

# Factors associations and with health-related quality of life in individuals with diabetic foot ulcers: cross-sectional study

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## ABSTRACT

**Background** Patients with diabetic foot ulcers (DFUs) experience a significant decrease in their health-related quality of life (HRQoL).

**Aim** To evaluate the HRQoL of patients with DFUs using the Diabetic Foot Scale-Short Form.

**Methods** A cross-sectional study was carried out in a general outpatient clinic of a university hospital, from November 2022 to September 2023, among 103 patients. A negative small significant correlation was found between diabetes' length and the negative emotions domain ( $r=-0,1991$ ;  $p=0,0460$ ). Women showed significantly lower scores than men in physical health ( $p=0.0260$ ), dependence/daily life ( $p=0.0439$ ), and worried about ulcers/feet ( $p=0.0310$ ) domains. Patients who smoke had low scores for the leisure domain ( $p=0.0121$ ). Patients who did not follow a diabetes or diet and physical exercise showed lower scores in dependence/daily life ( $p=0.0014$ ) and were more bothered by ulcer care ( $p=0.0117$ ). Scores for the physical health ( $p=0.0355$ ) and dependence domains ( $p=0.0195$ ) were lower in patients who did not use oral antidiabetic agents. Patients using insulin had poor HRQoL for the dependence ( $p=0.0398$ ) and negative emotions domains ( $p=0.0441$ ).

**Conclusion** According to the results of this cross-sectional study, patients with diabetic foot ulcers exhibit a low HRQoL.

**Keywords** diabetic foot, diabetes mellitus, quality of life, general health, self-care management

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## INTRODUCTION

Diabetes foot ulcers (DFUs) are a common and severe diabetes mellitus (DM) complication that play a significant role in both morbidity and mortality in these patients, presenting a challenging public health issue,<sup>1</sup> and several studies have demonstrated that patients with foot ulcerations experience a significant decrease in their health related quality of life (HRQoL) when compared to those without this complication.<sup>2-4</sup>

Although patients with DFU have been extensively investigated with regards to their HRQoL, most studies have evaluated them using different generic HRQoL instruments, such as the Short-Form Health Survey 36 (SF-36)<sup>5-7</sup> and EuroQol five-dimension questionnaire (EQ-5D-5L),<sup>8</sup> which makes the comparison and analysis of HRQoL in this population difficult. Moreover, due to their lack of specificity, these instruments may not accurately capture the real impact of DM on HRQoL,<sup>8</sup> generating imprecise results. For this reason, it is important to use specific instruments to evaluate

HRQoL in this population, such as the Diabetic Foot Ulcer Scale Short Form (DFS-SF).<sup>9</sup>

Nevertheless, despite the advent of the development of the (DFS-SF)<sup>9</sup> to evaluate HRQoL, and its satisfactory psychometric performance, the literature is scarce to this point.

The DFS-SF has been adapted and validated in several countries, demonstrating high scientific evidence quality with good capacity for use in populations with DFUs.<sup>10-12</sup> The version of the DFS-SF has also demonstrated high reliability, indicating its suitability for assessing QoL in patients with diabetic foot ulcer.<sup>13</sup>

Considering how challenging is the management of DFUs for patients, health professionals and health systems, it is pivotal to comprehend the perception of QoL of people with DFUs. These findings will inform the development of health strategies that meet the specific needs of this population. Thus, this is the first study conducted in Brazil with the DFU-SF

with the objective of evaluating the HRQoL of patients with DFU.

## METHODS

### Study Design and Setting

This was a cross-sectional study carried out in a general outpatient clinic of the university hospital of the State University of Campinas, Brazil, from November 2022 to September 2023. This report follows the STROBE recommendations for exploratory studies.<sup>14</sup>

### Sample size and participants

The calculation of the sample size for the purpose of evaluating the correlation between DFS-SF scores and sociodemographic and clinical characteristics was based on the methodology of a sample calculation for a Pearson correlation coefficient. A test power of 80%, a significance level of 5%, an estimate for the correlation coefficient equal to 0.30, which according to Cohen<sup>15</sup> can be considered a moderate degree coefficient, and a correlation coefficient equal to 0.00 as a null hypothesis were assumed. The calculation resulted in a minimum sample of 84 subjects. To prevent possible losses, an additional 20% (n=17) was added to the minimum sample size, with a total of 101 participants. The G\*Power 3.1.9.2 software was used to perform the sample calculations.

Patients were included if they were 18 years or older, diagnosed with type 1 or 2 DM with at least one current DFU. Patients who had suffered major lower limb amputations and who had had documented diagnosis of dementia or cognitive impairment were excluded.

### DATA COLLECTION

Data was gathered using individual face-to-face interviews in a private setting.

