

ORIGINAL PAPER

PAINFUL ULCERATION AND QUALITY OF LIFE OF PATIENTS WITH THE DIABETIC FOOT SYNDROME

Radka Vymětalová, Renáta Zeleníková

Department of Nursing and Midwifery, Faculty of Medicine, University of Ostrava, Czech Republic

Received May 9, 2016; Accepted July 28, 2016. Copyright: This is an open access article distributed under the terms of the Creative Commons Attribution International License (CC BY). <http://creativecommons.org/licenses/by/4.0/>

Abstract

Aim: The aim of this study was to evaluate the influence of pain on quality of life of patients with diabetic foot syndrome. **Design:** Cross-sectional study. **Methods:** Quality of life was assessed using a Czech version of the Diabetic Foot Ulcer Scale (DFS), a standardized questionnaire. The sample consisted of 247 patients with diabetic foot syndrome. The intensity of pain in diabetic ulcers was measured using a visual analogue scale (VAS) from 0 (no pain) to 10 (maximum pain). Data was collected between April 2014 and December 2014 in 18 podiatric and chronic wound outpatient clinics throughout the Czech Republic. **Results:** Quality of life in patients with permanent pain was lower in all domains of the DFS questionnaire in comparison with patients who reported no pain. For patients who attended chronic wound outpatient clinics quality of life was significantly lower in four domains of the DFS (Leisure, Physical health, Emotions, and Friends) than for patients who did not attend chronic pain outpatient clinics. A statistically significant moderate negative correlation was found between intensity of pain and quality of life in the following domains: Physical health ($r = -0.592$), Daily activities ($r = -0.456$), Emotions ($r = -0.503$), and Treatment ($r = -0.434$). **Conclusion:** Pain ulceration affects quality of life of patients with diabetic foot syndrome.

Keywords: diabetic foot syndrome, pain, quality of life, Diabetic Foot Ulcer Scale.

Introduction

Painful diabetic neuropathy can significantly impair patients' quality of life (Bouhassira et al., 2013) and affect many areas of daily life (Huizinga, Peltier, 2007). Pain is associated with the progression of the underlying disease, and adds to patients' general morbidity. It leads to a significant deterioration in quality of life, and is a frequent cause of other adverse symptoms – mostly in terms of deterioration in quality of sleep, the emergence of, or worsening of, depression and anxiety, and reduced performance in work and other conventional activities (Černý 2012; Mazanec 2012). The prevalence of pain varies between 10–20% of patients with diabetes mellitus, and 40–50% of patients with diabetic neuropathy (Didangelos, Doupis, Veves, 2014). Bouhassira et al. (2013) report that a third of patients with diabetes mellitus have experienced painful diabetic neuropathy at certain periods of their lives, and that the experience was stressful, affecting them both physically and emotionally.

Although recently there has been significant progress in understanding ways of managing biomedical risk factors associated with the complications of diabetic foot ulcers, the number of ulcerations and amputations is still unacceptably high. According to the currently available data of the Institute of Health Information and Statistics, the number of people affected by diabetes in the Czech Republic (CR) in 2013 increased by 2.4% compared to 2012. In 2013 diabetes affected 861,647 patients, of which 789,900 cases involved type 2 diabetes. The number of registered chronic diabetic complications in 2013 also showed an upward trend: 251,712 complications, compared to 241,043 in 2012. The proportion of diabetics with chronic complications of diabetes was approximately the same as in the previous year – almost 29% (UZIS, 2013). In 2013, diabetic foot was diagnosed in 44,657 cases, of which 11,168 required amputation. In 2012 43,248 patients suffered from diabetic foot, of which 10,425 required amputation). The figures indicated for amputations include amputations both above and below the ankle (Zvolský, 2013).

Diabetic foot syndrome is defined by the World Health Organization as ulceration or destruction of the tissues of the feet of diabetic patients, with neuropathy, associated with varying degrees

