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A study on non-healing plantar diabetic foot ulcers to assess the effect of compliance of using customised footwear in wound healing

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ABSTRACT

Background: Foot infection is one of the commonest reasons for hospital admission of individuals with diabetes in India. Prescription footwear is an intricate aspect of a treatment program, not a therapy unto itself. Custom-made footwear can only be effective in preventing diabetic foot ulcers if worn by the patient as advised. This study was done in patients who are already prescribed customised footwear and evaluated the need for compliance based on the healing of these plantar foot ulcers.

Methods: 85 diabetic patients with severe neuropathy and a non-healing callus ulcer or trophic ulcer (diameter 1-3 cm) for more than 3 months were included in the study. All these patients were followed up on weekly basis for 3 months and questioned about the use of customized footwear on regular basis. At the end of three months, the healing of these foot ulcers was compared based on whether they had been compliant with the customized footwear advice.

Results: Of the 85 patients, 25 (29.4%) had shown improvement in wound healing with regular use of footwear. 60 (70.5%) patients who were not using the customized footwear had not shown any improvement in the plantar ulcers. The reasons for not using the recommended footwear were many commonest being wearing footwear only when going out and not inside the home.

Conclusions: Non-compliance with customised footwear is emerging as an important cause of delay in wound healing of plantar foot ulcers.

Keywords: Customised footwear, Compliance, Diabetic foot plantar ulcers

INTRODUCTION

The study was done to assess the improvement in wound healing of non-healing diabetic foot ulcers in patients with compliance of using customized footwear. Selected patients are those who are already prescribed customized footwear and then evaluation is done to assess compliance based on the healing of these plantar foot ulcers. The "diabetic foot syndrome" and attendant sequelae account for direct medical expenditures of hundreds of millions of rupees annually, long hospital stays, and lengthy periods of disability.¹⁻³ Unfortunately, many of these patients will require lower extremity

amputation at some level as a consequence of fulminating infection or peripheral ischemia, in concert with neuropathy as a predisposing factor. Foot ulceration is recognized as one of the major risk factors for amputation. 4-6

Although the triad of neuropathy, deformity, and trauma are frequent component causes in its pathogenesis, the diabetic foot ulcer can further be attributed to numerous other important risk factors.⁷⁻¹¹ Early detection of these risk factors as well as of foot ulcers themselves are key components in the overall management of diabetic foot disorders and amputation prevention programs.¹²

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Appropriate relief of pressure and off-loading the wound should be initiated at first presentation. Ill-fitting footwear should be discarded and replaced with a surgical sandal, wedged surgical shoe, or other type of temporary footwear that can accomplish the goal of removing pressure from the foot ulcer. 13,14 When the lesion is on the dorsum of a toe or on either side of the foot, a simple cutout can be made in the patient's shoe. If total non-weight bearing with crutches is not feasible, a pressureattenuating felt, foam, or plastazote insert should be used in the surgical shoe. However, the total-contact cast (TCC) is considered the optimal method to protect the nonischemic ulceration during ambulation by virtue of its ability to redistribute high pressures from under the ulcer to the entire foot and leg encompassed by the cylindrical cast.15 Acceptable alternatives to the TCC are the scotchcast boot or removable walking brace.¹⁵ However, any removable device raises the concern for patient noncompliance with the prescribed off-loading therapy.

METHODS

This was a prospective study conducted in Amrita Institute of Medical Sciences, Kerala from May to July 2008. Total of 85 diabetic patients with a plantar non healing foot ulcer from 3 months with VPT >25 V were included in the study. Those patients with ulcer extending to the dorsum foot and the patients with gangrene on any toe were excluded from the study.

Age, sex, type/duration of diabetes, cause of ulceration, duration of ulcer, previous history of ulceration, presenting signs and symptoms of ulceration and previous treatment and socioeconomic status of the subjects were recorded. All the diabetic patients included in the study were evaluated with basic investigations to assess the renal function and status of anaemia.

