Screening developments for the foot in diabetes

Aditya Dutta, Ashu Rastogi and Edward B Jude

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Article points

1. Major risk factors to be screened for diabetic foot in people with diabetes are diabetic peripheral neuropathy, peripheral arterial disease, foot deformities, past history of ulcer or amputation and end-stage renal disease.
2. Screening for the diabetic foot can reduce amputations and financial burden in people with diabetes.
3. Annual clinical examination for diabetic peripheral neuropathy and peripheral arterial disease is recommended.

Key words

- Diabetic foot
- Diabetic peripheral neuropathy
- Peripheral arterial disease
- Screening

Authors

Aditya Dutta is Resident Doctor, Foot Care Division, Department of Endocrinology, PGIMER, Chandigarh, India; Ashu Rastogi is Assistant Professor, Diabetes and Endocrinology Department, Tameside and Glossop Integrated Care NHS Foundation Trust, Ashton under Lyne, UK; Edward B Jude is Professor of Medicine, Tameside and Glossop Integrated Care NHS Foundation Trust; Honorary Professor, University of Manchester; Honorary Professor, Manchester Metropolitan University

Foot complications in people with diabetes are often neglected, which leads to significant morbidity and even mortality. Screening of the foot at initial diagnosis of type 2 diabetes and periodically on subsequent clinic visits is helpful in early recognition of foot complications. Foot screening involves a thorough history pertaining to risk factors for foot complications and prior pedal ulcers; assessment for diabetic peripheral neuropathy, peripheral vascular disease and foot deformities. A simple tuning fork, monofilament sensation, palpation of pedal pulses and Ankle Brachial Index assessment provide necessary information for categorising the risk for future foot complications.

Foot complications in people with diabetes is an outcome of increased longevity (Bhansali and Rastogi, 2016). As people with diabetes live longer, they develop microvascular complications like neuropathy and macrovascular complexity of vasculopathy, both of which contribute to foot complications. Once people with diabetes develop foot complications then it contributes to excess economic burden, morbidity and even mortality (Boulton et al, 2005; Al-Rubeaan et al, 2017; Kerr et al, 2019). Unfortunately, most patients are referred late to healthcare professionals, which adds to the seriousness of the condition. Therefore, screening for foot complications and especially the 'foot at risk' in a given individual with diabetes takes a precedence during each visit to the healthcare facility. The following review provides an overview of screening procedures for the foot in diabetes and their pragmatic use in resource constraint settings.

What is the diabetic foot?

The 'diabetic foot' has been defined as infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or arterial disease in the lower-extremity of a person with diabetes (van Netten et al, 2019). The risk factors for diabetic foot include presence of signs or symptoms of diabetic peripheral neuropathy (DPN), autonomic neuropathy, peripheral arterial disease (PAD), pre-ulcerative lesions (like callus), foot deformities (like hallux valgus), previous foot ulcer or amputation, oedema, smoking or nicotine use, male sex, duration of diabetes, complications of diabetes (especially end-stage renal disease and retinopathy) and post-transplant status (Boulton et al, 2018).

Numerous classification schemes are available to guide the risk stratification and follow-up frequency in a diabetic foot patient on a case-to-case basis (Boyko et al, 2006; Boulton et al, 2008; Scottish Intercollegiate Guidelines Network [SIGN], 2010; International Diabetes Federation, 2017; Bus et al, 2020). These classification systems point out five key risk factors related to diabetic foot ulcer (DFU) development. First, DPN itself can increase the risk of development of first foot ulcer by seven-fold by virtue of an insensate foot, decreasing

proprioception and hampering the balance (Young et al, 1994). Second, PAD has a causal role in pathway to ulceration in up to 35% of cases (Reiber et al, 1999) and its prevalence in patients with DFU is nearly 50% (Prompers et al, 2007). Third, foot deformities worsen plantar pressures and result in DFU at areas of high pressure and recurrent stress (Singh et al, 2005; Chatwin et al, 2019). Fourth, 30–50% ulcers may recur in individuals with prior history of DFU and/or amputation (Armstrong et al, 2017). In addition to the above, end-stage renal disease (ESRD) and dialysisare independent risk factors for foot ulceration (Lavery et al, 2010; Ndip et al, 2010). The role of these risk factors have been assessed in a recent systematic review (Crawford et al, 2015).