Corresponding author: Radka Vymětalová, Středomoravská nemocniční, a.s., odštěpný závod Nemocnice Přerov, Dvořákova 75, Přerov, Czech Republic, email: vymetalovaradka@seznam.cz

of peripheral arterial disease, often with infection (CDS). Clinically, diabetic foot syndrome is categorized by its predominant pathogenetic factors: neuropathic, ischemic and neuroischemic (mixed). In neuropathic cases, the clinical symptoms of neuropathy are significant: the foot is warm and pink, peripheral pulsations are easily palpable, and ulcers tend to be painless. By contrast, the ischemic foot is cold and livid, peripheral pulsations are not palpable, and ulcers are usually very painful. In neuroischemic foot, symptoms are mixed (Pitřhová, 2010). Although most patients with diabetic peripheral neuropathy experience no pain, approximately 11% of patients have chronic, painful symptoms, which decrease quality of life, disrupt sleep, and can lead to depression in patients (Argoff et al., 2006). Wound pain is an important determinant of quality of life, involving a sensory aspect (patients' perception of how painful the wound is), an affective aspect (how wound pain affects mental health in terms of fear, anxiety, anger, depression, sleep disorders, and others.) and a cognitive aspect (patients' opinions regarding the cause and significance of the pain); this includes expectations of pain during the redressing procedure on the basis of previous experience. These dimensions (components) affect the perception of pain (Stryja, 2011). A study by Bouhassira et al. (2013) on a sample of 885 patients showed that patients with chronic pain with neuropathic characteristics have significantly lower quality of life, more sleep problems, and a higher level of anxiety and depression than patients with chronic pain without neuropathic characteristics. Diabetic ulcers have a significant impact on patient quality of life (Vileykite, 2001). Although the negative correlation between the intensity of pain and quality of life in diabetic ulcers has already been demonstrated (Nemcová, Parish, Hlinková, 2013), according to the authors Aslam et al. (2014), there are relatively few research studies monitoring the impact of painful diabetic neuropathy on quality of life and mental health.

Aim

The aim of the research was to determine the influence of pain on quality of life in patients with diabetic foot syndrome.

Methods

Design

Cross-sectional study.

Sample

The research sample consisted of adult patients (over 18 years of age) from the Czech Republic, with at least one diabetic ulcer of the type associated with diabetic foot syndrome. It comprised 247 patients with diabetic foot syndrome who attended a podiatric or chronic wounds outpatient clinic in the Czech Republic. An exclusionary criterion was refusal to participate in the study.

Data collection

Data were collected from April 2014 to December 2014 in 18 foot clinics and chronic wound outpatient clinics throughout the Czech Republic.

Quality of life of patients with diabetic foot syndrome was measured by a specific standardized questionnaire: the Diabetic Foot Ulcer Scale (DFS ©), which was originally created by Johnson & Johnson in English (DFS© 1999 Janssen Global Services, LLC USA. All rights reserved). The Diabetic Foot Ulcer Scale is a specific tool designed to assess the impact of diabetic ulcers on quality of life (Abetz et al., 2002). Permission to use the DFS© questionnaire, and to translate the questionnaire into Czech, was requested by the Mapi Research Institute. A translation and linguistic validation of the questionnaire were made according to the manual "Linguistic validation of patient-reported outcomes measure" (2005). The translation was executed according to three steps recommended in the manual:

1. *Forward translation*: translation into Czech by two independent professional translators, resulting in the creation of a single Czech version;
2. *Reverse translation*: reverse translation from Czech into English;
3. *Patient testing*: pilot testing on ten patients with at least one diabetic ulcer in the Central Moravian hospital a.s., Přerov, Czech Republic. During the pilot test, in addition to completing the questionnaire, patients also answered questions concerning the clarity of the instructions, their comprehension of the issues, and the response options provided. In addition, they were asked to indicate any expressions they found difficult to understand and to describe how they might be reformulated. Patients included in the pilot test were not included in the final sample.

Clinical assessment of the final version of the DFS© questionnaire was conducted by Jan Stryja, MD, Ph.D. from the Centre of Vascular and Mini-invasive Surgery, and the foot clinic at Hospital Podlesí a. s. A report was prepared after every stage, and all steps

were discussed with the Mapi Research Institute. The linguistic validation process took ten weeks.

The DFS© questionnaire contains 58 items organized into 11 domains: Leisure, Physical Health, Daily activities, Emotions, Non-compliance, Family, Friends, Treatment, Satisfaction, Positive attitude, and Financial. Each domain contains 1–17 questions answered according to a five or six-point Likert scale (1 to 5, or, in some issues, 0 to 5), a higher score meaning higher quality of life.

The intensity of pain of diabetic ulcers was measured on the visual analogue scale (VAS), from 0 (no pain) to 10 (maximum pain). Demographic data recorded included gender, age and marital status. Clinical data recorded included duration of ulceration, whether or not treatment was received in a chronic pain outpatient clinic, and presence of pain and its intensity.

