

Clinical Assessment of Diabetic Foot patient

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Abstract: As the incidence of diabetes mellitus rises, so too does the number of patients at risk of diabetic foot problems, particularly ulcers. Goal of a primary care practitioner is to prevent diabetic foot complications, including amputations.

Clinicians can do this by screening and assessing patients with diabetes at risk of developing foot ulcers and assessing and managing patients with diabetic foot ulcers.

'A minute spent on screening a foot could save a leg.'

A thorough history and physical examination is the first step necessary to determine the patient and ulcer status, establish a baseline for treatment, develop a treatment plan, determine a patient's risk status, and provide a prognosis for wound closure. Historical information should include diabetes control, current and past complications and treatments, and co morbidities. Physical examination should include information on vascular, neurological, and musculoskeletal status.

All diabetic patients must have their feet evaluated at least at yearly intervals for the presence of the predisposing factors for ulceration and amputation. If abnormalities are present, more frequent evaluation of the diabetic foot is recommended depending on risk category. It is through systematic examination and risk assessment, patient education, and timely referral to higher centres (where a multidisciplinary team can handle these problems) that a clinician may reduce the high prevalence of lower-limb amputation in diabetic patients.

Diabetic foot ulcer is a rising health problem with rising prevalence of diabetes. The most common triad of causes that interact and ultimately result in ulceration has been identified as neuropathy & or Ischemia, deformity, and trauma¹ and are frequently complicated by infection. The lifetime risk of a person with diabetes developing a foot ulcer may be as high as 25%, whereas the annual incidence of foot ulcers is <2%²⁻⁶. Up to 50% of older patients with type 2 diabetes have one or more risk factors for foot ulceration^{2,5}. A number of component causes, most importantly peripheral neuropathy, interact to complete the causal pathway to foot ulceration^{2-4,6}. Principal contributory factors that might result in foot ulcer development could be risk factors for foot ulcers^{3,5}

- h/o Previous foot ulcer
- h/o Previous amputation
- Peripheral neuropathy
- Foot deformity
- Peripheral vascular disease
- Visual impairment
- Diabetic nephropathy (especially patients on dialysis)
- Poor glycemic control
- Cigarette smoking

Despite the frequency of complications involving diabetic patient's lower limbs, primary care practitioners frequently neglect to examine their feet. Surveys of physicians and patient chart evaluations in USA & Canada have determined that fewer than 50% of diabetic patients receive appropriate foot evaluation as part of their annual medical checkups⁷⁻⁹.

Patients themselves are often unaware of serious foot problems because neuropathy removes the pain that would normally alert them. A community study discovered that 10% of patients diagnosed with diabetic foot ulcers did not know themselves that they had ulcers until they were advised by physicians¹⁰.

Consensus panels have recommended annual foot examinations be performed for all diabetic patients older than 15 years and even more frequent assessments if patients are at risk from peripheral

ischemia or neuropathy^{11,12}.

Clinical examination and investigations are focused on identifying the aetiology as well as the extent of foot disease. The monofilament test is a simple, bedside test that can predict the risk of neuropathic ulceration. The majority of amputations are preventable through a combination of good foot care and appropriate education for patients and healthcare providers and appropriate footwear.

Many studies have been published proposing a range of tests that might usefully identify patients at risk of foot ulceration, creating confusion among practitioners as to which screening tests should be adopted in clinical practice.

As identification of those patients at risk of foot problems is the first step in preventing such complications, this article will focus on key components of the foot examination.

COMPONENTS OF THE FOOT EXAMINATION

History

While history is a very important component of risk assessment, a patient cannot be fully assessed by history alone; a careful foot exam remains the key component of this process. Key components of the history include previous foot ulceration or amputation. Other important assessments in the history (Table 1) include neuropathic or peripheral vascular symptoms^{5,13}, impaired vision, or renal replacement therapy. Lastly, tobacco use should be recorded, since cigarette smoking & Tobacco consumption in any form is a risk factor not only for vascular disease but also for neuropathy.

GAIT

In OPD as soon as patient starts walking towards you, his or her neuropathy status can be guessed.

