Time spent barefoot predicts diabetic foot ulcer depth

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Article points

- 1. Footwear and foot care practices can play a major role in the development of ulceration in the neuropathic or ischaemic diabetic foot.
- 2. The authors assessed footwear practices, wound depth and amputation incidence in an Indian cohort.
- 3. Increased time spent barefoot was significantly associated with increased wound depth, and increased wound depth was significantly associated with increased risk of amputation.
- Going barefoot for any period should be discouraged among those with peripheral neuropathy or ischaemia.

Keywords

- Amputation
- Barefoot
- Footwear

Author details can be found on the last page of this article. Footwear practices and time spent barefoot were investigated in a cohort admitted to a tertiary care centre in India for the management of life- and/or limb-threatening foot ulceration. Therapeutic footwear use was negligible and the mean time spent barefoot was 2 hours/day. Participants who spent more than the mean number of hours per day barefoot were significantly more likely to have a wound extending to bone or joint. The risk of amputation among those whose wounds extended to bone or tendon was 5.8-times greater than those with shallower wounds.

Diabetic foot disease is a global social and economic burden (Boulton et al, 2005). The factors that contribute to ulceration, its severity and the risk of amputation are multiple, and the interplay between these factors is yet to be fully understood. Here, the authors report on the relationships between: (i) barefoot walking and diabetic foot ulcer depth; (ii) diabetic foot ulcer depth and lower-extremity amputation; and (iii) footwear practices and microbial infections in diabetic foot ulcers in an Indian inpatient cohort.

Methods

Consecutive people with type 2 diabetes hospitalised at the authors' institution (Podiatry Division, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences and Research Center, India) between January 2008 and March 2009 for the management of a diabetic foot wound were included in this study.

Hospitalisation criteria

As per the authors' institution's protocol, people with diabetic foot ulcers were hospitalised if they presented with: (i) limbor life-threatening infection (i.e. ascending plantar space infections; necrotizing fasciitis; osteomyelitis; sepsis); or (ii) critical limb ischemia; or (iii) multiple comorbidities. People with diabetic foot ulceration who did not meet one or more of these criteria were managed in an outpatient clinic and were not included in this study.

Footwear practice

The institution's podiatry nurse interviewed all participants on footwear behaviour,

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- 1. Footwear types were categorised as: (i) therapeutic; (ii) sandals; (iii) closed shoes.
- 2. Participants with clinical signs of infection at admission were treated prophylactically with intravenous antibiotics until the spectrum of therapy could be narrowed by microbiological investigation.
- 3. A deep tissue biopsy was taken and cultured for bacterial and fungal species.
- 4. Some 361 people were included in this study, the majority had profound diabetic peripheral neuropathy and 35.8% had peripheral ischaemia.

comprising questions on the primary type of footwear worn prior to ulcer development and the number of hours of barefoot walking per day. Footwear types were categorised as: (i) therapeutic (footwear prescribed by the podiatric surgeon or podiatrist and designed with consideration of the neurological function, peak pressure points, length, breadth and arch of the individual's foot); (ii) sandals (nontherapeutic open footwear fastened by straps or ties); (iii) closed shoes (non-therapeutic closed sport or dress shoes).

Criteria for surgical intervention

Standard protocol at the authors' institution was to conduct above- or below-knee amputation, depending on the extent of the infection, for patients who had lifethreatening sepsis or critical limb ischemia. Fore- and mid-foot amputations were carried out for patients who had plantar space infections or necrotizing fasciitis. Osteomyelitis (proven by X-ray or nuclear scan) was treated with bone curettage. In the event of soft tissue infections, surgical debridement was carried out. Toe amputation was performed for wounds with infection limited to the toes.

Surgical procedures were coded as per the International Statistical Classification of Diseases and Related Health Problems (ICD-9: 84.1, 84.10–84.18; grouped under lower-extremity amputation). Minor amputation was defined as an amputation distal to the ankle joint; major amputation was defined as an amputation through or above the ankle joint.

