

ORIGINAL PAPER

QUALITY OF LIFE IN PATIENTS WITH DIABETIC FOOT ULCERS

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Abstract

Aim: To ascertain quality of life in patients with ulcer affected diabetic foot (UADF), and to establish whether there was a relationship between respondents' gender, age, duration and type of treatment for DM, duration of treatment for and etiology of wound, intensity of pain, degree of UADF, method of off-loading pressure on the foot, and quality of life. **Design:** A cross-sectional study. **Methods:** A cross-sectional study was conducted on 167 patients with UADF. The data were acquired using the SF-36 and Wound-QoL questionnaires. Exploratory Regression analysis was used during the study as a descriptive technique. The model was realized using the ENTER method. **Results:** Of the patients who participated in this study, 68% were men and 32% women, their average age was 65 years, and the length of DM treatment was 19 years, with variations in DM treatment, UADF intensity, etiology, and size and degree of UADF, according to Wagner classification. Based on the values of beta coefficients, we can state that according to the SF-36, the main negative predictors of quality of life are: 1) DM treatment; 2) pain intensity; 3) age; 4) wound etiology; and 5) use of wheelchair. Whereas, according to the Wound-QoL, the main negative predictors of quality of life are: 1) DM treatment; 2) pain intensity; 3) size of the wound; 4) age; and 5) use of crutches. **Conclusion:** Although the results of the two models are similar in certain respects, there are also differences, explained by the fact that two different conceptions of measuring quality of life, with different scoring systems, were involved. Use of the Wound-QoL questionnaire proved particularly effective.

Keywords: assessment, Czech Republic, diabetic ulceration, HRQoL, life quality, SF-36, Wagner classification, Wound-QoL.**Introduction**

Diabetic foot is one of the most serious and devastating complications of diabetes mellitus (DM). It is defined as Diabetic Foot Ulcer (DFU), which, in a DM patient, is associated with neuropathy and/or peripheral arterial disease of the lower limb. It typically has a mixed etiology, with frequent diabetic neuropathy (Jirkovská et al., 2016). The prevalence of diabetic ulceration of the feet among diabetics is 4%–10%. The condition is more frequent in long-term cases of DM, and is more or less the result of long-term inadequate disease treatment (Alexiadou & Doupis, 2012; Lauterbach et al., 2010).

In the Czech Republic, diabetic foot is reported in 52,172 patients with DM (5.6%), 9,980 of whom (19%) have undergone foot amputations below the ankle (“low amputations”), or above the ankle (“high amputations”) (ÚZIS ČR, 2018a).

DFU is a serious complication of diabetes that worsens the patient's condition, and, at the same

time, has a significant socio-economic impact. It is also associated with increased mortality (Walsh et al., 2016). Its management requires a multidisciplinary approach (Alexiadou & Doupis, 2012).

In an international context, considerable effort had been made to categorize foot ulcers (Wagner, 1987). The Wagner classification is one of the most popular verified classifications, based on the assessment of the depth of ulceration and the presence of infection. Other classification systems for diabetic foot ulcers have been proposed and validated, for example, the Texas Classification (see Armstrong et al., 1998; Schaper, 2004; Wagner, 1987).

The gold standard for complex DFU treatment includes changes to metabolism, off-loading pressure on ulcers (with wheelchairs, crutches, special contact fixations and splints, therapeutic footwear, braces, special insoles, and bed rest), treatment of ischemia (revascularization processes), infection management (ATB, local treatment), systematic local therapy (debridement of the wound), and therapeutic education (Doupis & Veves, 2008; Jirkovská et al., 2016; Lebrun et al., 2010). However, it has been proven that physically restrictive regimes can lead to

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an increase in psychological stress (Fejfarová et al., 2014).

Additional complementary therapies have also been designed, such as hyperbaric oxygen therapy, the application of modern wound-care products, and vacuum therapy (Hinchliffe et al., 2008; Kudlová et al., 2015). However, sufficient data on the efficacy and cost-efficiency of these methods of complementary treatment have not yet been provided (Alexiadou & Doupis, 2012).

