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[1]—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.[2] Foot ulcerations affect 1 in 4 people with diabetes[3] and approximately 15% of diabetic foot ulcers result in amputation.[4] While diabetes-related amputations occur every 30 seconds, about 85% of these are preventable.[5] 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.[3] Diabetic foot care is one of the most ignored aspects of diabetes care in India and many other countries.[4–6] Patients try home remedies or visit non-physicians before visiting their physicians for treatment.

Amongst Indian urban and rural households, 70% of all visits of patients are to private-sector providers (over public).[7] These include primary healthcare physicians, non-physicians or non-degree allopathic practitioners (NDAPs).[8]

Other factors that add to the problem include low level of medical training among healthcare providers at the primary care level,[7] poor adherence to clinical checklists,[7] 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

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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 aforementioned 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 start with an ulceration.[11] Survival after amputation is poor. Perioperative mortality is 10%–15%, even in developed nations such as the UK.[12]

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 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 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[5] as it may be responsible for the foot ulcer—especially commonly seen with the use of open slippers or tight Velcro straps.[3,6] Vascular assessment of the foot should be done to check adequacy of blood supply (Table II). 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

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

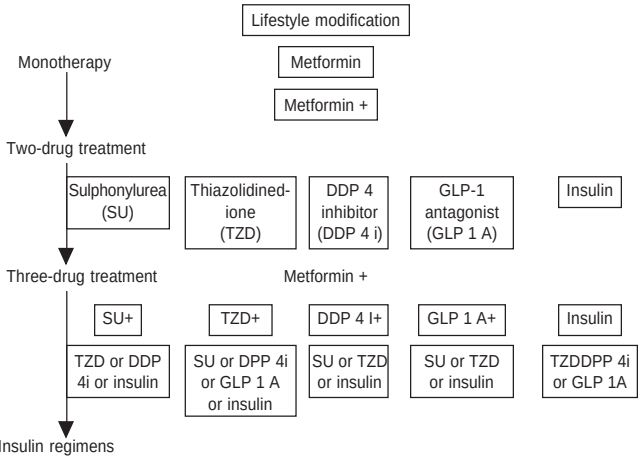

FIG 1. Possible combinations of anti-hyperglycaemic therapy

TABLE II. Physical examination of the foot

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

***** *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 for each vibration sensation 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 in a year. Appendix 1 (available at *www.nmji.in*) is a simple tool adapted and simplified from international guidelines,[15,18] 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.

Recommendations 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.[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.[22] Off-loading is essential and often considered the most important component of the management of predominantly neuropathic plantar foot wounds. The neuropathic plantar foot wounds may heal satisfactorily, when off-loaded.[22] With effective off loading, healing can generally be achieved in a period of 6–12 weeks.[22] The patient may be gradually transferred to appropriate footwear, which may need extra depth or in the case of severe deformity, custom moulded.[23]

Local wound care should be addressed based on the TIME principle for wound bed preparation,[24–26] (**T**issue, **I**nfection and Inflammation, **M**oisture and **E**dge 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

Risk category	Definition
0	No loss of protective sensation (LOPS), no peripheral arterial disease (PAD), no deformity
1	LOPS±deformity
2	PAD±LOPS
3	History of ulcer or amputation

TABLE IV. Recommended investigations

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

* *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.[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 Doppler ultrasound blood flow detector, commonly called Doppler wand or Doppler probe, and a sphygmomanometer (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 artery's pulse is re-detected through the Doppler probe the pressure in the cuff at that moment indicates the SBP of that artery. $ABI_{Leg} = P_{Leg}/P_{Arm}$ where P_{Leg} is the SBP of the dorsalis pedis or posterior tibial artery and P_{Arm} is the highest of the left and right arm brachial SBP. The ABPI 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 V. Treatment of diabetic foot disease according to risk category and wound type