Each patient underwent assessment of the vascular status by manual palpation of femoral, popliteal, dorsalis pedis and posterior tibial arteries to define patency and grades good volume, diminished volume or absent.

All these patients were subjected to biothesiometer. They had vibration perception threshold (VPT) of more than 25V. The patients were treated with relevant antibiotics if infected and educated comprehensively about the need for foot care. All were prescribed customized footwear according to their size and site of the ulcer as well as pressure points on biothesiometer. They were followed up every week with counselling on the use of footwear and footcare. After 3 months, they were asked some questions regarding compliance with footwear. The compliance was correlated with the healing of the plantar foot ulcers.

RESULTS

Patients included in the study were between 40 years to 80 years. Those in the 40-50 years age group were 15

(17.6%), 51-60 years were 41 (48.2%), 61-70 years were 16 (18.8%), 71-80 years were 13 (15.2%) (Table 1).

Table 1: Age distribution of the patients.

Age (in years)	No . of patients
40-50	15
51-60	41
61-70	16
71-80	13

There were 47 (55.2%) males and 38 (44.7%) females among the selected patients.

Table 2: Distribution based on gender of the patients.

Gender	Patients
Males	47
Females	38

Among 85 patients, 25 (29.4%) had wound healing whereas 60 (70.5%) has non healing wounds. All the patients had taken the prescribed medicines appropriately but there was difference in the compliance with the prescribed customized footwear.

Table 3: Healing based on compliance with customised footwear.

Compliance	Healed wounds	Unhealed wounds
Compliant	25	0
Non-compliant	0	60

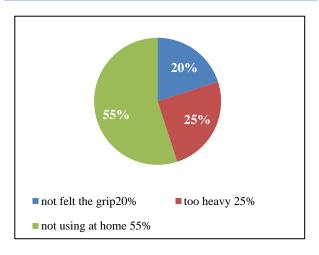


Figure 1: Reasons for non-compliance.

The reasons given for not using the recommended footwear were multiple with 12 patients saying they could not feel the grip while walking with the customized footwear. 15 patients mentioned that the footwear was quite heavier than the regular ones and 33 patients were using the footwear only when going out and not inside the home.

DISCUSSION

In this study, it was observed that though the treatment was similar to all the patients based on their clinical condition, except for the customized footwear which was tailored to the need of the individual, wound healing was the end result in only 29.4% of the patients who were strictly compliant with the wearing of footwear.

It is very obvious evident that compliance with customised footwear has a bearing on the healing of wounds as it was observed that patients who were not regularly using these did not have wound healing although they took other prescribed medicines appropriately. The reasons for non-compliance were ranging from not being able to feel the grip, too heavy than the previous footwear to non-usage at home. Females especially deferred from using the footwear inside the homes.

A 2014 study noted that, among 153 Dutch patients with diabetes presenting at a foot clinic, footwear use was low to moderate, with patients wearing the shoes for less than 60% of their daytime hours. Another study evaluated the thinking behind patient noncompliance, noting that those at risk for diabetic ulcerations often based their decision on the immediate risks and benefits of wearing the shoes. In other words, the threat of a future ulceration may not be enough to ensure compliance.

Patients may abandon their prescribed therapeutic footwear the minute they are home, either for cultural reasons or because they think the home is a safe environment. For example, a guideline published by the International Working group on the diabetic foot 18 states that custom-made footwear is recommended for patients with diabetes, peripheral neuropathy, and foot deformity to prevent foot ulceration, infection, and amputation. In addition, footwear that does not meet the needs of these patients can increase ulcer risk by increasing foot pressures.

In conclusion, the study emphasize that prescription of a customised footwear catering to the individual needs as well as ensuring that they are compliant with the use of such footwear would lead to improvement in number of patients with healed plantar ulcers and the global burden on health expenditure as well as the number of amputations would be reduced dramatically.

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Institutional Ethics Committee

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