 | None | Suspicion of PAOD | B/W coded |
| Metz *et al.*[32] | 1988 | 6 | No clinical description of patients | B/W and colour coded |
| Hübsch *et al.*[33] | 1988 | 4 | Patients referred for duplex examination | Colour coded |
| Hendrickx *et al.*[34] | 1989 | 6 | No description | Colour coded |
| Seifert and Jäger[35] | 1989 | 4, 5, 6 | No description | B/W coded |
| Cossman *et al.*[36] | 1989 | 4, 5, 6 | Patients referred for excimer laser angioplasty | Colour coded |
| Jager[37] | 1989 | None | No description | B/W coded? |
| Landwehr and Lackner[38] | 1990 | 3, 4, 5 | Patients referred for PTA | Colour coded |
| Mulligan *et al.*[39] | 1991 | 3, 4, 5, 6 | Symptomatic PAOD | Colour coded |
| Edwards *et al.*[40] | 1991 | 1, 5 | Ischaemic PAD | B/W coded |
| Baumgartner *et al.*[41] | 1991 | 1, 3 | Patients referred for PTA | B/W coded? |
| Ranke *et al.*[42] | 1992 | 4, 6 | Symptomatic PAOD | B/W coded |
| Van der Heijden *et al.*[43] | 1993 | 1, 5 | Patients referred for PTA | Colour coded |

Criteria for methodological quality: 1, clear definition of study population; 2, consecutive patients; 3, prospective study; 4, clear description of duplex technique used; 5, predefined cut-off values; 6, independent assessment of duplex and angiography. PAOD, peripheral arterial occlusive disease; PTA, percutaneous transluminal angioplasty; AOD, arterial occlusive disease; PAD, peripheral arterial disease; B/W, black and white



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and 2 studies are listed in *Table 2*. Results for the different vascular segment are presented separately†.

*Aortoiliac segment*

Five studies[10,12,15,18,20] provided raw data on detection of a stenosis greater than or equal to 50 per cent. Three studies[10,12,15] were excluded because waveform and PSV ratios in the common femoral artery were interpreted to infer disease, without complete visualization of the iliac artery, and were therefore considered not to represent the entire aortoiliac tract. Of the two remaining studies[18,20] heterogeneity of sensitivity and specificity could not be detected ($P = 1{\cdot}0$ and $P = 1{\cdot}0$ respectively), resulting in a pooled sensitivity (95 per cent c.i.) of 80 (61–93) per cent and specificity of 95 (91–98) per cent (*Table 2*). The same studies[18,20] provided data on detection of an occlusion (*Table 2*). As there were no false-positive or false-negative results, homogeneity of sensitivity and specificity was assumed giving a pooled (95 per cent c.i.) sensitivity of 94 (65–100) per cent and specificity of 99 (98–100) per cent. Six studies[13,16,18,21,24,30] reported on detection of a diameter reduction greater than or equal to 50 per cent, occlusions included (*Table 2*). Data from level 1 and 2 studies were pooled because sensitivities and specificities were not heterogeneous among studies ($P = 0{\cdot}78$ and $P = 0{\cdot}13$ respectively) and did not seem to be influenced by methodological level. This led to pooled estimates (95 per cent c.i.) of 86 (80–91) per cent for sensitivity and 97 (95–99) per cent for specificity.

*Femoropopliteal segment*

For assessment of the femoropopliteal segment all authors applied the same criteria as for the aortoiliac tract. Four level 1[10–12,15] and two level 2[22,23] studies provided raw data on detection of a stenosis greater than

