Perceived role of therapeutic footwear in the prevention of diabetic foot ulcers: A survey of patients with diabetes mellitus in Kaduna State

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ABSTRACT

Background: There is a paucity of literature about the status of therapeutic footwear and their role in prevention of diabetic foot ulcers in Nigeria. The purpose of this study is thus 2-fold. (1) To determine the perceived role of therapeutic footwear in the prevention of foot ulcers among patients with diabetes mellitus, (2) to establish strategies that will encourage the use of therapeutic footwear in the prevention of diabetic foot ulcers. Materials and Methods: This cross-sectional study was carried out among patients with diabetes mellitus in Kaduna state, between December 2012 and March 2013. All the participants in this study had a history of foot ulceration. Exclusion criteria were patients with amputations and non-ambulatory status. Pre-tested questionnaires were used to collect data. The questionnaire was divided into four sections. The first section illustrates the demographics of the respondents. The second section explores the anatomic location of diabetic foot ulcers. The third section evaluates the type of regular footwear worn and experience of participants. The fourth section explores the awareness of respondents regarding therapeutic footwear features. Simple descriptive statistics were used; frequency with percentage distribution for categorised variables. Results: The anatomic subunit in the plantar surface with the highest number of ulcer was the phalanges 23% in males and 26% in females. In the dorsolateral surface, the phalanges 22% and 17% were the most common location in males and females, respectively. Slippers were regularly worn by 71% of respondents, whereas only 1% of respondents were reported to wear therapeutic footwear. More than 75% of respondents were willing to use footwear, as well as buy therapeutic footwear. Conclusion: Majority of the patients are reported to have foot ulcers located on the phalanges and these are related to the wearing of inappropriate footwear. However, they are willing to use therapeutic footwear if recommended by a physician. Key Words: Diabetes mellitus, diabetic foot ulcers, prevention, therapeutic footwear

INTRODUCTION

Diabetes mellitus is a global health problem that is associated with disabling foot complications.1,2 An estimated 15% of patients with diabetes mellitus will develop a foot ulcer during their lifetime.3 This imposes a huge burden on the patient and the health-care system, with increased risk...
for amputation, lower health‑related quality of life and high treatment costs.[1‑3] Established risk factors for developing foot ulcers and subsequent amputation include peripheral neuropathy, peripheral vascular disease and repetitive trauma to the foot.[1‑3] Significant progress has been made in the treatment of neuropathic ulcers by better methods of microbiological control, localised wound care and treatment of arterial disease by revascularisation. However, these treatment modalities are not readily available in most developing countries.[4‑5]

A frequently referenced component in the prevention of diabetic foot ulcers is the use of therapeutic footwear.[4‑5] Current literature suggests that use of proper footwear plays a vital role in the prevention of foot lesions by reducing ulceration associated with peripheral neuropathy and that it is also essential in the maintenance of an intact foot once an ulcer has healed.[6‑8] Thus, footwear should be designed to relieve pressure areas, reduce shock and shear forces and be able to accommodate foot deformities by supporting and stabilising them.[9,10] It is necessary that shoes fit for both size and shape.[9,10] When footwear is fitted properly, it can reduce high‑pressure areas and hence reduce callus formation and the threat of ulcer formation. It will also fulfil its function as a barrier to the environment.[11,12]

Nigeria is Africa’s most populous Nation with an estimated 3 million patients with diabetes mellitus.[13] Despite their broad appeal and importance, there is a paucity of literature about the status of therapeutic footwear and their role in the prevention of diabetic foot ulcers in Nigeria.[14]

The purpose of this study is thus 2‑fold. (1) To determine the perceived role of therapeutic footwear in the prevention of foot ulcers among patients with diabetes mellitus, (2) to establish strategies that will encourage the use of therapeutic footwear in the prevention of diabetic foot ulcers.