In a patient with healed ulceration, there is a tendency to suffer from recurring ulcerations (up to 50% within one year) (Jirkovská et al., 2016).

DFU negatively affects patients' physical functioning, mental condition, and social situation (Goodridge et al., 2006; Meijer et al., 2002; Özlem et al., 2014; Willrich et al., 2005). All such adverse effects impede the quality of life of patients (Sehlo et al., 2016).

Health-Related Quality of Life (HRQoL) expresses the extent to which the disease and its treatment affect patients' chances of living a satisfactory life (Gurková, 2011). The most commonly used generic questionnaires (rather than those designed for a specific diagnosis) are: the SF-36, the EQ-5D (EuroQoL Research Foundation, 2019), the WHOQOL-100 (World Health Organization, 2019), and the WHOQOL-BREF-26 (World Health Organization, 2004, 2019; Skevington et al., 2004; Rogalewicz et al., 2017). There is also a specific questionnaire – the Diabetic Foot Ulcer Scale – DFS (©1999 all rights reserved by Janssen Global Services, LLC U.S.A., 2002), which is composed of 58 items organized into 11 domains (Abetz et al., 2002).

Evidence acquired from cross-sectional studies (e.g. Goodridge et al., 2006; Ikem et al., 2009; Ribu et al., 2007; Sekhar et al., 2015; Valensi et al., 2005; Yekta et al., 2011), and meta-analyses (Khunkaew et al., 2019) has indicated a decreased HRQoL in those with DFU. Reduced mobility and lifestyle changes contribute to decreased HRQoL in this population (Brod, 1998; Ribu & Wahl, 2004).

Poor HRQoL can also be attributed to other factors, such as pain, fatigue, wound infection, frequent dressing, reduced mobility, and social isolation (Alexiadou & Doupis, 2012).

Aim

The main aim was to establish the extent of quality of life in patients with DFU, and to establish whether there was a relationship between respondents' gender, age, length of DM treatment, etiology of the

wound (angio, neuro, mixed), degree of DFU by Wagner classification, method of off-loading pressure on the lower limb, and period of time for the treatment of the wound, and quality of life.

Research question

What is level of HRQoL in patients with DFU that attend the six selected workplaces in the Czech Republic?

Methods

Design

A cross-sectional study.

Sample

The cross-sectional study was carried out on 167 patients with DFU attending podiatric or surgical/vascular outpatient wards (a total of six workplaces), after 45 respondents with grade 0 wound classification (according to Wagner) had been dismissed from the study. The criteria set for the selection of respondents were: patients of either gender with DM and DFU lasting at least two weeks, aged 18 or older, and willing to complete the questionnaire. The degree of DFU (according to the Wagner classification) was assessed by a physician or podiatric nurse from a selected workplace. Once approval for the study was granted by the management of the various workplaces, data collection was completed between December 2018 and August 2019.

Although, for the sake of completeness, we have included values of statistical significance within the analysis, in order to interpret the results, we have primarily focused on data of material significance that are crucial to the application of the results in practice, irrespective of the representativeness and size of the research pool (Soukup, 2013).

Data collection

Data were acquired by means of the standardized questionnaires SF-36 and Wound-QoL.

The questionnaire was composed of three parts: 1) questions regarding health-related and socio-demographic data [age, gender, work position, duration of DM treatment (diet, PAD, insulin)], duration and etiology of DFU, DFU according to Wagner classification (grade 0–5, whereby 0 was used as the criterion for dismissing respondents from the study), size of the wound/ulcer in cm², method of relieving DN; 2) SF-36; and 3) Wound-QoL. Time allowed for completion of the questionnaire, in collaboration with healthcare professionals, was calculated at 20 minutes.