Why to screen for the diabetic foot?

The annual incidence of diabetic foot ulcers (DFU) is 2% (Abbott et al, 2002). The lifetime risk of DFU in a person with diabetes is thought to be between 19–34% (Armstrong et al, 2017). Diabetes-related lower-extremity complications (LEC) rank within the top-10 leading causes of the global disability burden (Lazzarini et al, 2018). Mortality data are staggeringly high, exceeding 70% at 5 years for people with diabetes with some level of amputation (Lavery et al, 2010). A study conducted in 1983 found the incidence of foot examination performed in people with diabetes by physicians to be only 12.3% (Bailey et al, 1985). Nearly three decades later, this figure has not improved much (Jayaprakash et al, 2011). Many studies have shown that provision of foot-care services and preventive care can reduce amputations and financial burden in people with diabetes (McCabe et al, 1998; Sloan et al, 2010; Carls et al, 2011). In one such study, visiting both a podiatrist and a LEC specialist in the year before diagnosis of LEC, was protective of undergoing lower-extremity amputation (Sloan et al, 2010).

In a recent survey, it has been estimated that one-third reduction in prevalence of DFU in England would result in an annual saving of £240m (Kerr et al, 2019). Unfortunately, these data are not corroborated with data from randomised control trials (RCT) (Dorresteijn and Valk, 2012). Rather, more data is available for secondary prevention, i.e., reducing the risk of foot ulcer recurrence. A systematic review of studies evaluating the role of integrated foot care, self-management, therapeutic footwear and foot surgery has shown a mean effect size ranging from 30.9% to 61.8% in reducing the risk of recurrent foot ulcer in the intervention groups (van Netten et al, 2020). Patient targeted education by itself is insufficient in providing clinical benefit at the level of secondary preventiondue to inherent constant physical abnormalities in the diabetic foot (Lincoln et al, 2008). Thus, there is a compelling need for clinical screening of the diabetic foot in people with diabetes.

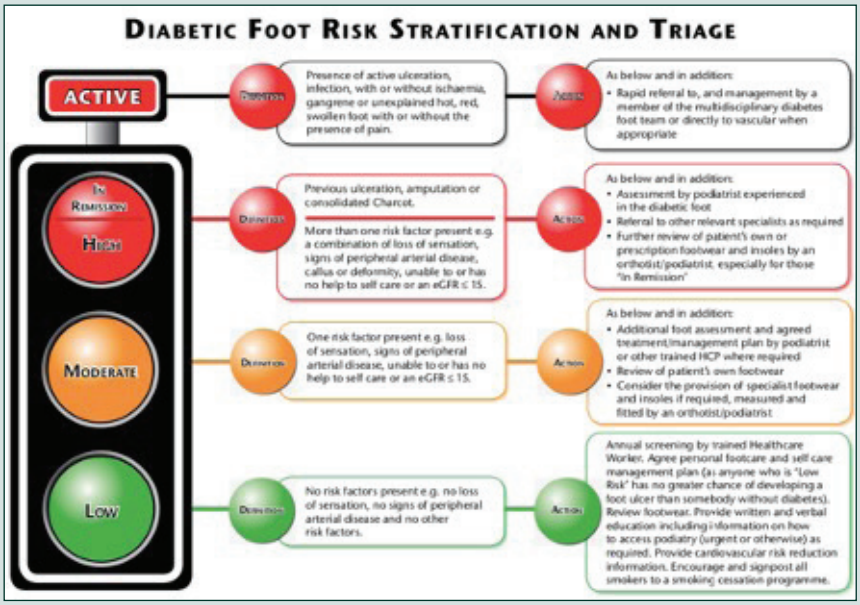

Figure 1. The updated Scottish diabetic foot risk stratification and triage system (Stang and Leese, 2016).

