

# QUALITY OF LIFE OF PEOPLE WITH DIABETIC FOOT ULCERS IN OUTPATIENT TREATMENT: CROSS-SECTIONAL STUDY

## QUALIDADE DE VIDA DE PESSOAS COM ÚLCERAS DO PÉ DIABÉTICO EM TRATAMENTO AMBULATORIAL: ESTUDO TRANSVERSAL

## CALIDAD DE VIDA DE PERSONAS CON ÚLCERAS DIABÉTICAS EN TRATAMIENTO AMBULATORIO: ESTUDIO TRANSVERSAL

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**Objective:** to analyze the quality of life of people with diabetic foot ulcers in outpatient treatment. **Method:** descriptive and cross-sectional study, conducted between February and April 2019, with 50 people with Diabetes Mellitus, followed in a specialized outpatient clinic. The sociodemographic and clinical questionnaire, the Freiburg Life Quality Assessment Wound Version (FLQA-WK), descriptive statistics and the Student's t-comparison and Anova tests were applied. **Results:** a lower score was observed in the physical symptoms domain (1.84) and a higher score in the daily life domain (3.52). The total quality of life score was 2.61, on a scale ranging from one to five, with significant correlation between clinical variables, such as time of diagnosis of diabetes >10 years (p-value=0.005), hospital admissions (p-value=0.019) and nephropathy (p-value=0.001). **Conclusion:** quality of life was considered regular, with changes in the daily life domain, being negatively influenced by clinical variables.

**Descriptors:** Diabetic Foot. Quality of Life. Diabetes Mellitus. Ambulatory Care. Nursing.

*Objetivo:* analisar a qualidade de vida de pessoas com úlceras do pé diabético em tratamento ambulatorial. *Método:* estudo descritivo e transversal, realizado entre fevereiro e abril de 2019, com 50 pessoas com Diabetes Mellitus, acompanhados em ambulatório especializado. *Foram aplicados o questionário sociodemográfico e clínico, o instrumento Freiburg Life Quality Assessment Wound Versão Feridas (FLQA-WK), estatística descritiva e os testes*

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*de Comparação t de Student e Anova. Resultados: observou-se menor escore no domínio sintomas físicos (1.84) e maior no domínio vida diária (3.52). O escore total de qualidade de vida foi de 2.61, numa escala que varia de um a cinco, com correlação significativa entre as variáveis clínicas, como tempo de diagnóstico de diabetes >10 anos (p-valor=0,005), internações hospitalares (p-valor=0,019) e nefropatia (p-valor=0,001). Conclusão: a qualidade de vida foi considerada regular, com alteração no domínio vida diária, sendo influenciada negativamente por variáveis clínicas.*

*Descritores: Pé Diabético. Qualidade de Vida. Diabetes Mellitus. Assistência Ambulatorial. Enfermagem.*

*Objetivo: analizar la calidad de vida de personas con úlceras diabéticas en tratamiento ambulatorio. Método: estudio descriptivo y transversal, realizado entre febrero y abril de 2019, con 50 personas con Diabetes Mellitus, acompañados en ambulatorio especializado. Fueron aplicados el cuestionario sociodemográfico y clínico, el instrumento Freiburg Life Quality Assessment Wound Versión Heridas (FLQA-WK), estadística descriptiva y los test de Comparación t de Student y Anova. Resultados: se observó menor escore en el dominio síntomas físicos (1.84) y mayor en el dominio vida diaria (3.52). El puntaje total de calidad de vida fue de 2.61, en una escala que varía de uno a cinco, con correlación significativa entre las variables clínicas, como tiempo de diagnóstico de diabetes >10 años (p-valor=0,005), internaciones hospitalarias (p-valor=0,019) y nefropatía (p-valor=0,001). Conclusión: la calidad de vida fue considerada regular, con alteración en el dominio vida diaria, siendo influenciada negativamente por variables clínicas.*

*Descriptorios: Pie Diabético. Calidad de Vida. Diabetes Mellitus. Atención Ambulatoria. Enfermería.*

## Introduction

Foot ulcers are a common complication of Diabetes Mellitus (DM), resulting from mechanical changes in the bone architecture of the foot, peripheral neuropathy and peripheral atherosclerotic disease<sup>(1)</sup>. They are characterized by the breakdown of the skin tissue and exposure of the layers underlying the skin. They are associated with osteomyelitis, lower limb amputations and significant increase in mortality<sup>(2)</sup>.