†Details on raw data can be provided by the authors

**Table 2** Results of quantitative analysis for detection of a stenosis greater than or equal to 50 per cent, an occlusion and a stenosis greater than or equal to 50 per cent or occlusion

| Reference | Duplex criteria* | *n* | Stenosis ≥ 50 per cent | | Occlusion | | Stenosis ≥ 50 per cent or occlusion | |
|---|---|---|---|---|---|---|---|---|
| | | | Sensitivity (%) | Specificity (%) | Sensitivity (%) | Specificity (%) | Sensitivity (%) | Specificity (%) |
| **Aortoiliac** | | | | | | | | |
| *Level 1* | | | | | | | | |
| Moneta *et al.*[13] | PSV ratio > 2·0† | 286 | — | — | — | — | 89 | 99 |
| *Level 2* | | | | | | | | |
| Jager *et al.*[16] | PSV ratio > 2·0 | 54 | — | — | — | — | 82 | 100 |
| Langsfeld *et al.*[18] | PSV ratio > 2·0‡ | 46 | 80 | 95 | 100 | 100 | 86 | 94 |
| Legemate *et al.*[20] | PSV ratio > 2·5 | 90 | 81 | 96 | 88 | 100 | — | — |
| Legemate *et al.*[21] | PSV ratio > 2·5 | 122¶ | — | — | — | — | 89 | 98 |
| Vashist *et al.*[24] | PSV ratio > 2·0 | 18 | — | — | — | — | 88 | 100 |
| Allard *et al.*[30] | PSV ratio > 2·0 | 99 | — | — | — | — | 83 | 96 |
| Pooled (95 per cent c.i.) | | | 80 (61–93) | 95 (91–98) | 94 (65–100) | 99 (98–100) | 86 (80–91) | 97 (95–99) |
| **Femoropopliteal** | | | | | | | | |
| *Level 1* | | | | | | | | |
| Koennecke *et al.*[10] | PSV ratio > 2·0 | 82 | 71 | 96 | 87 | 96 | 95 | 100 |
| Polak *et al.*[11] | PSV ratio > 2·0§ | 34 | 76 | 96 | 100 | 96 | 88 | 96 |
| Whelan *et al.*[12] | PSV ratio > 2·0** | 100 | 88 | 96 | 95 | 99 | — | — |
| Moneta *et al.*[13] | PSV ratio > 2·0† | 286 | — | — | — | — | 79 | 98 |
| Hatsukami *et al.*[14] | Waveform†† | 58‡‡ | — | — | 90 | 97 | 70 | 96 |
| Baxter *et al.*[15] | PSV ratio > 1·8 | 40 | 82 | 96 | — | — | — | — |
| Pooled (95 per cent c.i.) | | | 82 (67–92) | 96 (93–98) | 90 (80–96) | 97 (94–99) | 80 (70–87) | 98 (95–99) |
| *Level 2* | | | | | | | | |
| Jager *et al.*[16] | PSV ratio > 2·0 | 54 | — | — | — | — | 75 | 96 |
| Legemate *et al.*[21] | PSV ratio > 2·5 | 122¶ | — | — | — | — | 76 | 97 |
| Whyman *et al.*[22] | PSV ratio > 2·0 | 36 | 93 | 96 | 100 | 94 | 98 | 100 |
| Davies *et al.*[23] | PSV ratio > 2·0 | 65 | 97 | 97 | 94 | 98 | 96 | 100 |
| Vashist *et al.*[24] | PSV ratio > 2·0 | 20 | — | — | — | — | 100 | 92 |
| Allard *et al.*[30] | PSV ratio > 2·0 | 99 | — | — | — | — | 87 | 93 |
| Pooled (95 per cent c.i.) | | | 95 (85–99) | 96 (90–99) | 95 (84–100) | 96 (89–99) | 80 (74–85) | 96 (94–98) |
| **Infragenicular** | | | | | | | | |
| *Level 1* | | | | | | | | |
| Koennecke *et al.*[10] | PSV ratio > 2·0¶¶ | 49 | — | — | 73 | 95 | 94 | 91 |
| Moneta *et al.*[13] | No flow | 286 | — | — | 73 | 91 | — | — |
| Hatsukami *et al.*[14] | Waveform†† | 58‡‡ | — | — | 87 | 100 | 78 | 79 |
| Pooled (95 per cent c.i.) | | | | | 74 (66–81) | 93 (87–97) | 83 (59–96) | 84 (69–93) |