Data analysis

To test the relationships between variables associated with pain (e.g., presence of pain, treatment in a chronic pain clinic) and quality of life in individual domains, the Kruskal-Wallis and Mann-Whitney U-test were used. The correlation between intensity of pain and quality of life was verified by Spearman correlation coefficients. The SPSS 22 program was used for statistical evaluation.

Results

Of the 247 respondents, 123 (49.8%) were aged ≤ 65 . The average age of the entire group was 64 years. The group consisted of 177 men (72%), and 70 women (28%). Diabetic ulcers lasting longer than 12 months were reported by 73% of patients. 96 respondents (38.9%) were treated in a chronic pain outpatient clinic. Most respondents felt pain sometimes (45%) or intermittently (26%) (Table 1).

Table 1 Demographic and clinical data (n = 247)

Characteristics		n	%
Gender	male	177	72
	female	70	28
Marital status	married	174	70
	single	73	30
Duration of ulceration	up to 1 year	68	27
	longer than 1 year	179	73
Treatment in chronic pain outpatient	yes	96	39
	no	151	61
Presence of pain	permanent	25	10
	intermittently	64	26
	sometimes	110	45
	never	48	19

The lowest quality of life score for patients with diabetic foot syndrome attending a chronic pain outpatient clinic was found in the domain of Leisure time; i.e., the pain these patients suffer causes reduced enjoyment of their holidays, hobbies and leisure activities. On the other hand, the highest quality of life scores in both groups were found in the domain of Non-compliance, which includes two questions evaluating whether respondents adhere to the requirements or recommendations of their physicians. Statistically significant differences were found between the quality of life of patients who attended a chronic pain outpatient clinic and those who did not, in the four domains of DFS: Leisure, Physical health, Emotions, and Friends. Patients who did not attend a chronic pain outpatient clinic had a statistically significant higher index of quality of life in these domains (Table 2).

Table 2 The average quality of life scores for individual domains under treatment in a chronic pain outpatient clinic

Domains	Attendance of chronic pain outpatient clinic		p-value
	yes (n = 96)	no (n = 151)	
Leisure	43.89	52.66	0.039
Physical health	55.07	66.09	<0.001
Daily activities	56.47	61.24	0.220
Emotions	50.18	59.48	0.005
Noncompliance	83.33	85.43	0.430
Family	77.16	78.76	0.643
Friends	70.58	77.50	0.005
Treatment	59.54	64.78	0.090
Satisfaction	79.52	81.33	0.386
Positive attitude	56.28	51.21	0.064
Financial	54.95	60.74	0.090

p – level of significance

Quality of life of patients with permanent pain was lower in all domains of quality of life in the DFS questionnaire than quality of life of patients who

reported no pain. A statistically significant difference was found in all domains except two (Noncompliance and Positive attitude) (Table 3).

Table 3 The average quality of life scores in different domains with regard to the presence of pain

Domains	Permanent pain (n = 25)	Intermediate pain (n = 64)	Sometimes pain (n = 110)	No pain (n = 48)	p-value
Leisure	32.58	37.86	52.40	66.36	<0.001
Physical health	36.00	50.66	67.55	77.39	<0.001
Daily activities	39.83	48.70	63.64	74.05	<0.001
Emotions	38.40	45.08	59.15	71.81	<0.001
Noncompliance	86.50	84.38	83.41	86.72	0.335
Family	74.15	69.08	80.63	86.81	<0.001
Friends	62.00	66.80	77.73	85.63	<0.001
Treatment	48.25	55.37	65.08	74.87	<0.001
Satisfaction	82.00	75.40	80.56	86.98	0.030
Positive attitude	47.20	51.19	53.97	57.26	0.427
Financial	48.50	54.88	58.49	68.62	0.002

p – level of significance

Correlation analysis demonstrated a statistically significant moderate negative correlation between intensity of pain and quality of life in the following domains: Physical health ($r = -0.592$; $p < 0.001$), Daily activity ($r = -0.456$; $p < 0.001$), Emotions ($r = -0.503$; $p < 0.001$), and Treatment ($r = -0.434$; $p < 0.001$). A statistically significant weak negative correlation was also established between intensity of pain and quality of life in the following domains: Leisure, Noncompliance, Family, Friends, Satisfaction, Positive attitude, and Finance. The negative correlations mean that patients who reported a higher intensity of pain rated their quality of life worse, i.e., they had a lower score for quality of life in the DFS questionnaire (Table 4).