Infection control

Participants with clinical signs of infection at admission were treated prophylactically with intravenous antibiotics until the spectrum of therapy could be narrowed by microbiological investigation. Those presenting with non-limb-threatening infection were treated with clavulanate or moxifloxacin; those with limbthreatening infection with cefoperazone plus sulbactam plus metronidazole plus amoxicillin clavulanate; and those with lifethreatening infection with piperacillin plus tazobactam plus clindamycin plus linezolid or meropenem.

Following surgical intervention (debridement, amputation or bone curettage) while still in the theatre, a deep tissue biopsy was taken and cultured for bacterial and fungal species (two slants placed in Sabouraud's dextrose agar with chloramphenicol, incubated at 30°C and 35°C, observed for 4 weeks). Cultures were streaked on sheep's blood agar and MacConkey agar and species identified by microscopy (Chellan et al, 2010). Fungal species were identified morphologically and using ID32C strips (miniAPI; bioMérieux, Durham, NC).

Statistical analysis

Data were analysed using SPSS version 18 (IBM, Chicago, IL). Descriptive statistics were applied to analyse age, sex, diabetes duration, HbA_{1c}, ankle-brachial pressure (ABPI), transcutaneous partialindex pressure of oxygen (TcPO₂), vibration perception threshold (VPT), wound grade (University of Texas Diabetic Wound Classification System; Lavery et al, 1996), surgery type, microbes cultured, footwear practice and duration of ulcer. The Chisquare test was applied to assess the correlation between barefoot walking and wound depth, and the correlation between deep tissue infection and footwear type.

Results

Some 361 people were included in this study. Participant demographics are shown in *Table 1*. At presentation, the majority of participants (335/361, 92.8%) had profound diabetic peripheral neuropathy (VPT >25 volts) and 35.8% (129/361) had peripheral ischaemia (ABPI <0.9).

Footwear

Only 2.5% (9/361) of participants reported wearing primarily therapeutic footwear prior

to ulcer development, while sandals were the reported primary footwear of 79.8% (288/361) and 16.3% (59/361) closed shoes. Some 1.4% (5/361) reported primarily walking barefoot prior to ulcer development. More than half (212/361, 58.7%) of participants reported walking barefoot for some time each day, but the mean time spent walking barefoot (indoor or outdoor) was 1.98±1.6 hours per day.

Wound depth

Investigation revealed that 39.9% (144/361) of wounds were limited to the soft tissues of the foot. One-hundred and fifty-six (43.2%) participants had wounds that extended to the tendon or capsule, and the remaining 16 (16.9%) wounds involved bone or joint.

Amputation

The majority of participants (203/361, 56.2%) underwent an amputation (27.6% [56/203] major amputation; 72.4% [147/203] minor amputation) during the study period. The remaining 37.4% (135/361) and 6.4% (23/361) of participants underwent surgical debridement and bone curettage, respectively (*Table 2*).

Infection

The majority (295/361,81.7%) of participants' deep tissue biopsies indicated bacterial infections. Osteomyelitis was diagnosed in 16.9% (61/361) of participants. Enterococcus fecalis (42/295, Staphylococcus aureus (35/295, 14.2%), 11.9%), Pseudomonas aeroginosa (31/295, 10.2%), Klebsiella pneumonia (26/295, 8.8%), Escherichia coli (22/295, 7.5%) and metacilin-resistant Staphylococcus aureus (5/295, 1.7%) were the most common bacterial isolates. Deep tissue biopsies also revealed that 26.6% (96/361) of participants had fungal infections. Candida parapsilosis (25/361, 6.9%), Candida tropicalis (19/361, 5.3%), Trichosporon asahii (14/361, 3.9%), Candida albicans (11/361, 3.0%) and Candida guillermondii (4/361, 1.1%) were the most common fungal isolates.

