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Clinical examination and non-invasive screening tests in the diagnosis of peripheral artery disease in patients with diabetes related foot ulceration

Running title: Screening tests for peripheral artery disease in diabetes related foot ulceration

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What's new?

- We evaluated the utility of clinical examination and non-invasive bedside tests in screening for peripheral artery disease in patients with diabetes. This study is unique in both the wide variety of tests investigated but also that all patients had ulceration.
- Screening tests must reliably exclude the disease, as it is associated with both failure to heal and major amputation. According this criterion the only tests that would be considered suitable for screening are the toe brachial index and tibial waveform analysis. Simple bedside clinical examination such as pulse assessment are unreliable in excluding peripheral artery disease in this cohort.

Abstract:

Aims:

Peripheral artery disease (PAD) is common in patients with diabetes related foot ulceration and is a risk factor for amputation. The best method for the detection or exclusion of PAD is unknown. This study investigated the utility of clinical examination and non-invasive bedside tests in screening for PAD in patients with diabetes related foot ulceration.

Methods:

60 patients presenting with new onset ulceration, to a hospital diabetes foot MDT, were studied. The accuracy of pulses, ankle pressure, toe pressure, toe brachial index (TBI), ankle brachial pressure index (ABPI), pole test at ankle, TcPO2 and distal tibial waveform on ultrasound was examined. The gold standard diagnostic test used was > 50% stenosis in any artery or monophasic flow distal to calcification in any ipsilateral vessel on Duplex ultrasound.

Results:

The negative (NLR) and positive (PLR) likelihood ratio of pedal pulse assessment (0.75, 1.38) and the other clinical assessment tools was poor. Similarly, the NLR and PLR of ABPI (0.53, 1.69), TcPO2 (1.1, 0.81) and ankle pressure (0.67, 2.25) as screening tools was unsatisfactory. The lowest NLR was for tibial waveform assessment (0.15) and TBI (0.24). The highest PLRs were for toe pressure (17.58) and pole test at the ankle (10.29) but the NLRs were poor at 0.56 and 0.74 respectively.

Conclusions:

Pulse assessment and ABPI have limited utility in the detection of PAD in patients with diabetes foot ulceration. TBI and distal tibial waveforms are useful tools for selecting patients who may need further formal diagnostic testing.

Key words: diabetic foot, macrovascular disease, screening

Introduction:

Diabetes mellitus affects large numbers of people globally. Worldwide there has been a dramatic increase in the prevalence, resulting in an inevitable rise in diabetes related complications and costs (1,2). It is estimated that foot complications associated with diabetes cost the National Health Service up to £662m annually in England and Wales (3). As diabetes becomes more prevalent, these costs are likely to increase. Diabetes mellitus is an important factor implicated in the development of both peripheral artery disease (PAD) and foot ulceration. In the general population with diabetes the prevalence of PAD is 10-26%, and in patients with associated foot ulceration this increases to over 50% (4-6). It is imperative to identify PAD, as it is associated with both delayed healing and amputation, so that appropriate interventions can be offered (7).

Currently diabetes related foot ulcers are primarily managed by non-vascular specialists and a focussed clinical examination of the feet remains fundamental to patient assessment, particularly palpation of foot pulses (8,9). Nevertheless, palpation of foot pulses, especially in the presence of peripheral neuropathy, can be unreliable in screening for the presence of PAD in patients with diabetes (10). A range of non-invasive bedside screening tests are available as an adjunct to clinical examination, including ankle-brachial pressure index (ABPI), toe-brachial pressure index (TBI), and transcutaneous pressure of oxygen ($TcPO_2$) (8).

Non-invasive screening tests for the detection of PAD among individuals with diabetes are considered important to estimate the risk of amputation, ulceration, wound healing and the presence of cardiovascular disease, yet there are no consensus recommendations to support one modality over another (11,12). Surprisingly, to date, the number of studies assessing the utility of PAD screening tests in patients with established ulceration has been limited in both number and scope (8). Most studies have either excluded or not separately reported the efficacy of PAD screening tools in patients with ulceration. Those studies that did detail assessment of patients with ulceration have only investigated a narrow range of tools. This is unfortunate as the identification of PAD in diabetes in the cohort with ulceration is more influential on management than those with intact feet.