If patient having foot ulcer is walking with a limp, that means he might be suffering from mild to moderate Neuropathy. If he walks having foot ulcer without limp, that means he has severe neuropathy. If DFO patient walks with foot drop or high stamping gait possibility

Table 1: Essential features of history**Past History**

- Ulceration
- amputation
- Charcot joint
- vascular surgery
- angioplasty
- Cigarette smoking- Duration,Quantity,Type(Cigarette/Beedi/Hukka)
- Consumption of Tobacco in other form (e.g.Gutka/Khainee/Paan/Jarda etc.)

Neuropathic symptoms

- Positive e.g., burning or shooting pain, electrical or sharp sensations,Tingling etc.
- negative e.g., numbness, feet feel dead, walking on 'mattress'

Vascular symptoms

- Claudication- Distance
- Rest pain
- Coolness of feet

Other diabetes complications

- Renal (Microalbuminurea /Increased Urea or Creatinine / Dialysis/ Transplant)
- Retinal (visual impairment)
- Cardio vascular(CAD, Cardiomyopathy, CHF, Stroke etc.)

of motor neuropathy can be there.

If while walking patients Slippers or “Chappals” are slipping out of his feet possibility of sensory as well as motor neuropathy can not be ruled out.

GENERAL INSPECTION

Patient should be asked to remove his shoe wear along with socks and a careful inspection of the feet in a well-lit room should always be carried out .Because inappropriate footwear and foot deformities are common contributory factors in the development of Diabetic foot ulceration^{1,6}, one should always inspect Shoe wear and patient should be asked about the suitability of shoe wear. Examples of inappropriate shoes include, shoes who are excessively worn off or are too small for the person's feet (too narrow, too short, toe box too low), resulting in rubbing, erythema, blister, or callus.

Features that should be assessed during foot inspection are outlined in Table 2 and are discussed below.

Table 2: Key components of the diabetic foot exam**Inspection****Dermatologic**

- Skin status: color, thickness, Sweating/Dryness-Autonomic Neuropathy
- Turgid Veins: Autonomic neuropathy with A.V. Shunting
- Nails: Hard but brittle in neuropathy
- Loss of hair: Vasculopathy
- Any infection: Cellulitis, Boil, Abscess, check between toes for fungal infection
- Any Ulceration : Number, site, size, shape, edges, base, discharge, status of granulation tissue.
- Calluses/blistering: hemorrhage into callus?

Musculoskeletal

- Different foot deformities, e.g., Hammer toes,claw toes, prominent metatarsal heads, Charcot joint, Hallux Valgus
- Muscle wasting -guttering between metatarsals,

Neurological assessment

10-g monofilament + 1 of the following 4

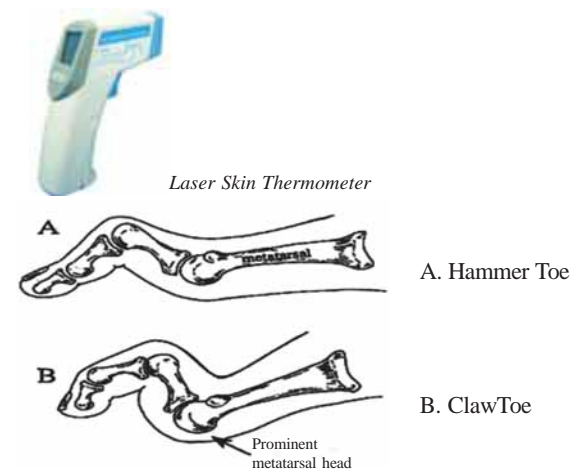
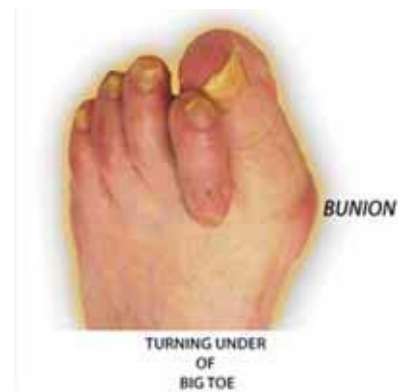
- vibration using 128-Hz tuning fork
- pinprick sensation
- ankle reflexes
- VPT