Risk category	Management recommendation	Type of wound					
		Clean non-infected	Infected		Dry gangrene	Necrotic	Non-responsive
			Low exudate	High exudate			
0	Patient education* including advice on appropriate footwear	Normal saline to wash, Paraffin gauze ± prophylactic antimicrobial dressing	Non-adherent antimicrobial absorbent	NPWT, alginates, foam dressings, sterile absorbent pads Advanced dressings for infection: Silver (including nano-crystalline) dressings with foam or hydrocolloids (refer to a specialist)	Keep dry and clean	Chemical debridement–papain-urea (enzyme debrider), collagenase	Growth factors such as PDGF, tissue engineered dermal substitutes
1	—Consider prescriptive or accommodative footwear —Consider prophylactic surgery (refer to a specialist) if deformity cannot be safely accommodated in shoes —Continue patient education						
2	—Consider prescriptive or accommodative footwear —Consider vascular consultation for combined follow-up						
3	Same as category 1 —Consider vascular consultation for combined follow-up, if PAD is present						

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*[3,6,11,18,20]

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 VI. Local wound care (TIME principle for wound bed preparation)[24–26]

Factor	Tissue non-viable (T)	Infection and inflammation (I)	Moisture (M)	Edge of wound (E)
Wound factors	Necrotic tissue or slough present	Increased exudates, surface discoloration or increased odour	Risk of maceration (heavy exudates) or desiccation (dry wound bed)	Chronic wound with prolonged inflammation, non-advancing or undermined edges
Clinical action	Debridement (episodic or continuous) using autolytic, sharp surgical, enzymatic, mechanical or biological agents	Remove or reduce bacterial load by removing infected foci, using topical/systemic antimicrobials and anti-inflammatory agents	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.	Address T/I/M issues and root cause, with corrective measures including debridement, skin grafts, biological agents and adjunctive therapies
Wound care options	Hydrogels, silver gels, enzyme debriders, hydrosurgical system, biological agents, other autolytic debriding agents	Silver dressings (including nanocrystalline), silver gels, other antimicrobial dressings, topical steroids (only on specialist's advice for hyper-inflammatory/ eczematous changes[24])	Foam dressings, hydrocolloids, alginates, sterile absorbent pads, collagen dressings, NPWT, hydrogels	NPWT, tissue substitutes, growth factors such as PDGF

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

Diabetic Charcot foot

Charcot foot (neuropathic osteoarthropathy) is a progressive condition characterized by joint dislocation, pathological fractures and severe destruction of the foot anatomy[27] due to involvement of bones, joints and soft tissues of the foot and ankle.[28] This condition can result in debilitating deformity or even amputation.[27,28] 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.[28]

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.[28]

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.[27]

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).[29]

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.[30]

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.[31]

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.[30]

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.[12,18]

Lifestyle modifications

Lifestyle modifications such as diet, exercise, cessation of smoking and moderation of alcohol are essential components of management of DFD[29,32] (Fig. 3). Cessation of smoking should be encouraged in order to decrease the risk of vascular complications.[33]

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 .[20]