Whom and when to screen?

The microvascular complications can be observed at the onset of type 2 diabetes (T2D); hence, screening of the diabetic foot should start at the outset. The Diabetic Foot Risk Stratification and Triage System (*Figure 1*) outlines the screening frequency (the traffic light) and the subsequent intervention (Stang and Leese, 2016). Certain populations like patients who have end-stage renal disease (ESRD) or post-renal transplant should be screened more frequently (Bus et al, 2020). However, in young people with diabetes (especially type 1 diabetes) the screening protocol is not well defined. In the latter subgroup, we believe that screening for neuropathy (at least) should begin within 5 years after diagnosis, mirroring the retinopathy assessment (American Diabetes Association [ADA], 2020). For vasculopathy, the ADA suggests at least annual history and examination of pulses in a person with diabetes, and Ankle Brachial Index (ABI) in patients with symptoms or signs

of PAD (ADA, 2020). There are multiple other recommendations for (Gerhard-Herman et al, 2017; National Institute for Health and Care Excellence [NICE], 2018; Bus et al, 2020) and against (US Preventive Services Task Force et al, 2018) the use of ABI for screening of PAD in asymptomatic but high risk individuals (like people with diabetes). In short, for screening of PAD in people with diabetes, annual clinical examination is a must and the use of ABI is at the discretion of the healthcare professional. Screening for cardiovascular risk and emphasis on smoking cessation can be integrated in the diabetic foot annual assessment (Stang and Leese, 2016).

How to screen?

History

A detailed history should be taken keeping in mind the following points:

- Neuropathy symptoms (positive: burning or shooting pain, tingling sensations; negative: numbness, walking on cotton/air and loss of temperature sensation)
- Musculoskeletal symptoms (feet too large for the shoe, slippage of slippers and foot drop)
- Vascular symptoms (claudication, rest pain, discolouration, non-healing ulcer and fatigue)
- Diabetes duration, complications of diabetes (retinopathy precludes foot-care and dialysis or post-transplant status)
- Past history of DFU, gangrene, amputation, revascularisation, cardiovascular disorder and tobacco use.

Inspection of the foot

Examination of the foot should start withscrutiny of the skin, nails, interdigital areas, skin over the deformities, pre-ulcerative signs, oedema, prominent veins and erythema.

- Pre-ulcerative signs (callus, maceration, blisters, fissures and bleeding in callus) serve as pointers for diabetic foot
- Callus develops due to abnormal foot pressures at sites like deformities (claw toes and prominent metatarsal heads), dorsum of toes (cramped footwear) or midfoot (Charcot neuroarthropathy)
- Presence of nail changes (ingrown nail, onychomycosis, onychogryphosis and onycholysis) and nail or interdigital infection (paronychia, intertrigo and dermatophytosis) should prompt a visit to the specialist
- Lack of hair and skin/nail discolouration point to existence of PAD
- Ill-fitting, worn-out or lack of footwear should also be recorded.

Musculoskeletal assessment

Common structural deformities in a diabetic foot include hammer toes, mallet toes, claw toes, hallux valgus (bunion), hallux rigidus, prominent metatarsal heads, pes cavus, pes planus and rocker-bottom foot (residual of Charcot neuroarthropathy). Dorsal and plantar flexion of the foot, guttering of the foot and gait (loss of proprioception) should also be checked.

Neurological assessment

Establishing the presence of DPN is fundamental to identify the diabetic foot. Diabetes is characterised by a 'dying back' axonopathy affecting C (small) and A (large) fibres. This causes impairment of sensory functions in the foot (e.g. loss of pain sensation, unsteadiness and dryness etc.) and predisposes to deformities and ulceration. The past decade has seen a trend to objectify the neurological testing in order to minimise the receiver-operator bias and make it easy to execute at the patients' bedside. Several clinical examination methods, point-of-care (POC) devices, instruments and chemical indicators are now available for screening of neuropathy (*Table 1*).

