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Interobserver Variation of Colour Duplex Scanning of the Popliteal, Tibial and Pedal Arteries

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Objectives: *to determine interobserver variation in the measurement of Peak Systolic Velocity (PSV) and grading of disease by means of Duplex scanning (DS) in the popliteal, tibial and pedal arteries.*
Design: *prospective validation study.*
Materials: *twenty-four consecutive patients with severe claudication (n = 6), ischaemic rest pain (n = 11) and tissue loss (n = 7).*
Methods: *two vascular technologists independently examined the popliteal, tibial and pedal arteries. The PSV was recorded in 15 arterial segments that were graded with B-mode and Doppler parameters as fully patent, severely diseased or occluded. Concordance in PSV recordings was expressed as intraclass correlation coefficients (ICC). Agreement in artery assessment was expressed as weighted κ-values.*
Results: *the ICC for PSV measurements was 0.90 (95% CI, 0.86 to 0.93) within the popliteal and tibial arteries and 0.64 (95% CI, 0.37 to 0.81) within the pedal arteries. Agreement for grading disease was good within the popliteal and tibial arteries (κ 0.66, 95% CI, 0.58 to 0.74), and moderate within the pedal arteries (κ 0.54, 95% CI 0.33 to 0.74). The presence of diabetes or stage of disease did not influence interobserver agreement.*
Conclusion: *interobserver agreement of DS is good within the popliteal and tibial arteries and moderate within the pedal arteries.*

Key Words: Duplex scanning; Interobserver variation; Lower leg arteries.

Introduction

Duplex scanning (DS) is a rapidly evolving technique for non-invasive imaging of the lower leg arteries. The severity of disease of the popliteal, tibial and pedal arteries can be graded by means of Peak Systolic Velocity (PSV) ratios, colour Doppler and B-Mode parameters. Several studies have shown that the diagnostic accuracy of DS compared to arteriography for detection of significant lesions within the lower leg arteries is high, but not perfect.[1–5] However, in experienced hands, DS can safely supplant arteriography, even before distal bypass surgery.[6–9]

An essential part of the evaluation of new diagnostic tests is the study of its interobserver variation.[10] Among other factors, imperfect diagnostic accuracy may be attributable to a lack of interobserver agreement. The accuracy of a test can never be perfect if assessment by different observers shows significant variation. In addition, poor interobserver agreement is likely to cause variation in clinical decision making. This is certainly applicable to DS of the lower leg arteries which requires special skills and expertise. DS is often criticised for being operator dependent but, in the case of the (infra)popliteal arteries, this can neither be denied nor confirmed because there are no data available from the literature.

We conducted this study to determine interobserver variation of PSV recordings and grading of disease within the popliteal, tibial and pedal arteries with DS. It was explicitly not our aim to compare the diagnostic accuracy of DS with arteriography, which we did in a previous study of 120 patients with severe lower leg ischaemia.[6]

Methods

The study protocol was approved by the Medical Ethics committee. All consecutive patients referred to our outpatient clinic for evaluation of chronic severe claudication, ischaemic rest pain or tissue loss, over a 4-month period, were eligible. Patients who gave

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informed consent were included. Patients with aortic or iliac aneurysmal disease, an aortoiliac stenosis detected with DS if the PSV ratio between the level of stenosis and the nearest normal segment exceeded 2.5, or occlusion, were excluded. Further exclusion criteria were acute ischaemia and mild claudication caused by diffuse superficial femoral artery (SFA) disease or a simple lesion in the SFA. As the latter patients are generally treated conservatively or by percutaneous transluminal angioplasty, we do not require a complete evaluation of the infrapopliteal vessels.

