Primary Care Diabetes 15 (2021) 145–149

Contents lists available at ScienceDirect

Primary Care Diabetes

journal homepage: http://www.elsevier.com/locate/pcd

Original research

Fit for purpose? Footwear for patients with and without diabetic peripheral neuropathy: A cross-sectional study

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ARTICLE INFO

Article history:
Received 16 July 2020
Received in revised form 11 August 2020
Accepted 14 August 2020
Available online 27 August 2020

Keywords:
Diabetic foot
Diabetic peripheral neuropathy
Fit
Footwear

ABSTRACT

Aim: This paper determines whether patients with and without Diabetic Peripheral Neuropathy use suitable footwear, taking into account that these persons are subject to a significant loss of sensitivity in the feet.
Methods: Cross-sectional observational study was conducted of 108 participants with diabetes mellitus. Inclusion criteria were at least five years' progression of diabetes, the ability to walk unaided and no distal amputation of the foot. The presence of DPN was evaluated according to the criteria of the International Working Group on the Diabetic Foot. Foot length was measured using a Brannock® device and internal shoe length was determined using a CEGI® pedometer.
Results: In relation to adjustment, 21.6% of the shoes examined had no type of closure. The most common form of closure was laces, which were used in 32.4% of the shoes. 92.5% of footwear had internal seams. No significant relationship was found between the presence or otherwise of DPN and the use of appropriate shoe closure ($p = 0.304$), recommended heel height ($p = 0.18$), leather material ($p = 0.77$) and absence of internal seams ($p = 0.759$).
Conclusions: The majority of our participants living with DPN do not wear fitting shoes. Therefore, it is advisable to evaluate their use of footwear, both in primary health care and in podiatry clinics, to forestall potential complications.

1. Introduction

Diabetes mellitus (DM) is a physiological disorder provoked by endogenous insulin deficiency and impaired insulin efficiency, or both. It is characterised by hyperglycaemia and is associated with chronic complications that can affect nearly all organs in the body [1]. According to the International Diabetes Federation, 425 million people worldwide, or 8.8% of adults aged 20–79 years, had DM in 2017, four times more than in 1980. This figure is expected to increase to 642 million by 2040 [2].

A frequent complication of DM is diabetic peripheral neuropathy (DPN), i.e., "the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes, after the exclusion of other causes" [3]. Patients with DPN typically exhibit gait changes, such as reduced speed, increased double support time, slower reaction time, joint stiffness [4], reduced ankle movement and strength, diminished vibration perception thresholds and reduced muscle strength [5,6]. These changes may coexist and differ significantly between patients with or without neuropathy [7,8].

Ill-fitting footwear (or walking barefoot) can provoke increased mechanical foot pressure, leading to infection and/or plantar foot ulceration [9,10]. The latter is a significant risk, affecting 15% of DM patients [11], although only about half of these patients are actually aware of the lesion [12]. Furthermore, the risk of ulceration increases if the patient presents deformities such as claw toes or corns [1].

Among other functions, correctly-fitting footwear offers physical protection, acts as an environmental barrier for the foot, provides biomechanical support and enables pressure redistribution across the foot, thus reducing the formation of calluses. Poorly-fitting footwear, on the other hand, whether tight or loose, can increase plantar pressures and friction and provoke foot ulcers [13,14], possibly leading to infection and even amputation [15].

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https://doi.org/10.1016/j.pcd.2020.08.009
1751-9918/

This question is particularly important for DM patients with DPN, who need footwear that relieves pressure areas, reduces shock and shear forces and manages deformities [9,16].

To achieve these effects, appropriate footwear must be wide enough around the heel, made of leather, have no internal seams, present a semi-rigid buttress, with a wide anatomical sole, enable adjustment with laces or velcro, and have a heel that is 2–3 cm high, providing cushioning, volume and width appropriate to foot size. Shoes should be fitted while the patient is weight bearing [17].

In this study, our main aim is to determine whether patients with DPN use suitable footwear, taking into account that these persons are subject to a significant loss of sensation in the feet, which makes them vulnerable to increased tissue stress and hence ulcers.