Traditional screening methods

Current American Diabetes Association (ADA) recommendations include taking a detailed history, and assessment of either temperature or pinprick sensation (small fibre) and vibration perception threshold (VPT) using a 128-Hz tuning fork (large fibre) along with 10-g monofilament testing (ADA, 2020). DPN has been defined as presence of loss of protective sensation (LOPS) along with absence of either pin-prick, temperature sensation, vibration sensation or ankle reflex. The diverse options given by the ADA are based on regional practices and near-similar performance of tests against each other (Perkins et al, 2001; Jayaprakash et al, 2011).

10-g Semmes-Weinstein monofilament has been the most advocated test for foot examination due to ease in performing the same and widespread availability. Its outcome measure, loss of protective sensation (LOPS) is defined as inability to sense

Table 1. Various modalities for bedside screening of diabetic peripheral neuropathy.

Bedside Tool	Description/Method	Interpretation	Nerve fibre	Remarks
10-g mono-filament test	Buckling of the nylon microfilament when a 10-g force is applied at first, third, fifth metatarsal heads and plantar surface of distal hallux on plantar surface of the foot	Loss of the ability to detect pressure (buckling) at one or more sites	Large fibre	Perform a mock test before actual testing. Avoid callused/ ulcerated skin Patient should recognise the correct site of pressure with eyes closed Single-use disposable monofilaments are preferred
128-Hz Tun-ing fork	Vibratory sensation tested over the tip of the great toe	Patient senses no vibration while the examiner still perceives it	Large fibre	Perform a mock test before actual testing
Vibratip	Small, disposable battery run 128-Hz vibration device with a round tip and an on/off switch	Patient senses no vibration while the examiner still perceives it	Large fibre	Perform a mock test before actual testing
VibroSense Meter	A device to investi-gate seven frequencies between 8 to 500-Hz (vibrogram)	Patient senses no vibration while the examiner still perceives it	Tests multiple mechano-receptors	Connected to computer and controlled via software
NC-stat DPNCheck	Automatic point of care device assessing conduction studies of su-ral nerve (distal lateral thigh)	Patient per-ceives a 100-mA current to obtain velocity and action potential	Large fiberElectro-chemical skin conductance	Consists of nerve stimulator, sensor unit, thermometer (23–300C appropriate skin temperature) and a screen
NeuroQuick	Handheld device with a fan emitting cold air and two crossing laser beams, to be used on dorsum of the foot	Threshold: Lowest fan velocity level at which air-flow is recognised	Small fibre	Fan velocity can be adjusted across 10 levels Patient must keep eyes closed
Smartphone-generated vibrations	Most smartphones have an inbuilt oscillating motor for vibrating alert	Patient senses no vibration while the examiner still perceives it	Large fibre	Future potential for VPT and temperature assessment (smartphone also generates heat)
Neuropad	A patch applied to plantar surface of the foot detecting colour change to sweat from skin	Lack of or in-complete (patchy) colour change considered abnormal	Small fibre	Water from sweat reacts with anhydrous CoCl2 (blue) to form hydrous CoCl2 (pink) The change should occur in <10 minutes
Sudoscan	Uses a reaction between sodium chloride of seat and nickel of the electrodes to produce electric current: reverse iontophoresis	Electrochemical skin conductance (ESC) measured, lower ESC associated with DPN	Small fibre	ESC: ratio between the resultant current (hand/feet) and the one produced by the device
Ipswich Touch Test (IpTT)	Physician's index finger to touch on first, third, fifth toes for 1–2 seconds in random order	Lack of sense of touch is abnormal (>2 toes)	Small fibre	Patient's to close their eyes Touch must be light (feather-like)

light pressure (10-g force). A recent meta-analysis of monofilament tests (using nerve conduction study as a reference) has shown pooled sensitivity and specificity of 0.53 and 0.88, respectively, with heterogeneous sensitivities (16.7%–95.8%; Wang et al, 2017). These results may reflect inconsistency in the technique (number and sites of testing), reference standards and wear and tear. To maintain the accuracy, the monofilament should be regularly replaced (6 monthly or if bent). Other monofilaments available in clinical practice include Bailey's (retractable) 10-g monofilament and Owen Mumford's Neuropen.

