Screening developments for the foot in diabetes

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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.

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Foot complications in people with diabetes is an outcome of increased longevity (1). 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 (2–4). Unfortunately, most patients are referred late to health care 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 health care facility. The following review provides an overview of screening procedures for the diabetic foot and their pragmatic use in resource constraint settings.

What is thediabetic foot?

"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 (5). 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, , edema, smoking or nicotine use, male sex, duration of diabetes, complications of diabetes (especially end-stage renal disease, retinopathy) and post-transplant status (6). 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 (7–11). 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 7-fold by virtue of an insensate foot ,decreasing proprioception and impaired balance (12). Second, PAD has a causal role in pathway to ulceration in up to 35% of cases (13) and its prevalence in patients with DFU is nearly 50% (14). Third, foot deformities worsen plantar pressures and result in DFU at areas of

high pressure and recurrent stress (15,16). Fourth, 30-50% ulcers may recur in individuals with prior history of DFU and/or amputation (17). In addition to the above, end-stage renal disease (ESRD) and dialysisare independent risk factors for foot ulceration (18,19). The role of these risk factors have been assessed in a recent systematic review (20).

Why to screen for the diabetic foot?

The annual incidence of diabetic foot ulcers (DFU) is 2% (21). The lifetime risk of DFU in a person with diabetes is thought to be between 19-34% (17). Diabetes-related lower extremity complications (LEC) rank within the top 10 leading causes of the global disability burden (22). Mortality data are staggeringly high, exceeding 70% at 5-years for people with diabetes with some level of amputation (18). A study done in 1983 found the incidence of foot examination performed in people with diabetes by physicians to be only 12.3% (23). Nearly three decades later, this figure has not improved much (24). Many studies have shown that provision of foot-care services and preventive care can reduce amputations and financial burden in people with diabetes (25–27). 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 (26). 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 £240 million (2). Unfortunately, these data are not corroborated with randomized control trials (RCT) (28). 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 (29). 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 (30). Thus, there is a compelling need for clinical screening of the diabetic foot in people with diabetes.

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 screening frequency depends on the risk category as suggested by American Diabetes Association (ADA) guidelines (31). Certain populations like patients who have end stage renal disease (ESRD) or post-renal transplant should be screened more frequently. 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 (31). 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 (31). There are multiple other recommendations for (8,32,33) and against (34) 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 health care professional.

How to screen?

History

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

a) Neuropathy symptoms (positive: burning or shooting pain, tingling sensations; negative: numbness, walking on cotton/air, loss of temperature sensation)

b) Musculoskeletal symptoms (feet too large for the shoe, slippage of slippers, foot drop)

c) Vascular symptoms (claudication, rest pain, discoloration, non-healing ulcer, fatigue)

d) Diabetes duration, complications of diabetes (retinopathy precludes foot-care, dialysis or post-transplant status)

e) Past history of DFU, gangrene, amputation, revascularisation, 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, edema, prominent veins and erythema.

a) Pre-ulcerative signs (callus, maceration, blisters, fissures, bleeding in callus) serve as pointers for diabetic foot

b) Callus develops due to abnormal foot pressures at sites like deformities (claw toes, prominent metatarsal heads), dorsum of toes (cramped footwear) or midfoot (Charcot neuroarthropathy)

c) Presence of nail changes (ingrown nail, onychomycosis, onychogryphosis, onycholysis) and nail or interdigital infection (paronychia, intertrigo, dermatophytosis) should prompt a visit to the specialist

d) Lack of hair and skin/nail discoloration point to existence of PAD

e) 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, dryness etc.) and predisposes to deformities and ulceration. The last decade has seen a trend to objectify the neurological testing in order to minimize 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 2*).

Traditional screening methods

Current American Diabetes Association (ADA) recommendation includes taking a detailed history, and assessment of either temperature or pinprick sensation (small fiber) and vibration perception threshold (VPT) using a 128-Hz tuning fork (large fiber) along with 10-g monofilament testing (31). 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 (24,35).

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 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%) (36). 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 modality for neuropathy (12,24). It is validated, inexpensive, durable and easy to perform with high sensitivity (>80%) (37,38). Grading of severity of DPN (mild, moderate and severe) is done with the use of the biothesiometer or neurothesiometer. Here a vibration 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 (39,40). It is unreliable as a single test due to high incidence of absent ankle reflex in general population and older adults (41).

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 (Table 1)

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 (=0.88; P<0.0001), and positive predictive value (89%) in detecting LOPS (42). It

has been validated in various studies (43,44) 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%) (45,46). 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 found to have better (accuracy 0.88) than either the tuning fork or the 10-g monofilament although larger studies are needed (47).

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 (48).It has been validated in people with diabetes with DPN (49) 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 recognized. It has been studied in early DPN, and found to outperform traditional thermal testing and tuning fork test (50).

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 (51). It has been shown to predict the development of DPN in people with diabetes and prediabetes (52). Conversely, due to poor specificity, abnormal results require confirmation by additional testing (51). Neuropad automated continuous image analysis software has been tested which may improve the diagnostic yield of this test (53).