**MATERIALS AND METHODS**

This cross‑sectional study was carried out among patients with diabetes mellitus in Kaduna state, between December 2012 and March 2013. All the participants in this study had a history of foot ulceration. A foot ulcer was defined as a skin defect that penetrated its full thickness and took more than 30 days to heal (the duration was used to exclude minor skin trauma from being falsely classified as a diabetic foot ulcer).[15] Exclusion criteria were non‑ambulatory status. Ethical approval for this study was obtained from Ahmadu Bello University Teaching Hospital, Zaria, and the Ministry of Health Kaduna state, Nigeria. Pre‑tested questionnaires were used to collect data. The questionnaire included multi‑choice questions and closed questions with the answer options as Yes or No as well as a range of open‑ended questions. The questionnaire was divided into four sections. The first section illustrates the demographics of the respondents. The second section explores the anatomic location of diabetic foot ulcers.[16] Three views of the foot; plantar, dorsal‑lateral and dorsal‑medial were presented to the participants to indicate the most recent location of a foot ulcer. Each view is subdivided into anatomic units.[16] Plantar surface (anatomic units 1–7) [Figure 1]; dorsal‑lateral surface (anatomic units 8–14) [Figure 2] and dorsal‑medial (anatomic units 15–21) [Figure 3]. The third section evaluates the type of regular footwear worn and experience of participants. Qualitative analysis of written responses and comments on the experience of participants with regular footwear were segregated into three distinct themes. The utility of regular footwear, influence of footwear on developments of foot ulcers and perceived role of therapeutic footwear in the prevention of diabetic foot ulceration. The fourth section explores the awareness of respondents regarding therapeutic footwear features. Before completing the questionnaires, participants were provided with instructions regarding the nature of the study, the informed consent process and confidentiality of personal data. To maintain confidentiality, questionnaires were made anonymous. Data were analysed with Excel 2010. Simple descriptive statistics were used; frequency with percentage distribution for categorised variables.

**RESULTS**

One hundred and eighty‑four questionnaires were distributed, and 156 were completed and returned, giving a response rate of 85%. The mean age of the respondents was 54.1 years (male 55.3 and female 52.9 years). Seventy‑five respondents (48%) were males and 81 (52%) were females. The duration of diabetes mellitus was a mean of 7 years, with 93% of respondents being classified as Type 2 and 7% classified as Type 1 diabetes mellitus [Figure 4].

Majority of the respondents had ulcers in the plantar surface of the foot. The anatomic subunit in the plantar surface with the highest number of ulcer was the phalanges 23% in males and 26% in females [Table 1]. The lateral midfoot subunit accounted for the least number of ulcers in the plantar surface of the foot; males (8%) and females (9%). In the dorsolateral surface, the phalanges (22%) and the medial midfoot (19%) were the most common location of ulcers in males, whereas the phalanges (17%) and the heel (16%) were the most common location of ulcers in females [Table 1].
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The anatomic subunits with the highest number of ulcers in the dorsomedial surface were the phalanges and the heel 41% and 31% respectively. Only 9% of males had ulcers located at the instep, whereas 13% of females had ulcers located around the Achilles subunit [Table 1].

The distribution of the most common footwear worn by gender is shown in Figure 5. The reported shoe types most frequently worn by men were sandals (35%), slippers (26%) and half shoes (17%) [Figure 6]. The three most common shoe types that women were reported to wear were slippers (45%), sandals (24%) and half shoes (18%). Slippers were regularly worn by 71% of respondents, whereas only 1% of respondents were reported to wear custom-made or therapeutic footwear.

Thematic analysis of the experience of participants with regular footwear is summarised in Table 2. They are in descending frequency (total number of responses): Utility of non-therapeutic footwear (56%), influence of footwear in ulceration (23%) and awareness of appropriate footwear (21%).

Only 28% of males and 34% of females were aware that their shoes may need modification to accommodate the feet well. More than 50% of the participants were not aware of the

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**Table 1: Anatomic location of diabetic foot ulcers based on gender**

| Anatomic subunit                  | Male (%) | Female (%) |
|-----------------------------------|----------|------------|
| Plantar anatomic subunit          |          |            |
| Hallux                            | 16       | 11         |
| 2-5th phalanges                   | 23       | 26         |
| 1st metatarsal                    | 15       | 14         |
| 2-5th metatarsal                  | 08       | 12         |
| Medial midfoot                    | 14       | 14         |
| Lateral midfoot                   | 08       | 09         |
| Heel                              | 16       | 14         |
| Dorsolateral anatomic subunit     |          |            |
| Phalanges                         | 22       | 17         |
| Medial metatarsals                | 08       | 15         |
| Lateral metatarsals               | 08       | 15         |
| Medial midfoot                    | 19       | 13         |
| Lateral midfoot                   | 08       | 12         |
| Achilles                          | 16       | 15         |
| Heel                              | 13       | 16         |
| Dorsomedial anatomic subunit      |          |            |
| Phalanges                         | 26       | 15         |
| Lateral metatarsals               | 10       | 14         |
| Medial metatarsals                | 13       | 15         |
| Medial midfoot                    | 13       | 14         |
| Instep                            | 09       | 14         |
| Achilles                          | 13       | 13         |
| Heel                              | 16       | 15         |
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need to wear socks regularly. Majority of the participants 88% of males and 94% of females were not aware that diabetic patients may require different sizes of shoes for the left and right foot. More than 75% of respondents were willing to use footwear with extra insert materials as insoles, as well as buy therapeutic footwear, if recommended by a doctor [Table 3].