The Short Form Health Survey – 36 (SF-36) is a generic questionnaire designed for measuring quality of life in respondents over 14 years of age with various types of disease and treatment. The questionnaire, which takes 20 minutes to complete, was created in 1992 by Ware et al. The original version was translated, validated and standardized within The International Quality of Life Assessment project in more than 15 countries. Copyright for the SF-36 is held by the nonprofit organization, the Medical Outcomes Study Trust, and the tool is administered by the nonprofit organization, RAND (RAND Health Care, 2019). The questionnaire was translated into Czech by Sobotík and Petr (in Gurková, 2011; Sobotík, 1998; Ware et al, 1993). The version of the SF-36 questionnaire used is freely available at ÚZIS ČR (2018b), and contains a total of 36 items divided into eight dimensions (Physical functioning – ten questions; Physical role – four questions; Bodily pain – two questions; General health – five questions; Vitality – four questions; Social functioning – two questions; Emotional role – three questions; and Mental health – three questions (ÚZIS ČR, 2018b).

An additional item, which does not fit into any of the dimensions above, concerns changes to health in the previous year. Each item contains several proposed answers based on a Likert scale of 1–5: 1 – excellent, 2 – very good, 3 – good, 4 – quite good, 5 – bad (Ware et al., 1993). *Assessment of the SF-36*: In each dimension, the questions are first assessed and assigned points, which are then added together and the sum transformed into a scale of 0–100 points, whereby 100 points indicates higher, and 0 indicates lower quality of life. To calculate the score from the questionnaire in the Czech Republic, we used a table created by ÚZIS ČR (ÚZIS ČR, 2018b). A score of under 50 may be interpreted as being below the norm for the general population. The questionnaire may further be assessed as a whole, or the results used as they are for each dimension separately. In our study, we focused on the questionnaire as a whole, i.e., overall quality of life.

The Wound-QoL is a questionnaire focusing specifically on quality of life of patients with a non-healing wound. The Wound-QoL was developed and standardized in Germany by Augustin et al. in 2014, and translated into Czech by Procházková and Pokorná in 2016 (Augustin et al., 2014; Procházková & Pokorná, 2017). We acquired the the authors' permission to use the validated Czech version (Procházková & Pokorná, 2017). The questionnaire is composed of 17 items that are assessed retrospectively for the previous seven days. The respondent completes the questionnaire alone,

or, if required, with the assistance of healthcare professionals. The items are divided into three domains: Physical – items 1–5 of the questionnaire; Mental – items 6–10; Everyday life – items 11–16; while item 17, the final item, assesses the economic burden faced by patients during treatment of their non-healing wounds. *Assessment of the Wound-QoL questionnaire*: The answers to each question are assessed on a Likert scale of 0–4 whereby 0 points – not at all; 1 – a little; 2 – moderately; 3 – quite a lot; and 4 – a lot. The assessment of each domain is completed by adding together the points from all its items. A total score from 0 to 68 points is calculated from the sum of all individual item scores, and can be calculated if the respondent answers at least 75% of all items (13 out of 17). The higher the total, the higher the impact on quality of life (Augustin et al., 2014; Procházková & Pokorná, 2017).

During the study, overall quality of life results were established first, using the two afore-mentioned questionnaires (see Tables 1 and 2).

Data analysis

Overall quality of life was further examined as a dependent variable under the influence of independent variables (i.e., demographic and clinical characteristics of the respondents). Our goal was to determine which of the monitored independent variables had the most significant influence on quality of life. In order to perform complex monitoring of the relationships between the variables within the study, we conducted an exploratory regression analysis (see Tables 3 and 4) as a descriptive technique, regardless of the value of statistical significance, and without attempt to generalize. The model was realized using the ENTER method. Our goal was to include all the above variables. We then estimated the relative power of influence using a standardized beta coefficient.

Results

A total of 167 respondents participated in the study (113 men; 68% : 54 women; 32%), with an average age of 65 years (36–79; SD = 9.75). Twelve respondents (7%) were government employees, 12 (7%) were self-employed, 116 (69%) were retired, 21 (13%) were retired due to invalidity, and six respondents (4%) were receiving long-term invalidity benefit. Retirees formed the largest single group, with other groups considerably less well represented, resulting in this variable's omission from the regression analysis.

On average, the respondents with DM had been receiving treatment for 19 years (1–63 years;

SD = 12.14). All respondents had been treated for diabetes mellitus with special diet, 59 (35%) with diet and PAD, 133 (80%) with diet and insulin, 32 (19%) with diet, PAD, and insulin.

