DISABILITY AND REHABILITATION, 1998; VOL. 20, NO. 9, 330–336

Clinical and functional correlates of foot pain in diabetic patients

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Accepted for publication: February 1998

Keywords diabetes mellitus, pain, diabetic foot, podiatry.

Abstract

Purpose: Patients with diabetes mellitus frequently suffer from foot pain. This pain seems to be a neglected area in studies on the diabetic foot. The purpose of this study was to identify clinical variables associated with foot pain in diabetic patients. In addition, the relationships between foot pain and several functional impairments and disabilities were explored.

Method: The research group consisted of 29 diabetic patients with any symptoms possibly associated with a diabetic foot, who were referred to podiatry. The relationships between several clinical measures and foot pain were analysed by means of Mann-Whitney U-tests. In addition, Spearman rank correlations coefficients were computed to assess the relationships between foot pain and measures of functional health.

Results: Diabetic patients suffering from sensory neuropathy experience more severe foot pain. Furthermore, patients with more severe foot pain experience more fatigue, more disabilities in walking and a lower level of affective well-being.

Conclusion: Based on these findings this paper concludes that foot pain in diabetic patients is an important impairment, which deserves further scientific attention.

Introduction

Diabetic patients who have been ill for several years frequently suffer from foot problems due to late complications of the disease, for instance neuropathy, peripheral vascular insufficiency and limited joint mobility.[1,2] These impairments may cause skin lesions, fractures, pain, fatigue and disabilities in mobility, and consequently may affect the patient's well-being. Boulton assesses the frequency of diabetic patients with feet at risk at 25%.[3] Most and Sinnock come to a similar percentage of diabetic patients who will develop foot problems during their lifetime.[4]

When considering the scientific literature about the diabetic foot, one may conclude that most studies are concerned with the dangers of ulceration. Ulcers on the feet are responsible for considerable morbidity and mortality among diabetic patients. Because of the frequent and long-lasting hospitalization of diabetic patients with foot ulcers, the medical costs and economic loss caused by sick-leave are very high.[5] The attention paid to ulcers seems therefore well justified. Nevertheless, other impairments of the diabetic foot are also frequently noticed by clinicians, for instance pain.

Although empirical studies of foot pain in diabetic patients are scarce, clinical experience suggests that many impairments frequently seen in diabetic patients can be attended with pain. When stance deviations, skin abnormalities or nail problems are diagnosed, podiatry consisting of rather simple intervention methods such as podiatric insoles and instrumental treatment are applied to reduce the pain.[6] Other impairments that can occur with foot pain are peripheral polyneuropathy, peripheral vascular disease or other diseases frequently diagnosed in diabetic patients.[1,7] These latter impairments are much more difficult to treat. Even so, their impact should be taken into account in order to form a notion of all clinical factors involved in foot pain.

Foot pain can have a further negative impact on the quality of life of diabetic patients. The degree to which functional problems such as fatigue and disabilities in walking are related to foot pain indicates to what extent

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foot pain affects other domains (e.g. social, functional) of life.

The study described here is a first step to fill some of the gaps in knowledge about the clinical and functional correlates of foot pain in diabetic patients. The purpose of this exploratory study is to identify the clinical factors that are associated with foot pain in diabetic patients, and to reveal how this foot pain relates to the patients' functional capacity and well-being.

Methods

PROCEDURE

The study took place in two outpatient clinics in the Netherlands, one associated with an academic hospital and one with a general hospital. Both outpatient clinics have a regional function to provide specialized podiatric care. All patients with diabetes mellitus referred to podiatry between January and April 1996 were considered for participation. Subjects were selected on the basis of the following inclusion and exclusion criteria. Patients should suffer from Insulin Dependent Diabetes Mellitus (IDDM) or Non-Insulin Dependent Diabetes Mellitus (NIDDM), they should have symptoms or impairments associated with a diabetic foot, and they should have been referred to podiatry. Patients aged younger than 18 or older than 80 were excluded. Furthermore, patients who did not give informed consent, who did not have command of the Dutch langauge or who did not have adequate mental capacity to participate were also excluded.

When a patient met the criteria, he/she received written information about the study and was asked to participate. With the patients who consented to participate an appointment was made to collect data during their first visit at the outpatient clinic.

DATA COLLECTION

Data were collected by means of standardized self-rating questionnaires which were filled in with the help of a researcher, the diagnostic research of the podiatrists, and additional clinical tests performed by a research assistant. The following variables and measuring instruments were used in the study.