Vascular assessment

- foot pulses
- ABL, if indicated

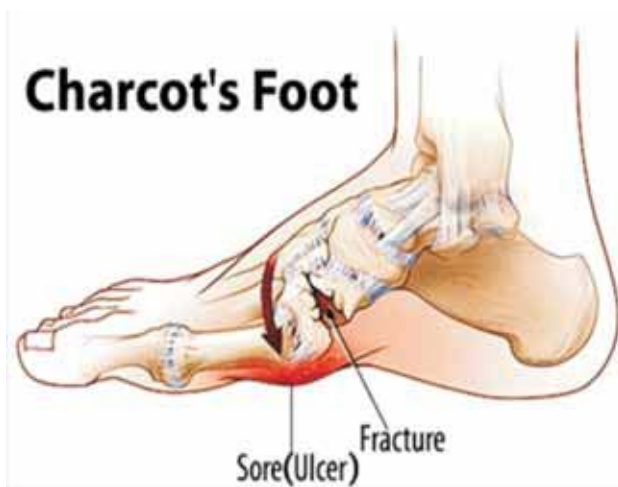
DERMATOLOGICAL ASSESSMENT

The dermatological assessment should initially include a global inspection,(interdigitally also), for the presence of ulceration or areas of abnormal erythema. The presence of callus (particularly with haemorrhage), nail dystrophy, ingrown toe nail or paronychia should be recorded¹⁴, Focal or global skin temperature differences between one foot and the other may be predictive of either vascular disease or Cellulitis associated with or without ulcer. Local Skin temperature can be judged crudely by back of the hand otherwise Laser Thermometer is ideal and more precise.

**Musculoskeletal assessment.(Foot Deformities)**

Foot deformities lead to high pressure areas leading to diabetic foot ulceration. The musculoskeletal assessment should include evaluation for any gross foot deformity¹⁵. Rigid deformities are defined as any contractures that cannot easily be manually reduced and are most frequently found in the digits. Common forefoot deformities that are known to increase plantar pressures and are associated with skin breakdown include claw toe or hammer toe¹⁶⁻¹⁸.

An important and often overlooked or misdiagnosed condition is Charcot arthropathy. This occurs in the neuropathic foot and most often affects the mid foot. This may present as a unilateral red, hot, swollen, flat foot with profound deformity¹⁹⁻²¹. A rocker-bottom deformity secondary to Charcot arthropathy can cause excessive pressure at the plantar mid foot, increasing risk for ulceration at that site. A patient with suspected Charcot arthropathy should be immediately referred to a specialist for further assessment and care.



NEUROLOGICAL ASSESSMENT

Peripheral neuropathy is the most common component cause in the pathway to diabetic foot ulceration^{1,3,5,6}. The clinical exam recommended, however, is designed to identify loss of protective sensation (LOPS) rather than early neuropathy. The diagnosis and management of the latter were covered in a 2004 ADA technical review⁵. The clinical examination to identify LOPS is simple and requires no expensive equipment.

Five simple clinical tests (Table3) each with evidence from well-conducted prospective clinical cohort studies, are considered useful in the diagnosis of LOPS in the diabetic foot^{1-6,22}. The task force agrees that any of the five tests listed could be used by clinicians to identify LOPS, although ideally two of these should be regularly performed during the screening exam—normally the 10-g monofilament and one other test. One or more abnormal tests would suggest LOPS, while at least two normal tests (and no abnormal test) would rule out LOPS. However, identification of the patient with LOPS can easily be carried out without Biothesiometer or other expensive equipment.

Table 3 : Simple bed side Clinical tests for LOPS

S. No.	Clinical Tests
1.	10-g monofilaments.
2.	Pinprick sensation.
3.	Ankle reflexes
4.	Tuning fork test
5.	VPT(Vibration perception threshold) testing.