A physician or podiatric nurse helped the respondents determine etiology of DN. Within this study, various etiologies were encountered: ischemic in 65 cases (39%), neuropathic in 57 cases (34%), and mixed in 44 cases (26%). In terms of size of wound, (ranging from 1 to 100 cm²), 13 cm² represented the average (SD = 18.32). Forty-four patients (26%) had wounds of 1 cm²; 78 patients (47%) had wounds of 2–10 cm², and 45 patients (27%) had wounds of 11–100 cm².

Ulceration according to Wagner classification was found in 117 respondents (70%): grade one (external) four cases (2%); grade two (deeper) 73 cases (44%); grade three (deep) 40 cases (24%), and (gangrene) 50 cases (30%); grade four (localized) 34 cases (20 %); grade five (extensive gangrene) 16 cases (10%). The duration of treatment of DFU was up to four weeks in 14% of respondents, and over four weeks in 86% of respondents.

In terms of treatment regime, 13% of respondents stated that they did not off-load pressure on the

affected foot in any way, 10% used a wheelchair, 41% used crutches, and 75% used shoes. Responses to DM treatment, verified by the value of glycated hemoglobin (HbA1c), were between 42 and 103 (mean value of 65; SD = 14.95). In terms of international classification, the value was good in three patients (2%), satisfactory in 27 patients (16%), and unsatisfactory in 103 patients (62%). Unfortunately, there were no data for 34 patients (20%). Therefore, this variable was eventually omitted from regression analysis, as it would have meant excluding these 34 patients from the analysis.

Aim 1: To find total scope of quality of life using the standardized questionnaires SF-36 and Wound-QoL. 0–100 points can be achieved in the standardized Short Form Health Survey (SF-36) – the more points, the higher the quality of life. The respondents averaged 40 points (which corresponds to low quality of life) (Table 1).

0–68 points can be achieved in the Wound-QoL questionnaire, the more points, the worse the quality of life. The respondents averaged 36 points (which corresponds to medium life quality) (Table 2).

Table 1 Total scope of quality of life using the SF-36

| | n | min. | max. | mean | SD |
|-------------|----------|-------------|-------------|-------------|-----------|
| SF-36 Total | 167 | 17.22 | 68.61 | 40.04 | 11.72 |

min. – minimum; max. – maximum, SD – Standard Deviation

Table 2 – Total scope of quality of life using the Wound-QoL

| | n | min. | max. | mean | SD |
|-----------------|----------|-------------|-------------|-------------|-----------|
| Wound-QoL Total | 167 | 3.00 | 67.00 | 35.60 | 14.01 |

min. – minimum; max. – maximum, SD – Standard Deviation

Aim 2: To find the relationship between variables (age, gender, duration of treatment of DM, type of DM treatment (diet; PAD and insulin); etiology of DN (ischemia, neuropathy, mixed wound); size of wound; degree of DN/DFU according to the Wagner classification [gangrene – 50 cases (30%), ulceration – 117 cases (70%)], method of relieving DN (75% shoes, 41% crutches, 10% wheelchair, 13% nothing); duration of treatment of ulceration (14% within four weeks, 86% over four weeks); scaled intensity of pain (not at all – 1; a little – 2; moderate – 3; quite severe – 4; very severe – 5) merged into two variables: mild – 38% and severe – 62%; and overall quality of life (SF-36 and Wound-QoL). Neither model contained the “employment” category, since Category 1 significantly outnumbered all others. In addition, in terms of Wagner classification, grade 1 was poorly represented for further modeling,

hence this variable was divided into two basic categories (gangrene vs. ulceration).

Furthermore, it was not possible to include the variable reflecting those who were treated with diet, PAD, and insulin at the same time (19%) into both models. This variable is the result of combining two preceding variables (diet and PAD; diet and insulin), and caused multi-collinearity in the models. A multi-collinearity check was performed for both final models. Tolerance values of over 0.2 indicated that this was not a problem in either model.

