Diagnosis of arterial disease of the lower extremities with duplex ultrasonography

Authors’ objectives
To evaluate the accuracy of duplex ultrasonography in diagnosing arterial disease of the lower extremities.

Searching
MEDLINE was searched between 1976 and June 1994 to retrieve publications in English, German or Dutch on diagnostic tests in PAOD, using the keywords ‘arterial occlusive disease’, ‘arteriosclerosis’, ‘claudica*’ and ‘vascular disease’ under the conditions of vascular and lower extremity. Bibliographies from selected articles were used for additional references.

Study selection
Study designs of evaluations included in the review
All diagnostic accuracy studies comparing duplex with angiography were eligible for inclusion. Case reports, reproducibility studies, reviews and formal analysis studies with unspecified cut-off criteria, study population, unspecified investigated segment or unclear angiographic criteria, were excluded. Multiple publications of same study population were included once only.

Specific interventions included in the review
Studies of duplex ultrasonography for the evaluation of peripheral arterial occlusive disease (PAOD) were eligible for inclusion.

Reference standard test against which the new test was compared
The included studies had to use angiography as the reference standard; there were no restrictions in relation to the angiographic technique or definition of disease.

Participants included in the review
No inclusion criteria relating to participants were defined. Studies were excluded if they dealt with children, adolescence, anaesthesia, neoplasm, wound, injury or varicose veins. The participants included patients with chronic or symptomatic PAOD, claudication, critical ischaemia, cellulitis, rest pain, gangrene or calf claudication (referred for PTA).

Outcomes assessed in the review
No inclusion criteria were defined in relation to the outcome measures used in the primary studies. The outcome measures calculated by the reviewers were the sensitivity and specificity for detecting the following in the aortoiliac segment, femoropopliteal segment or infragenicular arteries: a stenosis greater than or equal to 50%; an occlusion; an occlusion or a stenosis of at least 50%.

How were decisions on the relevance of primary studies made?
One reviewer assessed the titles and abstracts of the papers. A random sample of 100 papers was selected and checked for accuracy of selection. Agreement was quantitatively assessed by the use of Kappa statistics.

Assessment of study quality
The methodological quality of diagnostic accuracy studies was assessed on two essential predefined criteria (clear definition of study population and of the duplex scanning technique) and on secondary criteria (series of consecutive patients, prospective study, predefined test criteria, independent assessment of duplex scanning and angiography). Studies satisfying all essential criteria were graded 1; those satisfying two essential criteria were graded 2; the remaining studies were graded 3. Three independent reviewers graded methodological quality, with any discrepancies discussed to arrive at a unanimous decision.
Data extraction
The data were extracted by two reviewers.

Methods of synthesis
How were the studies combined?
Two approaches were used. Where homogeneity could not be rejected, pooled estimates of sensitivity and specificity, along with the 95% confidence intervals (CIs), were derived using the DerSimonian and Laird random-effects model. Where studies were affected by heterogeneity, the Spearman correlation between separate sensitivities and (100 minus specificities) was determined. A summary receiver operating curve was fitted to determine the optimal test criteria where a positive correlation occurred.

How were differences between studies investigated?
Homogeneity was assessed using Fisher's exact or chi-squared test among studies of comparable methodological quality.

Results of the review
Fourteen studies were apparently included in the quantitative analyses. Of these, 7 studies assessed the sensitivity and specificity of detecting outcomes in the aortoiliac segment, 12 studies assessed the sensitivity and specificity of detecting outcomes in the femoropopliteal segment, and 3 studies assessed the sensitivity and specificity of detecting outcomes in the infragenicular arteries.

Thirty-four studies met the initial inclusion criteria; 6 studies were graded as level 1, 15 as level 2, and the remaining as level 3. All level 3 and four level 2 studies were excluded from the quantitative analyses.

Aortoiliac segment.
For the detection of a stenosis greater than or equal to 50%, the methodological quality was level 2 (2 studies), the sensitivity was 80% (95% CI: 61, 93) and the specificity was 95% (95% CI: 91, 98). For the detection of an occlusion, the methodological quality was level 2 (2 studies), the sensitivity was 94% (95% CI: 65, 100) and the specificity was 99% (95% CI: 98, 100). For the detection of an occlusion or a stenosis of at least 50%, the methodological quality was level 1 and 2 (one level 1; five level 2 studies pooled as no heterogeneity between levels), the sensitivity was 86% (95% CI: 80, 91) and the specificity was 97% (95% CI: 95, 99).

Femoropopliteal segment.
For the detection of a stenosis greater than or equal to 50%, for level 1 methodological quality (4 studies), the sensitivity was 82% (95% CI: 67, 92) and the specificity was 96% (95% CI: 93, 98); for level 2 methodological quality (2 studies), the sensitivity was 95% (95% CI: 85, 99) and the specificity was 96% (95% CI: 90, 99). For the detection of an occlusion, for level 1 methodological quality (4 studies), the sensitivity was 90% (95% CI: 80, 96) and the specificity was 97% (95% CI: 94, 99); for level 2 methodological quality (2 studies), the sensitivity was 95% (95% CI: 84, 100) and the specificity was 96% (95% CI: 89, 99). For the detection of an occlusion or a stenosis of at least 50%, for level 1 methodological quality (4 studies), the sensitivity was 80% (95% CI: 70, 87) and the specificity was 98% (95% CI: 95, 99); for level 2 methodological quality level (6 studies), the sensitivity was 80% (95% CI: 74, 85) and the specificity was 96% (95% CI: 94, 98).

Infragenicular arteries.
For the detection of an occlusion, the methodological quality was level 1 (3 studies), the sensitivity was 74% (95% CI: 66, 81) and the specificity was 93% (95% CI: 87, 97). For the detection of an occlusion or a stenosis of at least 50%, the methodological quality was level 1 (2 studies), the sensitivity was 83% (95% CI: 59, 96) and the specificity was 84% (95% CI: 69, 93).

Authors' conclusions
Duplex scanning is an accurate tool for the assessment of atherosclerotic lesions in the aortoiliac and femoropopliteal tract, and can replace routine interventional angiography in a substantial number of patients.

**CRD commentary**
This study represents a reasonably good review and meta-analysis of duplex ultrasonography. The objectives, interventions, outcomes, participants, study designs, validity criteria, methods of applying the inclusion and validity criteria, data extraction, methods of pooling, heterogeneity assessment and the results of the review were all clearly stated and appropriately applied. Weaknesses are evident in the search strategy, which was limited to MEDLINE and the reference lists of retrieved studies. It is therefore possible that further unidentified published studies may have been available. In addition, no attempt was made to assess the impact of publication bias. These issues raise questions about the completeness of the review.

The included primary studies were relatively poorly described. In addition, the paper indicates that 16 studies were included in the meta-analysis, yet only 14 studies were presented in the data table and pooling. No cost data were presented. The authors’ conclusions follow broadly from their results, although they are perhaps somewhat too firm given the confidence intervals presented.

**Implications of the review for practice and research**
Practice: The authors make no specific recommendations for practice.

Research: The authors state that further research is needed to determine the significance of duplex scanning in the evaluation of the distal outflow tract.

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