RESEARCH STUDY

Initial and continued adherence to wearing appropriate footwear in people with diabetic foot disease: results of a pilot study

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ABSTRACT

Background: For the prevention and healing of diabetic foot ulcers, appropriate footwear or medical devices are utilized. However, initial and continued adherence of patients with diabetes-related foot problems in using such therapeutic means, is not satisfactory.

Objective: To explore initial and continued adherence to wearing appropriate footwear in people with diabetic foot disease.

Methods: A cross-sectional study was conducted, from March to November 2016, at general and special hospitals in Athens, Greece. Forty-one outpatients with type 1 and 2 Diabetes Mellitus, with medical recommendation for wearing appropriate footwear, participated. A structured quantitative interview guide and medical measuring instruments were used. For data analysis, descriptive and inferential statistic methods were applied using the IBM SPSS 24 software package.

Results: Suitable for diabetes footwear were worn from the 56.1% of participants. The 27.3% of risk patients wore their preventive shoes ≥60% (≥9.6 hours) of daytime. The patients with active foot ulcers wore appropriate footwear at a lesser percentage than the ones at risk (44.4% versus 78.6%, x2(1) =4.36, p=0.037; OR 4.58, 95% CI 1.04-20.24, p=0.045) and the initially adherent group had significantly subordinate Visual Analogue Scale score in relation to the satisfaction from the footwear price (Mdn=5.00) than the one that was not initially adherent (Mdn=8.00), U=97.00, z=-2.36, p=0.019, r=-.38.

Conclusion: For the enhancement of initial and continued adherence in wearing appropriate footwear, health care professionals could pay more attention to the education of patients with active foot ulcers, underling the importance of using right shoes. Additionally, they could provide patients with multiple price options concerning their footwear (e.g. by suggesting effective and affordable products).

Keywords: appropriate footwear, continued adherence, diabetic foot disease, initial adherence

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INTRODUCTION

High plantar pressure is one of the causes of developing diabetic foot ulcers (DFUs). Therefore, the adequate off-loading of the plantar surface, locally or totally, is necessary for their prevention and healing (Cavanagh & Bus 2010). The lifetime risk of developing DFUs, in persons with Diabetes Mellitus (DM), was calculated to be 25% (Singh et al 2005). The risk of ulcer recurrence, in a three years period, is 17-60% higher than in patients without relevant medical history (Apelqvist et al 1993). DM is responsible for the 8 of 10 non-traumatic amputations, 85% of which are a foot ulcer consequence, whereas the age-adjusted annual incidence of them ranges from 2.1 to 13.7 per 1000 persons and the following mortality is 39-80% in 5 years (Singh et al 2005). A Swedish study (Tennvall et al 2000), conducted from 1986 to 1995, has found that the estimated cost of a DFU, without ensuing amputation, was $18000, while the cost amounted to $34000 when an amputation was performed (Tennvall et al 2000, Singh et al 2005). Implementing prevention and treatment strategies, in relation to the foot ulcers, is critical for avoiding the human and economic burden of diabetic foot disease (Netten et al 2016). For the prevention of DFUs, as off-loading measure, appropriate footwear is used (Cavanagh & Bus 2010, Bus et al 2016). Preventive footwear incorporates the conventional diabetic shoes or slippers-sandals (off-the-self, semi-custom-made, custom-made) and the running shoes, which should be worn by the risk patients at least for the 60% of the time walking or standing up (Chantelau & Haage 1994, Cavanagh & Bus 2010, Kossioris et al 2014). However, by a simple calculation, almost half of the patients (52%) wear their specially manufactured footwear ≥60% daily (Chantelau & Haage 1994, Macfarlane & Jensen 2003, Churchman 2008, Waaijman et al 2013, Arts et al 2014).