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

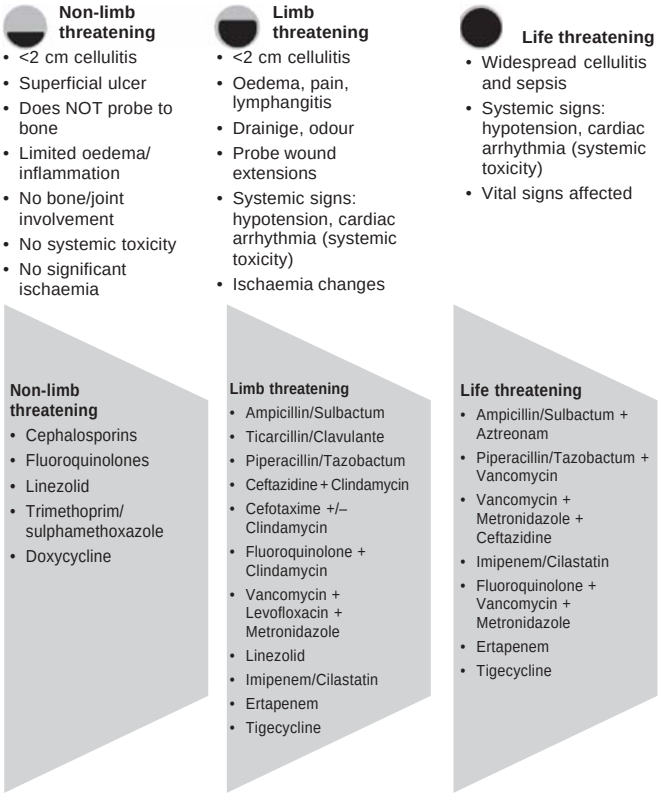

FIG 2. Management of infection

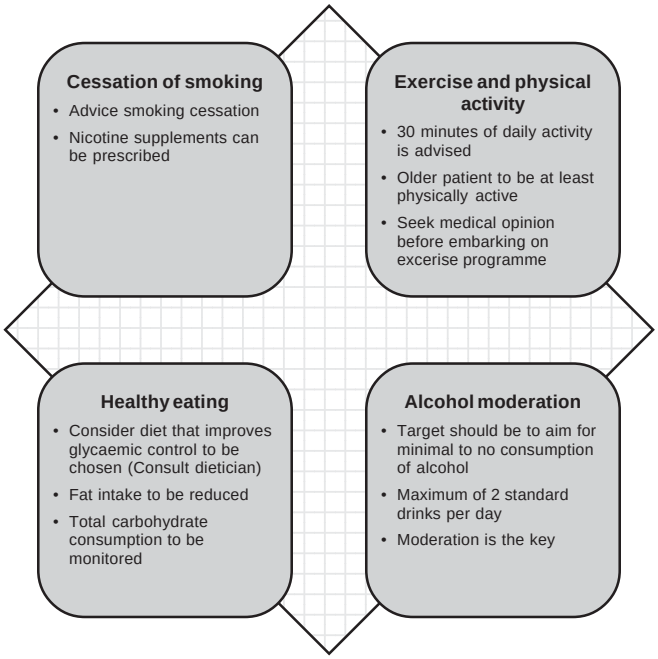

FIG 3. Lifestyle modifications

TABLE VII. Recommendations for prevention

Risk status of patient	Action plan
Low risk, e.g. no loss of sensation, no signs of peripheral vascular disease and no other risk factors	• Annual screening[33] • Agreed diabetes self-management plan • Patient education [33] • Advise appropriate foot care measures[20] —Strictly no barefoot walking (even indoors) —Well padded, broad toed, no metal, enough space in the toe box —No slippers —Sandals/strap-ons with Velcro —No toe separator —Socks mandatory: Clean, soft, thick, white cotton without a tight elastic band —Foot jewellery to be avoided —Avoid oil foot massages, local feet warming at bonfires and colloquial quack remedies
High risk **(o**ne or more risk factors present), e.g. loss of sensation or signs of peripheral vascular disease without callus or deformity, previous ulceration or amputation	• Quarterly assessment by specialist • Agreed and tailored management/treatment plan according to patient needs • Patient education with contact details of emergency medical services[17] • Referral for specialist intervention if/when required • Advise appropriate foot care measures (as for low-risk patients)[20] • Customized off-loading footwear preferred and use toe separators if required

peer-reviewed protocols for management of DFD at the primary care level. Most diabetic foot amputations are preventable with an early diagnosis and a multidisciplinary approach. Timely diagnosis with simple methods, assessment with easy tools and treatment, with judicious referral are essential to prevent complications of DFD and must be started at the primary physician interface. The treatment of DFD consists of local wound care in accordance with 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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