Everyday Practice

Multispecialty consensus statement for primary care management of diabetic foot disease in India

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INTRODUCTION
India ranks second in terms of the number of people with diabetes in the world—an estimated 66.8 million with an alarming rise in the incidence of type 2 diabetes mellitus (T2DM), especially among obese people and increasing diabetes-associated complications. In people with diabetes a common complication is diabetic foot disease (DFD). Foot disorders are the leading cause of hospitalizations and amputations with varying prevalence in different countries. In the USA, up to 120 000 amputations are performed every year. People with diabetes have a 10-fold higher risk of amputation compared to those who do not have diabetes. Foot ulcers affect 1 in 4 people with diabetes and approximately 15% of diabetic foot ulcers result in amputation. While diabetes-related amputations occur every 30 seconds, about 85% of these are preventable. Due to social, religious and economic reasons, many people in India walk barefoot. Moreover, poverty and illiteracy lead to the use of inappropriate footwear and late presentation of foot lesions. Diabetic foot care is one of the most ignored aspects of diabetes care in India and many other countries.

Patients try home remedies or visit non-physicians before visiting their physicians for treatment. Amongst Indian urban and rural households, 70% of all visits are to private-sector providers (over public). These include primary healthcare physicians, non-physicians or non-degree allopathic practitioners (NDAPs).

Other factors that add to the problem include low level of medical training among healthcare providers at the primary care level, poor adherence to clinical checklists, absence of DFD in the curriculum of healthcare practitioners (HCPs) and low adoption of existing national and international guidelines due to a non-established patient referral/consultation pathway in DFD. There is also the problem of turf-sharing between multiple specialists, who manage these patients currently. These include plastic surgeons, general surgeons, vascular surgeons, orthopaedic surgeons, podiatrists, diabetes specialists, general practitioners, etc. Evidence-based guidelines or peer-reviewed protocols for
management of DFD at the primary healthcare level do not exist in India.

   It has been established that reduction in the frequency of foot complications, incidence of major leg amputation and in-patient admissions can be achieved by adopting a rational and multidisciplinary approach in the management of DFD.9

   With this background, the expert panel of the Wound Health Council (WHC), comprising representatives from the afore-mentioned specialties attempted to objectively analyse the existing literature, critically review the national and international guidelines and form an evidence-based consensus for DFD with an objective to guide primary HCPs in India (usually the first point of contact for the patient) with the requisite tools to assess, diagnose, manage and prevent DFD and related complications in their clinical practice.

   While the recommendations in this consensus are not intended to dictate the care of all affected patients by primary HCPs, the goal is to provide evidence-based, practical clinical guidance for general practice, which if incorporated into patient management protocols, may lead to better outcomes and a reduction in limb amputations due to diabetes.

PREVENTION AND MANAGEMENT OF DFD

The WHO criteria for the diagnosis of diabetes is fasting plasma glucose (FPG) ≥126 mg/dl or plasma glucose ≥200 mg/dl at 2 hours after a 75 g oral glucose tolerance test (OGTT).10

The circulatory and neuropathic sequelae of diabetes can turn minor breakdowns into severe ulcerations, which may need amputation. Evidence suggests that about 15% of all people with diabetes will develop an ulcer, and about half of all amputations due to diabetes will develop an ulcer, and about half of all amputations are due to diabetes. Evidence suggests that about 15% of all people with diabetes will develop an ulcer, and about half of all amputations due to diabetes.

EARLY DIAGNOSIS AND MANAGEMENT OF DFD

Identification of historical and/or physical findings can improve the prognosis and lead to a favourable outcome through appropriate treatment and early referral. The importance of recognition of risk factors and treatment of DFD is crucial to prevent potential limb loss and/or life-threatening complications.

   Early detection and effective management of diabetic foot ulcers can reduce complications, including preventable amputations and possible mortality.13 Long-term efforts have reduced amputation rates by 37%–75% in different European countries over 10–15 years.14 Even when healed, diabetic foot ulcers should be regarded as a lifelong condition and managed accordingly to prevent recurrence.14

RECOMMENDATIONS FOR DIAGNOSIS AND ASSESSMENT OF DFD

Effective management of DFD requires skills to diagnose, manage, treat and counsel the patient. Assessment of DFD includes carefully recording and reviewing of patient’s history, symptoms and physical signs with the results of necessary investigative procedures.

   An assessment tool may prove to be valuable in evaluating the patient and determining the risk level (Appendix 1; available at www.nmji.in). It is recommended that for adequate evaluation clinicians should at least have the following as a part of their bedside diagnostic armamentarium:15,16 (i) 128 Hz tuning fork and (ii) 10 g monofilament.