Two vascular technologists (JvG, HdV) with over 4 years of experience of lower leg artery DS performed the examinations immediately after another and unaware of each other's results. The popliteal, tibial and common plantar arteries were examined with a 4.5 MHz imaging linear array transducer and the dorsalis pedis and deep plantar arteries with a 7.5 MHz transducer using a Hewlett Packard Sonos 2000 scanner (Hewlett Packard, Andover, Mass., U.S.A.). Peak Systolic Velocities were recorded at a 60° angle with 3.7 and 5.5 MHz Doppler probes. The anterior tibial (AT), dorsalis pedis and deep plantar arteries were scanned with the patient supine. The popliteal artery, tibioperoneal trunk, peroneal, posterior tibial (PT) and common plantar arteries, as well as the origin of the AT, were examined with the patient in the lateral decubitus position. All arteries were identified by detection of a colour signal or the presence of the vessel wall when it was occluded. For the purposes of the study the popliteal/tibial/pedal outflow tract was divided into 15 segments; supra- and infrageniculate popliteal artery, tibioperoneal trunk, proximal, mid and distal AT, PT and peroneal artery, and dorsalis pedis, deep plantar and common plantar artery. In each of these segments the PSV was recorded.

Segments were graded as:

2 – for no or minor vessel wall irregularities as seen on B-Mode imaging and fully patent lumen determined by the presence of a colour Doppler signal;
1 – for severe vessel wall irregularities (B-Mode), diffuse narrowing (colour Doppler or PSV ratio between the level of the stenosis and the nearest normal arterial lumen ≥ 2.5) or an isolated subtotal stenosis;
0 – for occlusion indicated by a present vessel wall (B-Mode) and an absent colour and pulsed Doppler signal.

The localisation of lesions was recorded in centimetres below the cranial edge of the patella which served as reference point in all patients. A segment with both stenosis and occlusion was considered to be occluded. If evaluation of a segment was inadequate, e.g. due to severe calcifications, DS was considered non-diagnostic.

Analysis

The concordance between PSV recorded by the two technologists was expressed as intraclass correlation coefficients (ICC), after the PSVs were logarithmically transformed because they were not normally distributed. The ICC is a measure of concordance for continuous variables that corrects for systematic bias. The ICC ranges between -1 and 1, with higher values in case of better correlation. An ICC >0.75 can be interpreted as good agreement.[11,12] Agreement on artery grading between the two technologists was expressed as simple and weighted kappa (κ) values. Kappa is a measure of the probability of agreement beyond chance. Strength of agreement can be interpreted as poor (κ<0.20), fair (κ 0.21–0.40), moderate (κ 0.41–0.60), good (κ 0.61–0.80) and excellent (K 0.81–1.00).[13] Calculations were performed with SPSS 8.0 for Windows (SPSS, Chicago, IL, U.S.A.) and SAS 6.12 for Windows (SAS Institute Inc, Cary, NC, U.S.A.) statistical packages.

Results

Patients

From a total of 28 eligible patients, 24 were included (Table 1). Two patients were excluded due to logistic constraints, one patient declined consent and one patient could not lie still long enough for a repeat examination.

PSV recordings

Technologist I could not adequately assess 6/360 (1.7%) segments, and technologist II 13/360 (3.6%) segments. The rate of such non-diagnostic examinations was 8/288 (2.7%) within the popliteal and tibial arteries and 11/72 (15.2%) within the pedal arteries, leaving a total of 346 segments for comparison. PSV recordings were available for 287 of 346 (83%) segments. The median PSV measured by technologist I was 10 cm/s (range 0–120) and 12 cm/s (range 0–125) by technologist II. The ICC was 0.88 (95% confidence interval (CI), 0.84–0.91) for the entire lower leg, which

Table 1. Demographics of the 24 patients.

Characteristic	*n* (%)
Median age	67 years (range 50–83)
Claudication	6 (25%)
Rest pain	11 (46%)
Tissue loss	7 (29%)
Male sex	17 (70%)
Diabetes	9 (38%)
Smoking (current or prior)	9 (38%)
Hypertension (on medication)	11 (46%)
Hyperlipidaemia (on medication)	6 (25%)
End stage renal disease	2 (8%)
Coronary artery disease (angina, AMI, PTCA, CABG)	9 (38%)
Cerebrovascular disease (TIA, stroke)	7 (29%)
Prior intervention (PTA, bypass, patch angioplasty)	10 (42%)

AMI = acute myocardial infarction, PTCA = percutaneous transluminal coronary angioplasty, CABG = coronary artery bypass graft, TIA = transient ischaemic attack, PTA = percutaneous transluminal angioplasty.

indicates good agreement. Within 230 popliteal and tibial artery segments the median PSV measured by technologist I was 13 cm/s (range 0–120) and 14 cm/s (range 0–125) by technologist II. The ICC was 0.90 (95% CI, 0.86–0.93) which indicates good agreement. The median PSV in 57 pedal artery segments was 8 cm/s (range 0–55) for technologist I and 10 cm/s (range 0–60) for technologist II. The ICC was 0.64 (95% CI, 0.37–0.81) indicating moderate agreement.