Barefoot walking and wound depth

Participants who reported walking barefoot for greater than or equal to the cohort's mean number of hours per day (≥ 2 hours/ day) were significantly more likely to have deeper wounds than those who reported walking barefoot for less than 2 hours per day (*Figure 1*; *P*=0.013).

Amputation and wound depth

Participants whose wounds involved only soft tissue underwent amputation in 19.4% (28/144) of cases, whereas those whose wounds involved tendon or bone underwent amputation significantly more frequently

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- 1. Investigation revealed that 39.9% of wounds were limited to the soft tissues of the foot, 156 extended to tendon or capsule, and the remaining 16 wounds involved bone or joint.
- 2. The majority of participants' deep tissue biopsies indicated bacterial infections.

Variables	n (361)	Mean	SD	%
Sex (men)	272			
Age (years)		60.62	9.89	
Diabetes duration (months)		194.16	97.13	
Lesion duration (days)		45.30	72.55	
HbA _{1c} (%)‡‡		9.7†	2.2	
ABPI§		1.00	0.37	
TcPO ₂ (mmHg)‡		33.29	15.98	
VPT (volts)††		44.36	9.00	
Participants with				
HbA _{1c} >8.5% [>69 mmol/mol]‡‡				65
VPT >25 volts				92.7
TcPO ₂ <30 mmHg				44.6
ABPI <0.9				35.7

†83 mmol/mol. §ABPI data available for only 286 participants. ‡TCPO₂ data available for only 233 participants. ††VPT data available for only 290 participants. ‡‡ At admission. ABPI, ankle–brachial pressure index; TCPO₂, transcutaneous partial-pressure of oxygen; VPT, vibration perception threshold.

Table 2. A breakdown of surgical interventions in the study population.

Surgery	Frequency	%
Surgical debridement	135	37.4
1st toe amputation	43	11.9
Below-knee amputation	33	9.1
Mid-foot amputation	27	7.5
Above-knee amputation	24	6.6
Bone curettage	23	6.4
Fore-foot amputation	20	5.5
Lesser toe amputation	15	4.2
Ray amputation	9	2.5
3rd, 4th, 5th toe amputation	7	1.9
2nd toe amputation	6	1.7
3rd toe amputation	6	1.7
5th toe amputation	5	1.4
4th, 5th toe amputation	5	1.4
4th toe amputation	3	0.8
Total	361	100.0

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- Participants who reported primarily wearing closed, non-therapeutic shoes prior to presentation with foot ulceration had a significantly increased risk of bacterial infection of their wound compared with those reporting to wear open, nontherapeutic sandals.
- 2. Well-designed therapeutic footwear and good foot care practices can reduce these risks, but in the present cohort only a minority of participants reported wearing therapeutic footwear.
- 3. The high number of fore- and mid-foot amputations suggests that the non-therapeutic footwear, or time spent barefoot, in this profoundly neuropathic population provided little plantar pressure relief in the metatarsal head region, leading to ulceration at that site.

(175/217, 80.6%; P<0.0001). The risk of amputation among those whose wounds extended to bone or tendon was 5.8-times greater than those with shallower wounds (95% confidence interval, 0.34–0.99).

Footwear type and infection

Participants who reported primarily wearing closed, non-therapeutic shoes prior to presentation with foot ulceration had a significantly increased risk of bacterial infection of their wound (54/59, 91.5%) compared with those reporting to wear open, non-therapeutic sandals (231/288, 80.2%; *P*=0.039). Similarly, fungal infections were more common among closed shoes wearers (18/59, 30.5%) than open sandal wearers (73/288, 25.3%), although the difference was not significant (P=0.412).