Vibration sensation testing by 128-Hz tuning fork is considered one of the best screening modalities for the foot in diabetes (Young et al, 1994; Jayaprakash et al, 2011). It is validated, inexpensive, durable and easy to perform with high sensitivity (>80%; Meijer et al, 2003; Martin et al, 2010). Grading of severity of DPN (mild, moderate and severe) is done with the use of the biothesiometer or neurothesiometer. Here, a vibration

Table 2. ABI interpretation for clinically suspect peripheral arterial disease.

ABI value	Interpretation
>1.3	Medial arterial calcification (poor compression)
0.91–1.3	Normal
0.7–0.91	Mild obstruction
0.41–0.69	Moderate obstruction
<0.41	Severe obstruction (critical limb ischaemia)

perception threshold (VPT) of ≥25 is considered as diagnostic for neuropathy. However, these take longer time to operate and are expensive.

Absence of ankle reflex is an easy bedside sign to demonstrate DPN. Studies evaluating ankle reflex alone or as part of neuropathy disability score (NDS) have found high sensitivity (>80%) but variable specificity (Shehab et al, 2012; Malik et al, 2013). It is unreliable as a single test due to high incidence of absent ankle reflex in general population and older adults (Bowditch et al, 1996).

By combining traditional methods (like ankle reflex and VPT) and the appearance of the foot during inspection, several scores like Michigan Neuropathy Screening Instrument (MNSI) and NDS have been developed to aid in quick out-patient screening.

Advances in neuropathy screening

The Ipswich Touch Test (IpTT) is a simple bedside test for neuropathy screening. It has been prospectively evaluated in a head-to-head trial with 10-g monofilament and was found to have good sensitivity and specificity (k=0.88; P<0.0001), and positive predictive value (89%) in detecting LOPS (Rayman et al, 2011). It has been validated in various studies (Sharma et al, 2014; Madanat et al, 2015) and is likely to supplant 10-g monofilament in diabetic foot examination.

VibraTip is a small handheld battery-operated device. It has been studied prospectively against the neurothesiometer and NDS thresholds and has demonstrated good sensitivity (>80%) and specificity (>82%) (Bracewell et al, 2012; Papanas et al, 2020). Smartphones appear to have future potential for checking VPT, as well as temperature sensation testing as they are able to generate vibration of 25-Hz. This feature has been tested in a small trial of 21 patients with DPN and was found to fare better (accuracy — 0.88) than either the tuning fork or the 10-g monofilament (May and Morris, 2017).

NC-stat DPNCheck is a POC device that measures conduction velocity and action potential of sensory nerves in lateral thigh (sural nerve). It is free of patient bias and also identifies patients without symptoms of neuropathy (Poulose et al, 2015). It has been validated in people with diabetes with DPN (Binns-Hall et al, 2018) and seems to be a promising tool.

NeuroQuick is another handheld device emitting cold air at a standardised distance to the dorsum of the foot. With its 10 levels of fan velocity, one can grade the temperature sensation at which cold airflow is recognised. It has been studied in early DPN, and found to outperform traditional thermal testing and tuning fork test (Ziegler et al, 2005).

Neuropad indicator test to study the sudomotor function of the plantar skin is a good screening test to exclude DPN, with a high negative predictive value (98%) and reproducible results (Manes et al, 2014). It has been shown to predict the development of DPN in people with diabetes and pre-diabetes (Ziegler et al, 2012). Conversely, due to poor specificity, abnormal results require confirmation by additional testing (Manes et al, 2014). Neuropad automated continuous image analysis software has been tested which may improve the diagnostic yield of this test (Ponirakis et al, 2015).

