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REVIEW ARTICLE

Diabetic Foot: "The Next Public Health Crisis for India"

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Abstract | Diabetic foot complications remain one of the most common and neglected complications of diabetes. With the increase in incidence of diabetes across South East Asia; especially India, we are staring at a problem which promises to blow up into a massive public health crisis unless all the stakeholders including the Government of India wakes up and takes the necessary initiatives to prepare the Health system to tackle the upcoming "TSUNAMI" of diabetic foot. The below article highlights the magnitude of problem that India faces along with the different ways in which it can be handled. It also talks about the different aspects of diabetic foot and the recent updates and the technology available in India. Even with the surge in technology and improving healthcare system; proper diabetic foot care still remains one of the most difficult services to obtain even in metropolitan cities across India.

Keywords: *Diabetic foot care, Diabetic neuropathy, Amputations, Peripheral arterial disease, Diabetic foot ulceration, Treatment of diabetic foot*

Diabetic foot complications remain one of the most challenging and costly complications associated with Diabetes across the world. India accounts for 1 in 7 of all adults living with diabetes worldwide. Over 1 in 2 (51.2%) adults living with diabetes are undiagnosed. Diabetes has been responsible for 747,000 registered deaths in 2021 in India alone. (IDF-2021 data). The majority of these deaths are due to cardiovascular and diabetic foot complications.

Although the complications of diabetes, like cardiovascular and eye complications, have been getting the required importance, the diabetic foot has been slowly building up in the background and threatens to be the next huge public health "tsunami" that India might be facing in the near future. The fact that India is not ready to face this threat would be an understatement, as the required education, training and infrastructure to diagnose and manage this public health "tsunami" is presently lacking in India.

Diabetes foot problems are common and neglected because of cultural and awareness issues in India. So, half of the people with diabetes have a diabetic foot condition, and half of them have a diabetic foot ulcer, leading to nearly one million registered major amputations annually. Extrapolating the data from the published with reference to the USA, we can estimate that about 1400,000 major and minor amputations occur in India due to diabetes.

Most amputations in diabetics are preceded by foot ulceration. Therefore, a thorough understanding of the causes and management of ulceration is essential. It is estimated that in India, the annual incidence of foot ulcers in diabetes is approximately 19%. Ulcers develop because of internal and external factors, including specific lower limb pathologies and environmental and cultural aspects. Evidence shows that the recurrence of ulcers is most common, so much so that within 2 years of the occurrence of the first ulcer, 50% of the patients end up having a second ulcer.

Diabetic patients need a multi-disciplinary team approach to manage their foot problems. These patients are treated by physicians, general surgeons, vascular surgeons, plastic surgeons, orthopaedic surgeons, podiatrists, orthotists, dermatologists, physiotherapists, and nutritionists.

An in-depth understanding of the etiopathogenesis of foot ulcerations is necessary to prevent them from happening and help patients recover.

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A multidisciplinary approach is one of the main pillars of reducing the amputation rates of diabetic lower limbs in India.

1 Peripheral Neuropathy

Diabetes causes peripheral sympathetic dysfunction, resulting in decreased sweating and dry skin in the foot and lower limbs, increasing the risk of callus formation and xerosis. Warm feet are also observed due to vasoconstriction (in the absence of peripheral artery disease) and small fibre neuropathy, resulting in pain loss of pain and temperature perception. Patients lose the "gift of pain" that protects them from tissue damage. Large nerve fibre dysfunction causes unsteadiness leading to recurrent falls, unnoticed minor injuries and an increased risk of Charcot neuroarthropathy. Motor neuropathy leads to small muscle wasting and a potential imbalance in flexor and extensor function in the foot, which can result in plantar calluses. All the above factors, in turn, lead to abnormal biomechanical loading of the diabetic foot and repetitive soft tissue injury making the foot prone to ulceration.

1.1 Peripheral Arterial Disease

PAD is a major risk factor in diabetics patients with diabetes. In India, around 50% of diabetic foot ulcers are neuropathic, about 15% are ischemic, and the rest are neuroischemic. It is often observed that neuropathy and PAD co-exist, leading to a higher prevalence of neuroischemic ulceration. The accessibility of the patient to a clinical setup that can diagnose and treat such pads will lead to a further decrease in the amputation rates in the diabetic foot.

1.2 Biomechanics and Deformity

Any deformity in a foot with other risk factors increases the risk of ulceration. For example, clawing of the toes, known as hammer toes, is common, leading to increased localized pressures and microvascular injuries, resulting in skin breakdown due to repetitive moderate stress to an insensate area. In addition, repetitive minor trauma can occur as a consequence of high pressures or from ill-fitting footwear.