*n*, number of limbs. *Or no signal in case of occlusion; †or peak systolic velocity (PSV) greater than 200 cm/s; ‡or spectral broadening or monophasic waveform in case of greater than 50 per cent stenosis; ¶61 patients, 921 (96 per cent) of 960 segments adequately visualized; §or narrowing of transverse lumen with colour Doppler or a combination; **and waveform change from triphasic to monophasic, or PSV greater than 200 cm/s; ††occlusion; no flow, present collaterals, greater than 50 per cent stenosis; no triphasic signal, poststenotic turbulence or bruit; ‡‡29 patients, 928 segments, 292 excluded for various reasons; ¶¶no specification of grade of stenosis



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or equal to 50 per cent (*Table 2*). At level 1 homogeneity among studies for sensitivity ($P = 0{\cdot}52$) and specificity ($P = 1{\cdot}0$) could not be rejected, leading to a pooled (95 per cent c.i.) sensitivity of 82 (67–92) per cent and specificity of 96 (93–98) per cent. At level 2 sensitivity ($P = 0{\cdot}47$) and specificity ($P = 0{\cdot}50$) were also homogeneous; pooled (95 per cent c.i.) estimates were 95 (85–99) per cent and 96 (90–99) per cent for sensitivity and specificity respectively. From the same studies accuracy of detection of an occlusion was estimated (*Table 2*). Heterogeneity of sensitivity and specificity among level 1 studies could not be demonstrated ($P = 0{\cdot}69$ and $P = 0{\cdot}37$ respectively), yielding pooled (95 per cent c.i.) estimates of 90 (80–96) per cent for sensitivity and 97 (94–99) per cent for specificity. Raw data of level 2 studies were pooled ($P = 1{\cdot}0$ for both sensitivity and specificity), giving a sensitivity of 95 (84–100) per cent and 96 (89–99) per cent for specificity. Five more studies[13,16,21,24,30] provided raw data on detection of a diameter reduction greater than or equal to 50 per cent, occlusions included (*Table 2*). Sensitivity and specificity were homogeneous among level 1 studies ($P = 0{\cdot}27$ and $P = 0{\cdot}23$ respectively). Pooled (95 per cent c.i.) estimates were 80 (70–87) per cent and 98 (95–99) per cent for sensitivity and specificity respectively. Among level 2 studies sensitivity was heterogeneous ($P = 0{\cdot}005$). Spearman correlation of the sensitivity and (100-specificity) was $-0{\cdot}67$, indicating concordance in duplex criteria. Four studies[16,21,24,30] could be pooled as among these sensitivity and specificity were homogeneous ($P = 0{\cdot}36$ and $P = 0{\cdot}23$ respectively), resulting in a sensitivity of 80 (71–86) per cent and 95 (90–98) per cent for specificity. Pooling data of level 1[10,11,13,14] and 2[16,21,24,30] studies resulted in sensitivity of 80 (74–85) per cent and 96 (94–98) per cent specificity.

*Infragenicular arteries*

Few studies evaluated duplex scanning of the infragenicular arteries and all were rated level 1. Three studies[10,13,14] provided raw data on detection of an occlusion (*Table 2*) with homogeneous estimates of sensitivity ($P = 0{\cdot}73$) and specificity ($P = 0{\cdot}14$). The resulting pooled (95 per cent c.i.) sensitivity was 74 (66–81) per cent at a specificity of 93 (87–97) per cent. Two studies[10,14] provided data on detection of a stenosis greater than or equal to 50 per cent or an occlusion (*Table 2*). Despite different test criteria heterogeneity of sensitivity and specificity could not be demonstrated ($P = 0{\cdot}34$ and $P = 0{\cdot}28$ respectively). Pooled (95 per cent c.i.) estimates were 83 (59–96) per cent for sensitivity and 84 (69–93) per cent for specificity (*Table 2*).