10-G MONOFILAMENTS

Monofilaments, sometimes known as Semmes-Weinstein monofilaments, were originally used to diagnose sensory loss in leprosy²³. Many prospective studies have confirmed that loss of pressure sensation using the 10-g monofilament is highly predictive of subsequent ulceration^{2,23,24}. Screening for sensory loss with the 10-g monofilament is in widespread use across the world, and its efficacy in this regard has been confirmed in a number of trials, including Seattle Diabetic Foot Study^{3,23,25,26}.

A prospective study published in Diabetes Care in 1992 showed the loss of sensation to the 10-g filament on the sole of the foot was

associated with a 10-fold risk of foot ulceration and a 17-fold risk of amputation over a 32-month follow-up period²⁷.

The most important areas to assess are uncalloused regions of the plantar surface of the metatarsal heads, although some authors advocate assessing as many as 10 spots over the sole of the foot from the toes to the heel²⁸.

Nylon monofilaments are constructed to buckle when a 10-g force is applied; loss of the ability to detect this pressure at one or more anatomic sites on the plantar surface of the foot has been associated with loss of large-fibre nerve function. It is recommended that six sites (1st, 3rd, and 5th metatarsal heads, plantar surface of distal hallux, Instep & Heel) be tested on each foot while the patient's eyes are closed.



For performance of the 10-g monofilament test, the device is placed perpendicular to the skin, with pressure applied until the monofilament buckles. It should be held in place for <“1 s and then released.

Caution is necessary when selecting the brand of monofilament to use, as many commercially available monofilaments have been shown to be inaccurate. Single-use disposable monofilaments or those shown to be accurate by the Booth and Young²⁵ study are recommended. The sensation of pressure using the buckling 10-g monofilament should first be demonstrated to the patient on a proximal site (e.g., upper arm). The sites of the foot may then be examined by asking the patient to respond “yes” or “no” when asked whether the monofilament is being applied to the particular site; the patient should recognize the perception of pressure as well as identify the correct site. Areas of callus should always be avoided when testing for pressure perception.

PINPRICK SENSATION

Inability of a subject to perceive pinprick sensation has been associated with an increased risk of ulceration³. A disposable pin should be applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. Inability to perceive pinprick over either hallux would be regarded as an abnormal test result.

ANKLE REFLEXES

Absence of ankle reflexes has also been associated with increased risk of foot ulceration³. Ankle reflexes can be tested with the patient either kneeling or resting on a couch/table. The Achilles tendon should be stretched until the ankle is in a neutral position before striking it with the tendon hammer. If a response is initially absent, the patient can be asked to hook fingers together and pull, with the ankle reflexes

then retested with reinforcement. Total absence of ankle reflex either at rest or upon reinforcement is regarded as an abnormal result.

TUNING FORK TEST

The tuning fork of 128-Hz is widely used in clinical practice and provides an easy and inexpensive test of vibratory sensation. Vibratory sensation should be tested over the tip of the great toe bilaterally. An abnormal response can be defined as when the patient loses vibratory sensation and the examiner still perceives it while holding the fork on the tip of the toe^{2,3}.

VPT (VIBRATION PERCEPTION THRESHOLD) TESTING



Vibration perception threshold Machine

The biothesiometer (or neurothesiometer) is a simple handheld device that gives semi quantitative assessment of vibration perception threshold (VPT). Vibration perception using the biothesiometer is also tested over the six points over plantar surface. With the patient lying supine, the stylus of the instrument is placed over the plantar point and the amplitude is increased until the patient can detect the vibration; the resulting number is known as the VPT. This process should initially be demonstrated on a proximal site, and then the mean of three readings is taken. A VPT >15 V is regarded as abnormal and higher VPT readings has been shown to be strongly predictive of subsequent foot ulceration^{16,24}.

CIRCULATORY ASSESSMENT

Peripheral arterial disease (PAD) is a component cause in approximately one-third of foot ulcers and is often a significant risk factor associated with recurrent wounds^{1,29}. Therefore, the assessment of PAD is important in defining overall lower-extremity risk status. Assessment of peripheral circulation in diabetic patients includes the standard evaluation for pedal pulses; however, examiner s should be aware of the possible pitfalls of using presence of pulses alone to exclude clinically significant peripheral ischemia. Rivers et al³⁷ describe a series of diabetic patients who had sufficiently severe peripheral ischemia to warrant distal surgical bypass procedures despite the presence of readily palpable pedal pulses. Vascular examination should include palpation of the posterior tibial and dorsalis pedis pulses^{30,31}, which should be characterized as either "present" or "absent"³¹. Consequently, in addition to clinical parameters, non invasive measures of circulation are frequently used to complement physical examination in assessing the degree of arterial obstruction.