1.2.1 Other Microvascular Problems

The risk of foot ulceration is known to increase with other conditions. As a result of retinal impairment, visual impairment (sight-threatening diabetic retinopathy) is an established risk factor for foot lesions in the elderly. The most high-risk group for ulceration is perhaps the dialysis population. Diabetic kidney disease and ESRD are independent risk factors for peripheral vascular disease. Haemodialysis further increases the risk of diabetic foot ulceration. At all stages of nephropathy, patients have an increased risk of ulceration.

Preventing unnecessary amputations requires early screening. "A comprehensive foot examination including assessment of neuropathy, vasculopathy, dermatological conditions and biomechanics is the need of the hour. And risk categorizing using standard risk assessment tools must be performed yearly or more frequently if the patient is at risk. Risk stratification using standard risk assessment tools must be performed at least once a year for all diabetic patients, irrespective of the presence or absence of symptoms or signs. Risk stratification of a diabetic foot by assessing the above will help in prognostication and deciding the duration of revisits.

Therapeutic shoes and insoles are the mainstays for preventing diabetic foot ulcers. Therapeutic footwear must be custom designed and fabricated based on the patient's biomechanics, structural foot deformities, joint range of motion, sensory neuropathy and peripheral perfusion.

Evaluation of high-risk patients' footwear, insoles and feet should be a routine part of clinical examinations. In addition, patients with foot ulcers, puncture wounds, ingrown toenails, or infections need a prompt referral to a wound care centre with expertise in DFU.

1.2.2 Off-Loading in Diabetic Foot

Off-loading refers to using devices or surgeries that remove pressure or reduce the "load" at the site of ulceration or callus to improve healing and prevent ulcers from developing. In patients with diabetic sensory neuropathy, the callus is formed at the bottom of the foot where a pressure point is usually located, which are generally unrecognized. These calluses are the precursors for dfus (pre-ulcerative lesions).

When the patient continues to walk on an ulcer, every step crushes new tissue, trying to organize and fill the existing soft tissue void. People without sensory neuropathy find walking on an open wound painful and instinctively avoid any weight-bearing forces on a wounded foot. They alter their gait or limp to protect the injured. In people with sensory neuropathy, however, ulcers are painless and often unrecognized unless they leave a stain on socks or blood on the

floor. They continue to bear weight at the injury site because neuropathy blocks the pain response.

Offloading devices facilitates healing in many ways. The most effective offloading strategies reduce pressure and shear forces at the site of the callus or ulcer. They reduce the movement of the joints of the foot and are usually associated with decreased activity. Reducing pressure and shear forces and decreasing the number of steps or loading cycles per day allows healing tissue to bridge the wound without continual damage. It is one of the most critical interventions for treating foot ulcers. "

2 Debridement

Debridement is the excision of dead, damaged or infected tissues to optimize the healing potential of the remaining viable tissue.

The fundamentals in managing most lower extremity wounds include eradication of infection, optimization of tissue perfusion, and adequate offloading of wounds.

2.1 Types of Debridement

2.1.1 Mechanical

Mechanical debridement is perhaps the oldest form of debridement. It involves using moist or wet dressings, which enables the removal of non-viable tissue and physical disruption to the wound base causing non-selective debridement of loose tissues and sloughing. Typical examples include direct wound irrigation with saline dry dressings and hydrotherapy, including bath and whirlpool treatments. Dressing changes are simple and can be performed by patients independently. Mechanical destruction is considered non-selective and thus may remove or damage healthy tissues if not meticulously performed.

2.1.2 Enzymatic

Enzymatic debridement involves using chemical agents to remove necrotic tissue and slough from the wounds. These enzymes are derived from microorganisms such as clostridium histolyticum or plants, including papain and bromelain.

2.1.3 Autolytic

Autolytic debridement uses the body's enzymatic processes to debride necrotic tissue and slough. This process disrupts dead and devitalized tissue over time by allowing wound fluids to maintain constant contact with the bed to hydrate, soften and liquefy necrotic tissue. With occlusive or semi-occlusive dressings with or without supplementation of hydrocolloids, hydrogels and transparent films, this method is suitable for cases where the amount of dead tissue is not extensive and there is no infection.

2.1.4 Biologic

Biologic Debridement uses medical maggots grown in a sterilized environment in a laboratory. Maggots feed selectively on the necrotic tissue of the host without injuring the living tissue and can quite effectively debride a wound in just a few days. The larvae derive nutrients by secreting a broad spectrum of enzymes that liquefy necrotic tissue for consumption, thus leaving a clean wound free of necrotic tissue.

2.1.5 Surgical

Surgical debridement is the most common type of debridement deployed. A myriad of instruments and adjuncts are used to physically excise non-viable tissue from the wound bed. Then, the surgeon will debride the tissue until viable tissue is visible. In addition, devices such as the micro water jet and ultrasonic debrider have been developed for even more precise and selective debridement.