Medical history

A thorough medical and foot history must be obtained from the patient.15,16 The history of the patient should cover several issues related to DFD, including some general and specific points (Table I). History of neuropathic and peripheral vascular symptoms should be elicited. History of smoking is important because it may be a risk factor for DFD. Though history plays an important role, it alone is not sufficient for a complete assessment of the risk factors for DFD. A thorough examination of the patient should also be done.

Examination

Along with general physical examination, such as height and weight, all patients with diabetes require a thorough examination of the foot.16,17 Patients should be examined after removing their shoes and socks to avoid missing any foot deformity. Gait and foot arch during movement must be observed too, for abnormal pressure points and deformities. During physical examination of the foot, skin, neurological, vascular and musculoskeletal examination should be done. Dermatological examination should include inspection of dryness or change in skin status and signs of infection or ulceration. Any deformity or wasting should be looked for during musculoskeletal examination. In addition to examination of the foot, footwear should also be examined as it may be responsible for the foot ulcer—especially commonly seen with the use of open slippers or tight Velcro straps.16 Vascular assessment of the foot should be done to check adequacy of blood supply (Table I). The tuning fork and monofilament tests are important in diagnosing loss of protective sensation (LOPS).

### Table I. Key points to be asked for in the history

<table>
<thead>
<tr>
<th>General</th>
<th>Foot-specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes status</td>
<td>Foot ulcer</td>
</tr>
<tr>
<td>Type of diabetes</td>
<td>Injury</td>
</tr>
<tr>
<td>Duration of diabetes</td>
<td>Infection</td>
</tr>
<tr>
<td>Social habits (smoking, alcohol, etc.)</td>
<td>Bleeding</td>
</tr>
<tr>
<td>Allergies</td>
<td>Varicosities (swollen tortuous veins)</td>
</tr>
<tr>
<td>Glycosylated haemoglobin</td>
<td>Pain</td>
</tr>
<tr>
<td>Renal disease</td>
<td>Altered sensation</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>Altered foot grip or mobility</td>
</tr>
<tr>
<td>Stroke</td>
<td>Amputation/foot surgery</td>
</tr>
<tr>
<td>Any other disease</td>
<td>Revascularization</td>
</tr>
</tbody>
</table>

![FIG 1. Possible combinations of anti-hyperglycaemic therapy](image-url)
TABLE II. Physical examination of the foot

<table>
<thead>
<tr>
<th>Skin</th>
<th>Neurological</th>
<th>Musculoskeletal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance: Colour, texture, elasticity, quality, dryness</td>
<td>Vibration sensation: Using a tuning fork (Tuning fork test*)</td>
<td>Biomechanical deformities</td>
</tr>
<tr>
<td>Calluses</td>
<td>Light pressure: Using a 10 g monofilament (monofilament test†)</td>
<td>Gait</td>
</tr>
<tr>
<td>Fissures</td>
<td>Light touch: Cotton wool</td>
<td>Foot deformities such as</td>
</tr>
<tr>
<td>Nails</td>
<td>Pain: Needle prick</td>
<td>Charcot</td>
</tr>
<tr>
<td>Web spaces</td>
<td>Temperature sensation: Hot/cold</td>
<td>Previous amputation</td>
</tr>
<tr>
<td>Hair growth</td>
<td>Deep tendon reflexes: Patella and Achilles</td>
<td>Joint mobility</td>
</tr>
</tbody>
</table>

* Tuning fork test. The tuning fork is struck against the palm of the hand hard enough that it will vibrate for about 40 seconds. The base of the tuning fork is then applied to the patient’s forehead or sternum to ensure that the sensation of vibration is understood. With the patient’s eyes closed, the tuning fork is applied to the bony prominence situated at the dorsum of the first toe just proximal to the nail bed to check if the vibration is perceived. The patient is asked to mention when the vibration stops. One point is assigned if the correct timing of dampening of the vibration is perceived (vibration ‘on’). Another point is assigned if the correct timing of dampening of the vibration is perceived (vibration ‘off’). This procedure is repeated again on the same foot, then twice on the other foot in an arrhythmic manner so the patient does not anticipate when the stimulus is to be applied. This test can be used to rule out the presence of neuropathy.
† Monofilament test. The 10 g monofilament is an objective, simple instrument used in screening for loss of protective sensation (LOPS) in a diabetic foot. The examination should be done in a quiet and relaxed setting and the patient should not be able to see when and where the examiner applies the filament. First, the monofilament is applied on the inner wrist so the patient knows what to expect. This also serves to ‘warm’ the monofilament. Sufficient force is applied to cause the filament to bend or buckle. The total duration of the approach, skin contact and departure of the filament should be approximately 2 seconds. The filament is applied along the perimeter and not on the ulcer site, callus, scar or necrotic tissue. The filament is not allowed to slide across the skin or make repetitive contact at the test site. The filament is pressed to the skin such that it buckles at one of two times as you say ‘time one’ or ‘time two’. Patients identify at which time they were touched. The sequence of application of the filament is haphazard throughout the examination. A site can be repeated to ensure accuracy. At least 10 sites are tested. These sites of testing have been illustrated in the diagrams in Appendix 1. No feeling in less than eight sites is interpreted as LOPS. The monofilament should be wiped with a detergent cloth after use.