Table 4 Correlation between intensity of pain and scores for individual domains

Domains	Correlation coefficient <i>r</i>	p-value
Leisure	-0.388	<0.001
Physical health	-0.592	<0.001
Daily activities	-0.456	<0.001
Emotions	-0.503	<0.001
Noncompliance	-0.134	0.035
Family	-0.336	<0.001
Friends	-0.394	<0.001
Treatment	-0.434	<0.001
Satisfaction	-0.195	0.002
Positive attitude	-0.136	0.035
Financial	-0.190	0.003

p – level of significance

Discussion

Pain can be considered as, possibly, the most important factor affecting quality of life. Although several studies have examined the influence of pain on quality of life of patients with diabetic ulcers, most researchers have used a generic instrument for measuring quality of life - for example, the 12-item Short-Form Health Survey (Van Acker et al., 2009), or the 12-item Medical Outcomes Short Form 12 scale (MOS SF-12), derived from the SF-36 (Bouhassira et al., 2013). In our research, a specific instrument for measuring the impact of ulceration on quality of life of patients with diabetic foot syndrome – the Diabetic Foot Scale (DFS) was used (Abetz, 2002). In nine out of eleven domains of quality of life, DFS patients rated their quality of life worse if they felt pain more frequently. For two domains (Noncompliance, and Positive attitude) the difference in quality of life was not statistically significant. In the studied group, patients with more frequent occurrence of pain experienced lower quality of life. Similarly, with regard to attending a chronic pain outpatient clinic, patients who did attend assessed their quality of life as worse than that of those who did not. It can be assumed that the patients attending a clinic had long-term, painful ulcerations that reduced their quality of life. These patients, therefore, rated their quality of life as worse than that of patients who did not attend a chronic pain outpatient clinic. A study by the French authors Valensi et al. (2005) involving 355 diabetic patients confirmed the differences in quality of life scores between patients who see a specialist (diabetologist or endocrinologist), and those who are treated by

their general practitioner or other medical expert. Patients visiting an endocrinologist or diabetologist were more satisfied with care, reported less deterioration in health status and shorter duration of diabetic ulcers (Valensi et al., 2005).

The theme of pain in diabetic ulcerations was addressed in 2006 by a team of Norwegian researchers (Ribu et al., 2006). To obtain an index of quality of life, they used both the DFS questionnaire and the SF-36 questionnaire. Their findings are very clear – for all domains (with the exception of Positive attitude), it was confirmed that patients with higher intensity of pain had lower quality of life. These results are consistent with our findings, in which, with the exception of the domains of Noncompliance and Positive attitude, it was confirmed in all other domains that patients with more frequent pain have worse quality of life. A study by Davies et al. (2006) found painful diabetic peripheral neuropathy in up to 26.4% of respondents. Worsening neuropathy was associated with increasing risk of painful diabetic peripheral neuropathy, which had a significant negative impact on all aspects of quality of life (Davies et al., 2006). The influence of pain caused by diabetic ulcers was examined in a study by Bradbury and Price (2011), who, on the basis of their results, conclude that pain affects patients both physically (sleep, mobility) and psychologically (feelings of depression, loss of motivation, resignation to their situation).

According to Bouhassira et al. (2013), chronic pain with neuropathic characteristics affects one in five patients with diabetes, significantly affecting their quality of life, and is not adequately treated. When patients with diabetic foot syndrome experience pain, this should be taken into account, particularly when dressing diabetic ulcers.

Conclusion

Ulcer pain significantly affects quality of life of patients with diabetic foot syndrome. Patients with more frequent pain experience lower quality of life. Similarly, patients who attend chronic pain outpatient clinics have lower quality of life than those who do not. Awareness of the impact of pain on different aspects of life should inform the care of patients with diabetic foot syndrome. The results emphasize the importance of quality of life in the management of patients with diabetic foot syndrome. Pain in patients with diabetic foot syndrome should be strictly monitored and controlled.

Ethical aspects and conflict of interest

The study was carried out in accordance with the Helsinki Declaration. The research was approved by the Ethics Committee of the Medical Faculty of the University of Ostrava (9/2014) and by the Ethics Committee of the General Faculty Hospital, Prague (1664/14 S-IV). The authors are not aware of any conflict of interest.

Acknowledgements

The authors would like to thank Jan Stryja, MD, PhD for the clinical assessment of the questionnaire, all healthcare workers from outpatient clinics, who participated in the research and helped with data collection, and, finally, all patients who completed the questionnaire.

Author contribution

Concept and design (RV, RZ), data collection (RV), analysis and interpretation of data (RV, RZ), the drafting of the manuscript (RV, RZ), a critical revision of the manuscript (RV, RZ), the final completion of the article (RV, RZ).