This study is the first to investigate the efficacy of both clinical assessment and a wide battery of PAD screening tools in patients with diabetes related foot ulceration.

Participants and Methods:

Ethical approval for the study was granted by the NHS Health Research Authority (NRES Committee London – City Road and Hampstead (Reference 12/LO/1579) and the research was performed according to the Declaration of Helsinki (2008).

Study design and participants

Patients with diabetes presenting to either a multidisciplinary diabetes foot clinic or emergency department with foot ulceration of less than 2 months duration were recruited into this prospective, single-centre observational study at a large teaching hospital.

All patients with diabetes, regardless of type, presenting with primary lower limb ulceration were potentially eligible. The following patients were excluded: aged less than 18 years, previous revascularisation, non-diabetes related ulceration, patients lacking capacity to consent to inclusion in the study, and pregnant women. Informed, written consent was obtained from all patients who were willing to participate in the study.

All study assessments were undertaken during the routine clinical visit of the patient. The management of the patient followed routine local protocols which are themselves compliant with national guidance (13).

Clinical and Radiological Assessors

Participants were clinically assessed, and the screening tests performed by a single post completion of training vascular surgical fellow, experienced in the management of diabetes related ulceration and familiar with the screening tools. Additional training was provided to the screener by the vascular laboratory for toe pressure and $TcPO_2$ assessment to ensure compliance with manufacturer recommendation.

The patient and their medical records were consulted for demographic data.

Clinical examination included documentation of characteristics of the lower limbs, namely hair loss, muscle atrophy, dependent rubor, cool skin, blue or purple skin, capillary refill time and venous filling time. A capillary refill time of greater than 2 seconds and a venous filling time of over 15 seconds were classified as screen positive for peripheral artery disease.

The presence of peripheral neuropathy was determined using a 10g monofilament (14). Peripheral pulses (femoral, popliteal, dorsalis pedis, and posterior tibial) were palpated bilaterally and classified as being either absent, weak, normal, or expansile.

The ulcer was examined, and the severity was staged using the Site, Ischemia, Neuropathy, Bacterial infection, Area, Depth (SINBAD) classification (14,15). The Society of Vascular Surgery Wound Infection Ischaemia (SVS WIfI) score was used to classify the clinical status of the foot (16).

Screening tests

Screening tests were performed after a 20 minute rest period in a normal temperature (18-20^{o}C) room. Patients were placed in a 30^{o} reclined position on a clinical examination couch. DUS examination was performed by a single experienced and accredited vascular sonographer. The investigator and sonographer were blinded to each other's findings.

Ankle pressure and ABPI's

The ankle and brachial pressures were measured using a manual inflatable cuff and a handheld continuous wave Doppler probe (Huntleigh Dopplex MD2, Huntleigh, UK). Ankle pressure of < 70 mmHg was considered abnormal. A resting ABPI was performed by using the brachial pressure on the right arm and the pressure values at the level of the posterior tibial artery and dorsalis pedis artery. The highest calculated ABPI value was used for the analysis with a value of < 0.9 or > 1.3 classified as abnormal.

Toe Pressures, TBI's and $TcPO_2$

Toe pressures were measured using a laser Doppler probe and toe pressure cuff (Periflux 5000 with PF 5010 Laser Doppler perfusion monitor unit and PF 5050 pressure unit with PF 5051 pressure accessory kit, Perimed AB, Datavägen, Sweden) on the largest available toe. Three separate readings were obtained over a 5 minute interval and the mean of these values was used. Toe pressure of < 50 mmHg was considered abnormal. A TBI of ≤ 0.75 was considered abnormal.

$TcPO_2$ measurements were taken from the dorsum of the foot using (Periflux 5000 with PF 5010 Laser Doppler perfusion monitor unit and PF 5020 temperature unit, Perimed AB, Datavägen, Sweden). The skin was cleaned with normal saline and then an adhesive ring applied and the manufacturer recommended contact liquid introduced. The probe was then

attached and left in place for 15 minutes whilst the trace was recorded. $TcPO_2$ < 30 mmHg was considered abnormal (17).