Generally, a patient with one or more comorbid conditions should undergo careful foot examination at least once a year. Appendix I (available at www.nmji.in) is a simple tool adapted and simplified from international guidelines,\textsuperscript{15,16} which could be of help in a holistic, systemic and local assessment of the patient with DFD.

On the basis of history, physical examination and assessment, DFD can be categorized into four categories (Table III). Investigations can be recommended based on the risk categorization (Table IV). Appropriate management, including referral or specialist consultation, must be planned.

Recomendations for the management of DFD

The goal of treatment of DFD is to obtain wound healing and closure as early as possible. Complete remission and non-recurrence can lower the chances of amputations in patients with DFD.\textsuperscript{21} The essential components of DFD management are:

1. Wound management
2. Medical management: Glycaemic and infection management
3. Lifestyle modifications: Although recommendations are made here, other currently available therapies should not be ruled out.

Wound management

Off-loading, i.e. effective reduction in pressure, is the main objective of any treatment programme for healing of diabetic foot wounds.\textsuperscript{22} Off-loading is essential and often considered the most important component of the management of predominantly neuropathic planar foot wounds. The neuropathic planar foot wounds may heal satisfactorily, when off-loaded.\textsuperscript{22} With effective off loading, healing can generally be achieved in a period of 6–12 weeks.\textsuperscript{22} The patient may be gradually transferred to appropriate footwear, which may need extra depth or in the case of severe deformity, custom moulded.\textsuperscript{23}

Local wound care should be addressed based on the TIME principle for wound bed preparation.\textsuperscript{24–26} (Tissue, Infection and Inflammation, Moisture and Edge of wound; Table VI).

Treatment of DFD according to foot examination risk categorization, along with points of referral or specialist consultation, is provided in Table V.

TABLE III. Recommended assessment of foot risk in people with diabetes

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No loss of protective sensation (LOPS), no peripheral arterial disease (PAD), no deformity</td>
</tr>
<tr>
<td>1</td>
<td>LOPS or deformity</td>
</tr>
<tr>
<td>2</td>
<td>PAD or LOPS</td>
</tr>
<tr>
<td>3</td>
<td>History of ulcer or amputation</td>
</tr>
</tbody>
</table>

TABLE IV. Recommended investigations

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Ankle–brachial index (ABI)* Monofilament test (to definitively determine LOPS) Complete blood count HbA1c/Random/Fasting blood glucose test Routine urine examination</td>
</tr>
<tr>
<td>1</td>
<td>Same as category 0 and X-ray of the foot and chest preferably refer to a specialist for further evaluation</td>
</tr>
<tr>
<td>2</td>
<td>Same as category 1 and 2D echocardiography preferably refer to a specialist for Doppler and requisite angiogram/vascular checkup</td>
</tr>
<tr>
<td>3</td>
<td>Same as category 2</td>
</tr>
</tbody>
</table>

