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Research

Management of diabetic foot and amputations due to diabetes: Role of prostheses and orthoses

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Introduction

Diabetes mellitus is a major health problem worldwide and especially more so in India. The rising rate of diabetes in India over last few years is alarming. Currently, India is ranked second in terms of the total number of people living with diabetes after China. According to the estimates, there are more than 65.1 million people with diabetes in India [1].Moreover, it has been documented that Asian Indians are at higher risk for type 2 diabetes compared to other races because of genetic predisposition [2].

It is well known that long standing diabetes mellitus can cause numerous microvascular and macro vascular complications. Non-healing ulcers leading to minor or major amputation of (especially lower) extremities is one of the serious complications of diabetes. Though the causes of amputations may differ from country to country, limb loss due to diabetes mellitus remains one of the major health concerns worldwide.

The rates of lower-leg amputation in general population range between 5-25 people per 100 000 while in diabetes it is 6-8 per 1000 population [3]. A retrospective study from Kolkata involving 155 amputation cases showed trauma as the most important cause of amputation accounting for 70.3% cases followed by the second cause peripheral vascular disease[4].Amputations due to diabetes mellitus are not uncommon in India too. Analysis of data from 1295 Indian type 2 diabetes patients who had undergone amputations showed infection in almost about 90% patients while 4.5% had a history of trauma. Major amputations were performed in 29.1% and minor amputations in others. Of the major ones, more than 50% amputations were below knee. Similarly, out of total, over 50% amputations involved toes and rays [5].Demographic features related to amputation have evolved over the years, with older people, patients requiring insulin and long standing diabetes and foot ulcers being more commonly undergoing amputation compared to past[6].Over the years, surgeons' confidence in improved prosthetic outcomes may also have contributed to the increased number of amputations in this population.

Plantar neuropathic foot ulcers in diabetes

Ulcers affecting lower extremity especially in people with diabetes mellitus are a major clinical concern because of its associated morbidity and mortality.

Multiple factors are involved in the pathogenesis of ulcers in diabetes mellitus. Peripheral neuropathy, ischemia due to peripheral vascular disease, trauma, deformity and high plantar pressures are some of the predisposing factors for the development of ulcers in these patients [7, 8]. Neuropathy i.e. damage to the innervations of intrinsic foot muscles can result in foot deformities. Pressure points generated as a result of such abnormalities [7] are generally the sites of ulceration due to skin breakdown over a period of time [7]. For instance, commonly; skin under the metatarsal heads is the pressure point which becomes the sites of ulceration [9].

Pressure mitigation is an important strategy used to prevent/treat foot ulcers in diabetes. Concurrent modalities like adequate perfusion, debridement and infection control are used simultaneously. Novel approaches to stimulate wound healing like new dressings, growth factors, bioengineered skin and tissue substitutes, hyperbaric oxygen, negative pressure wound therapy are also used [10-15] .A large number of pressure mitigation modalities are available: Bed rest, wheelchair use, crutches, total contact cast (TCC), therapeutic shoes, custom orthoses, removable (figure 1) and non-removable walkers. Although TCC is considered by many as a gold standard for pressure mitigation [16-19]. It has inherent barriers when it comes to actual application.

Instant Total Contact Cast (ITCC) which is created by wrapping a removable, prefabricated walker with bandage/casting tape is an alternate option. The ITCC can be a quicker, easier and more cost effective alternative to TCC.However, transitioning of the modalities as the healing progresses is also important. A step down approach could be used where a less intrusive modality is used subsequent to healing progression, the final step being 'maintenance offloading' using shoes or orthoses once the healing is complete [20].

Figure 1: Removable pneumatic walker

Certain design characteristics of special foot wears and insoles designed to prevent formation/recurrence of ulcers is described below. Special footwear, usually with extra wide toe box, extra depth and rocker bottom for easy rollover [21] are useful in relieving peak pressures and thus help in prevention of ulcer in diabetic patients [8]. The deep inserts in special shoes are either flat or molded as per the contours of the patient's foot. A soft material is used to prepare flat inserts in the shoe wears to provide local soft cushioning in the metatarsal region which helps in spreading the load of each head to larger

area to avoid discomfort and future complications [9].

Preventive care

Prevention of ulcer formation is the best way to avoiding intermittent periods of reduced mobility, hospitalization, infections and in a worst case scenario, a major amputation. Patient awareness and education plays an important role in the management and successful outcome of diabetic foot ulcer. The patients should be educated about foot hygiene, daily inspection of the foot for presence of any abnormal sign, and use of properly fitting and comfortable footwear [8].The authors firmly believe that preventive footwear and insoles play such a crucial role in determining prognosis that they cannot be left to be treated by under-qualified technicians. The referring doctors must place a heavy emphasis on design and customization by knowledgeable, qualified professionals who are a part of the multidisciplinary team.

Amputations and selection of amputation levels

Formation of ulcer increases the risk of wound progression eventually leading to amputation. In the diabetic foot patient, about 85% patients have leg ulcer prior to limb amputation [22]. Lower extremity amputations are common, disabling and costly complication of type 2 diabetes[23,24] Moreover, factors increasing risks of amputation in patients with diabetic foot ulcers include irregular monitoring of HbA1c levels, improper footwear, and smoking[25].