Model for the SF-36

Due to missing data for some of the variables, 160 out of 167 patients were included in the analysis using the method of listwise deletion in the SSP program. Thus, only patients without any missing

Table 3 Model of regression analysis for the SF-36

| | Non-standardized coefficients | | Standardized coefficients | t | p-value | Collinearity statistics tolerance |
|-------------------------------------|-------------------------------|------------|---------------------------|--------|---------|-----------------------------------|
| | Beta | Std. Error | Beta | | | |
| (Constant) | 88.230 | 7.250 | | 12.170 | 0.000 | |
| women vs. men | -2.728 | 1.796 | -0.110 | -1.519 | 0.131 | 0.628 |
| age | -0.421 | 0.088 | -0.352 | -4.783 | 0.000 | 0.608 |
| duration of treatment of DM (years) | -0.115 | 0.069 | -0.120 | -1.664 | 0.098 | 0.638 |
| treatment of DM: diet and PAD | -13.135 | 1.988 | -0.541 | -6.608 | 0.000 | 0.492 |
| treatment of DM: diet and insulin | -14.953 | 2.342 | -0.522 | -6.383 | 0.000 | 0.493 |
| ischemic vs. mixed wound | 8.394 | 2.134 | 0.349 | 3.933 | 0.000 | 0.419 |
| neuropathic vs. mixed wound | 2.974 | 2.126 | 0.122 | 1.399 | 0.164 | 0.437 |
| intensity of pain - severe | -13.953 | 2.042 | -0.521 | -6.383 | 0.000 | 0.493 |
| size of wound in cm ² | -0.020 | 0.048 | -0.029 | -0.421 | 0.674 | 0.715 |
| gangrene vs. ulceration | -4.886 | 1.845 | -0.186 | -2.649 | 0.009 | 0.667 |
| form of relief used – shoes | -0.635 | 2.564 | -0.023 | -0.248 | 0.805 | 0.380 |
| form of relief used – crutches | -3.590 | 1.722 | -0.150 | -2.085 | 0.039 | 0.637 |
| form of relief used – wheelchair | -10.727 | 2.736 | -0.259 | -3.921 | 0.000 | 0.758 |
| form of relief used – nothing | -6.510 | 3.317 | -0.188 | -1.963 | 0.052 | 0.361 |
| wound lasts over 4 weeks | 0.332 | 2.308 | 0.010 | 0.144 | 0.886 | 0.746 |

t – t-statistics (t-statistic is the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error); DM – Diabetes Mellitus; PAD – peroral antidiabetics

answers were included in the analysis – a strict but clear solution. The model ($F = 11.302$; $df = 14$; $sig < 0.0005$) was characterized by the scope of explained variation $R^2 = 52\%$, in adjusted form, reduced to 47%, which was a good result (for more see Table 3).

The main predictors of quality of life were (including all the given variables, in accordance with standardized beta coefficients): 1) treatment involving diet, PAD, or insulin; 2) intensity of pain (mild vs. severe); 3) age; 4) type of wound (ischemic or mixed); and 5) use of a wheelchair. In some cases, the coefficients were well-balanced, so their order is somewhat approximate.

Interpretation using non-standardized beta coefficients suggested that lower quality of life is reported by patients using diet and PAD for treatment (-13 points), or insulin (-15 points). Worse quality was reported by patients suffering from greater pain (-14 points). Patients with mixed wounds were worse off than those with ischemic wounds (by eight points). Additionally, age was also of great importance. When age increased by one year, life quality fell by 0.4 points (thus ten years would result in a four-point drop). Furthermore, use of a wheelchair decreased reported quality of life by 11 points.

Other results were not considered significant in terms of material significance, since they were based on low values of standardized beta coefficients.

Model for the Wound-QoL

This model included 160 patients out of 167 ($F = 11.439$; $df = 14$; $sig < 0.0005$) and was

characterized by the scope of explained variation $R^2 = 53\%$ (in adjusted form reduced to 48%), which was a good result (for more see Table 4).

In this case, the interpretation was reversed – the higher the number of points, the worse the quality of life.