One in four people with DM shall develop a foot ulcer during life<sup>(1)</sup>. Seventy percent of these ulcers remain without healing after 20 weeks of treatment and 60% progress to infection, of which 20% result in different levels of amputation<sup>(3)</sup>. In Brazil, a multicenter study showed a prevalence of 25% for foot ulcers<sup>(4)</sup>, occurrence higher than world estimates, estimated at 6.3% (95% confidence interval, 5.4–7.3%)<sup>(5)</sup>.

Diabetic foot ulcers (DFU) are the main cause of hospitalization and amputations in people with DM, representing a significant burden for patients, families and society in general<sup>(6)</sup>, emphasizing the need for health policies aimed at better prevention and care. In addition, they are often associated with pain and discomfort, with

a negative impact on several domains of Quality of Life (QoL), as demonstrated in international<sup>(6-9)</sup> and national studies<sup>(10-11)</sup>.

QoL is defined by the World Health Organization (WHO) as the perception that the individual has of his/her position in life, according to his/her cultural context, value system and in relation to his/her objectives, expectations, actions, standards and concerns<sup>(12)</sup>. Low QoL has been associated with higher hospitalization rates and mortality in patients with DM<sup>(7)</sup>. Moreover, QoL tends to worsen as complications related to the disease worsen<sup>(8)</sup>, and DFU is one of the complications that most affect QoL<sup>(9)</sup>.

Although the negative impact of DFU on the QoL of people with DM is recognized<sup>(6,9)</sup>, the aspects involved in this relationship are not fully understood. In view of the chronicity of these lesions, impairments in mobility, the possibility or the realization of an amputation, the need to investigate the factors related to DFU that affect QoL is justified. This approach is believed to enable the development of nursing interventions aimed at strengthening self-care practices, reducing current complications and, consequently, improving QoL of these people.

Therefore, the objective of this study was to analyze the quality of life of people with diabetic foot ulcers in outpatient treatment.

## Method

Descriptive, cross-sectional study with a quantitative approach, guided by the recommendations established in Guideline The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). The research was conducted in an outpatient endocrinology clinic of a public hospital in the city of Campina Grande (PB), a specialized reference service for DM in the region, which annually performs 1,800 procedures for diabetic foot dressing, and a mean of 150 visits per month.

The study sample consisted of people with DM who attended the outpatient clinic during the data collection period, February to April 2019. The sample was of the non-probabilistic intentional type, consisting of 50 people in outpatient treatment. The criteria for the inclusion of the participants were: medical diagnosis of DM and present DFU, with no limit of time of ulceration, and to be aged equal or greater than 18 years. The exclusion criteria established were: people with altered cognitive and mental state reported in medical records, without condition to understand and/or express answers verbally.

During the research period, 400 people were seen in the outpatient clinic. Of these, 150 were addressed (33.3%), 30 people were excluded because they had physical/cognitive limitations and 40 because they did not meet the other inclusion criteria. There were 30 refusals, for the following reasons: concern with the time of the medical consultation or care for the dressing and lack of time to answer the questionnaire. Therefore, the sample had 50 people, which corresponds to 12.5% of the potential population to be studied.

The capture of the participants occurred verbally, by one of the researchers, in the waiting room of the outpatient clinic, while waiting for care. Data collection was performed through individual interviews in a reserved room to ensure

the privacy of the participant. Two instruments were used: a structured questionnaire, created by the authors, with sociodemographic and clinical variables, and the translated, validated<sup>(13)</sup> and reduced version of the Freiburg Life Quality Assessment - Wound Version (FLQA-WK)<sup>(14)</sup>.

The sociodemographic and clinical variables investigated were: age (<60 years, ≥60 years), sex (male and female), educational level (illiterate, incomplete and complete elementary school, incomplete and complete high school, and incomplete and complete higher education), years of study (4 years, 5 to 8 years and ≥9 years), marital status (single, married, divorced/separated, widowed, stable union, people with partner/without partner), current paid work (yes, no), family income (less than one minimum wage, 1 to 3 salaries, 3 to 5, higher than 5 minimum wages), time of diagnosis of DM (<10 years, ≥10 years), verification of capillary blood glucose (daily, weekly, monthly), frequency of medical appointments (monthly, every two months, every three months, every six months, none), type of drug treatment (exclusive use of insulin, insulin + oral antidiabetic drugs, exclusive use of oral antidiabetic drugs), level of physical activity (performed physical activity ≥3 days/week, performed no physical activity for at least 10 continuous minutes during the week), adherence to dietary treatment (yes, no), chronic complications of DM (retinopathy, nephropathy, neuropathy, heart disease), previous hospitalizations related to the disease (yes, no, what reason). This information was obtained by self-report and consultation of medical records.