Different factors help in determining the level of amputation. The important criteria include clinical examination, presence of circulation as determined by various investigative methods (e.g. Doppler, venography etc) and the experience of surgeon [26]. Risk of complications and secondary amputation are also considered while deciding the site of amputation. Once the decision of amputation is made the site of amputation is selected to create a stump which provides good place for prosthetic attachment [27].

The amputations of lower extremity owing to diabetes can be broadly classified into three types; toe and partial foot amputations, Transtibial (below knee) amputations and transfemoral (above knee) amputations.

Hind foot amputations are generally considered for people with poor mobility and poor vision because of the possibility of ambulation without a prosthesis. When the surgical wound is healed, patients are offered customized shoes and they are encouraged to walk for short distances [28].

Trans-metatarsal amputation, another surgery in diabetes patients is debated due to high risk of requirement of extra surgery. However, if the procedure is successful, these patients can have good quality of life and can go back to previous lifestyle. A study evaluating outcomes of trans-metatarsal amputations in 46 patients with diabetes showed 26% required higher amputation level and another 22% required a wound revision. The patients in whom the original amputation level was maintained were able to walk without prosthesis [29]. The orthosis/footwear, if used to treat toe and partial foot amputations must consider the altered biomechanics as well as patient prognosis.

Modified Pirogoff's amputation is an effective method for the management of diabetic foot infections in properly selected patients. This procedure is useful in patients having palpable posterior tibial pulse, ankle brachial index more than 0.7, good haemoglobin level and distal infections not extending proximally beyond the midfoot level. Good wound healing and tibio-calcaneal arthrodesis of the stump can be achieved in these patients [30]. Patients can ambulate without prosthesis at home. For ambulation in community and in workplace, the authors recommend using prosthesis. Provision of a prosthetic foot can replace the important biomechanical function of roll over, leading to a natural walking pattern and protection of the intact leg from extended loading time.

Of the different approaches, transtibial amputation is preferred due to easy prosthetic fitting.Transtibial amputation may provide similar mobility and quality of life and fewer complications and re-amputations compared to partial foot amputations [31] Further, the authors experience of treating several diabetic transtibial amputees suggests that with the availability of modern technology, a comfortable prosthesis can be provided to these patients. A customised, light weight functional prosthesis using modern technology can help restore mobility and self-confidence for patients and improve quality of life. Transtibial amputation is generally performed at the junction of the upper and middle third of the tibia.

A prospective study among 151 patients evaluated the factors affecting the clinical outcome of below knee amputations in diabetic foot patients. Overall, outcomes were good in 73.5% patients. This prospective study has shown that about half patients undergoing below knee amputation due to diabetic foot can attain mobility with prosthesis after one year [32].

Generally when the transfemoral amputation is performed, the residual limb length of minimum 4-6 inches from the groin is left in order to fit the prosthesis [33].

Expectations from prostheses

The prosthesis must help in ambulation and all types of movements without significant discomfort and improve the quality of life of the amputee. Ambulation and self-esteem derived out of independence in day-to-day activities are factors critical to control blood sugar levels in diabetic amputees. It is important that the prosthesis prompts prosthetic user to spend equal time on both feet. If the 'intact' foot has to carry body weight for a longer time, then its condition is bound to deteriorate eventually. In most amputations, the 'intact' contralateral foot will also be affected because of the unequal distribution of forces [34]. Protection of the 'intact' leg is an important function that the prosthesis has to carry out.

Having said this, while evaluating outcomes of prosthetic rehabilitation, one must also consider that prosthesis alone is not responsible for poor functions in amputees. Many patient-related factors also play a role in post-prosthetic ambulation. Elderly people, those with depression, dialysis, chronic obstructive pulmonary disease create limitations in mobilization, though most people have uneventful prosthetic fitting by one year after lower limb amputation [35].

Prosthetic Rehabilitation

The loss of entire or part of limb is a catastrophic event for a patient because it limits physical activities and poses psycho-social challenges. The challenges need to be overcome by coordinated efforts of medical professional, para-medical staff and patient himself as well as his family.

Choice of a Prosthetic prescription is determined by factors like patient's mobility grade (indoor mobility/everyday activity/active user), residual limb condition and the patient's expectations from the prosthesis. In the authors' opinion, following prosthetic factors play a key role in producing a positive prosthetic outcome:

a. Pre-amputation counselling and rehabilitation goal setting with patient & carers

Alignment of patient's and carers' expectations from prosthetic rehabilitation with what is actually 'achievable' is extremely important. Consultations by experienced, qualified prosthetists or peer members can prepare the patient in advance and avoid much anxiety and fear that ensues following the amputation. A goal-oriented rehabilitation plan at this stage can help speed up the recovery and eventual prosthetic rehabilitation.

b. Pre-prosthetic preparation: therapy to prepare the patient for an early prosthetic fitment

The time between amputation to actual prosthetic fitment can extend from a few weeks to months. In an Indian setting where the patient is discharged after amputation with less or no access to therapeutic intervention, he/carer must be informed about importance of oedema control, balance and strengthening and skin care and hygiene. This can reduce the time required for prosthetic fitment.