Discussion

Changes in foot architecture and increased peak plantar pressures associated with peripheral neuropathy are frequently the cause of skin breakdown and ulceration in people with diabetes (Gregg et al, 2004; Dorsey et al, 2009), yet well-designed therapeutic footwear and good foot care practices can reduce these risks (Edmonds et al, 1986; Uccioli et al, 1995; Lavery et al, 1997). In the present cohort, only a minority of participants reported wearing therapeutic footwear. While the scarcity of diabetic

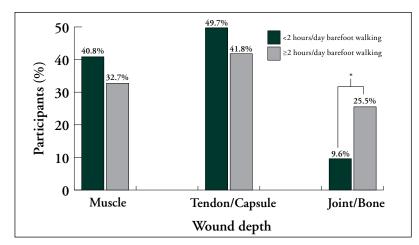


Figure 1. Relationship between barefoot walking and depth of diabetic foot ulcers. *P=0.013.

foot care centres and issues of expense limit access to effective therapeutic shoes in India, therapeutic footwear is only effective if worn and a number of studies have suggested that adherence – even when shoes are provided free – is low (Knowles and Boulton, 1996; Macfarlane and Jensen, 2003).

People with diabetes and peripheral neuropathy who do not wear therapeutic shoes may be at increased risk of ulceration from ill-fitting retail alternatives. Harrison et al (2007) report that only 20-24% of their cohort wore the correct length and width high street shoes for both feet, with the majority fitted for shoes that were too narrow. The high incidence of toe amputation seen in the present cohort may be related to the shear pressures exerted by poorly fitted shoes leading to toe ulceration. Likewise, the high number of fore- and mid-foot amputations suggests that the non-therapeutic footwear (open sandals and closed shoes), or time spent barefoot, in this profoundly neuropathic population provided little plantar pressure relief in the metatarsal head region, leading to ulceration at that site (Viswanathan et al, 2004).

The majority of the cohort reported walking barefoot for some period of time each day, and longer periods spent barefoot were significantly associated with greater wound depth. Barefoot walking outdoors is more common in warmer climates - like that of the study population - and is a signification risk factor for ulceration in the developing world (Jayasinghe et al, 2007). Diabetes education programmes and public health messages for people with diabetes in populations who frequently walk barefoot should strongly advise the use of footwear for the greater part of the day. Viswanathan et al (2000) reported that people with diabetes who wore shoes both inside and outside the home developed fewer foot problems than those who only wore shoes outside the home. This finding suggests that indoor barefoot walking alone - which is a common practice in many countries - increases the risk of ulceration (Viswanathan et al, 2004).

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- Diabetic foot infection is a common cause of hospitalisation in India, constituting approximately 10% of all of diabetes-related hospital admissions.
- Approximately 19% of participants had uninfected wounds, which may have been the result of empirical antimicrobial therapies received prior to biopsy.
- 3. The scarcity of diabetic foot care centres, poor foot care knowledge, delayed referrals and reporting, limited income and low levels of education contribute to the increased incidence of diabetic foot complications, and poorer outcomes, in India.

Diabetic foot infection is a common cause of hospitalisation in India, constituting approximately 10% of all of diabetes-related hospital admissions (Viswanathan et al, 2005). The rate of infection in the present population was high (81.7% bacterial; 26.6% fungal). The significant association between bacterial infection and wearing closed shoes in the present cohort may be related to wearing closed footwear in a warm climate, which - along with poor foot care routines - may prevent the evaporation of moisture from the foot and encourage microbial growth. Approximately 19% of participants had uninfected wounds, which may have been the result of empirical antimicrobial therapies received prior to biopsy.

A wide variation in the incidence of diabetes-related lower-limb amputation has been reported worldwide. In England, 39.4% of all people who undergo a major amputation have diabetes (Moxey et al, 2010), while the in the USA approximately 67% of people who undergo any amputation have diabetes (Morbidity and Mortality Weekly Report, 2001). The scarcity of diabetic foot care centres, poor foot care knowledge, delayed referrals and reporting, limited income and low levels of education contribute to the increased incidence of diabetic foot complications, and poorer outcomes, in India (Viswanathan et al, 2005). In the present study, 56% of participants underwent an amputation, which is higher than that reported by centres of excellence (e.g. Krishnan et al, 2008), but reflects the high disease burden of the cases referred to the authors' institution.