Foot pain

The level of foot pain was measured by the Pain subscale of the Foot Function Index (FFI).[8,9] The Pain scale consists of seven† items measuring the level of foot pain in a variety of situations. The items are rated on visual analogue scales which were coded next with values ranging from 0 to 9. To obtain an overall score of foot pain, the items were totalled and divided by the maximum total possible for all of the scale items which the patient indicated were applicable. For instance, if a patient indicated that he/she did not perform an activity such as walking barefoot, the item was marked as not applicable. The scores were multiplied by 100, resulting in scale scores ranging from 0 to 100.[8] Higher scores indicate more severe pain.

Clinical variables

Several impairments frequently diagnosed in diabetic patients were clinically evaluated by means of standardized tests. Patients were screened for loss of sensation (sensory neuropathy) by means of the Semmes-Weinstein monofilament 5·07. Birke and Sims, together with other authors, conclude that the 5·07 monofilament is the best indicator of protective sensation.[10] The plantar side of the hallux and MTP1, and the dorsal surface between MTP1 and MTP2 on both feet were tested. Each location was tested three times at random, and scored 0 and 1. A total score on this test was computed to range between 0 and 18. For the purpose of this study the scores were dichotomized at the median score of 15. Vascular disease was clinically assessed by palpation of the dorsalis pedis and tibialis posterior arteries. A score was assigned on the base of the perceived pulsations: 0 (no or abnormal pulsations) and 1 (normal pulsations). Limited joint mobility was assessed at MTP1 by measuring the passive range of dorsal flexion by means of a standard goniometer three times. The average scores were dichotomized with a cut-off point of 45 grades being the median score.

Other clinical variables were assessed during the history taking and clinical examination by the podiatrist. These variables were stance deviations of feet or toes, stable Charcot deformity, exostosis, excessive callus, ulcers, and nail impairments. The type of diabetes and comorbidity had been registered by a medical specialist.

† The original Pain scale consists of nine items. For the purpose of this study, we excluded two items 'standing with orthotics' and 'walking with orthotics'. These items were considered relevant by only eight patients wearing orthotics. Furthermore, the patients rated these items in the same way as the two items referring to walking and standing with shoes, since the latter items had already been answered taking the use of orthotics into account.

All these variables were scored 0 (absence of impairment) and 1 (presence of impairment). In the case of stance deviations, the study distinguished between 'no or mild deviations' and 'moderate to severe deviations', since in nearly all patients some kind of a stance deviation was diagnosed.

Functional variables

Functional variables that were included in the study were: fatigue, functional ability, walking distance, and global well-being.

Fatigue was measured by a standardized self-rating questionnaire, the Multidimensional Fatigue Inventory.[11] This measure consists of 20 items measuring five dimensions: general fatigue, physical sensations, reduction in activity, reduction in motivation, and mental tiredness. Each subscale consists of four items with a five-category response format. The subscale scores can range between 4 and 20; higher scores indicate more severe fatigue. Cronbach's alphas in this study range from 0·68 (reduction in motivation) to 0·91 (physical sensations).

Functional ability was measured by three subscales of a shortened version of the Sickness Impact Profile (SIP-68): somatic autonomy (17 items), mobility control (12 items) and mobility range (10 items).[12] Somatic autonomy describes the degree to which an individual is autonomous in basic somatic functioning. Functions referred to are getting dressed, standing, eating, etc. Mobility control is related to the degree to which an individual has control over his body. Six out of the 12 items of this dimension directly refer to walking. Mobility range is concerned with the influence of health status on a number of usual tasks such as shopping, house cleaning and taking care of personal and/or business affairs. The scores of the subscales can range between 0 and 100; higher scores indicate more severe disability. Cronbach's alphas in this study are 0·72 for somatic autonomy, 0·90 for mobility control, and 0·83 for mobility range.

Walking distance was clinically evaluated by measuring the distance (m) patients were able to walk in 6 minutes at their usual speed and—if relevant—with their usual walking aid.[13]

Global well-being was measured by two questions of De Haes, one referring to affective well-being ('In general, how did you feel during the past week?') and one referring to the cognitive aspect ('To what extent did you feel satisfied with your life the past week?').[14] A seven-category response format was used, ranging from 'very good/satisfied' to 'very bad/unsatisfied'.

ANALYSIS

Scalability and reliability of foot pain

First, the scalability and reliability of the Pain scale was assessed. The Pain scale can be considered a hierarchical unidimensional scale with items indicating mild to severe foot pain. In order to test the postulated existence of one latent unidimensional construct, Mokken scale analysis was performed. Scale criteria are met when all coefficients of scalability for pairs of items ($H_{g,h}$) are positive, while the scalability coefficients for items (H_g) and for the scale (H) do not fall below a positive constant (c) which is usually set at 0·30. Higher values of H_g and H implicate a better hierarchy. In general, $H \geqslant 0{\cdot}50$ indicates a 'strong' scale.[15] Furthermore, rho and Cronbach's alpha were computed as measures of the intra-test reliability.