Grading of disease

Table 2 presents the results for grading arteries as occluded, severely diseased or normal. Overall inter-observer agreement was good with a weighted κ of 0.64 (95% CI, 0.56–0.71). For the popliteal and tibial arteries agreement was good with a weighted κ of 0.66 (95% CI, 0.58–0.74). Agreement was moderate within the pedal arteries, with a weighted κ of 0.54 (95% CI, 0.33–0.74). Table 3 lists detailed results for agreement within the respective vascular segments. One technologist did not grade any proximal posterior tibial artery segment as severely diseased. As the calculation of κ requires an equal number of categories for both observers, κ could not be calculated for this segment. For the popliteal and tibial arteries agreement was good, with weighted κ values ranging between 0.60 and 0.70. Agreement was good within the proximal and middle parts of all tibial arteries and moderate within the distal parts. The latter was due to disagreements in grading the distal part of the peroneal artery. Agreement within the respective pedal arteries was moderate.

In all 360 popliteal, tibial and pedal artery segments technologist I found 20 segments to be severely diseased or normal, judged as occluded by technologist II, whereas the reverse occurred in 26 segments. When a distinction was made between occluded vs patent (severe disease or normal) segments, agreement was good, with a simple κ of 0.66 (95% CI 0.58–0.74). Four of 72 (6%) popliteal and tibioperoneal trunk segments were judged occluded by one technologist and deemed patent by the other. This happened in 8% of posterior tibial artery segments and more often in the anterior tibial (14%), peroneal (15%) and pedal arteries (18%). Separate analysis for assessment of the popliteal and tibial arteries with a showed good agreement, simple κ of 0.72 (95% CI 0.64–0.80), and moderate agreement for the pedal arteries, simple κ of 0.45 (95% CI 0.27–0.63).

Agreement for occluded vs patent popliteal, tibial and pedal arteries was good for diabetics, (simple κ 0.79, 95% CI, 0.69–0.91) and non-diabetics, (simple κ 0.62, 95% CI, 0.51–0.73). Subgroup analysis for stage of disease yielded simple κ values of 0.75 (95%, CI 0.60–0.90), 0.66 (95% CI, 0.53–0.79) and 0.65 (95% CI, 0.48–0.81) for claudication, ischaemic rest pain and tissue loss, respectively.

Discussion

Duplex scanning is increasingly used for clinical decision-making in patients with severe lower leg ischaemia. PSV ratios have become the cornerstone for grading the severity of lesions in the aortoiliac and femoropopliteal arteries. Previous studies demonstrated that the PSV is a highly reproducible parameter within the femoropopliteal tract.[14,15] We found

Table 2. Interobserver agreement for popliteal and tibial artery assessment with duplex scanning.

	Technologist I				
Technologist II	Occluded	Severe	Normal	Non-diagn	Total
Occluded	64	7	13	1	85
Severe	6	12	16	1	35
Normal	6	19	140	0	165
Non-diagn	0	0	0	3	3
Total	76	38	169	5	288

Weighted $\kappa = 0.66$ (95% CI, 0.58–0.74).
Normal = no or minor vessel wall irregularities. Severe = severe vessel wall irregularities, diffuse luminal narrowing, isolated subtotal stenosis. Non-diagn = non-diagnostic.

Interobserver agreement for pedal artery assessment with duplex scanning.

	Technologist I				
Technologist II	Occluded	Severe	Normal	Non-diagn	Total
Occluded	14	1	5	5	25
Severe	2	1	0	0	3
Normal	6	2	32	1	41
Non-diagn	1	0	0	2	3
Total	23	4	37	8	72

Weighted $\kappa = 0.54$ (95% CI, 0.33–0.74).
Normal = no or minor vessel wall irregularities. Severe = severe vessel wall irregularities, diffuse luminal narrowing, isolated subtotal stenosis. Non-diagn = non-diagnostic.