2. Methods

2.1. Ethical approval

This study was approved by the Ethics Committee of San Juan University Clinical Hospital (Alicante, Spain) (Reg. No. 13/305) and was performed in accordance with the Declaration of Helsinki and all applicable legislation and regulations on ethical standards for human experimentation. Signed informed consent was obtained from all participants

Participants. This cross-sectional study with a convenience sample was obtained of 108 participants (216 feet) with a confirmed diagnosis of DM, who attended the hospital's endocrinology department of San Juan University Clinical Hospital during the period from February to June 2019. Sampling was consecutive from the participants who attended the consultation and met the inclusion criteria, namely being diagnosed with DM1 or DM2 (according to ADA criteria), being aged over 18 years and having signed the informed consent form. The exclusion criteria were pregnancy, the presence of neuropathy due to causes other than diabetes (vitamin B12 deficiency, the presence of an open ulcer at the time of the study, prior surgery to the foot, inability to walk, hypothyroidism, systemic neurological disease) or distal amputation of the foot, or the prior use of custom shoes, braces or plantar orthoses.

2.2. Procedure

A member of the research team conducted clinical interviews face to face with the study participants to compile sociodemographic, information on the type of diabetes and its duration, the presence of toxic habits (smoking) and the frequency of physical activity. Body weight was calculated with a calibrated Tanita TBF 300 scale, and height was measured with a Harpenden® stadiometer (Holtain Limited). Body mass index (BMI) was calculated from these data. Blood pressure was measured using the Colin BP-8800C automatic measuring device, correctly calibrated and in accordance with AHA recommendations [18]. Peripheral vascular assessment was performed by palpation of the posterior and dorsalis pedis tibial pulses. The ankle brachial index was determined with a bidirectional Smartdop 45 Hadeco® Doppler probe, following the recommendations of the European Society of Cardiology [19]. The presence/absence of DPN was determined according to criteria stipulated in a clinical guidelines the International Working Group on the Diabetic Foot [20], (altered sensitivity to pressure, measured with a 10 g monofilament assessed in three areas of the foot: plantar aspect of the first toe, plantar area of the 1st and 5th metatarsal heads; altered sensitivity to touch assessed by the cotton wisp test and altered sensitivity to vibration assessed by the 128 Hz tuning fork test). Foot length was measured with the participants standing on a calibrated Brannock® device [12], and internal shoe length was assessed with a CEGI® pedometer (Fig. 1). The shoe size was deemed correct when the latter measurement was 1–1.5 cm greater than that of the foot [21]. Other footwear characteristics were gauged visually (type of footwear, closure, material and type toe box) and by palpation (buttressing, internal seams and flexion point). Heel height was measured with a flexometer (Fig. 2) (Brico Tech, Elmira, NY, USA). Footwear was considered optimal when at least five of the following parameters were observed [17].

Fig. 1. CEGI® pedometer.

Fig. 2. Flexometer (Brico Tech, Elmira, NY, USA).

- The outer part of the shoe was made of natural leather.
- The shoe had no internal seams.
- Adjustment of the dorsal area was by laces or velcro (thus allowing the shoe to adapt to changes in foot volume during the day).
- Heels no more than 3 cm high, with a good support surface to avoid instability and displacement of the centre of gravity.

Table 1
Sociodemographic characteristics.

Variables	Subjects with DPN (N = 17)	Subjects without DPN (N = 91)
Sex (n [%]) male/female	13 (76.5)/4 (23.5)	57 (62.6)/34 (37.4)
Mean age ± SD [years]	59.6 ± 10.3	57.7 ± 13.7
Mean duration of diabetes ± SD [years]	18.9 ± 12.2	17 ± 10.2
Type of diabetes (n° [%]) DM 1/DM 2	5 (29.4)/12 (70.6)	27 (29.7)/64 (70.3)
Obesity (n [%]) (BMI > 30 kg/m^2)	9 (52.9)	43 (48.3)
Peripheral arteriopathy (n [%])	10 (58.8)	28 (31.1)
Sedentary lifestyle (n [%])	3 (17.6)	14 (15.4)
Smoking habit (n [%])	13 (76.5)	53 (58.2)

- Round or circular toe design closed and wide enough to allow toe mobility, whilst avoiding friction against the upper surface of the foot.
- Point of flexion in the area of the metatarsophalangeal joints.