* Ankle–brachial index (ABI). Ratio of systolic blood pressure (SBP) measured at the ankle to the SBP at brachial artery. The most commonly used ABI threshold is <0.90.\textsuperscript{19} ABI is the ratio of the blood pressure in the lower legs to the blood pressure in the arms. Compared to the arm, a lower blood pressure in the leg is an indication of peripheral arterial disease (PAD). The ABI is calculated by dividing the SBP at the ankle by the SBP in the arm. The patient must be placed supine, without the head or any extremities dangling over the edge of the table. Measurement of the ankle blood pressures in a seated position will overestimate the ABI. A Dopper ultrasound blood flow detector, commonly called Doppler wand or Doppler probe, and a spaghmometer (blood pressure cuff) are needed. The blood pressure cuff is inflated proximal to the artery in question. Measured by the Doppler wand, the inflation continues until the pulse in the artery ceases. The blood pressure cuff is then slowly deflated. When the arm’s pulse is re-detected through the Doppler probe the pressure in the cuff that moment indicates the SBP of that artery. ABI = P_{\text{Ankle}} / P_{\text{Arm}} where P_{\text{Ankle}} is the SBP of the dorsalis pedis or posterior tibial artery and P_{\text{Arm}} is the highest of the left and right arm brachial SBP. The ABI test is a popular tool for the non-invasive assessment of PAD. Skilled operators are required for consistent and accurate results. In a primary healthcare set-up, a BP instrument-based ABI (without a Doppler probe) can be used.
### TABLE VI. Local wound care (TIME principle for wound bed preparation)\(^{24-26}\)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Tissue non-viable (T)</th>
<th>Infection and inflammation (I)</th>
<th>Moisture (M)</th>
<th>Edge of wound (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound factors</td>
<td>Necrotic tissue or slough present</td>
<td>Increased exudates, surface discoloration or increased odour</td>
<td>Risk of maceration (heavy exudates) or desiccation (dry wound bed)</td>
<td>Chronic wound with prolonged inflammation, non-advancing or undermined edges</td>
</tr>
<tr>
<td>Clinical action</td>
<td>Debridement (episodic or continuous) using autolytic, sharp surgical, enzymatic, mechanical or biological agents</td>
<td>Remove or reduce bacterial load by removing infected foci, using topical/systemic antimicrobials and anti-inflammatory agents</td>
<td>Moisture balance to be restored: (i) apply moisture balancing dressings; (ii) compression, negative pressure or other methods of removing fluid, if exudates; (iii) use hydrogels or rehydrants, if dry dessicated wound.</td>
<td>Address T/I/M issues and root cause, with corrective measures including debridement, skin grafts, biological agents and adjunctive therapies</td>
</tr>
<tr>
<td>Wound care options</td>
<td>Hydrogels, silver gels, enzyme debriders, hydrosurgical system, biological agents, other autolytic debriding agents</td>
<td>Silver dressings (including nanocrystalline), silver gels, other antimicrobial dressings, topical steroids (only on specialist’s advice for hyper-inflammatory/eczematous changes(^{25}))</td>
<td>Foam dressings, hydrocolloids, alginates, sterile absorbent pads, collagen dressings, NPWT, hydrogels</td>
<td>NPWT, tissue substitutes, growth factors such as PDGF</td>
</tr>
</tbody>
</table>

NPWT negative pressure wound therapy (technique using a vacuum-enabled dressing to promote healing) with both portable and non-portable options available in the market
PDGF platelet-derived growth factor  PAD peripheral arterial disease

* Patient education\(^{1,11,18,20}\)

- Cleaning
  - Wash and dry feet daily with mild soap and warm water, pat them dry thoroughly and use a lotion on the sole of the foot to prevent skin from cracking. Do not use lotion between toes (for risk of maceration and infection)
- Self-examination
  - Check the condition of the skin (dry/cracked), appearance of blisters, crust, scratches or other sores, redness, warmth or tenderness in any area, ingrown toe nails, corns, calluses, etc.
- Care of toenails
  - Cut toe nails straight across, avoid cutting corners, do not cut cuticles, visit a podiatrist in case of an ingrown nail
- Appropriate footwear
  - Avoid Velcro straps, tight footwear, loose/ill-fitting shoes or open slippers or slippers/sandals with toe-pedicle/separator for grip. Wear comfortable, closed (on all sides) well-cushioned shoes with natural fibre clean socks and wear proper size shoes.
- Contact your physician
  - Physician should examine patient’s feet at every visit. Patient should reach out to the physician in case there are sores and wounds, ingrown toe nails, redness, blackening, bunions, hammer toes, infection, etc.

### TABLE V. Treatment of diabetic foot disease according to risk category and wound type

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Management recommendation</th>
<th>Clean non-infected</th>
<th>Infected</th>
<th>Dry gangrene</th>
<th>Necrotic</th>
<th>Non-responsive</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Patient education* including advice on appropriate footwear</td>
<td>Normal saline to wash, Paraffin gauze + prophy- lactic antimicrobrial dressing</td>
<td>Non-adherent antimicrobial absorbent</td>
<td>NPWT, alginites, foam dressings, sterile absorbent pads</td>
<td>Keep dry and clean</td>
<td>Chemical debridement- papain-urea (enzyme debrider), collagenase</td>
</tr>
<tr>
<td>1</td>
<td>—Consider prescriptive or accommodative footwear</td>
<td>Advanced dressings for infection: Silver (including nano-crystalline) dressings with foam or hydrocolloids (refer to a specialist)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Consider prophylactic surgery (refer to a specialist) if deformity cannot be safely accommodated in shoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Continue patient education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>—Consider prescriptive or accommodative footwear</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Consider vascular consultation for combined follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Same as category 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>—Consider vascular consultation for combined follow-up, if PAD is present</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Diabetic Charcot foot
Charcot foot (neuropathic osteoarthropathy) is a progressive condition characterized by joint dislocation, pathological fractures and severe destruction of the foot anatomy due to involvement of bones, joints and soft tissues of the foot and ankle. This condition can result in debilitating deformity or even amputation. No single cause can be pinpointed for the condition can result in debilitating deformity or even amputation. No single cause can be pinpointed for the development of Charcot foot. Different factors and events such as uncontrolled inflammation in the foot, osteolysis and neuropathy may be associated with its pathogenesis.