Table 3. Interobserver agreement on assessment with duplex scanning of the respective arterial segments by two vascular technologists.

Arterial segment	*n*	κ (95% CI)
Popliteal and crural arteries		
Supragenicular popliteal	24	0.67 (0.38–0.95)
Infragenicular popliteal	24	0.83 (0.66–1.00)
Tibioperoneal trunk	24	0.65 (0.33–0.96)
Proximal anterior tibial	23	0.61 (0.34–0.91)
Middle anterior tibial	23	0.60 (0.31–0.91)
Distal anterior tibial	23	0.61 (0.35–0.86)
Proximal posterior tibial	22	NA
Middle posterior tibial	24	0.74 (0.49–0.99)
Distal posterior tibial	24	0.69 (0.47–0.92)
Proximal peroneal	24	0.78 (0.58–0.99)
Middle peroneal	24	0.74 (0.52–0.96)
Distal peroneal	24	0.43 (0.14–0.72)
Overall	283	0.66 (0.58–0.74)
Pedal arteries		
Dorsalis pedis	22	0.56 (0.26–0.87)
Deep plantar	19	0.55 (0.19–0.93)
Common plantar	22	0.49 (0.14–0.84)
Overall	63	0.54 (0.33–0.74)

n = number of segments, 95% CI = 95% confidence interval, NA = not applicable (see text).

good agreement between two technologists for PSV recordings within the popliteal and tibial arteries, which would justify the use of PSV or PSV ratios for grading disease in these arteries. However, the diagnostic usefulness of PSV ratios to grade stenoses within the tibial arteries has not yet been established. Karacagil *et al.*[1] investigated too few patients with stenoses to actually appreciate its accuracy, and Sensier *et al.*[5] applied PSV ratios >2.0 with a sensitivity of only 20%. It may be that the clinical significance of a quantitative assessment of vessels with a diameter of 2–3 mm is debatable, and that grading based on semi-quantitative parameters can also be appropriate. In a previous study we have demonstrated that the combined use of the B-Mode and colour Doppler imaging to identify vessel wall irregularities and pulsed Doppler to identify high PSVs is accurate for determining artery patency and allows clinical decision making without pre-operative arteriography in the majority of patients with severe ischaemia.[6] The results of the current study indicate that assessment of the popliteal and tibial arteries with such parameters is possible with good interobserver agreement. Yet the distinction between patent and occluded arteries is of paramount importance before bypass surgery and in this regard we found discrepancies within the anterior tibial and peroneal arteries. It is known that assessment of the peroneal artery is technically demanding due to its deeper plane and the preserves of fascial borders between the transducer and the artery. An obvious explanation for the discrepancies with regard to anterior tibial artery cannot be given. The presence of diabetes and severity of ischaemia did not influence interobserver agreement.

The results for the pedal arteries were less favourable. For reasons unknown, there were more non-diagnostic examinations in the current study (15.2%) than in our previous series (6%).[6] Moreover, agreement between both technologists on PSV recordings and grading of disease was moderate. As previously stated, the clinical significance of detecting a >50% stenosis within very small arteries such as the pedal arteries is limited; however, distinguishing occluded from fully patent pedal arteries is important. In this respect we found 11 out of 63 (17%) major discrepancies. This may be explained, at least in part, by the fact that DS is able to detect flow velocities as low as 5 cm/s in the superficially located pedal arteries. Applying too much pressure with the probe on the artery may mimic an occlusion in patent vessel. Alternative explanations include the detection of flow in collateral arteries that are mistaken for the native vessel and occlusion of the dorsalis pedis artery when the foot is held in plantar flexion. These pitfalls should be considered when the pedal arteries are examined.

It would have been interesting to investigate intra-observer variation. Logistic constraints prevented us from doing so, and this is a limitation of this study. Given the fact that there will be some intra-observer variation, one may only speculate that the agreement shown between both technologists may be all the more robust because of this.

Both technologists have ample experience in duplex scanning of the lower extremity arteries. Their skills have been improved by continuous feedback from radiologists and surgeons of findings during diagnostic arteriography or operation. In this way we have shown that it is possible to achieve good interobserver agreement on assessment of popliteal and tibial arteries.

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