The main predictors of quality of life in this instance were (including all given variables, in accordance with standardized beta coefficients): 1) treatment involving diet; PAD, or insulin; 2) intensity of pain; 3) size of wound; 4) age; and 5) use of crutches. In all cases, they had a negative impact on quality of life.

If we specify interpretation using non-standardized beta coefficients, we can say that lower quality of life was reported by patients who used diet and insulin (+18 points), and diet and PAD (+12 points) as treatments, and patients suffering from greater pain (116 points), and patients using crutches for pressure relief (+ six points). The size of the wound also played a role, with an increase of 1 cm² leading to a 0.3 point increase in questionnaire score (therefore a 10 cm² increase would result in a three-point increase in the questionnaire score).

Other results were not considered significant in terms of material significance, as they were based on low values of standardized beta coefficients.

The results of both models indicated similar findings (the form of insulin treatment and PAD, and age all affected quality of life); however, they also differed in some respects, due to the fact that two different ways of measuring quality of life, with different scoring systems, were used.

Table 4 Regression analysis model for the Wound-QoL

| | Non-standardized coefficients | | Standardized coefficients | t | p-value | Collinearity statistics |
|-------------------------------------|-------------------------------|------------|---------------------------|--------|---------|-------------------------|
| | Beta | Std. Error | Beta | | | Beta |
| (Constant) | -3.210 | 8.608 | | -0.373 | 0.710 | |
| women vs. men | -2.238 | 2.132 | -0.076 | -1.050 | 0.296 | 0.628 |
| age | 0.301 | 0.104 | 0.212 | 2.883 | 0.005 | 0.608 |
| duration of treatment of DM (years) | 0.067 | 0.082 | 0.058 | 0.810 | 0.419 | 0.638 |
| treatment of DM: diet and PAD | 11.722 | 2.360 | 0.405 | 4.967 | 0.000 | 0.492 |
| treatment of DM: diet and insulin | 18.189 | 2.781 | 0.533 | 6.540 | 0.000 | 0.493 |
| ischemic vs. mixed wound | -3.544 | 2.534 | -0.124 | -1.398 | 0.164 | 0.419 |
| neuropathic vs. mixed wound | -5.328 | 2.524 | -0.183 | -2.111 | 0.036 | 0.437 |
| intensity of pain – severe | 16.188 | 2.571 | 0.532 | 6.522 | 0.000 | 0.483 |
| size of wound in cm ² | 0.288 | 0.057 | 0.344 | 5.082 | 0.000 | 0.715 |
| gangrene vs. ulceration | 3.558 | 2.190 | 0.114 | 1.625 | 0.106 | 0.667 |
| form of relief used – shoes | -4.396 | 3.044 | -0.134 | -1.444 | 0.151 | 0.380 |
| form of relief used – crutches | 5.754 | 2.044 | 0.202 | 2.815 | 0.006 | 0.637 |
| form of relief used – wheelchair | -2.893 | 3.248 | -0.059 | -0.891 | 0.375 | 0.758 |
| form of relief used – nothing | 6.649 | 3.938 | 0.161 | 1.688 | 0.093 | 0.361 |
| wound lasts over 4 weeks | -1.404 | 2.740 | -0.034 | -0.512 | 0.609 | 0.746 |

t – t-statistic; DM – Diabetes mellitus; PAD – peroral antidiabetics

Discussion

In our study we focused on detailed examination of the relationship between certain variables and quality of life, assessed by two standardized questionnaires – the SF-36 (ÚZIS ČR, 2018b) and the Wound-QoL (Procházková & Pokorná, 2017). During pre-research, we tested the generic WHOQOL-BREF-26 questionnaire (Skevington et al., 2004). This short version of the WHOQOL-BREF, containing 26 items, is very popular in the Czech Republic and Slovakia, and was used, for example, in the cross-sectional study by Nemcová et al. (2017) on a sample of 525 respondents with DFU from Visegrad Four countries. In the Czech Republic, it exists in two “official” Czech translations by Mravčík & Lajčková from 2004 and Dragomirecká & Bartoňová from 2006 (in Rogalewicz et al., 2017). These versions differ in verbatim formulations and instructions for use. The differences are so significant that they can lead to differences in the interpretation of research results (Rogalewicz et al., 2017). We therefore decided to use the generic SF-36 questionnaire for the main study.