Surgical debridement is best suited for progressive or recalcitrant wounds, larger-sized wounds, and those in abnormal or precarious locations and grossly infected wounds. Surgical debridement affords superior control over which tissues and how much of them are removed and is the fastest way to achieve a clean wound bed, and can speed the healing process in most patients.

2.2 Management of Infection

About half of the diabetic patients with foot ulcers have clinical evidence of infection. The onset of a diabetic foot infection typically begins with a break in the skin and often spreads to deeper soft tissues, including bone. For people with diabetes, diabetic foot infections (DFI) are the most common reason for hospitalizations and lower-extremity amputations. Recent studies, however, showed that rapid recognition and appropriate management of DFI could usually avert these adverse consequences.

All open wounds will be colonized with microorganisms; therefore, we define DFI's by the presence of classic signs and symptoms of inflammation and infection, including secondary signs such as friable granulation tissue or undermining wound edge as evidence of infection.

Using standard criteria to classify the infection's severity helps define the treatment approach and prognosis. Patients with diabetic foot ulcer (DFU) should be probed for depth and extent and to seek palpable bone, highly suggestive of osteomyelitis. The findings of the systemic inflammatory response, particularly fever or leukocytosis, define a severe infection.

The clinicians should obtain a complete blood count and plain x-rays to look for foreign bodies, tissue gas or bone abnormalities across all cases of Diabetic Foot Ulcers. In addition, diagnosing bone infection may require advanced imaging like MRI or Bone tissue culture.

3 Culture and Sensitivity

A wound specimen is not required for the culture of clinically uninfected diabetic foot wounds because they don't require antimicrobial therapy, but cultures are indicated for all DFI's. Tissue specimens obtained through curettage or biopsy provide more specific and sensitive culture results than swabs. Any superficial swab taken from a diabetic foot wound/ulcer will invariably detect polymicrobial commensals, creating more clinical dilemmas rather than guiding the antimicrobial treatment.

3.1 Treatment of Diabetic Foot Infection (DFI)

The clinician should initiate empiric antibiotic therapy for DFI while awaiting the results of the cultures or any additional diagnostic studies. Most DFI's require systemic antibiotic treatment. The initial parenteral therapy, usually for a few days, is often best; otherwise, oral antibiotics with good bioavailability are sufficient. Choosing a regimen based on the clinical characteristics and severity of the infection, history of recent antibiotic therapy, and local antibiotic resistance patterns is the most important.

Antibiotics treat infections but don't heal wounds or prevent them. Therefore, although a DFI may take months to heal, antibiotic treatment of 10–14 days is sufficient for most soft-tissue infections and treatment for 4–6 weeks is adequate for bone infections.

The biofilm production by causative pathogens appears to contribute to the difficulty in eradicating infections and healing wounds.

Typically, most patients with a DFI require some surgical procedure which ranges from bedside sharp debridement to more extensive operative soft-tissue and bone resections. In addition, surgeons must thoroughly understand how to drain infections that may involve several compartments in the foot.

It is better to perform surgical drainage of deep soft tissue infections, especially abscesses, as soon as possible rather than waiting for the infectious process to cool off with medical treatment. Surgical resections are recommended to be conservative, removing only necrotic tissue while trying to spare as much of the foot.

3.2 Peripheral Arterial Disease

The presence of clearly palpable pedal pulses is reassuring. However, pulse palpation is unreliable for assessing ischemia measurement of skin perfusion, ABI (ankle-brachial index)/TBI (toe brachial index), and thermal imaging, which helps diagnose early signs of PAD.

Patients with foot ulcers and an ischemia grade of 3 will require revascularization. Still, the decision regarding revascularization also depends on the wound stage, presence or absence of infection and a variety of patient factors such as ambulatory capability and age.

In summary, studies have shown that identifying the presence of PAD in patients with dfus and timely revascularization reduces amputation rates. Therefore, patients with DFU where significant ischemia is detected (ischemia grades 2 and 3) should be referred to vascular specialists.

3.2.1 Evidence-based adjunctive therapy for diabetic foot ulcers

Managing dfus is expensive. One in six patients with DFU undergoes an amputation accounting for nearly 100,000 amputations every year in India, making diabetes the leading cause of non-traumatic amputations. It is not yet proven that healing of DFU's improves longevity, but patients with a history of DFU have an increased risk of 5 and 10-year mortality. The estimated cost of standard treatment for one single DFU to heal is 1.37 lacs on average in India. The standard care includes:

- Ensuring good vascular supply, preventing and treating soft-tissue and bone infections.
- Performing initial excisional debridement.
- Maintenance debridement and grafts where ever necessary.

3.3 Charcot Foot (Neuropathic Foot)

Primary care providers need to have a high index of suspicion that a red, hot, swollen foot is

Charcot neuroarthropathy, especially in patients with sensory neuropathy.