Pole test

The pole test was performed using a handheld Doppler probe (Huntleigh Dopplex MD2, Huntleigh, UK). With the patient supine the leg was elevated passively at the hip whilst continuing to listen for the Doppler signal. The height in centimetres at which the Doppler signal was lost was recorded. To confirm flow was lost, the leg was lowered and considered positive if the flow to the vessel returned. The test was repeated on both the dorsalis pedis and posterior tibial arteries bilaterally. The highest of the two measurements was used for analysis. If there was no loss of flow this was recorded or if the patient was unable to elevate the leg this was recorded (18,19).

Waveform analysis

Waveforms recorded at the level of the distal tibial arteries were included in the analysis to verify whether Doppler waveforms at this level could be discriminatory in identifying peripheral artery disease. Recordings were made at the level of the medial malleolus, the dorsalis pedis and in the mid-calf for the peroneal artery. It is important to note that this part of the analysis was not blinded i.e. the vascular sonographer performing the reference scan also performed the tibial waveform analysis.

Gold standard test

Duplex ultrasound scan (DUS) was performed by an accredited vascular scientist using a GE Logic E9 ultrasound scanner (GE, Wisconsin, USA). The abdominal, femoral and lower limb arteries (femoral, popliteal and tibial) supplying the ulcerated limb were studied. A C5-1MHz curvilinear array was used to assess the abdominal vessels while a linear 3-9 MHz transducer was used for the lower limb arteries. All the arteries were examined by using a combination of B-mode imaging, colour Doppler and Spectral Doppler ultrasound in transverse and longitudinal planes. Peak systolic velocity (PSV) were measured throughout the iliac, femoral, popliteal and tibial arteries and were recorded for further analysis only in the distal tibial arteries. PSV was measured at the point in the vessel where the highest velocity was detected. The PSV ratio between a stenosed region and the proximal PSV were used to grade stenosis and were classified as abnormal when the PSV ratio was > 2, which represents a stenosis of > 50%.

Flow velocity waveforms were also recorded. Triphasic or biphasic waveforms with fast systolic rise time and no flow at end-diastole were considered normal lower limb resting waveforms. Monophasic (damped) waveforms were considered abnormal and indicative of proximal arterial obstructive disease. At the site of a stenosis the flow waveform has abnormally high velocities throughout the cardiac cycle with a ragged outline due to the presence of turbulent flow. Distal to a stenosis the waveform is damped with a prolonged systolic rise time and forward flow throughout the cardiac cycle.

PAD was defined as > 50% stenosis in any named lower limb artery or monophasic flow beneath a calcified segment (13,20,21).

Statistical Analysis

Statistical analysis was performed using R 3.1.1 (R Core Team, R Foundation for Statistical Computing, Vienna, Austria).

The negative likelihood ratio (NLR) was the primary outcome of interest. The positive likelihood ratio (PLR), sensitivity, specificity, positive and negative predictive values are also reported. The NLR is the ratio of the probability of testing negative in an individual without versus with the disease. The PLR is the ratio of the probability of testing positive in an individual with versus without the disease.

Results

Some 60 limbs in 60 patients with diabetes related foot ulceration were included in the study (Table 1). The ulcer characteristics of the study patients are detailed in table 2 and 3. A total of 20 (33%) of the patients had PAD on DUS.

The NLR and PLR of pedal pulse assessment (NLR 0.75, PLR 1.38) and the other physical examination findings was poor (Table 4). Similarly the NLR and PLR of ABPI (0.53, 1.69), TcPO2 (1.1, 0.81) and ankle pressure (0.67, 2.25) as screening tools to identify PAD was unsatisfactory. The lowest NLR was for tibial waveform assessment (0.15) and toe brachial pressure index (0.24). The highest PLRs were for toe pressure (17.58) and pole test at the ankle (10.29) but the NLRs were again poor at 0.56 and 0.74 respectively (Table 4).