Clinical correlates

Bivariate analyses were performed in order to identify the clinical variables associated with foot pain. Since most of the clinical variables were dichotomous variables in itself (for instance, the presence/absence of an impairment), all other clinical variables were dichotomized as has been described under the heading data collection. Nonparametric Mann-Whitney U-tests were performed to assess the relationship between these clinical variables and foot pain.[16]

Functional correlates

For the purpose of assessing the functional correlates of foot pain with fatigue, functional ability, walking distance and global well-being, nonparametric Spearman rank correlation coefficients were computed.[17]

Results

PATIENTS

A total of 38 patients who met the criteria received written information about the study. Three patients who gave permission to participate in the study did not show up at the appointment with the podiatrist. Finally, six patients refused to participate. Twenty-nine patients gave permission and actually participated in the study. Thus, the net response rate was 76%.

Table 1 shows the socio-demographic and illness-related characteristics of the patients involved in the study. The participants proved to be relatively young with a mean age of 58 years. The number of male

Table 1 Socio-demographic and illness-related characteristics of the participants ($n = 29$)

Variable		*Number*	*%*	*Mean (SD)*	*Range*
Age				57·8 (17·2)	18–81 years
	18–45 years	8	27		
	46–65 years	8	27		
	66 years and older	13	45		
Gender	Male	16	55		
	Female	13	45		
Marital status	Single	6	21		
	Married/cohabited	20	69		
	Divorced	1	3		
	Widowed	2	7		
Insurance ($n = 27$)	Health insurance fund	18	67		
	Private insurance	9	33		
Type of diabetes	IDDM	10	35		
	NIDDM	19	66		
Duration of illness				15·2 (13·1)	0–42 years
($n = 27$)	Shorter than 1 year	2	7		
	1–2 years	3	11		
	3–5 years	3	11		
	6–10 years	4	15		
	11–20 years	7	26		
	21 years or longer	8	30		
Treatment ($n = 28$)*	Diet	3	11		
	Oral medication	7	25		
	Insulin	23	82		
Hba_{1c} ($n = 23$)	$Hba_{1c} < 6{\cdot}5\%$	1	4		
	$6{\cdot}5\% \leqslant Hba_{1c} < 8{\cdot}0\%$	9	39		
	$Hba_{1c} \geqslant 8{\cdot}0\%$	13	57		
Comorbidity ($n = 25$)	Absense of comorbidity	8	32		
	Presence of comorbidity	17	68		

* The total percentage is higher than 100, because combinations of treatment are possible.

patients was slightly higher than the number of female patients. Most patients were married or cohabited. With regard to the type of insurance, the percentages of patients with a private or public insurance were in accordance with the percentages found in the Dutch population.

About one third of the patients suffered from IDDM; this percentage is higher than would be expected from the prevalence rate of IDDM compared to NIDDM. The mean duration of illness was 15 years; however, there was a broad range from 0 to 42 years. More than 80% of the patients used insulin with or without other types of treatment. The majority of the patients had a Hba_{1c} greater or equal than 8·0%, indicating inadequate regulation of diabetes. About two thirds of the patients were suffering from other diseases besides diabetes.

SCALABILITY AND RELIABILITY OF FOOT PAIN

The scalability of the Pain scale consisting of seven items proved to be good: no negative $H_{g,h}$ coefficients, $H = 0{\cdot}56$ and H_g-values ranging from 0·33 to 0·74. The items can be ordered hierarchically on the basis of the average pain score (see table 2). This hierarchy implicates that in general, foot pain in diabetic patients is more severe at the end of the day than in the morning. In addition, the patients experienced more pain while walking than while standing, both when wearing shoes and when barefooted. Furthermore, patients experienced more pain wearing shoes than barefoot. The intra-test reliability of the Pain scale was good; rho = 0·89 and Cronbach's alpha = 0·88. The mean score of the patients

Table 2 Hierarchical ordering of items of the Pain scale based on their mean scores

Rank number	*Item*	*Mean score*	*SD*
1	Foot pain standing barefoot	1·62	2·75
2	Foot pain before getting up in morning	1·72	2·39
3	Foot pain walking barefoot	1·95	2·71
4	Foot pain standing with shoes	2·07	2·59
5	Foot pain walking with shoes	2·55	2·95
6	Foot pain at the end of the day	2·79	2·80
7	Foot pain at its worst	4·34	3·43