Sudoscan is another non-invasive test for testing small fiber and autonomic neuropathy. It relies on the production an electric current from sodium chloride in the sweat. No discomfort is felt during the test and the results are reproducible (Gin et al, 2011). The test correlated well with both NDS and VPT in a prospective study for asymptomatic diabetic neuropathy (Mao et al, 2017). However, the test lacks consistent normative data on its outcome measure, namely the electrochemical skin conductance (ESC) (Rajan et al, 2019).

Vascular assessment

Historical points relevant to PAD assessment are mentioned in section 4.1. It is imperative to suspect PAD in a patient with current or prior history of non-healing DFU of >6 weeks duration (Hinchliffe et al, 2016). Examination for PAD should include:

- Observing the feet for lack of hair and skin/nail discolouration
- looking at calf muscle girth (for atrophy)

- Checking pedal pulses (femoral, popliteal, posterior tibial, dorsalis pedis) bilaterally
- Evaluating for bruit and slow venous filling time.

Regrettably, none of these clinical markers are accurate enough to detect PAD (Collins et al, 2006). Currently, the ADA suggests at least annual history and examination of pulses in a patient with diabetes, and ABI in patients with symptoms or signs of PAD (ADA, 2020). ABI represents the ratio of the systolic blood pressure (SBP) at the ankle divided by SBP at the arm. SBP of both the arms is noted and the higher value becomes the denominator. A value between 0.91–1.30 is considered as normal (*Table 2*). Depending on the device function, doppler waveforms can also be generated or printed. The test is easy to perform at the bedside, requires minimal training, is cost-effective, non-invasive and less time consuming. Sensitivity can further be improved by 6-minute treadmill walk test. In a systematic review, the sensitivity of ABI<0.9 in diagnosing PAD, ranged from 29 to 95% (median at 63%), and its specificity varied between 58% and 97% (median 93%) (US Preventive Services Task Force et al, 2018). Limitations include inconsistent inter- and intra-tester reliability (Casey et al, 2019), non-reliability in patients with medial arterial calcification (especially patients with ESRD) and operator bias (Tóth-Vajna et al, 2019). Despite these limitations, handheld ABI measurement is unlikely to lose its importance as a valuable tool in screening undiagnosed PAD. Automated oscillometric ABI devices have been developed to minimise operator bias. These have been found to be as reliable as colour doppler sonography in detecting PAD in people with diabetes (Ma et al, 2017).

PAD in diabetes: difficulties in screening

PAD in diabetes has certain distinctive features. It is insidious, preferentially affects infra-popliteal arterial system, has diffuse involvement, has poor collateral formation and has faster progression. It is associated with a high risk for first foot ulcer, non-healing DFU, amputation, cardiovascular events and mortality. Thus, it seems appropriate to institute early screening for PAD in diabetes. However, three difficulties are commonly encountered. First, diabetic neuropathy may shield the symptoms of PAD and predispose to medial arterial calcification (Jeffcoate et al, 2009). Second, pedal pulses may remain palpable even when underlying stenosis is present, and is otherwise unreliable in a busy clinic (Lundin et al, 1999). Third, screening of asymptomatic population may have undue financial repercussions. Still, three small studies have yielded a high prevalence of undiagnosed PAD (26–57%) using handheld ABI Doppler in people with diabetes (Formosa et al, 2012; Ogbera et al, 2015; Tummala et al, 2018).

Screening in resource-constrained settings

The screening practices in resource constraint settings should be the ones that are cost-effective, accessible, less technically demanding, less time consuming and reliable. The 10-g monofilament, 128-Hz tuning fork, ankle reflex, IpTT, palpation of pedal pluses and the handheld ABI device have been used successfully in community-based studies in developing nations (Viswanathan et al, 2005; Jayaprakash et al, 2011; Formosa et al, 2012; Malik et al, 2013; Madanat et al, 2015; Tummala et al, 2018). A plethora of both short and comprehensive examinations are available at our behest (Boulton et al, 2008; Miller et al, 2014). While a detailed examination entails assessment of dermatological, sensory, musculoskeletal and vascular systems, it is often not practical in resource constraint settings. The authors suggest the use of the 3-minute foot examination module to actively screen and triage people with diabetes for various risk factors (Miller et al, 2014). The foot examination should be followed by at least an annual risk stratification (traffic light system, ADA or IWGDF risk scores) to allow for timely intervention.