Recommendations for the diagnosis and management of Charcot foot
The diagnosis of active Charcot foot is done based mainly on the patient’s history and clinical examination. For confirmation of the diagnosis, imaging is required. X-rays may detect abnormal findings such as subtle fractures or subluxations. In case, no changes are seen on X-rays and the clinician has a strong suspicion then MRI or nuclear imaging may be done to confirm the clinical suspicions.

Although immobilization and stress reduction are the mainstay of treatment for Charcot foot, immediate referral of the patient to a diabetic foot specialist for further evaluation, diagnosis and treatment is recommended.

MEDICAL MANAGEMENT
Glycaemic control
Though glycaemic control is usually supervised by a diabetologist or specialist consultant, one must be aware of the general norms and overall guidelines. The aim is to maintain blood glucose between 140 and 180 mg/dl, which could be self-monitored too. However, the glycaemic targets and blood glucose-lowering therapies are required to be individualized. Similarly, HbA1c targets should be individualized and monitored at least twice a year, since it is a good indicator of consistent blood glucose control over the past 2–3 months. Diet, exercise and education are the foundation of any T2DM therapy programme. Ultimately, many patients will require insulin therapy alone/in combination with other agents to maintain glycaemic control (Fig. 1).

Infection management
Foot infections are common and serious complications in people with diabetes, due to predisposition to infections and poor healing. Patients may present with either local and/or systemic signs of infections. Local signs may include pain or tenderness (might be absent in neuropathy), redness, local oedema, foul smelling purulent discharge, whereas systemic signs may include fever, chills, anorexia, nausea, and sometimes change in mental status.

Medication history should include use of past or current antibiotics by the patient.

Limb infections may be classified into different categories based on severity as below.

The wound management may be broadly divided into medical and surgical management.

Medical management includes use of appropriate antimicrobial therapy for the diabetic wound (Fig. 2), which may be used based on the wound category, with advice from a specialist. An antibacterial agent active against Gram-positive cocci especially methicillin-resistant Staphylococcus aureus (MRSA) may be needed in high-risk patients. Patients with gangrenous and foul-smelling discharge from the wound may need treatment with anti-anaerobic agents. However, the definitive therapy should be selected based on the results of culture and sensitivity analysis.

Moderate-to-severe wound infections in DFD often needs incision, drainage and debridement of non-viable soft tissue and bone. A note of caution would be to avoid use of strong medications or antiseptics such as dettol or iodine DFD.

Lifestyle modifications
Lifestyle modifications such as diet, exercise, cessation of smoking and moderation of alcohol are essential components of management of DFD (Fig. 3). Cessation of smoking should be encouraged in order to decrease the risk of vascular complications.

Recommendations for prevention of DFD
Identifying risk factors is critical for effective prevention of foot disease in people with diabetes.

Based on the presence or absence of risk factors, people with diabetes may be broadly classified into two categories: low risk and high risk. Based on the risk category, the patient may be given an action plan (Table VII). Annual foot examination is recommended for all patients with diabetes in order to identify risk factors which may lead to DFD while those with high-risk of foot disease should undergo more frequent foot examination. Feet of patients with neuropathy should be inspected at every visit, as distal symmetric polyneuropathy is an important predictor for foot ulcer.

SUMMARY
Over the years, there has been an increase in the prevalence of diabetes in India and the numbers are continuously rising. DFD is a neglected aspect of diabetes care in India because of various reasons including absence of awareness, training, guidance or...
the TIME principle, overall glycaemic and infection management with various traditional and advanced wound care options, and lifestyle considerations for the patient. With the tools and approach outlined along with key recommendations, which aims at equipping the first-point contact for DFD with appropriate protocols at the primary healthcare level, it is hoped that the burden and morbidity related to DFD in India would decrease.

Conflict of interest:
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