The skin of the residual limb is highly susceptible to complications. However, skin disease and stump site pain may delay mobility. This skin needs to be adjusted to the humid environment inside the prosthetic socket. Moreover, it has to survive in presence of compression and friction during walking and standing. Presence of diabetes increases the risk of complications due to immunological alterations. Considering these factors, the objective of the rehabilitation is to increase adaptation and durability of the amputation stump by decreasing the rates of skin complications[36].

c. Thorough clinical assessment and selection of components by a qualified and experienced professional

Appropriate choice of prosthetic socket design and technology as well as functional components is extremely important. For example while choosing socket design for a diabetic amputee, choice of suitable interface material can protect the residual limb skin from friction and shear that is encountered in the prosthesis. Use of skin friendly, non-allergenic gel liners (Fig 2) is prevalent in developed countries, slowly also permeating in Indian situation. Socket design itself plays a key role in reducing peak pressures. With advent of vacuum assisted suspension systems, more effective suspension can be provided. A better suspension promotes the feeling that the prosthesis is a part of the body itself and improves proprioception, thus enhancing outcomes.

Figure 2: Soft liners as interface between prosthetic socket and residual limb

Soft liners provided as an interface between prosthetic socket and residual limb provide comfort to the patients and prevent repeated injuries to the stump during movements (figure 2).

Similarly a light-weight prosthetic foot will help reduce 'feeling of weight' of the prosthesis, hence impacting wearing time. Use of energy returning materials and components will help reduce energy cost of walking, again contributing to increasing the usage time. A foot with a soft heel will help reduce the impact on the residual limb at the time of heel contact, thereby offering protection.

d. A comfortable and functional prosthetic fitment & usage training

A comfortable, well-fitting socket will prompt the patient to wear it for longer hours and thus improve his mobility and independence. Conversely, a poor socket fit results in discomfort, gait abnormalities and difficulty in performing routine work [37]. Hence it is important that the fitting prosthetist is sufficiently skilled and delivers staged, customised usage training to the patient.

e.Scheduled follow-up with prosthetic adjustments whenever necessary till full rehabilitation is achieved

Prosthetic rehabilitation is an ongoing process. The patient's body and requirements change from time to time. Scheduled follow ups are necessary to align the prosthetic function with these ever-changing requirements.

Disease prevention in general

Medical and surgical complications resulting in readmission is a common problem after lower extremity amputations [38]. Amputations may also result in serious complications including mortality. A systematic review has shown five year mortality rates of 40-82% and 40-90% after below-the-knee and above-the-knee amputation respectively. Higher rates of mortality are seen in elderly people and those with renal disease, proximal amputation, and peripheral vascular disease [39].

In order to reduce the rates of amputation, it is important to prevent the diabetic complications. Regular monitoring of HbA1c levels is important [25] along with the tight control of blood sugar level. Educational programs and increasing awareness, examination of diabetic foot during each visit will be useful in preventing the diabetes related complications. Preventive diabetic foot services and identification of diabetic foot at risk should be the priorities for effective approach of preventing amputations [3].

Up to 88% of all diabetes-related amputations have been shown to be preceded by foot ulcers [24]. In patients with diabetic foot/ulcer, good wound care helps in healing in large number of patients while some require longer duration of therapy and different therapeutic measures such as special wound dressings or wound medication for promoting wound healing. Measures should be taken to decrease the wound healing time in diabetic ulcers to reduce secondary infection which is the most common cause of major amputation in these patients [40].

Overall, patients with high risk of limb amputation should be identified and preventive treatment should be started at the earliest [24].

A multi-disciplinary team involving experts from different domains such as orthopedicians, vascular surgeons, diabetologists, infectious disease specialists, and a specialized nursing staff should work together for reducing the rates of amputations in diabetes patient [22].

Summary

Diabetes mellitus is a major health problem globally including in India. Chronic diabetes mellitus can cause numerous complications including non-healing ulcers requiring amputation of limb (especially lower limb). Pressure mitigation (wheelchair, crutches, total contact cast etc), along with other approaches is an important aspect in the treatment of ulcers in diabetes. Instant Total Contact Cast (ITCC), is a better option compared to total contact cast due to challenges associated with routine use. Maintenance offloading with shoes or orthoses after complete healing is critical to prevent recurrence of ulcer. In this regard, special foot wears and insoles play an important role. Emphasis should be given on the design and customization of preventive footwear and insoles, considering its crucial role in the management of diabetic ulcers. If amputation is inevitable, the site of amputation should be such that the stump provides good place for prosthetic fitment (e.g transtibial amputation) and need for repeated surgical interventions is avoided. A customised, light weight functional prosthesis using modern technology, soft liners between prosthetic socket and residual limb can help in comfort and better outcome. Ongoing prosthetic rehabilitation is another important aspect in overall management of patient. Educational programs and mass awareness are useful to reduce burden of the disease.

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