In regard to the DFUs treatment, without infection and blood circulation complications there might need up to 6 weeks of immobilization (Uccioli & Giacomozzi 2012). Total contact casts (TCCs), removable cast walkers (RCWs), half-shoes, fore foot off-loading shoes and cast shoes are utilized, as off-loading aids-devices-related intervention (Cavanagh & Bus 2010, Bus et al 2016). Nevertheless, it has been detected that removable devices were worn by the patients for only a minority of daily steps (Armstrong et al 2003).

Considering the above mentioned facts, it could be argued that adherence in wearing appropriate foot medical devices (Busch & Chantelau 2003), both in at risk for ulceration and with active ulcer/s patients, is notably problematic. Still, for accomplishing even this troublesome adherence, which presupposes the possession of the footwear or aids by the patients, it is firstly needed these products to be provided to them. This first step of adherence is referred in the literature as "initial", "primary" or "first-fill" adherence (Zeber et al 2013). Initial adherence has two phases for the patient (Forestal 2016):

- Bringing the prescription to the pharmacy or the special store and
- Getting back the medication or medical device.

No study yet has concretely and systematically examined the initial adherence to wearing appropriate footwear in patients with diabetes-related foot problems. The aim of this study was to explore the initial and continued adherence, as well as the role of related factors affecting people with diabetic foot disease in their wearing appropriate footwear. Its main objectives were:

- The assessment of initial and continued adherence in wearing appropriate footwear
- The evaluation of satisfaction from the footwear aesthetics and footwear cost/price.

METHODS

This study was designed as a cross-sectional research. It took place at three diabetic foot clinics of general hospitals and one wound unit of a special hospital, all located in Athens, Greece. Ethical approvals were granted by the scientific committees of the hospitals.

Subjects - recruitment

Initially, 65 persons with Type 1 and 2 DM were conveniently approached by the principal investigators during their scheduled visit to the healthcare facilities, from March to November 2016. Forty-nine of the patients (response rate 75%) were willing to participate in the study and 41 met the inclusion criteria. All the participants were enrolled after providing written informed consent. The only inclusion criteria, except the diagnosis of diabetes, were having medical recommendation for wearing appropriate footwear and the absence of cognitive disturbances.

Data collection

The head researcher interviewed one-on-one each patient collecting demographic and medical data, and afterwards confirmed the validity of the data by checking their medical history files. For collecting the data, a structured quantitative interview guide was used. The researcher asked closed-ended questions to interviewees and recorded their responses. Two of the interview guide items were Visual Analogue Scales 0-10.

Measurements

The measurements which took place for the purposes of the study encompassed parameters related to:

Sociodemographic characteristics: Age, sex, marital status, education level, profession and place of residence

Anthropometric characteristics: Height and weight

Clinical characteristics (history, biochemical, hemodynamic and imaging examinations): Diabetes duration and type, type of treatment, HbA1c, number of hypoglycemic episodes in the last 30 days, systolic blood pressure, diastolic blood pressure, SpO2, heart rate, risk category for foot ulceration, severity of foot deformities and presence or absence of complications, such as active foot ulcerationm history of previous ulceration, retinopathy, hypertension, coronary artery disease, renal complications, peripheral neuropathy, autonomic neuropathy and peripheral artery disease (PAD)

Life style characteristics: Smoking habit, frequency of alcohol consumption

Footwear characteristics (constructive, aesthetic and financial): shoe type, satisfaction from the aesthetics and price

Level of initial and continued adherence: Prevalence of using appropriate footwear and hours per day.

Instrumentation – procedures

For measuring the sociodemographic and life style characteristics, appropriate interview guide items were used. Because the items asked mainly objective information, the interview guide subjected only to validity examination. For testing the validity of all the interview guide items, the face validity method was applied.

Concerning the anthropometric characteristics, a stadiometer and a weighing scale were utilized. In terms of the clinical characteristics, appropriate objective interview guide items regarding diabetes duration, diabetes type, type of treatment, number of hypoglycemic episodes in the last 30 days, risk category for foot ulceration, severity of foot deformities and the presence or absence of active foot ulceration, history of previous foot ulceration, coronary artery disease, renal complications, peripheral neuropathy and peripheral artery disease the following were used.