In addition, the footwear was considered to be properly fitting when the inner part of the shoe exceeded foot length by 5%. The space for toe width and height should be equal within the shoe, allowing easy movement [22]. The intraclass correlation coefficient was used to evaluate the reproducibility of measurement on a calibrated Brannock® and CEGI® pedometer device with a sample of ten subjects measured at baseline and after 24 h, using a one-way random effect model, and found to be excellent ICC 0.94: (95% CI: 0.90–0.96) and 0.87 (95% CI: 0.80–0.92). Statistical analysis

Statistical analysis was performed with SPSS v.26 statistical software. The normality of the distributions was assessed by the Kolmogorov-Smirnov test. The results are reported as means and standard deviations. Since a non-normal distribution of data was consequently established, in order to assess the association for the comparison of independent means; for the association of qualitative variables, the chi-square test was used for the comparison of proportions. Differences were considered significant if $p < 0.05$, with a confidence interval of 95%

3. Results

Although 153 persons were initially analysed, only 108 fully met the criteria for inclusion. Of these, 70 men (64.8%) and 38 women (35.2%), with a mean age of 57.9 ± 13.2 years. After clinical examination, the presence of peripheral neuropathy was detected in 17 participants, with a mean age of 59.6 ± 10.3 years and an average duration of DM of 18.9 ± 12.2 years (Table 1).

In the study population, the most common types of footwear were sandals (26.1%) and moccasins (21.6%). The latter, therefore, had no type of closure. Where a means of adjustment existed, laces were most commonly present (32.4%). The footwear material was leather in 55.0% of cases. The most frequent types of shoe tip were circular, round or oval (61.3%). Only 7.5% of participants wore shoes that were appropriate for their condition.

Of the 216 feet included in this study, the length adjustment only be assessed at 160 feet who wore closed shoes (the rest the feet used open toe sandals). Of these 160 items of footwear, only 65 (40.6%) were of correct length, while 32 (20%) were too small (exceeding foot length by less than 1–1.5 cm) and 63 (39.4%) were too large. DPN was observed in 24 feet, but correctly-sized footwear was worn in only 8 of these cases (34.8%). No significant correlation was found between footwear fit and the presence of DPN (right foot: $p = 0.67$; left foot: $p = 0.43$) (Table 2).

No significant relationship was found between the presence or otherwise of DPN and the use of appropriate shoe closure ($p = 0.304$), recommended heel height ($p = 0.18$), leather material ($p = 0.77$) and absence of internal seams ($p = 0.759$) (Table 3).

Only 10.2% of participants had optimal footwear (meeting five or six of the characteristics specified in Table 3). In 17 participants with DPN, two wore optimal footwear, eleven wore sub-optimal footwear (three or four items matching the specifications) and four wore unacceptable footwear (zero to two matching items) ($p = 0.215$) (Table 4).

Table 2
Relationship between shoe length fit and the presence of DNP.

Footwear	DNP present N = 24 feet (%)	DNP absent N = 136 feet (%)
Too small (< 1 cm)	7 (29.2)	25 (18.4)
Correct length (1–1.5 cm)	8 (33.3)	57 (41.9)
Too large (> 1.5 cm)	9 (37.5)	54 (39.7)
	p = 0.67 (right foot); p = 0.43 (left foot)	

Table 4
Number of correct footwear characteristic in patients with and without DPN.

Number of correct characteristics		With DPN	Without DPN
	N = 17 (%)	N = 91 (%)	
Incorrect	0	1 (5.9)	6 (6.6)
	1	1 (5.9)	7 (7.7)
	2	2 (11.7)	28 (30.8)
Regular	3	7 (41.2)	25 (27.5)
	4	4 (23.5)	16 (17.6)
Optimal	5	2 (11.8)	7 (7.7)
	6	0 (0)	2 (2.1)

Table 3
Footwear characteristics.

Footwear characteristics		N = 108 patients		
	DPN present	DPN absent DPN	p	
Type of closure	Correct	9 (52.9)	36 (39.6)	p = 0.30
	Incorrect	8 (47.1)	55 (60.4)	
Manufacturing material	Correct	10 (58.8)	51 (56.1)	p = 0.77
	Incorrect	7 (41.2)	40 (43.9)	
Type of shoe tip	Correct	12 (70.6)	53 (58.2)	p = 0.34
	Incorrect	5 (29.4)	38 (41.8)	
Heel height	Correct	11 (64.7)	36 (39.6)	p = 0.18
	Incorrect	6 (35.3)	55 (60.4)	
Internal seams	Correct	1 (5.9)	9 (9.9)	p = 0.76
	Incorrect	16 (94.1)	82 (90.1)	
Metatarsophalangeal joint flexion	Correct	10 (58.8)	52 (57.1)	p = 0.87
	Incorrect	7 (41.2)	39 (42.9)	

4. Discussion

Our main study aim was to determine whether the study population (diabetic participants with and without DPN) used inappropriate footwear, due to their lack of protective sensitivity.