We also tested the specific DFS questionnaire (Abetz et al., 2002) during pre-research. However, this questionnaire did not prove suitable due to its excessive number of questions (58). In our main research we used the specific standardized Wound-QoL questionnaire. This questionnaire is short, simple to understand, and contains assessment of all important events of the previous seven days in the lives of patients with non-healing wounds. Completion of the questionnaire is straightforward.

Once everything has been explained by the nurse or doctor, patients are able to complete it unassisted. In 2017, it was used by Augustin et al. (2017) on patients with DFU. In our study, in accordance with the Wagner classification, four respondents (2%) were classified with first grade, 73 (44%) with second grade, 40 (24%) with third grade, 34 (20%) with fourth grade, and 16 (10%) with fifth grade ulceration. In the study by Nemcová et al. (2017) 62% of the patients were classified with the first and second grades, and 38% of the patients with third, fourth, and fifth grade ulceration.

The Wagner classification was used in our study since it is the most widely known and used in the Czech Republic. This classification was described by Meggitt in 1976 and popularized by Wagner in 1981 (in Wagner, 1981, 1987). It is used despite the fact that it does not take into account the presence of ischemia, and that the presence of early infection always results in categorization of such ulceration as third grade, regardless of the scale of infection. Another deficiency of the Wagner classification is the fact that it has two modifications (Jirkovská et al., 2016; Schaper, 2004; Wagner, 1987).

In our study, more than half of the patients with DFU reported severe pain (62%), confirmed as having a significant impact on quality of life. In the study by Nemcová et al. (2017), 78% of the respondents reported pain, and the significant relationship between experience of foot pain and QoL was confirmed. The same conclusion was reached in a study by Vymětalová & Zeleníková (2016). In the multi-centric study by Ribu et al. (2007), 75%

of the respondents with DFU suffered from pain while walking or standing, and during the night. However, there is discussion in scientific literature as to whether pain is, in fact, the decisive factor in HRQOL.

The results of our study showed that the duration of ulcer treatment did not have a significant impact on quality of life. Vymětalová & Zeleníková using the DFS © (2016; 2019), and a team of French experts using the SF-36 (Valensi et al., 2005), came to the opposite conclusion. On the other hand, a further study found that ulcers with a duration shorter than one week, or between one week and three months, affected HRQoL more negatively than ulcers with a duration of over three months (Kiadaliri et al., 2013).

Studies using the SF-36 reported poor HRQOL in people with DFU (Meijer et al., 2002; Ribu et al., 2007) compared to people without.

Conclusion

In our cross-sectional study, we focused on detailed examination of the relationship between certain variables and quality of life of patients with DFU, assessed by two standardized questionnaires, the SF-36 and Wound-QoL. Based on the beta coefficients, we can state that the results of our two models show similar findings (quality of life is affected by the form of DM treatment, intensity of pain, and the age of respondents), but also certain differences, explained by the fact that two different conceptions of measuring quality of life, with different scoring systems, were used.

The Wound-QoL contains all important assessment criteria for quality of life. At the same time, it is short and understandable to patients. We therefore recommend use of the Wound-QoL for patients with DFU.

Ethical aspects and conflict of interest

The authors declare that there were no conflicts of interests regarding the publication of this paper. This work was supported by RVO excellent/MSM – RVO/FHS/2019/003 as part of the project “Multidisciplinary approaches to chronic disease”.

All patients were informed of their voluntary participation in the study in an accompanying section of the questionnaire. The ethical committee of UTB in Zlín found no conflict with existing rules and regulations relevant to the implementation of the research and publishing of its results.

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Author contributions

Concept and design (PK), data collection (PK), analysis and interpretation of data (IK, PK), processing the manuscript draft (PK), critical review of the manuscript (PK, IK), finalizing of the article (PK, IK).

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