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 (54). The test correlated well with both NDS and VPT in a prospective study for asymptomatic diabetic neuropathy (55). However, the test lacks consistent normative data on its outcome measure, namely the electrochemical skin conductance (ESC) (56).

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 (57). Examination for PAD should include

a) Observing the feet for lack of hair and skin/ nail discoloration

b) looking at calf muscle girth (for atrophy)

c) checking pedal pulses (femoral, popliteal, posterior tibial, dorsalis pedis) bilaterally

d) evaluating for bruit and slow venous filling time

Regrettably, none of these clinical markers are accurate enough to detect PAD (58). 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 (31). 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%) (34). Limitations include inconsistent inter- and intra-tester reliability (59), non-reliability in patients with medial arterial calcification (especially patients with ESRD) and operator bias (60). 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 minimize operator bias. These have been found to be as reliable as color doppler sonography in detecting PAD in people with diabetes (61).

4.5.1. 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. Itis 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 (62). Second, pedal pulses may remain palpable even when underlying stenosis is present, and is otherwise unreliable in a busy clinic (63). 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 (64–66).

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 (24,40,44,64,66,67).These simple tests often pave the way for simple foot-care education implementation (68,69). A plethora of both short and comprehensive examinations are available at our behest (7,70). 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 (70). 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 diabetic foot.

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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.

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Online CPD activity

Visit www.diabetesonthenet.com/cpd to record your answers and gain a certificate of participation

Participants should read the preceding article before answering the multiple choice questions below. There is ONE correct answer to each question. After submitting your answers online, you will be immediately notified of your score. A pass mark of 70% is required to obtain a certificate of successful participation; however, it is possible to take the test a maximum of three times. A short explanation of the correct answer is provided. Before accessing your certificate, you will be given the opportunity to evaluate the activity and reflect on the module, stating how you will use what you have learnt in practice. The new CPD centre keeps a record of your CPD activities and provides the option to add items to an action plan, which will help you to collate evidence for your annual appraisal.

1. What approximate percentage of people diagnosed with diabetes mellitus in England and Wales have their anonymised data held by the National Diabetes Foot Care Audit (NDFA)? Select ONE option only.

   A. 33
   B. 50
   C. 66
   D. 75
   E. 100

2. Approximately how many new diabetic foot ulcer episodes in England and Wales are currently registered with the NDFA in any 12-month period? Select ONE option only.

   A. 7,500
   B. 15,000
   C. 30,000
   D. 60,000
   E. 120,000

3. In any 12-month period, what percentage of the estimated total number of new diabetic foot ulcers occurring annually in England and Wales are currently registered with the NDFA? Select ONE option only.

   A. 10
   B. 20
   C. 40
   D. 60
   E. 80

4. Which one of the following most accurately represents how the NDFA records new foot ulcers? Select ONE option only.

   A. Every new ulcer
   B. Every new ulcer which does not heal within 12 weeks
   C. Every new ulcer in people who have never had an ulcer before
   D. Every new ulcer in people who have no co-existent ulcer already
   E. Each episode of one or more ulcers occurring in a person who was free from any other active ulcers on either foot at the time it started

5. A 56-year-old man with type 2 diabetes mellitus has developed two small and two large new areas of foot ulceration over the past 2 weeks.

   According to NDFA guidance, how many ulcers will be officially registered? Select ONE option only.

   A. 0
   B. 1
   C. 2
   D. 3
   E. 4

6. According to the 2019 NDFA annual report, which has NOT been shown to be linked to ulcer severity at the time of first expert assessment. Select ONE option only

   A. Time elapsed since first presentation to any healthcare professional
   B. Being alive and ulcer-free 12 weeks after presentation
   C. Major (above ankle) amputation within 6 months
   D. Minor (below ankle) amputation within 6 months
   E. Death within 6 months

7. Which is the single most likely explanation for the lack of an NDFA annual report this year? Select ONE option only.

   A. A decision to avoid highlighting locality variation
   B. Failure to comply with new GDPR regulations
   C. Insufficient referrals from primary care clinicians
   D. Insufficient referrals from secondary care clinicians
   E. Lack of commissioning

8. Which single additional question will be included, from April 2020, in the proposed new NDFA data collection forms? Select ONE option only.

   A. First ever ulcer on the currently affected foot
   B. First ever ulcer on either foot
   C. History of previous re-vascularisation
   D. History of chiropody treatment in the previous three months
   E. Presence of Charcot foot

9. According to the 2019 NDFA annual report, 54.5% of people with a new diabetic foot ulcer were alive and ulcer free at 12 weeks if they were referred by which one of the following routes? Select ONE option only.

   A. Community NHS chiropody
   B. GP
   C. Hospital specialist
   D. Private podiatrist
   E. Self

10. According to the 2019 NDFA annual report comparing clinical care networks in England and Wales, what approximate percentage of new referrals underwent expert assessment within 14 days of first presentation? Select ONE option only.

	Worst network	Best network
A	10	50
B	20	60
C	30	70
D	40	80
E	50	90