DISCUSSION

In this study, majority of the respondents had ulcers on the phalanges of the feet. This is consistent with the findings by Beuker et al.[17] that foot ulcers in diabetic subjects commonly occur in the forefoot [Figure 7].

The neuropathic foot is characterised by loss of motor and sensory nerve function. [18] Several detailed reviews suggest the pathogenesis of diabetic foot ulcers may involve atrophy of the intrinsic muscles of the foot and limited joint mobility as a result of motor neuropathy. [1,2,19] These features lead to prominent metatarsal heads and clawing of the toes, making the foot unable to normally distribute pressure during weight-bearing. [19] With this structural deformity, higher than normal pressures occur at the metatarsal heads and the hallux during the active propulsion phase of the gait cycle. [20] When these elements are combined with repetitive stress, tissue production can exceed tissue degeneration resulting in skin that is physically harder and less elastic. [19] Overactivity of this keratinisation process remains adaptive,
but can become maladaptive as ultimately signified by the necrosis of tissue.\cite{21,22} Normally, injury to tissue would warn the individual with painful sensations, but in those with sensory neuropathy from diabetes, this warning does not exist.\cite{18,23} Relief of pressure with appropriate footwear is generally accepted as an effective modality in the prevention of diabetic foot ulcers.\cite{24} Pressure-relieving therapeutic footwear provides proper fit and prevents foot ulceration by reducing peak pressures at high-risk fore-foot sites through pressure redistribution.\cite{20,21,24}

This study indicates that therapeutic footwear was the least frequently worn. This finding is similar to an earlier study which revealed that the use of protective footwear was sub-optimal among diabetic patients.\cite{25} Friction from regular footwear was identified as the definite cause of 35% of foot ulcers reviewed in a prospective study conducted in the United Kingdom. Similarly, the follow-up of 472 patients at the Royal Prince Alfred Hospital Diabetes Centre, revealed that 54% of all foot ulcers in the study could be directly attributed to trauma from inappropriate footwear.\cite{9} Ill-fitting footwear is also a common trigger for foot ulceration because wearing inappropriate footwear exposes the patient to the direct effects of friction and/or irritation as well as indirect damage because of inappropriate pressure distribution and foot protection.\cite{18,24}

In this study, majority of the patients are not aware of the features of therapeutic footwear. However, they are willing to use therapeutic footwear if recommended by a physician. This may reflect the limited information on therapeutic footwear and perhaps a low level of awareness of the success achievable. To accommodate changes in foot structure, therapeutic footwear is designed to redistribute and reduce pressures underneath the foot and avoid mechanical stress on the dorsum of the foot [Table 4 and Figure 8].\cite{9} This can involve the fabrication of accommodative insoles that follow the contours of the plantar foot surface, but it can also incorporate corrective elements such as arch supports, metatarsal pads and bars or specific outsole configurations. A recent study by Rizzo et al.\cite{24} found that patients who received standardised care (consisting of an in-depth educational session and recommendation to use comfortable shoes) had a 72% incidence of ulceration by 5-year follow-up compared to only 23.5%, who had received therapeutic footwear along with a structured prevention programme. Evidence from a randomised controlled trial has also shown ulcer recurrence to be significantly lower in patients equipped with therapeutic shoes compared to ordinary footwear.\cite{26,27}

| Table 3: Participants response regarding awareness of therapeutic footwear features |
|---------------------------------|-----------------|-----------------|
| **Question**                  | **Response** | **Male n (%)** | **Female n (%)** |
| Shoes need modification in order to accommodate feet well | Yes | 19 (28) | 23 (34) |
| No | 48 (72) | 45 (66) |
| Finds it difficult to put on shoes or to take off shoes | Yes | 21 (31) | 22 (28) |
| No | 47 (69) | 56 (72) |
| Wear shoes without socks | Yes | 48 (66) | 60 (75) |
| No | 24 (34) | 20 (25) |
| Comfortable with own shoes | Yes | 55 (76) | 65 (86) |
| No | 17 (24) | 11 (14) |
| Patient knows his/her correct shoe size | Yes | 68 (92) | 72 (92) |
| No | 06 (08) | 06 (08) |
| Patient may need different sizes of shoes for the left and right feet | Yes | 08 (12) | 04 (06) |
| No | 58 (88) | 66 (94) |
| Receive information about type of footwear to wear | Yes | 17 (25) | 25 (34) |
| No | 51 (75) | 48 (66) |
| Willing to use footwear with extra insert materials as insoles | Yes | 54 (78) | 65 (83) |
| No | 15 (22) | 13 (17) |
| Willing to buy footwear if recommended by a doctor | Yes | 61 (88) | 62 (80) |
| No | 08 (12) | 16 (20) |