Charcot's foot is a fracture dislocation process that affects the bones, joints and ligaments of the foot and ankle, especially in patients with peripheral sensory neuropathy.

The diagnosis of the hot, swollen diabetic foot is often delayed by weeks or months or missed entirely, resulting in severe deformity, loss of function, ulceration, infection, and lower-extremity amputation. One of the most accessible screening tools is to ask whether a patient has symptoms of neuropathy (polyneuropathy—sensory, motor or autonomic) (i.e. numbness, tingling, and or burning sensation) and then to test for sensory neuropathy.

The classic presentation is of a patient with painless unilateral swelling without a history of trauma. However, sometimes the patient will recall an accidental injury, such as a misstep when stepping from a footpath or a slight ankle inversion.

Charcot neuroarthropathy is diagnosed based on medical history, physical examination and plain radiographs. The differential diagnostics diagnoses include cellulitis, deep vein thrombosis and trauma. Patients with an early diagnosis often have routine x-rays and a routine musculoskeletal clinical examination. Untreated injuries have more severe bone and joint damage and dislocations. Clinical examination frequently shows good peripheral pulses and severe sensory loss. Examination of the foot and ankle joints can show abnormal alignment, joint effusion, and painless dislocations. Dislocation at the lis franc joint in the midfoot is a common presentation that can be missed even by experienced radiologists unless concerns about possible Charcot neuroarthropathy are indicated while seeking the study.

Charcot patients sometimes also have ulcerations. The patient may have both disease processes if there is a wound, fractures and dislocations, and cellulitis. Many people with diabetes who have cellulitis do not have leucocytosis, so using this in the decision process will be helpful to confirm infection when there are both leucocytosis and or other systemic signs of infection.

Treatment of Charcot neuroarthropathy requires prompt referral to a podiatric or orthopaedic surgeon with experience in treating this complication. It may take weeks or months for the acute inflammatory process to subside. Late treatment requires reconstructive surgery to repair the deformity and obtain a plantigrade foot.

3.4 Prevention of Re-ulceration

The overall risk of developing a wound in people with diabetes is ~ 2% annually. This risk increases to 7.5% for patients with neuropathy. However, the risk jumps to 40% in people with a history of ulceration. The risk rises to nearly 60% at 3 years and up to 75% at 5 years. Re-ulceration is not only expected, but it is also likely. The goal is not necessarily to prevent every wound but to maximize ulcer-free, hospital-free, and activity-rich days by making each wound recurrence as uncomplicated as possible.

Four key strategies are maximizing ulcer-free days, integrating foot care self-management, therapeutic footwear, and preventive offloading surgery. First, as described earlier, integrated foot care focuses on regular visits to podiatrists and other diabetes foot care team members. Second, self-management involves daily evaluation of the patients, family members and caregivers. Third, therapeutic footwear that offloads the foot by at least 30% appears to be associated with a lower risk of ulcer recurrence. Finally, preventive offloading surgery seems to reduce the severity of deformity and plantar pressure and thus reduce the risk of recurrence.

3.4.1 What Can be Done?

The pillars on which a programme to tackle this public health "tsunami" can be built will have to include -

1. Political will—India is a diverse country with even diverse socio-cultural practices. The political machinery of the state and the centre will have to take it seriously and have to put into action the existing machinery to help organisations like RSSDI, IPA, DFSI to raise awareness.
2. Training the trainers—The medical community, including the paramedical staff, will require to be trained using the resources at hand to come up with strategies to identify high-risk feet and to give appropriate care. The medical colleges' network will have to be used to start at least the basic training as part of the curriculum.
3. Public awareness campaigns—The importance of public awareness programmes should not be underestimated. The campaigns should focus on the do's and don'ts of diabetic foot care for diabetic patients. Foot counselling should become a norm

for all hospitals/clinics dealing with diabetic patients.

4. Improve/tweak the infrastructure—The infrastructure required for diagnosing and treating diabetic foot complications already exists in the PHC/SHC/Medical college set-ups. The responsibility and accountability for using these to treat/screen diabetic foot conditions, however, is lacking.
5. Identifying podiatry/diabetic foot care as a super speciality—The collective will of the political and medical machinery of the state will be required to identify this as a speciality which should pave the way for the training of post-graduates to take up this speciality and start departments in multiple medical colleges which will go a long way in decreasing the amputation rates in diabetic lower limbs.

4 Conclusions and Directions for Future

Diabetic foot complications are common, complex and expensive. Moreover, demographic trends suggest that these complications, including ulcers, infections, PAD and amputations, will continue to be highly prevalent in the coming years.

Future directions should focus not only on promising therapeutic advances but also on novel monitoring and prevention methods. The combination of the evidence-based and common-sense therapies described here with emerging technologies has the potential to help us maximize ulcer-free and hospital-free days for patients with diabetes.

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