Emphasis by the healthcare professional on foot-care education, including daily foot inspection, avoiding walking barefoot, not to cut callosities with razors or knives at home, use of appropriate footwear in high-risk patients and early presentation to the hospital at the onset of a foot lesion, can serve to offload the burden of the foot in diabetes. ■

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Online CPD activity

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1. Which single one of the following is NOT a recognised risk factor for 'diabetic foot'. Select ONE option only.

   A. Autonomic neuropathy
   B. Callus
   C. Female sex
   D. Hallux valgus
   E. Renal transplant

2. What is the approximate prevalence (%) of peripheral arterial disease (PAD) in people with a diabetic foot ulcer (DFU)? Select ONE option only.

   A. 33
   B. 50
   C. 66
   D. 75
   E. 99

3. What is the approximate five-year predicted mortality rate (%) after any amputation for DFU? Select ONE option only.

   A. 30
   B. 40
   C. 50
   D. 60
   E. 70

4. What is the clinical benefit, if any, of patient-targeted education in reducing the risk of recurrent diabetic foot ulcers? Select ONE option only.

   A. Improved ABPI scores
   B. Increased ulcer healing rates
   C. No clinical benefit
   D. Reduced amputation rates
   E. Reduced diabetic peripheral neuropathy incidence

5. Which single one of the following is a 'positive' symptom of diabetic neuropathy? Select ONE option only.

   A. Loss of temperature
   B. Numbness
   C. Sensation of walking on cotton wool
   D. Reduction in capillary return
   E. Shooting pain

6. Which single one of the following callus sites is more specific to Charcot neuroarthropathy? Select ONE option only.

   A. Dorsum of toe
   B. Heel
   C. Medial malleolar
   D. Metatarsal head
   E. Mid foot

7. The 10g Semmes-Weinstein monofilament is the most advocated test for diabetic foot examination.

   Which one of the following is the single most likely explanation why a recent meta-analysis showed heterogeneous sensitivies ranging from 16.7 to 95.8% with an overall pooled sensitivity of 0.53? Select ONE option only.

   A. Inconsistent technique
   B. Lack of reference standards
   C. Lack of replacement after three months' usage
   D. Poor patient understanding of what is being tested
   E. Use of alternative monofilaments, such as Bailey's and Owen-Mumford

8. Which one of the following is most likely to replace the 10-g monofilament in diabetic foot examinations? Select ONE option only.

   A. Ipswich Touch Test
   B. NC-stat DPNCheck sural nerve test
   C. Neuropad indicator test
   D. NeuroQuick cold air device
   E. Sudoscan sweat test

9. A 72-year-old woman has a non-healing DFU.

   Which one of the following clinical signs most likely supports a diagnosis of underlying PAD? Select ONE option only.

   A. Calf muscle atrophy
   B. Excessive lower-limb hair
   C. Medial malleolar pigmentation
   D. Onycholysis
   E. Pedal oedema

10. A 69-year-old man with type 2 diabetes has had a left DFU for eight weeks. His regular medications are metformin 1g twice daily, losartan 100 mg and rosuvastatin 10 mg daily.

    His clinical records from yesterday show a temperature of 37.2°C, pulse 82 regular, BP 159/85 mmHg and palpable bilateral dorsalis pedis pulses.

    An ABPI today is 0.88 (right) and 0.39 (left).

    Which is the single most appropriate management? Select ONE option only.

    A Amlodipine 5mg
    B. Aspirin 75 mg
    C. Refer to high-risk foot clinic
    D. Refer to vascular surgery outpatient clinic
    E. Same-day admission