## Discussion

The purpose of this study was to evaluate the diagnostic accuracy of duplex scanning for assessment of arterial occlusive disease in the lower extremity, in methodologically sound studies. In studies considered suitable for quantitative analysis, accuracy of duplex scanning for the respective vascular segments was in the same range, despite the use of different criteria for detection of a stenosis greater than or equal to 50 per cent. The homogeneity of sensitivity and specificity among studies indicates that duplex scanning is reproducible in different study centres in patients with claudication and critical ischaemia. The heterogeneity of sensitivity for detection of a stenosis greater than or equal to 50 per cent or occlusion in the femoropopliteal tract among level 2 studies could not be explained by differences in diagnostic criteria or duplex technique, but was probably due to the different aims of the studies and, as a consequence, the composition of patient collectives. Whereas four studies[16,21,24,30] determined accuracy of duplex scanning for localization and characterization of atherosclerotic lesions, Whyman[22] *et al.* and Davies *et al.*[23] used duplex scanning explicitly to identify lesions in the superficial femoral artery suitable for percutaneous transluminal angioplasty (PTA) on clinical examination.

The meta-analysis shows that duplex scanning is an accurate non-invasive test for assessment of arterial occlusive disease in the aortoiliac and femoropopliteal tract in patients with claudication or critical ischaemia. There was no difference in the accuracy of duplex scanning to detect a significant stenosis or occlusion. This implies that duplex scanning has the potential to replace angiography for determination of treatment strategy, especially in patients with localized lesions as these can be treated by PTA[22–24,40,43,44]. Although diagnostic angiography can be combined with PTA in the same session, duplicate angiography is not uncommon. This increases the complication rate and is inconvenient for the patient. As duplex scanning has a high negative predictive value, significant lesions in the aortoiliac and femoropopliteal tract can be reliably excluded. This may help reduce the number of diagnostic angiographies in patients with symptoms not justifying a surgical or endovascular procedure.

For planning operative treatment most surgeons will feel that diagnostic angiography is still mandatory, especially when the patient needs a femorodistal reconstruction. In these patients assessment of the outflow tract quality (i.e. the cruropedal arteries) is of paramount importance to choose the distal anastomosis site and to predict operation success. Because of the small number of patients studied and the resulting wide confidence intervals of the pooled sensitivity ((95 per cent c.i.) of 83 (59–96) per cent) and specificity of 84 (69–93) per cent) for detection of haemodynamically significant lesions in the below-knee arteries, reliable clinical decisions regarding surgical treatment cannot be based on duplex scanning alone and angiography remains a prerequisite. Further research is warranted to determine the significance of duplex scanning in the evaluation of the distal outflow tract. Alternatives for non-invasive detection of run-off vessels like pulse generated run-off[45,46] and magnetic resonance imaging[36,47,48] have been suggested, but have as yet not found widespread application.

In the University of Amsterdam the integrated use of duplex scanning has significantly reduced the need for diagnostic angiography. The majority of patients with localized lesions are directly scheduled for PTA based on the information from the non-invasive work-up and in selected cases (such as isolated external and/or common iliac artery occlusions) reconstructions are performed without complementary angiography. Elsman *et al.*[44] evaluated a similar strategy in a prospective study of 112 consecutive patients. In the majority of patients treatment strategy could be determined based on the non-invasive work-up, reducing the need for diagnostic angiographies by 50 per cent.

Duplex scanning is an excellent tool in the non-invasive

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work-up of patients with arterial occlusive disease in the aortoiliac and femoropopliteal tract and because of its high diagnostic accuracy can replace routine diagnostic angiography for planning surgical intervention or PTA in a substantial number of patients. For assessment of the crural arteries angiography remains a prerequisite.

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