Conclusions

A strong association between time spent barefoot and the depth of diabetic foot ulcers, depth of wound and lower-limb amputation, and the wearing of closed shoes and bacterial wound infection were demonstrated in the present cohort. The use of therapeutic footwear among the this population was almost negligible. Poverty, illiteracy and lack of awareness regarding diabetic foot care are likely contributors to the high rate of amputation in the present study. Public health campaigns to improve foot care practices among people with atrisk diabetic feet – and awareness among physicians – may reduce the morbidity and mortality of this condition in the developing world.

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- Chellan G, Shivaprakash S, Karimassery Ramaiyar S et al (2010) Spectrum and prevalence of fungi infecting deep tissues of lower-limb wounds in patients with type 2 diabetes. *J Clin Microbiol* 48: 2097-102
- Dorsey RR, Eberhardt MS, Gregg EW, Geiss LS (2009) Control of risk factors among people with diagnosed diabetes, by lower extremity disease status. *Prev Chronic Dis* 6: A114

Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J (2005) The global burden of diabetic foot disease. *Lancet* **366**: 1719–24

"Public health campaigns to improve foot care practices among people with at- risk diabetic feet – and awareness among physicians – may reduce the morbidity and mortality of this condition in the developing world."

- Edmonds ME, Blundell MP, Morris ME et al (1986) Improved survival of the diabetic foot: the role of a specialized foot clinic. *Q J Med* **60**: 763–71
- Gregg EW, Sorlie P, Paulose-Ram R et al (2004) Prevalence of lower-extremity disease in the US adult population >=40 years of age with and without diabetes: 1999-2000 national health and nutrition examination survey. *Diabetes Care* 27: 1591–7
- Harrison SJ, Cochrane L, Abboud RJ, Leese GP (2007) Do patients with diabetes wear shoes of the correct size? *Int J Clin Pract* **61**: 1900–4
- Jayasinghe SA, Atukorala I, Gunethilleke B et al (2007) Is walking barefoot a risk factor for diabetic foot disease in developing countries? *Rural Remote Health* 7: 692
- Knowles EA, Boulton AJ (1996) Do people with diabetes wear their prescribed footwear? *Diabet Med* 13: 1064-8
- Krishnan S, Nash F, Baker N et al (2008) Reduction in diabetic amputations over 11 years in a defined U.K. population: benefits of multidisciplinary team work and continuous prospective audit. *Diabetes Care* 31: 99–101
- Lavery LA, Armstrong DG, Harkless LB (1996) Classification of diabetic foot wounds. J Foot Ankle Surg 35: 528-31
- Lavery LA, Vela SA, Fleischli JG et al (1997) Reducing plantar pressure in the neuropathic foot. A comparison of footwear. *Diabetes Care* 20: 1706–10

- Macfarlane DJ, Jensen JL (2003) Factors in diabetic footwear compliance. J Am Podiatr Med Assoc 93: 485-91
- Morbidity and Mortality Weekly Report (2001) Hospital Discharge Rates for Nontraumatic Lower Extremity Amputation by Diabetes Status. Centres for Disease Control and Prevention, Atlanta, GA
- Moxey PW, Hofman D, Hinchliffe RJ et al (2010) Epidemiological study of lower limb amputation in England between 2003 and 2008. *Br J Surg* 97: 1348-53
- Uccioli L, Faglia E, Monticone et al (1995) Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 18: 1376–8
- Viswanathan V, Rajasekar S, Snehalatha C, Ramachandran A (2000) Routine foot examination: the first step towards prevention of diabetic foot amputation. *Practical Diabetes International* 17: 112-4
- Viswanathan V, Madhavan S, Gnanasundaram S et al (2004) Effectiveness of different types of footwear insoles for the diabetic neuropathic foot: a followup study. *Diabetes Care* 27: 474–7
- Viswanathan V, Madhavan S, Rajasekar S et al (2005) Amputation prevention initiative in South India: positive impact of foot care education. *Diabetes Care* 28: 1019–21