Discussion

The identification of PAD is crucial to the management of diabetes related foot ulceration as it risk stratifies patients that are at greater risk of failure to heal, amputation and, perhaps more importantly, those who may potentially benefit from revascularisation (7). The most important characteristic of a screening tool in patients with established ulceration is therefore the ability to exclude PAD. Any screen positive patient will need to undergo one or more reference investigation to confirm or exclude PAD as well as detail the anatomy of the lower limb arterial tree. The consequences of a false negative are potentially more severe, than a false positive, as the initial diagnostic tests utilised by most units are non-invasive and unlikely to lead to harm. To this end a negative likelihood ratio of less than 0.1 provides convincing screening evidence that the disease is absent (22). In our study no test achieved this cut off but the toe brachial pressure index and tibial waveform analysis were close enough that they can be recommended as screening tools. We would recommend that clinicians without access to these tools request formal imaging to exclude PAD. Unfortunately, the commonly used clinical assessments including pulse assessment and screening tests such as ankle pressure and ABPI are not very useful for disease exclusion in patients with established ulceration.

This analysis is consistent with previous research that has demonstrated that the utility of pulse assessment, ankle pressure and ABPI to identify PAD in patients with neuropathy (85% of our cohort) is low. It is anticipated that the utility of these tests diminishes further in patients with ulceration. This is expected as oedema, calcification and arteriovenous shunting all increase with progression of diabetes and unduly influence the outcome of these screening tests (23). Previous studies assessing the utility of ABPI in patients with intact feet have demonstrated NLRs from < 0.1 to 0.5 (25,26). Although Aboyans et al. reported a NLR of <0.1 in a cohort with 94% ulceration most other studies which explicitly include some patients with ulcers report NLRs ranging from 0.3 to 0.7 (20, 26-28). Williams et al. reported that the NLR for TBI was <0.1 for patients with intact feet and neuropathy (24). Predictably in our cohort with ulceration TBI performed less well with an NLR of 0.24. Nevertheless toe brachial index probably represents the most useful screening tool for PAD in the community foot clinic where access to diagnostic tests may be limited. Unfortunately, due to previous minor amputations or digital ulcers not all patients can undergo this investigation.

Waveform analysis was the best screening tool to exclude PAD in our study and Normahani and colleagues demonstrate that it is possible to train podiatrists to perform a focused Duplex ultrasound scan of the tibial vessels at the ankle (29). The costs of training and availability of ultrasound machines may be a limitation. There are medical devices available that can record the ankle pulse waveform but their utility in patients with established ulceration remains to be assessed (30). We did not have access to this technology at the time of the study. An alternative is to refer all patients with ulceration for a limited tibial waveform scan by a vascular sonographer. Only those who screen positive could then proceed to full Duplex ultrasound

Strengths and Limitations

This study focused on the identification of PAD as the primary outcome of interest. Despite the importance of PAD, not all patients with PAD require revascularisation to heal their ulcer. The additional consideration is whether perfusion is adequate to heal the ulcer with best medical and wound care i.e. is revascularisation required. This is a more complex and different question and would require a different study design to reach a conclusion. Screening tools that exclude PAD can help to identify patients that do not warrant ongoing referral to an MDT that includes a vascular specialist who can clinically address this question by assessing the severity of artery disease, ulcer characteristics and presence of infection.

We chose a definition of abnormal ABPI < 0.9 or > 1.3. Most studies assessing ABPIs utility as a screening test for PAD use < 0.9. Our reason was once again that we were restricting our paper to those with established ulceration were robust exclusion is more important than specificity.

To our knowledge this is the first paper that tests such a wide variety of PAD screening tools in patients with ulceration. Other screening tools are available that were not included in this study such as pulse oximetry.

The clinical assessment of our patients was performed by a post completion of training vascular fellow. The applicability of this assessment to non-specialist nurse or podiatrists is unknown. We would anticipate that the ability of pulse assessment to exclude PAD would be even worse if undertaken by non-specialists.