Our findings show that only 40.6% of participants used footwear of appropriate length, despite the fact that poorly-fitting footwear can provoke foot ulcers and other lesions in persons with diabetes [23]. Participants with DPN were equally prone to wear poorly-fitting shoes; thus, 29.2% of these participants wore footwear that was too small for them, possibly due to their lack of sensitivity in the feet. Thus, we corroborate previous studies that have also concluded that diabetic participants (including those with DPN) often wear ill-fitting shoes.

While it is important for the population in general to wear the correct shoe size, this is especially so for the elderly, 72% of whom have been reported to wear inappropriate footwear [24]. In this respect, problems arise whether the footwear is too large or too small [25]. Due to the fact that the length of the feet may be asymmetrical, is important to size both feet to check the setting of the footwear [26]. Excessive pressure (in the first case) or friction (in the second) can provoke the development of ulcers [14]. Moreover, shoes that are too large may produce a continual slipping of the foot within the shoes, producing shear forces on the skin and promoting risk of falls [8].

During the warmer months, many people, particularly women, wear sandals most of the time, both indoors and out. In our study population, however, there were relatively few women and so the effect of this type of footwear could not be reliably evaluated. As was the case in an earlier study [27], these participants were not elderly, but their footwear still tended to be ill fitting.

Other recent studies have concluded that participants with DM or foot deformities (including those produced by other pathologies, such as rheumatoid arthritis) should wear therapeutic footwear in order to prevent complications [2,15] such as friction ulcers, falls [28] and possible amputation [6]. Participants with different foot sizes should be able to adjust the shoe size to correlate with the longer foot, thus avoiding pressure on the smaller foot and stress on the tissues [29,30]. This kind of preventive measure would avoid foot injuries, reducing the need for surgical intervention and costs to the health system.

This study has certain limitations that should be acknowledged. In particular, the sample size was relatively small, and it was not homogeneous in terms of male vs. female participants. However, it also presents important strengths. Firstly, all measurements were carried out by the same researcher, and so the study data are not subject to inter-observer bias. In addition, a strict protocol was applied in obtaining the physical measurements; thus, foot length was always measured with the participants in a standing position, in order to ensure sufficient expansion of the fatty tissue (with the participants in a seated position, these measurements would have varied).

The study results presented in this paper, together with those of earlier research by Mclnnes et al. [31], Chantelau and Gede [32] and Paloma López et al. [33], consolidate our understanding of footwear characteristics among participants with DM and/or DPN. In future research in this area, it would be useful to increase the sample size, to recruit an equal number of male and female participants and to recruit higher proportions of participants with DPN and forefoot deformities (to focus the results more effectively on these types of participants). It would also be useful to obtain data on the participants' economic status, since this parameter is often a relevant factor when footwear is acquired. Finally, the study data should be obtained at different times of the year, as seasonal considerations also impact on the footwear choices made.

Participants with diabetes, whether or not associated with peripheral neuropathy, are at significant risk of developing foot injuries if they wear inappropriate footwear. If these participants also present some type of foot deformity, the risk of injury and ulceration is still greater. In both primary health care and specialist podiatry clinics, a well-organised multidisciplinary team can detect these abnormalities and check that the participants footwear is appropriate, thus helping prevent the risk of injury to the foot.

4.1. Conclusion

The majority of our participants living with DPN do not wear fitting shoes. Therefore, it is advisable to evaluate their use of footwear, both in primary health care and in podiatry clinics, to forestall potential complications.

Although our study conclusions should be taken with caution, given the limited sample size considered, it seems apparent that most DM patients, whether or not DPN is also present, do not wear correctly-fitting shoes. This finding highlights the need for greater attention to be paid to the healthcare of these patients, who are especially vulnerable to a loss of sensitivity in the feet and to resultant complications such as ulcers.

Author contributions

Esther Chicharro-Luna and Gabriel Gijon-Nogueron contributed to the conception of this study. Gabriel Gijon-Nogueron and Ana Belen Ortega-Avila performed the statistical analysis. Study data were compiled by Esther Chicharro-Luna and Requena Martínez Aranzazu, and Esther Chicharro-Luna and Gabriel Gijon-Nogueron were primarily responsible for writing the manuscript.

Ethical approval

This study was approved by the Ethics Committee of San Juan University Clinical Hospital (Alicante, Spain) (Reg. No. 13/305) and was performed in accordance with the Declaration of Helsinki and all applicable legislation and regulations on ethical standards for human experimentation. Signed informed consent was obtained from all participants.

Funding

This study did not receive any funding.

Conflict of interest

All the authors declare that they have no conflict of interest derived from the outcomes of this study.

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