Table 3 Bivariate analyses of the relationships between clinical variables and foot pain (Mann-Whitney U-tests)

Variable	n	*Mean pain score*	*SD*	*Median pain score*	*Range*[1]	*U*	*W*	*2-tailed* p
Type of diabetes								
NIDDM	19	34·9	25·8	32	0–84	53·0	108·0	0·06
IDDM	10	17·0	18·9	9·5	0–56			
Comorbidity								
Absent	8	15·1	16·2	11	0–43	43·5	79·5	0·16
Present	17	34·6	28·7	32	0–84			
Neuropathy (sensory)								
Absent	16	18·4	20·0	11	0–57	47·5	222·5	0·02
Present	12	41·3	26·0	39·5	0–84			
Angiopathy								
Absent	21	23·0	21·7	13	0–57	48·5	126·5	0·19
Present	7	38·9	26·1	32	0–84			
Limited joint mobility (MTP1)								
Absent	13	22·6	20·7	13	0–57	82·0	173·0	0·66
Present	14	29·9	26·4	27	0–84			
Stance deviation								
Absent/mild	11	25·0	22·7	25	0–57	85·0	151·0	0·55
Mod/severe	18	31·1	26·5	28	0–84			
Charcot deformity (stable)								
Absent	26	26·9	23·0	26	0–84	27·0	57·0	0·43
Present	3	45·0	40·4	57	0–78			
Exostosis								
Absent	20	27·4	26·7	26	0–84	71·0	154·0	0·39
Present	9	31·9	21·2	29	2–57			
Callus								
Normal	12	33·2	24·2	28	0–84	83·5	198·5	0·42
Excessive	17	25·6	25·6	11	0–78			
Ulcer								
Absent	24	29·0	24·3	27	0–84	55·5	70·5	0·80
Present	5	27·8	30·6	25	0–78			
Nail impairment								
Absent	13	22·8	28·1	11	0–84	69·0	160·0	0·13
Present	16	33·6	21·6	37·5	0–57			

[1] Pain score theoretical range: 0–100; higher scores indicate more pain.

Table 4 Scores on functional variables and their Spearman rank correlations with foot pain

Variable	*Mean*	*SD*	*Median*	*Range*	*rho*	n	*2-tailed* p
Fatigue							
General fatigue	11·6	5·8	11	4–20	0·63	29	0·000
Physical sensations	11·6	5·8	11	4–20	0·48	29	0·008
Reduction in activity	12·2	6·1	14	4–20	0·48	29	0·008
Reduction in motivation	8·6	4·2	8	4–20	0·25	29	0·20
Mental tiredness	8·6	4·4	8	4–16	0·21	29	0·28
Functional ability (SIP-68)							
Somatic autonomy	6·3	9·9	0	0–35	0·20	29	0·30
Mobility control	30·2	30·8	25	0–75	0·50	29	0·006
Mobility range	11·7	19·8	0	0–70	0·30	29	0·11
Walking distance (m)	373	101	365	192–630	−0·53	24	0·008
Global well-being							
Cognitive well being	5·1	1·5	5	2–7	−0·13	29	0·49
Affective well-being	4·9	1·4	5	1–7	−0·55	29	0·002

on the pain scale was 28·76 (SD = 24·87), with a range of 0 to 84. The median score was 27.

CLINICAL CORRELATES

Before considering the clinical correlates, we assessed the relationship between two socio-demographic variables and foot pain. Neither age nor gender were associated with foot pain (age: Pearson's $r = 0{\cdot}00$, $p = 0{\cdot}99$; gender: $t(27) = 0{\cdot}24$, $p = 0{\cdot}81$).

Table 3 contains the results of the bivariate analyses with the clinical variables being the grouping variables and foot pain the 'dependent' variable. It shows that diabetic patients with sensory neuropathy have considerably more pain than other patients. All other associations were not significant for alpha = 0·05.

FUNCTIONAL CORRELATES

The results concerning the functional correlates of foot pain are shown in table 4. Foot pain appears to be related to the 'physical' dimensions of fatigue, but not to the mental dimensions. With regard to functional ability, the Spearman rank correlations show that foot pain is associated with decreased mobility control, and not with somatic autonomy or mobility range. Furthermore, the walking test proved that patients with more severe foot pain have more difficulty walking long distances than patients with less severe or without pain. Finally, the affective dimension of well-being is associated with pain, while the cognitive dimension (life satisfaction) is not.