#### Questionnaires

- Clinical and sociodemographic characterisation: a structured questionnaire was used to collect data on age, assigned sex at birth, race and ethnicity, employment status, partner status, schooling level, lifestyle and clinical associated conditions.
- Health-Related Quality of Life (HRQoL): The DFS-SF was used. This instrument is composed of 29 items divided into six domains: leisure; physical health; dependence/daily life; negative emotions; worried about ulcers/feet; and bothered by ulcer care. Each item is rated on a 5-point Likert-type scale ranging from 1 (not at all or none of the time) to 5 (a great deal, all the time, or extremely). Individual items on the instrument were reverse coded, and high scores on the DFS-SF indicate a high (good) HRQoL.<sup>16</sup>
- The grade ulcers were evaluated by two diabetes specialist nurses according to Wagner's classification<sup>17</sup>, and it was: Grade 0 (skin intact but bony deformities lead to "foot at risk"); Grade 1 (superficial ulcer); Grade 2 (deeper, full thickness extension); Grade 3 (deep abscess formation or osteomyelitis); Grade 4 (partial gangrene of forefoot); Grade 5 (extensive gangrene).
- Ulcer depth was judged by inspection and graded as: intact skin; superficial lesion; lesion reaching to tendon;

periosteum or joint capsule; and lesion involving bone or joint space. Clinical parameters such as the presence of inflammation, purulent exudate, and a positive bone test were used to determine the diagnosis of infection. These data were sufficient to allow classification of each ulcer by the systems mentioned above.

### STATISTICAL ANALYSIS

The Statistical Package for Social Sciences (SPSS, version 23, IBM) was used. Descriptive statistics were used to analyse sociodemographic and clinical data. Qualitative variables were presented as frequencies and percentages, while quantitative variables were expressed as mean and standard deviation (SD). The Mann-Whitney test was used for comparisons between qualitative variables concerning the DFS-SF domains, and the Spearman correlation coefficient assessed associations between quantitative variables and the DFS-SF domains. The significance level adopted was  $p=0.05$ .

### ETHICAL ASPECTS

The study was approved by the local institutional review board (IRB, CAAE: 36413020.0.0000.5404). All of the patients included in the study were informed about the objectives and nature of the study. Written informed consent was obtained.

### RESULTS

A total of 103 patients were assessed. The sample was predominantly male (77.67%), white (55.34%), living with a partner (52.43%) with a mean age of 63.84 (SD=11.67) years. As for the clinical conditions, the diagnosis length of DM was 15.3 (SD=9.68) years, and A1c mean was 8.5% (SD=2.1). Regarding the DM treatment, about 77% of patients used oral antidiabetics and 45% received insulin in combination with oral antidiabetic. According to the Wagner Scale, 42.72% of the patients' ulcers were classified as Grade 2, meaning deeper, with full thickness extension (Table 1).

Figure 1 shows the median scores and dispersion (interquartile range) of the six subscales of DFS-SF. The subscales median were 35.00, 60.00, 55.00, 54.17, 43.75 and 62.50 for Leisure, Physical Health, Dependence/Daily Life, Negative Emotions, Worried about ulcers/feet and Bothered by ulcer care, respectively.

Correlations between sociodemographic characteristics and the DFS-SF domains are shown in Table 2. A negative correlation was found between the DM length and the negative emotions domain (Spearman's  $r = -0,1991$ ;  $p=0,0460$ ). No correlation was found between the other variables and DFS-SF domains.

The comparisons between the qualitative variables and the DFS-SF domains are shown in Table 3. Women scored significantly lower than men in physical health ( $p=0.0260$ ), dependence/daily life ( $p=0.0439$ ), and worried about ulcers/feet domains ( $p=0.0310$ ). The patients who used tobacco scored significantly lower than those who didn't use it in the leisure domain ( $p=0.0121$ ). Patients who did not follow DM diet or practice physical activity showed lower scores in the dependence/daily life domain ( $p=0.0014$ ), and were more bothered by ulcer care ( $p=0.0117$ ) than those who engaged in DM diet and physical activity. Scores for the physical health ( $p=0.0355$ ) and dependence domains ( $p=0.0195$ ) of DFS-

Table 1. Sociodemographic and clinical characteristics (n = 103).