The FLQA-WK is an instrument composed of 24 items distributed in six domains: physical symptoms, daily life, social life, psychological well-being, treatment and satisfaction. For each domain, a Likert scale is presented ranging from one (best QoL) to five (worst QoL), except for the "satisfaction" domain, which uses a subscale with inverted values, in which one means worse QoL and five, better QoL<sup>(13-14)</sup>. This instrument also presents three visual analog subscales, graduated from zero (very bad) to ten (very good), in which the person measures his/her

quality of life, health in general and wound conditions in the last week. The scores of the domains were calculated by means of the mean responses of the items of each domain, in the same way as the total score of the FLQA-WK.

The data were tabulated in the Microsoft Excel program and analyzed in the Statistical Package for the Social Sciences (SPSS), version 26.0. The FLQA-WK data were analyzed by means of central tendency (Mean, Maximum, Minimum and Standard Deviation). Sociodemographic and clinical data were analyzed descriptively by absolute and relative frequency. Student's t-tests and Analysis of Variance (ANOVA) were used to compare the sociodemographic and clinical variables and the means of the FLQA-WK domains. The parametric test was applied due to the result of the Kolmogorov Smirnov normality test, whose data presented a distribution with tendency to normality. A significance level of 5% was considered.

In compliance with the rules of Resolution 466/12 of the National Health Council, the project was approved by the Research Ethics Committee (REC) of the *Hospital Universitário Alcides Carneiro da Universidade Federal de Campina Grande*, Certificate of Presentation of Ethical Assessment (CAAE) 03062118.6.0000.5182.

## Results

Among the 50 participants evaluated in the study, 28 (56%) were male. The age ranged from 36 to 91 years, with a mean of 62.9 years. Regarding level of education and socioeconomic status, 22 (44%) participants had less than four years of schooling and 27 (54%) had an income below one minimum wage.

Concerning the clinical variables, 26 respondents (52%) had a medical diagnosis of DM for less than 10 years, 21 (42%) reported having medical appointments every six months, and 48 (96%) did not perform any physical activity for at least 10 continuous minutes during the week. Regarding associated comorbidities, 100% of the interviewees had neuropathy and six (12%) had diabetic retinopathy. Most had exclusive use of insulin (88%; n=44), had already been hospitalized for complications of DM (78%; n= 39), 32 (64%) lived with ulcers in the lower limbs for more than six months.

Table 1 shows the QoL scores of the FLQA-WK and its respective domains. The mean score of the instrument was 2.61, classified as regular. There was a lower mean score in the domain "physical symptoms" with 1.84 (SD=0.67), and higher in the domain "daily life", 3.52 (SD=0.86). Among the three visual subscales, the self-assessment of quality of life in the last week presented a higher mean (6.9; SD=2.02).

**Table 1** – Quality of life scores of patients with diabetic foot ulcers in outpatient treatment. Campina Grande, Paraíba, Brazil – 2019. (N=50)

Domains	n	Minimum	Maximum	Mean	Standard deviation
<b>FLQA-WK (0-5)</b>					
Physical symptoms	50	1	3.8	1.84	0.67
Daily life	50	1.6	5	3.52	0.86
Social life	50	1	5	3.264	0.91
Well-being	50	1	3.8	1.926	0.86
Treatment	50	1.5	4.5	2.762	0.71
Satisfaction	50	1	4.3	2.472	0.67
Total score	50	1.5	3.9	2.61	0.48
<b>Visual Scale (0-10)</b>					
Overall health status	50	0	10	6.64	2.56
In relation to your wound	50	0	10	6.36	2.90
Quality of life in the last week	50	0	10	6.9	2.02

Source: created by the authors.

Regarding the correlation of sociodemographic variables and QoL scores, schooling was positively related to the subscale of evaluation of the wound condition (p-value = 0.026), that is, the higher the level of schooling, the better the perception of the person with DFU about the state of his/her own wound. The total QoL score was negatively related to the following variables: diagnosis of DM for more than 10 years (p-value=0.005), hospitalizations due to the disease (p-value=0.019) and nephropathy (p-value=0.001).