Discussion

This study was performed to assess the clinical and functional correlates of foot pain in diabetic patients. Since most research on the diabetic foot is concerned with the prevention, diagnosis and treatment of ulcers, there is relatively little knowledge on other foot impairments caused by diabetes, such as pain. Nevertheless, foot pain seems to occur with many diabetic patients and can be expected to affect their well-being considerably. The purpose of this study was to identify clinical variables associated with foot pain. Because of the lack of insight due to the scarcity of research in this domain, the nature of this study was explorative using a cross-sectional design. Besides the clinical correlates of foot pain, the impact of the pain in terms of impairments, disabilities and overall well-being of diabetic patients was also of interest.

In order to assess the severity of the foot pain, a Pain scale was used that had earlier been used in research on patients with rheumatoid arthritis (RA). Mokken scale analysis showed that the Pain scale was a reliable measure of foot pain in diabetic patients. The mean score and SD found in this sample were in accordance with the mean score (29·7) and SD (28·1) found in patients with definite or classical active RA.[8] This suggests that the severity of foot pain in diabetic patients referred to podiatry is similar to the severity of foot pain experienced by these RA patients. The hierarchical ordering of the items on the basis of the average scores provides some information about the nature of the foot pain experienced by diabetic patients. Foot pain in diabetic patients seems to be more severe while walking, wearing shoes and at the end of the day. One should realize that the items of the Pain scale only refer to the severity of foot pain; they do not specify pain sensations. It is evident that such pain sensations may differ according to the source of foot pain, for instance, neuropathic pain is characterized by other sensations than ischaemic pain. Therefore, future research on foot pain in diabetic patients should pay attention to both severity and sensations.

With regard to the clinical factors under study, diabetic patients with a sensory neuropathy appeared to have considerably more pain than patients without neuropathy. When one considers that the median score for sensory neuropathy was 15 on a scale that could range between 0 and 18, it is obvious that most patients in this study did not experience a total loss of sensation. These patients are likely to suffer from pain. Intermittent burning pain that is worse at night is a common characteristic and may persist for years.[18] Many other impairments which can be expected to cause foot pain in diabetic patients did not show significant differences between cases and non-cases. Two limitations of the study may be responsible for these non-significant results. First, the total sample size of the study was small. As a consequence, the power of the study was low. Thus, only large differences between patients with or without specific impairments could be detected. Secondly, some impairments were diagnosed in only a few patients, for instance a Charcot deformity. In these cases, significant differences could not be demonstrated because of the small number of patients with the impairment. The difference in mean scores found in patients varying in type of diabetes, angiopathy, limited joint mobility, stance deviations, Charcot deformity and nail impairments urge for further research concerning the aetiology of foot pain.

Foot pain is not only burdensome in itself, but it also seems to have a negative impact on the level of fatigue, functional ability and well-being. When considering the correlations of foot pain with the several dimensions of

fatigue, it is obvious that foot pain is related to the physical dimension of fatigue; it is not associated with mental tiredness or a reduction in motivation. Similar mean scores of fatigue have been found in cancer patients receiving radiation therapy, while a reference group consisting of a general population sample scored significantly lower on the subscales referring more to the physical dimension of fatigue.[19] Furthermore, foot pain appears to be related to disabilities in walking. A significant relationship was found between pain and mobility control as measured by the shortened version of the Sickness Impact Profile. A large part of the items of this subscale are concerned with walking ability. The negative relationship between pain and walking ability was confirmed by the walking test in this study and no relationship was shown between the level of foot pain and somatic autonomy or mobility range. These two dimensions of functional ability seem less relevant for diabetic patients with foot pain; 16 and 19 patients respectively had a zero-score on these subscales, indicating no disability at all. As was already mentioned in the method section, these subscales refer to functional ability in a broader scope such as activities of daily life and household activities. Finally, this study showed that patients with more severe foot pain perceived their affective well-being to be lower than patients who suffered less from foot pain. Foot pain was not associated with cognitive well-being. Apparently, the level of foot pain experienced by the patients did not substantially affect their life satisfaction. The mean scores of affective and cognitive well-being were comparable to the mean scores of a generic sample of women with chronic ailments from the general population, but were lower than the mean scores of healthy women.[20]

Although the conclusions based on the results of this study are restricted by its design, they do give some indications of the factors associated with foot pain in diabetic patients. In addition, some insight into the 'gain' in functional health that can be achieved by reducing foot pain is provided. This gain may consist of less fatigue and improved walking ability, which consequently may lead to better physical and social functioning. These indications ask for more extensive research on the aetiology and treatment methods of foot pain in diabetic patients.

Acknowledgements

The authors wish to thank T. W. Vogelaar, physical therapist, for her assistance in the clinical examination of the patients.

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