The researcher, at first, interviewed the participants, inspecting where necessary (e.g. for foot deformities severity), and subsequently confirmed the validity of the data by checking their health history files. An example of the usefulness of this confirmation is that some patients were not aware about their peripheral neuropathy and only their health history file testified it.

For the classification of the foot deformities severity the Waaijman et al (2013) guidelines (p. 1617) were followed and for the risk for diabetic ulceration category classification guidelines of the IWGDF (Singh et al 2005). Diabetic foot ulcer was defined as a full thickness break of the skin, at least of Wagner stage 1, with or without inflammation, occurring distal to the malleoli. Neuropathy was diagnosed by the medical personnel of the clinics, by examining the pressure perception with the Semmes-Weinstein 5.07 monofilament as well as by assessing the vibration sensation using a 128 Hz tuning fork (according to the International Working Group on the Diabetic Foot guidelines (Bakker et al 2012).

As for the diagnosis of PAD, it was again assessed by the physicians of the healthcare structures by applying the ankle-brachial index (ABI) test (with values <0.90 and >1.40 being predictive of arterial problems) and by checking diagnostic tests such as duplex ultrasound and angiography. Furthermore, aneroid sphygmomanometer for measuring the systolic and diastolic blood pressure was used. The researcher measured the participant's blood pressure in concordance with the recommendations of the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research (Pickering et al 2005).

As for the footwear characteristics appropriate objective interview guide items with reference to wearing habits, preferences and events pertinent to the footwear were used. Contemplating that a medical recommendation has a diachronic nature, initial adherence could take place at any time the patients receive and start to use the medical product. Prevalence of using appropriate footwear was considered to be the indicator of initial adherence second step. As appropriate footwear, the ones that are accompanied by literature evidences (including expert opinion) regarding effectiveness (conventional off-the-self, semi-custom-made and custom-made diabetic shoes or slippers-sandals, running shoes and half-shoes) were counted.

Data analysis

Body mass index (BMI) was calculated as body weight (kg) divided by height squared (m2). Then, within the scope of inferential analysis, the numerical variable was transformed to a dichotomous categorical, as normal/overweight "21.5-29.9 kg/m2" and "30.0-42.7 kg/m2", implementing the obesity criterion (BMI $\geq$ 30 kg/m2) (Morris et al 2015).

Similarly, the parameter "severity of foot deformities" from a four categories variable (none/mild/moderate/severe) was altered to two classes one ("none/mild" and "moderate/severe").