Concerning the general health scale, the highest means were expressed by people that used oral antidiabetic drugs exclusively (p-value=0.001) and that followed the dietary plan (p-value=0.015). The lowest means were found in those who used insulin exclusively (p-value=0.003) and had previous hospitalizations (p-value <0.001).

## Discussion

The present study evaluated the quality of life of people with diabetic foot ulcers using the FLQA-WK. This instrument allows to measure the quality of life, the general state of their health and the wound conditions in the last week<sup>(13-14)</sup>. It is a short and easy-to-use instrument with satisfactory psychometric properties<sup>(14)</sup>. In Brazil, this questionnaire was used in research with people who had venous ulcers<sup>(15)</sup> and chronic wounds<sup>(16)</sup>.

The profile of the sample studied showed a higher proportion of men, elderly, with low education and few financial resources. A Korean study found higher QoL scores in people with DM with more than three family members and lower scores in those who were unemployed, single, divorced or widowed, without medical assistance and with lower economic status<sup>(17)</sup>. All these aspects can compromise QoL in any abnormal health condition<sup>(16)</sup>.

The low level of education is one of the factors related to the development of complications of DM, because it influences the ability of people to understand information

about the disease, hinders adherence to treatment and behavioral changes, in addition to recognizing the importance given to its control<sup>(18)</sup>. In the validation study of the FLQA-WK scale, conducted in the Southeastern region of Brazil, 97% of the participants had low education<sup>(13)</sup>.

When correlating or comparing QoL with sociodemographic variables, there was a significant difference between the level of education of the participants and the visual analog subscale of self-assessment of the wound conditions in the last week (p-value = 0.026). Thus, the highest mean is found among people with higher education ( $\geq 9$  years of study). The good evaluation of this subscale may be related to the fact that people with higher education have greater awareness of their clinical situation in general, have greater care with the feet and more access to materials for performing DFU dressings at home.

Among the domains evaluated by the FLQA-WK, the domain "daily life" presented the worst score (3.52), being significantly influenced by the variables longer time of diagnosis of the disease and hospitalizations. In contrast, the best score, that is, the lowest score, was concentrated in the domain "physical symptoms", with a mean of 1.84. These results demonstrate that the presence of DFU causes negative effects on the daily life of people with DM, and often requires rest for some periods of the day, causing people previously active to experience reduced labor activities, social cycles<sup>(16)</sup>, being directly associated with the emotional response to the physiological conditions of the aspects related to health<sup>(19)</sup>.

The second most affected domain of the FLQA-WK was the "social life" (3.26), especially the item "felt dependent", which presented the highest mean (3.78). These data reaffirm that the presence of a DFU can impact both emotionally and in the loss of autonomy of people with DM, causing losses in social relations, reducing the work and daily activities of previously active individuals<sup>(19)</sup>. This finding confirms the need to offer not only physical care for the healing of DFU, but also to explore the aspects that most

concern people in relation to the wound, in order to provide individualized emotional support<sup>(20)</sup>.

A systematic review of the QoL of people with DFU also identified impairment of the social functioning domain<sup>(6)</sup>. The reasons pointed out by the study refer to the person focusing his/her life only on the treatment of ulcers, not feeling able to socialize, and the reduced ability to work, which hinders social contacts. The authors stress the importance of developing strategies to prevent these people from becoming socially isolated. To this end, social support, combined with family support, can be effective in reducing social isolation among people<sup>(6)</sup>.

The analysis of the total score of the FLQA-WK revealed that QoL was perceived as regular by people with DM. The clinical variables that negatively impacted the QoL of people with DFU in outpatient treatment were the time of diagnosis of DM >10 years, higher frequency of hospitalizations and nephropathy.

The results also showed that participants who have been diagnosed with DM for more than 10 years had higher means in three of the six domains, "physical symptoms" (p-value=0.002), "daily life" (p-value=0.043), "treatment" (p-value=0.042), as well as the total score of the instrument (p-value=0.005) and the wound self-assessment scale.

A cross-sectional study<sup>(8)</sup>, conducted in the Southeastern region of Brazil, found that the time of diagnosis of the disease and poor glycemic control favor the development of comorbidities that contribute to worsening health and QoL of people with DM, which requires specialized care and/or treatments.