Conclusions

Toe brachial index and tibial waveform analysis at the ankle are viable screening tools to exclude PAD in patients with foot ulceration where the equipment and training for their utilisation exists or can be set up. Traditionally used clinical assessment and alternative screening tools perform poorly in excluding PAD in patients with established diabetes related foot ulceration. In the absence of appropriate TBI or tibial waveform analysis all patients with diabetes related foot ulceration should undergo diagnostic vascular imaging unless there is a very rapid response to best medical and wound care.

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Conflicts of Interest

The authors declare that they have no conflicts of interest associated with this study.

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Tables

Age	66 years (range 29-92)
Male	45 (75%)
Inpatient	15 (25%)
Duration of diabetes	2 years (range 0.04-62)
HbA1c	65 mmol/mol (range 36-106)
Diabetes:	
Type I	7 (12%)
Type II:	
Diet/Oral hypoglycaemic	23 (28%)
Insulin	30 (50%)
Smoking:	
Never or stopped > 10 years	44 (73%)
Stopped < 10 years ago	9 (15%)
Abstinence < 1 year or < 1 pack/day	3 (5%)
> 1 pack/day	4 (7%)
Hypertension	44 (73%)
Hyperlipidaemia:	
No	10 (17%)
Diet controlled	7 (12%)
Diet and drug therapy	43 (72%)
Previous TIA or stroke	4 (7%)
Cardiac disease	16 (27%)
Chronic kidney disease	23 (38%)
Pulmonary disease	6 (10%)

Table 1 Demographics of study patients

SINBAD	No.
Site	20 (33%)
Ischaemia	35 (58%)
Neuropathy	51 (85%)
Infection	19 (32%)
Area	25 (58%)
Depth	13 (22%)
Total score:	
0	3 (5%)
1	7 (12%)
2	22 (37%)
3	8 (13%)
4	7 (12%)
5	10 (17%)
6	3 (5%)

Table 2 SINBAD ulcer classification of study patients

SVS WIfI	No.
Wound:	
0	0
1	44 (73%)
2	8 (13%)
3	8 (13%)
Ischaemia:	
0	62 (37%)
1	23 (14%)
2	12 (7%)
3	3 (2%)
Infection:	
0	36 (60%)
1	10 (17%)
2	8 (13%)
3	6 (10%)

Table 3 SVS WIfI ulcer classification of study patients

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio
Either pedal pulse	0.55	0.60	0.41	0.73	1.38	0.75
Hair loss	0.8	0.4359	0.4211	0.8095	1.42	0.46
Atrophy	0.5	0.8718	0.6667	0.7727	3.90	0.57
Dependent rubor	0	1	Not discriminatory*	0.661	Not discriminatory*	1.00
Cool skin	0.3	0.8974	0.6	0.7143	2.92	0.78
Blue/purple skin	0	0.9211	0	0.6364	0	1.09
Capillary refill	0.4211	0.6316	0.3636	0.6857	1.14	0.92
Venous filling	0	1	Not discriminatory†	0.6512	Not discriminatory†	1.00
Ankle pressure	0.47	0.79	0.53	0.75	2.25	0.67
Toe pressure	0.45	0.97	0.90	0.78	17.58	0.56
Toe brachial pressure index	0.89	0.45	0.45	0.89	1.62	0.24
Ankle brachial pressure index	0.68	0.59	0.46	0.79	1.69	0.53
Pole test at ankle	0.28	0.97	0.83	0.73	10.29	0.74
$TcPO_2$	0.28	0.66	0.28	0.66	0.81	1.10
Waveform analysis	0.85	1.00‡	1.00 ‡	0.93	Diagnoses PAD‡	0.15

Table 4 Diagnostic utility of physical examination of and screening tests to identify peripheral artery disease compared to Duplex ultrasound scan

*Not discriminatory because dependent rubor was not elicited in any patient.
† Not discriminatory because impairment of venous filling was not elicited in any patient.
‡ The gold standard definition of PAD used included monophasic (damped) waveforms in any vessel, therefore the specificity and positive predictive value ratios are 1 and, positive likelihood is effectively infinite and diagnoses PAD.