Table 1. Frequencies of patients with diabetic foot disease characteristics

Sociodemographic characteristics	N	Results*
Sex	(41)	Men=80.5%; Women=19.5%
Age (years)	(41)	60.4 ± 8.4
Marital status	(41)	Married=56.1%; Single=22.0%; Divorced=12.2%; Widowed=9.8%
Education level	(41)	Secondary=63.4%; Tertiary=24.4%; Primary only=12.2%
Profession	(41)	Pensioner=56.1%; Freelance=12.2%; Unemployed=9.8%; Public-sector employee=9.8%; Private employee=7.3%; Housework=4.9%
Residence	(41)	Attica basin=85.4%; Countryside=7.3%; County capital=7.3%;
Clinical characteristics		
Diabetes duration (years)	(41)	18.9 ± 9.1
Diabetes type	(40)	Type 2=92.5%; Type 1=7.5%
Treatment	(41)	Insulin only=39.0%; Medications and insulin=36.6%; Medications only=24.4%
HbA1c (%)	(32)	7.1 ± 1.3
Number of hypoglycemic episodes in the last 30 days	(41)	1.0 (0.0-3.0)
BMI (kg/m2)	(41)	28.7 (25.2-29.8)
Systolic blood pressure (mmHg)	(41)	125 (113.8-141.3)
Diastolic blood pressure (mmHg)	(38)	73.5 ± 11.8
Retinopathy	(40)	62.5%
Renal complications	(28)	25.0%
SpO2 (%)	(37)	98 (96-98)
Heart rate (beats per minute)	(38)	76.8 ± 13.0
Hypertension	(37)	64.9%
Coronary artery disease	(39)	35.9%
Diabetic peripheral neuropathy	(38)	76.3%
Diabetic autonomic neuropathy	(33)	54.5%
PAD	(39)	48.7%
Severity of foot deformities	(38)	Moderate=39.5%; Mild=31.6%; None=26.3%; Severe=2.6%
Active foot ulceration	(41)	65.9%
History of previous ulceration	(40)	72.5%
IWGDF risk category	(14)	"3"=85.7%; "1"=7.1%; "0"=7.1%
Life style characteristics		
Smoking	(41)	36.6%
Alcohol drinking frequency	(40)	Never=52.5%; Twice a month=10.0%; Once a month=10.0%; Once a week=10.0%; Less than once a month=7.5%; Daily=5.0%; Three to four times a week=5.0%
Footwear characteristics		
Footwear type	(41)	Semi-custom-made diabetic shoes or slippers-sandals=24.4%; Running shoes=14.6%; Conventional non-specially made shoes=14.6%; Custom-made diabetic shoes=9.8%; Sandals (non-specially-made)=9.8%; Anatomic-comfort shoes=7.3%; Half-shoes=4.9%; Athletic leisure shoes=4.9%; Basketball shoes=4.9%; Off-the-self diabetic shoes=2.4%; Slippers (non-specially-made)=2.4%
Satisfaction from the footwear aesthetics (VAS score, 0-10)	(41)	8.0 (6.0-9.5)

Table 1. Frequencies of patients with diabetic foot disease characteristics (continuation)

Sociodemographic characteristics	N	Results*
Satisfaction from the footwear price (VAS score, 0-10)	(38)	6.0 (3.0-9.0)
Initial adherence to wearing appropriate footwear		
Prevalence of appropriate footwear	(41)	56.1%

**Results are % or median (interquartile range) or mean ± SD*

The estimation of daytime, continued, adherence in wearing appropriate shoes was based on the study of Chantelau and Haage (1994), in which daytime considered to have 16 hours.

Statistical analysis

For data analysis, descriptive and inferential statistics methods were applied using the IBM SPSS 24 software package. In the context of the descriptive analysis, frequencies of the sample and interview responses characteristics were estimated.

With regard to the inferential statistical analysis, Chi-square and Mann-Whitney U tests were performed for examining differences between the initially adherent and non-adherent groups (among all the participants). Subsequently, univariate regression investigation was carried out. The enter method of regression was used and 5% probability criterion was set for entering the linear model. The parameters which investigated as factors of the initial adherence were chosen based on the previous literature and after consensus of the research team.

RESULTS

Descriptive characteristics

Eighty five percent of the participants were men, 56.1% pensioners and 85.4% were residents of the Attica basin. In terms of the anthropometric attributes, the median BMI was 28.7 (interquartile range 25.2-29.8 kg/m2). In regard to the clinical characteristics, 92.5% were patients with Type 2 diabetes, 65.9% had active foot ulcer/s and median systolic pressure 125 (113.8-141.3) mmHg. As for the lifestyle, 36.6% were smokers and 20% frequent alcohol consumers. With respect to the appropriate footwear initial adherence, 56.1% wore suitable for diabetes shoes, while 43.9% inappropriate ones. The above mentioned data are presented in detail in table 1.

With reference to the entire (outdoors and indoors) continued adherence in wearing appropriate footwear among the "at risk for diabetic ulceration" subgroup (the majority of the group members belonged to the "3" IWGDF risk category (Singh et al 2005), 78.6% wore right preventive shoes (conventional off-the-self, semi-custom-made and custom-made diabetic shoes, or slippers-sandals, and running shoes) and the percentage of the patients who wore them ≥60% of daytime (9.6 or more hours) was 27.3%.