More reliable methods of assessing potential for healing foot ulcers in diabetic patients suspected of having peripheral ischemia involve measurement of Ankle Brachial Index, systolic toe pressure measurements or measurement of distal transcutaneous oxygen tension(TcPo2)^{32,33}.

ANKLE BRACHIAL INDEX (ABI)

Diabetic patients with signs or symptoms of vascular disease(like Intermittent claudication, Rest Pains, nocturnal pain, cold feet, blanching on elevation of limb & rubor on dependency, delayed

capillary filling, Impending tissue loss or established gangrene) or absent pulses on screening foot examination should undergo ankle brachial pressure index (ABI) pressure testing. The ABI is a simple and easily reproducible method of diagnosing vascular insufficiency in the lower limbs. Blood pressure at the ankle (dorsalis pedis or posterior tibial arteries) is measured using a standard Doppler ultrasonic probe. The ABI is obtained by dividing the ankle systolic pressure by the higher of the two brachial systolic pressures¹³. An ABI >0.9 to <1.3 is normal³⁶. ABI <0.8 is associated with claudication, and <0.4 is commonly associated with ischemic rest pain and tissue necrosis.

The ADA Consensus Panel on PAD recommended measurement of ABI in diabetic patients over 50 years of age and consideration of



ABI Measurement

ABI measurement in younger patients with multiple PAD risk factors, repeating normal tests every 5 years¹³. ABI may therefore be part of the annual comprehensive foot exam in these patient subgroups.

Although the ankle-brachial index (ABI) is used to indicate adequacy of peripheral blood flow in patients without diabetes, the ABI is less reliable in diabetic patients because calcification of the media of the distal arteries is common. This calcification makes the vessels relatively non-compressible, resulting in an artificially high systolic pressure in the ankle or supra-systolic ankle pressures³⁴.

In the presence of incompressible calf or ankle arteries (ABI >1.3), measurements of digital arterial systolic pressure (toe pressure) by photo plethysmography or transcutaneous oxygen tension(TcPo2) may be performed.

Both these latter assessments are performed in specialty diabetic foot clinics or vascular laboratories and offer an indication of potential for healing, before angiography is considered. A contrast angiogram remains the criterion standard of assessment in patients with peripheral vascular problems but has to be under taken with caution among patient s with diabetes who often already have nephropathy. Using contrast dye in patients with renal disease can result in complete renal shutdown.

CONCLUSIONS

It cannot be overstated that the complications of the diabetic foot are common, complex, and costly, mandating aggressive and proactive preventative assessments by Physicians. All diabetic patients must have their feet evaluated at least at yearly intervals for the presence of the predisposing factors for ulceration and amputation. If abnormalities are present, more frequent evaluation of the diabetic foot is recommended depending on risk category. It is through systematic examination and risk assessment, patient education, and timely referral that we may further reduce the unnecessarily high prevalence of lower-extremity morbidity & amputation in this subset of population.

REFERENCES

1. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, Boulton AJ:

- Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care* 22:157-162, 1999.
2. Singh N, Armstrong DG, Lipsky BA: Preventing foot ulcers in patients with diabetes. *JAMA* 293:217-228, 2005.
 3. Abbott CA, Carrington AL, Ashe H, Bath S, Every LC, Griffiths J, Hann AW, Hussain A, Jackson N, Johnson KE, Ryder CH, Torkington R, Van Ross ER, Whalley AM, Widdows P, Williamson S, Boulton AJ: The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort. *Diabet Med* 19:377-384, 2002.
 4. Boulton AJ, Kirsner RS, Vileikyte L: Clinical practice: neuropathic diabetic foot ulcers. *N Engl J Med* 351:48-55, 2004.
 5. Boulton AJ, Malik RA, Arezzo JC, Sosenko JM: Diabetic somatic neuropathies. *Diabetes Care* 27:1458-1486, 2004.
 6. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM: Preventive foot care in people with diabetes. *Diabetes Care* 21: 2161-2177, 1998.
 7. Bailey TS, Yu HM, Rayfield EJ. Patterns of foot examination in a diabetes clinic. *Am J Med* 1985;78:371-4.
 8. Payne TH, Gabella BA, Michael SL, Young WF, Pickard J, Hofeldt FD, et al. Preventive care in diabetes mellitus: current practice in urban health-care system. *Diabetes Care* 1989;12:745-7.
 9. Mayfield JA, Rith-Najarian SJ, Acton KJ, Schraer CD, Stahn RM, Johnson MH, et al. Assessment of diabetes care by medical record review. *Diabetes Care* 1994;17:918-23.
 10. Walters DP, Gatling W, Mullee MA, Hill RD. The distribution and severity of diabetic foot disease; a community study with comparison to a non-diabetic group. *Diabet Med* 1992;9:354-8.
 11. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. *Diabetes Care* 1998;21:2161-77.
 12. Meltzer S, Leiter L, Daneman D, Gerstein HC, Lau D, Ludwig S, et al. 1998 clinical practice guidelines for the management of diabetes in Canada. *Can Med Assoc J* 1998;159(Suppl 8):S1-S29.
 13. American Diabetes Association: Peripheral arterial disease in people with diabetes (Consensus Statement). *Diabetes Care* 26:3333-3341, 2003.
 14. Bristow I: Non-ulcerative skin pathologies of the diabetic foot. *Diabetes Metab Res Rev* 24(Suppl. 1):S84-S89, 2008.
 15. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, Landsman AS, Lavery LA, Moore JC, Schuberth JM, Wukich DK, Andersen C, Vanore JV: Diabetic foot disorders: a clinical practice guideline (2006 revision). *J Foot Ankle Surg* 45(Suppl. 5):S1-S66, 2006.
 16. Young MJ, Breddy JL, Veves A, Boulton AJ: The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds: a prospective study. *Diabetes Care* 17:557-560, 1994.
 17. Mueller MJ, Hastings MK, Commean PK, Smith KE, Pilgram TK, Robertson D, Johnson J: Forefoot structural predictors of plantar pressures during walking in people with diabetes and peripheral neuropathy. *J Biomech* 36:1009-1017, 2003.
 18. Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JG: Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Intern Med* 158:157-162, 1998.
 19. Armstrong DG, Todd WF, Lavery LA, Harkless LB, Bushman TR: The natural history of acute Charcot's arthropathy in a diabetic foot specialty clinic. *Diabet Med* 14:357-363, 1997.
 20. Apelqvist J, Bakker K, van Houtum WH, Nabuurs-Franssen MH, Schaper NC: International consensus and practical guidelines on the management and the prevention of the diabetic foot: International Working Group on the Diabetic Foot. *Diabetes Metab Res Rev* 16(Suppl. 1):S84-S92, 2000.
 21. Lavery LA, Peters EJ, Williams JR, Murdoch DP, Hudson A, Lavery DC: Reevaluating how we classify the diabetic foot: restructuring the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 31:154-156, 2008.
 22. American Diabetes Association: Preventative foot care in people with diabetes. *Diabetes Care* 26(Suppl. 1):S78-S79, 2003.
 23. Mayfield JA, Sugarman JR: The use of the Semmes-Weinstein monofilament and other threshold tests for preventing foot ulceration and amputation in persons with diabetes. *J Fam Pract* 49 (Suppl. 11):S17-S29, 2002.
 24. Armstrong DG, Lavery LA, Vela SA, Quebedeaux TL, Fleischli JG: Choosing a practical screening instrument to identify patients at risk for diabetic foot ulceration. *Arch Intern Med* 158:289-292, 1998.
 25. Booth J, Young MJ: Differences in the performance of commercially available 10-g monofilaments. *Diabetes Care* 23:984-988, 2000.
 26. Boyko EJ, Ahroni JH, Cohen V, Nelson KM, Heagerty PJ: Prediction of diabetic foot ulcer occurrence using commonly available clinical information: the Seattle Diabetic Foot Study. *Diabetes Care* 29:1202-1207, 2006
 27. Rith-Najarian SJ, Stolusky T, Gohdes DM. Identifying diabetic patients at high risk for lower-extremity amputation in a primary health care setting. *Diabetes Care* 1992;15:1386-9.
 28. Mueller MJ. Identifying patients with diabetes mellitus who are at risk for lower-extremity complications: use of the Semmes-Weinstein monofilament. *Phys Ther* 1996;76:68-71.
 29. Peters EJ, Armstrong DG, Lavery LA: Risk factors for recurrent diabetic foot ulcers: site matters. *Diabetes Care* 30:2077-2079, 2007.
 30. McGee SR, Boyko EJ: Physical examination and chronic lower-extremity ischemia: a critical review. *Arch Intern Med* 158:1357-1364, 1998.
 31. Khan NA, Rahim SA, Anand SS, Simel DL, Panju A: Does the clinical examination predict lower extremity peripheral arterial disease? *JAMA* 295:536-546, 2006.
 32. Apelqvist J, Castenfors J, Larsson J, Stenstrom A, Agardh CD. Prognostic value of systolic ankle and toe blood pressure in outcome of diabetic foot ulcer. *Diabetes Care* 1989;12:373-8.
 33. Ballard JL, Eke CC, Bunt TJ, Killeen JD. A prospective evaluation of transcutaneous oxygen measurements in the management of diabetic foot problems. *J Vasc Surg* 1995;22(4):485-90.
 34. Goss DE, Stevens M, Watkins PJ, Baskerville PA. Falsely raised ankle/brachial pressure index: a method to determine tibial artery compressibility. *Eur J Vasc Surg* 1991;5(1):23-6.
 35. Andrew JM, Boulton, Comprehensive Foot Examination & Risk Assessment ,10.2337/dc08-9021 *Diabetes Care* August 2008 vol. 31 no. 8 1679-1685
 36. Khan et al., *JAMA* 295:536-546, 2006
 37. Rivers SP, Scher L, Veith FJ. Indications for distal arterial reconstruction in the presence of palpable pedal pulses. *J Vasc Surg* 1990;12(5):552-7.