| Table 4: Therapeutic footwear features |
|---------------------------------|-----------------|
| **Shoe features** | **Criteria for choosing footwear features** |
| Upper part of shoe | These should be made from leather or a combination of materials (such as those used in sports shoes) with smooth inner lining and without bulky seams at the toe area |
| Correct length | 1 cm from end of the longest toe when the patient is standing |
| Correct depth | Should accommodate all the toes without causing pressure |
| Correct width | The sides of the shoe should not bulge over the sole when worn |
| Low heels | Should be ≤2 cm |
| Fastening | Adequate fastening such as laces or straps to keep the foot from sliding forward |
| Cushioned outer and inner soles | Approximately, 0.5-1 cm thick under the forefoot |
| Enclosed heel | Shoes with an open back can result in injury to the skin around the heel and usually require the individual to claw their toes to keep them on, also increasing risk of ulceration |
| Soles | Should not be slippery |

Adapted from Bergin et al.
We therefore support recommendations that all patients with diabetes mellitus should be offered foot care education aimed at improving footwear-related knowledge and practice to reduce the risk of diabetic foot ulcers.[14,25] All clinicians involved in the care of patients with diabetes need to define the level of risk for developing foot complications and thus tailor therapeutic footwear advice accordingly.[6] Risk stratification is determined following a basic foot assessment, which includes evaluation for the presence of peripheral neuropathy, peripheral arterial disease and foot deformity. In addition to the foot assessment, other factors that should be considered include the patient’s activity level, occupation and level of mobility. Risk stratification should be reassessed and upgraded on a yearly basis, given the potential for progression and development of new risk factors over time.[9] Cavanagh and Bus[28] introduced a therapeutic footwear prescription pyramid guideline. At the base of the pyramid is patients without foot deformity and a relatively low activity level for whom athletic shoes may be sufficient. For patients with increasing degrees of foot deformity and activity level (subsequent levels of the pyramid), a more protective, biomechanically effective and eventually, more customised solution is recommended. At the top of the pyramid is the patient with severe foot deformity and an active lifestyle, who is prescribed with fully customised therapeutic footwear.[28]

This study underscores the need for research to collect data on diabetic foot ulcers in Nigeria and appropriate prevention measures as outlined by the International Diabetes Federation and International Working Group on the Diabetic Foot.[29] Emphasis on footwear education is a critical component in the prevention of diabetic foot ulcer. Patients with diabetes need consistent and ongoing education from health-care providers regarding the role and importance of therapeutic footwear and the type most appropriate to their level of risk for ulceration.[9,14] This should be sought and promoted because of the potential cost-effectiveness and improved outcome for the patient.[30] In the near future, Diabetic Footwear Centres could be developed to design, fashion and manufacture footwear that is not only preventive, protective and therapeutic footwear but also it is aesthetic, affordable and culturally acceptable.[31]

Limitations
Some limitations need to be considered in the interpretation and application of the results of this study. First, this study was conducted in tertiary institutions in Kaduna state. A multi-institution population-based correlation analysis is desirable to build up the evidence base for the use of therapeutic footwear and to determine the value for clinical decision making in the prevention of diabetic foot ulcer in Nigeria. Second, the effectiveness of footwear in ulcer prevention and healing is always likely to be complicated by patient adherence to treatment. Exploration of predictors of adherence will have great value in guiding therapeutic footwear prescription practice. Third, this is a self-report survey research. While surveys are commonly used for needs assessments, the results are heavily dependent on the content and context of the questionnaire and the results must be considered from this standpoint.

CONCLUSION
Our study highlights the need for the use of appropriate footwear to prevent diabetic foot ulcers. Majority of the patients are reported to have foot ulcers located on the phalanges and these are related to the wearing of inappropriate footwear. In addition, majority of the patients are not aware of the features of therapeutic footwear. However, they are willing to use therapeutic footwear if recommended by a physician.

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Conflicts of interest
There are no conflicts of interest.

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