Comparisons and correlations

There was a significant relationship between the presence or absence of active foot ulcers and whether or not the participants wore right footwear at the time of research ($x2(1)=4.36$, $p=0.037$). The patients with active ulcers wore appropriate shoes at a lower percentage (44.4% versus 78.6%) than those without (the "at risk" patients).

The initially adherent group had significantly lower Visual Analogue Scale (VAS) score with respect to the satisfaction from the footwear price (Mdn=5.00) than the one that was not initially adherent (Mdn=8.00, U=97.00, $z=-2.36$, $p=0.019$, $r=-0.38$).

The univariate logistic regression analysis, in relation to the initial adherence outcome, was significant ($p=0.045$) only for the "presence or absence of active foot ulcers" parameter (OR 4.58, 95% CI 1.04-20.24) assuming a linear relationship between the categorical independent variable and the log odds of the dependent. The absence of active foot lesions had a positive influence on initial adherence ($B=1.52$, $SE=0.76$) and the Nagelkerke's R-square of 0.14 betokened a relatively weak association between the predictor variable and dependent one (Tables 2 and 3).

The size of the "at risk for ulceration" subgroup was quite small (n=11) and therefore inadequate for inferential analysis with respect to the continued adherence.

DISCUSSION

Although this was a small-scale pilot study, aiming in the background to assess the feasibility and workability of the methodology and measuring instruments that were chosen (Van Teijlingen & Hundley 2002), it attained to brought in weighty results.

The most important finding of the study was the fact that a considerable percentage of people with

Table 2. Cross-tabulations and means comparisons

		Appropriate footwear group*	Inappropriate footwear group§	P value
Sex	% Male	63.6	36.4	n.s**
	% Female	25.0	75.0	
Age (years)	% 40-61	57.9	42.1	n.s
	% 63-79	54.5	45.5	
Diabetes type	% Type 1	66.7	33.3	n.s
	% Type 2	54.1	45.9	
Mean of diabetes years (standard error)		20.5 (1.98)	16.9 (1.98)	n.s
BMI (kg/m^2)	% 22.1-29.9	56.3	43.8	n.s
	% 30.0-42.7	55.6	44.4	
Retinopathy	% Yes	56.0	44.0	n.s
	% No	53.3	46.7	
Renal complications	% Yes	71.4	28.6	n.s.
	% No	57.1	42.9	
Coronary artery disease	% Yes	50.0	50.0	n.s
	% No	56.0	44.0	
PAD	% Yes	57.9	42.1	n.s.
	% No	55.0	45.0	
Diabetic peripheral neuropathy	% Yes	51.7	48.3	n.s.
	% No	55.6	44.4	
Diabetic autonomic neuropathy	% Yes	38.9	61.1	n.s.
	% No	66.7	33.3	
Severity of foot deformities	% Moderate/severe	68.8	31.3	n.s.
	% None/mild	50.0	50.0	
Active foot ulceration	% Yes	44.4	55.6	0.037
	% No	78.6	21.4	
Smoking	% Yes	46.7	53.3	n.s.
	% No	61.5	38.5	
Satisfaction from the footwear aesthetics (VAS§§ score, 0-10, mean, standard error)		8.0	8.0	n.s.
Satisfaction from the footwear price (VAS score, 0-10, mean, standard error)		5.0	8.0	0.019

**Appropriate footwear frequencies: Semi-custom-made diabetic shoes or slippers-sandals=24.4%; Running shoes=14.6%; Custom-made diabetic shoes=9.8%; Half-shoes=4.9%; Off-the-self diabetic shoes=2.4%*

§Inappropriate footwear frequencies: Conventional non-specially made shoes=14.6%; Sandals (non-specially-made)=9.8%; Anatomic-comfort shoes=7.3%; Basketball shoes=4.9%; Athletic leisure shoes=4.9%; Slippers (non-specially-made)=2.4%

***Not significant (p value > 0.05)*

§§Visual analogue scale

Table 3. Univariate logistic regression analysis for "active foot ulceration"

	B (SE§)	Lower	Odds Ratio*	Upper
Included				
Constant	-0.22 (0.39)			
Active foot ulceration	1.52 (0.76)	1.04	4.58	20.24