DRUG PROFILE

DAPOXITINE

Composition: Each film-coated tablet contains: Dapoxetine hydrochloride equivalent to Dapoxetine 30mg

Indications : for the treatment of premature ejaculation in men 18 to 64 years of age.

Dose and administration: Starting dose: 30mg, taken as needed approximately 1 to 3 hours prior to sexual activity. The maximum recommended dosing frequency: once every 24hrs. If the effect of 30mg is insufficient and the side effects are acceptable, the dose may be increased to the maximum recommended dose of 60mg.

Contraindications: Hypersensitivity to the formulation. Significant ischemic heart disease; significant valvular disease. Concomitant treatment with monoamine oxidase inhibitors (MAOIs), thioridazole or within 14days of discontinuing treatment with MAOIs, thioridazole or within 7days after dapoxetine has been discontinued. Concomitant treatment of potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazadone, nelfinavir, atazanavir etc. Moderate and severe hepatic impairment.

Pregnancy and Lactation: Dapoxetine is not indicated for use by women.

Adverse effects: *Very common:* dizziness, headache, nausea *Common:* insomnia, anxiety, agitation, restlessness, libido decreased, abnormal dreams, somnolence, disturbance in attention, tremor, paraesthesia, vision blurred, tinnitus, flushing sinus congestion, yawning, diarrhoea, dry mouth, vomiting, constipation, abdominal pain, abdominal pain upper, dyspepsia, flatulence, stomach discomfort, abdominal distention, hyperhidrosis, erectile dysfunction, fatigue, irritability, increased blood pressure *Uncommon:* depression, depressed mood, nervousness, nightmare, sleep disorder, bruxism, euphoric mood, dizziness postural, ejaculation failure, feeling hot, feeling jittery