References

- Abetz L, Sutton M, Brady L, McNulty P, Gagnon DD. The Diabetic Foot Ulcer Scale (DFS): a quality of life in instrument for use in clinical trials. *Practical Diabetes International*. 2002;19(6):167–175.
- Argoff CE, Cole BE, Fishbain DA, Irving GA. Diabetic peripheral neuropathic pain: clinical and quality-of-life issues. *Mayo Clinic Proceedings*. 2006;81(4 Suppl):S3–11.
- Aslam A, Singh J, Rajbhandari SM. The impact of painful diabetic neuropathy on quality of life: an observational study. *Diabetes & Primary Care*. 2014;16(4):212–219.
- Bann CM, Fehnel SE, Gagnon DD. Development and validation of the Diabetic Foot Ulcer Scale-short form (DFS-SF). *Pharmacoeconomics*. 2003;21(17):1277–1290.
- Bouhassira D, Letanoux M, Hartemann A. Chronic pain with neuropathic characteristics in diabetic patients: a French cross-sectional study. *PLoS ONE*. 2013;8(9):e74195.
- Bradbury S, Price P. The impact of diabetic foot ulcer pain on patient quality of life. *Wounds UK*. 2011;7(4):32–49.
- Česká diabetologická společnost (ČDS). *Standardy léčby pacientů se syndromem diabetické nohy*. ČDS, 2006 [cited 2016 Apr 14]. Available from: <http://www.diab.cz/dokumenty/dianoah.pdf> (in Czech)
- Černý R. Novinky v léčbě neuropatické bolesti. *Interní medicína pro praxi*. 2012;14(1):30–32. (in Czech)
- Davies M, Brophy S, Williams R, Taylor A. The prevalence, severity, and impact of painful diabetic peripheral neuropathy in type 2 diabetes. *Diabetes Care*. 2006;29(7):1518–1522.
- Didangelos T, Doupis J, Veves A. Painful diabetic neuropathy: clinical aspects. *Handbook of Clinical Neurology*. 2014;126:53–61.

- Huizinga MM, Peltier A. Painful diabetic neuropathy: a management-centered review. *Clinical Diabetes*. 2007;25(1):6–15.
- Mazanec R. *Diabetes mellitus a bolest*. 1. vyd. Praha: Maxdorf; 2012. (in Czech)
- Nemcová J, Farský I, Hlinková E. Kvalita života pacientov s diabetickou ulceráciou. In: Sikorová L, Bužgová R, editors. *Ošetrovateľský výzkum a praxe založená na dôkazoch*. Ostrava: Ostravská univerzita v Ostravě, Lékařská fakulta; 2013. s. 92–93. (in Slovak)
- Pitřhová P. Syndrom diabetické nohy – možnosti diagnostiky a léčby. *Praktické lékařství*. 2010;6(3):130–133. (in Czech)
- Ribu L, Rustøen T, Birkeland K, Hanestad BR, Paul SM, Miaskowski C. The prevalence and occurrence of diabetic foot ulcer pain and its impact on health-related quality of life. *The Journal of Pain*. 2006;7(4):290–299.
- Stryja J. et al. *Repetitorium hojení ran 2*. 1. vyd. Praha: Nakladatelství GEUM; 2011. (in Czech)
- Valensi P, Girod I, Baron F, Moreau-Defarges T, Guillon P. Quality of life and clinical correlates in patients with diabetic foot ulcers. *Diabetes & Metabolism*. 2005;31(3 Pt 1):263–271.
- Van Acker K, Bouhassira D, De Bacquer D, Weiss S, Matthys K, Raemen H, Mathieu C, Colin IM. Prevalence and impact on quality of life of peripheral neuropathy with or without neuropathic pain in type 1 and type 2 diabetic patients attending hospital outpatients clinics. *Diabetes & Metabolism*. 2009;35(3):206–213.
- Vileikyte L. Diabetic foot ulcers: a quality of life issue. *Diabetes/Metabolism Research Reviews*. 2001;17(4):246–249.
- Zvolský M. Činnost oboru diabetologie, péče o diabetiky v roce 2013. *Aktuální informace Ústavu zdravotnických informací a statistiky České republiky*. ©ÚZIS ČR; 2010–2016 [cited 2015 Feb 10]. Available from: <http://www.uzis.cz/rychle-informace/cinnost-oboru-diabetologie-pece-diabetiky-roce-2013> (in Czech)