**95% CI for Odds Ratio*
§Standard error
R2 = .08 (Hosmer & Lemeshow), .11 (Cox & Snell) and .14 (Nagelkerke)
Model x2(1) = 4.58, p=0.032

diabetic foot disease (43.9%), did not wear appropriate footwear when they were examined, an occurrence that is translated to partially adequate initial adherence, the precondition for continued adherence (Zeber et al 2013, Forestal et al 2016). Similar result was yielded by the case-control study of Breuer (1994), in which the initial adherence, in using right footwear, of patients with a healed neuropathic ulcer was 60% (51 of the 85 participants). However, by the retrospective audit of Churchman (2008), it was found that only the 39% of high-risk patients wore suitable for diabetic foot shoes.

The second most notable detection of the study was the inferior continued adherence in relation to the subgroup that was at risk for ulceration. Only the 27.3% of the group members, initially adherent in wearing preventive shoes, wore their footwear ≥60% of daytime (9.6 or more hours per day). It could be reasoned that, in general, this finding is consistent with literature (Chantelau & Haage 1994, Macfarlane & Jensen 2003, Churchman 2008, Waaijman et al 2013, Arts et al 2014), in which continued adherence is not satisfactory (almost half of the risk patients have adherence ≥60%). Nevertheless, it should be pointed that the subgroup of initially adherent high-risk patients was too small, and hence, might not represent data tendencies of a future larger sample from the same health care structures.

By the inferential statistical analysis, it was found that the patients with active foot ulcers wore appropriate shoes at a subordinate percentage (44.4% versus 78.6%) than those without. A study by Breuer (1994), showed that the 100% (against 47% of the adherent group) of the participants who were pertained to the non-initially adherent group answered that they "would prefer normal shoes for cosmetic reasons" ($p<0.05$). Moreover, in the study of Waaijman et al (2013), the better appearance of the specially manufactured shoes, through multivariate ordinary least squares regression analysis, was associated with higher continued adherence by the patients (B=1.98 95% CI 0.18-3.78, p=0.032). Considering the above, it could be argued that initial and continued adherence in wearing specially manufactured footwear (therapeutic or preventive) have, to some degree, common determining factors. Therefore, the study of Armstrong et al (2003), in which individuals with active foot lesions wore their RCWs for only a minority of daily steps (28%), supports the difference that was detected in the present research.

With regard to the satisfaction from the footwear price, it was found that participants of the initially adherent group had lower satisfaction scores (Mdn=5.00) than those of the non-initially adherent one (Mdn=8.00). Taking into account that therapeutic footwear is more expensive than conventional ones (Sheffield Teaching Hospital 2015), this result could be strengthened by the study of Shah et al (2009), which demonstrated that the copays, regarding the purchase of diabetic medications, of <$10 were associated with improved initial adherence rates (OR 2.22, 95% CI 1.57-3.14, $p<0.0001$).

CONCLUSIONS

For the enhancement of initial adherence, and by extension of continued adherence among the total population of people with diabetic foot disease in wearing appropriate footwear, health care professionals could pay more attention to the education of patients with active foot ulcers, underling the importance of using right shoes. Additionally, they could provide patients with multiple price options concerning their footwear (e.g. by suggesting effective and affordable products from competitive economies). The greater coverage of the purchasing expenses from the health insurance organizations could be a solution as well.

CONTRIBUTION OF AUTHORS

AK: Collected the data, analyzed them and wrote the article. **NT:** Helped with the data collection, wrote a part of "data analysis" and "introduction" sections, as well as consulted regarding the statistical analysis. **VK:** Contributed in writing the "Material

and Methods" section. CVL: Helped regarding data collection and contributed in tables writing. **GM:** Helped with data collection. **GEM:** Helped with data collection and contributed in "data analysis" section. **EZ:** Helped with data collection. **MT:** Contributed in writing "Method - Material" section as well as in formatting the manuscript.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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