Regarding the drug treatment of DM, the participants who were exclusively using oral antidiabetic drugs presented a better mean in the health self-assessment scale 8.38 (p-value = 0.001). On the other hand, those who used insulin had a lower mean of 6.45 (p-value=0.003).

Confirming these findings, international studies<sup>(21-22)</sup> demonstrate that insulin use can affect the quality of life of people with DM, regardless of sociodemographic and clinical variables. The negative attitude towards insulin

therapy occurs due to social and psychological factors, such as fear of injection, need to conform to treatment, concerns about the way of life and the perception that they have reached a final stage in the course of the disease.

When DM coexists with other chronic diseases, the repercussions on QoL are even greater<sup>(23)</sup>. Among the complications of DM, nephropathy was the variable that negatively influenced four of the six domains of FLQA-WK, "physical symptoms" (p-value=0.045), "well-being" (p-value=0.004), "treatment" (p-value=0.005), "satisfaction" (p-value<0.001), in addition to influencing the means of the visual wound self-assessment scale (p-value = 0.006) and the total score of the instrument. These findings point to nephropathy as an important clinical condition that should be investigated in the assessment of QoL of people with DFU, because it affects the healing of ulcers and increases the time of inflammation of the lesion<sup>(23)</sup>.

Diabetic Nephropathy (DN) is the leading cause of End-stage Chronic Kidney Disease (ECKD) and can affect QoL because it requires arduous management throughout life. However, as the quality of life of people with DN is comparable to that of people with other types of ECKD, it is not well known. DN may follow an atypical progression, but most often, prevention of deterioration of renal function requires adequate control of DM, blood pressure, diet and exercise before evident proteinuria occurs. Patients are forced to follow a restricted diet, have to live with the burden of complying with medication instructions and often experience the risk of hypoglycemia and hyperglycemia in their daily lives<sup>(17)</sup>.

A retrospective study, conducted in a hospital in the Netherlands, found that there is an increase of four and almost eight times in the risk of foot ulceration in people with chronic kidney disease in stages 4-5 or in dialysis treatment, compared with individuals with chronic stage-3 kidney disease, resulting in high rates of amputation and mortality<sup>(23)</sup>. The authors highlight the importance of early recognition of foot ulcers in individuals with ECKD.

An important limitation of the present study concerns the particularity of having a single center analysis, thus not being able to ensure the generalization of the results in other contexts. However, it is a consensus that QoL is related to the perception of each individual, so it can be represented by different forms in each region.

This study contributes to the expansion of knowledge on the subject, since assessing QoL is as important as wound care, and favors the development of health actions capable of reducing the effects of DFU in the QoL of people with DM in outpatient treatment.

## Conclusion

The results showed that people with DFU in outpatient treatment have a QoL considered regular, with change in the domain “daily life”. The total QoL score was significantly influenced by the clinical variables: time of diagnosis of the disease >10 years, hospitalizations and nephropathy.

The FLQA-WK is an easy and feasible instrument to investigate the commitment of QoL of people with DFU, and can be used in nursing consultations to this population.

Moreover, it is important that health professionals implement interventions to improve care and reduce the impact on QoL. These strategies could include multiprofessional follow-up, focusing on regular evaluation of clinical factors, monitoring of metabolic control and implementation of self-care strategies to prevent the development of foot ulcerations.

## Collaborations:

1 – conception and planning of the project: Lidiany Galdino Félix and Mariana Pequeno de Melo;

2 – analysis and interpretation of data: Lidiany Galdino Félix, Mariana Pequeno de Melo, Rosângela Vidal de Negreiros, Jank Landy Simôa

Almeida, Maria Júlia Guimarães Oliveira Soares and Ana Elza Oliveira de Mendonça;

3 – writing and/or critical review: Lidiany Galdino Félix, Mariana Pequeno de Melo, Rosângela Vidal de Negreiros, Jank Landy Simôa Almeida, Maria Júlia Guimarães Oliveira Soares and Ana Elza Oliveira de Mendonça;

4 – approval of the final version: Lidiany Galdino Félix, Rosângela Vidal de Negreiros, Jank Landy Simôa Almeida, Maria Júlia Guimarães Oliveira Soares and Ana Elza Oliveira de Mendonça.

## Competing interests

There are no competing interests.

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