Variable	n (%)
<b>Assigned sex at birth</b>	
Male	80 (77.67)
<b>Partner Status</b>	
Living with partner	58 (56.32)
<b>Cohabiting</b>	
Living alone	14 (13.59)
With 1 relative or significant other 1	27 (26.21)
With 2 relatives or significant others	27 (26.21)
With 3 relatives or significant others	20 (19.42)
With 4 or more relatives or significant others	15 (14.56)
<b>Race or ethnicity</b>	
White	57 (55.34)
<b>Employment status</b>	
Retired	81 (78.65)
<b>Diet and physical exercise</b>	24 (23.30)
<b>Use of Insulin</b>	47 (45.63)
<b>Use of oral antidiabetic agents</b>	80 (77.67)
<b>No Diabetes treatment</b>	6 (5.83)
<b>Smoking use</b>	
Current use	9 (8.74)
Previous use	24 (23.30)
Never used	70 (67.96)

Variable	n (%)
<b>Alcohol use</b>	
Current use	5 (4.85)
Previous use	25 (24.27)
Never used	73 (70.87)
<b>Hypertension</b>	86 (83.50)
<b>Dyslipidemia</b>	22 (21.36)
<b>Cardiovascular disease</b>	23 (22.33)
<b>Cerebrovascular disease</b>	10 (9.71)
<b>Peripheral arterial disease</b>	32 (31.07)
<b>Neoplasm</b>	1 (0.97)
<b>Respiratory disease</b>	7 (6.80)
<b>Wagner classification</b>	
1	27 (26.21)
2	44 (42.72)
3	0
4	29 (28.16)
5	3 (2.91)
<b>Age, mean(SEM)</b>	63.84 (11.67)
<b>Schooling level, years, mean(SEM)</b>	6.92 (3.49)
<b>Diabetes Diagnosis Length, years, mean(SD)</b>	15.13 (9.68)
<b>Body Weight, kg, mean(SD)</b>	81.15 (18.48)
<b>Body Mass Index, kg/m<sup>2</sup>, mean (SD)</b>	28.12 (6.38)
<b>A1c, ean (SD)</b>	8.50 (2.10)

SD: standard deviation; SEM: standard error of mean

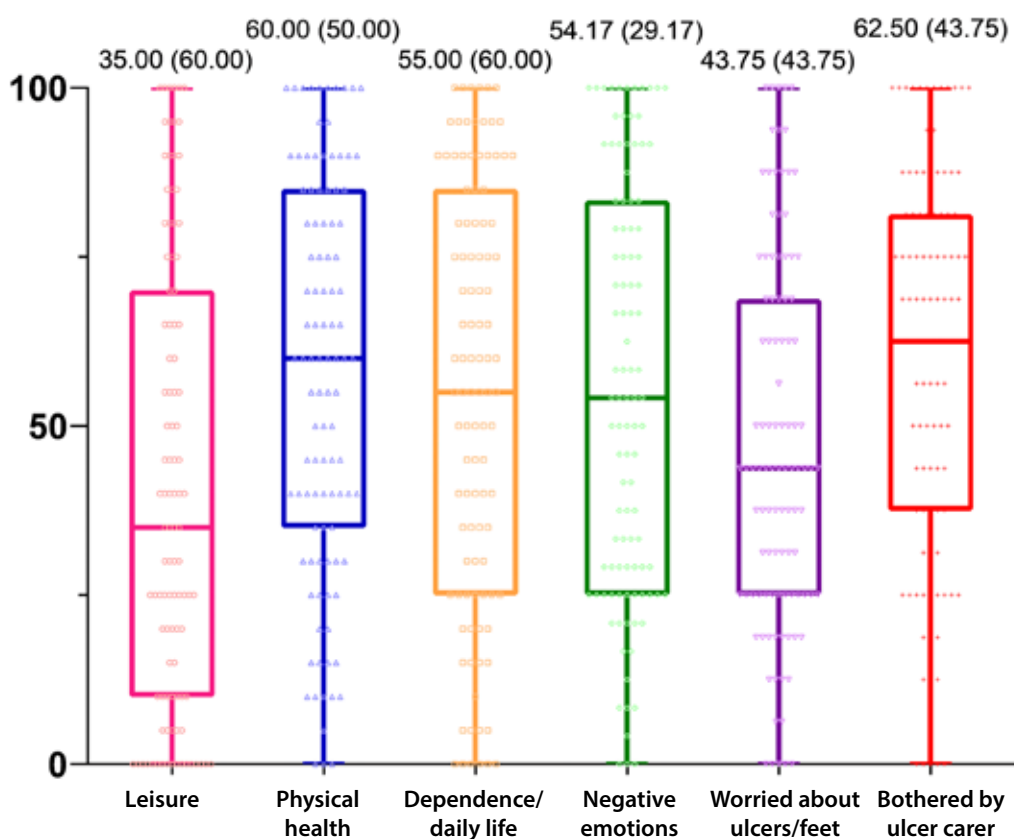


Figure 1. Mean/Median scores for the HRQoL in the six domains of the Diabetic Foot Ulcer Scale, Short Form; (standard deviation) Median (SD) - SD: standard deviation.

SF were lower in patients who did not use oral antidiabetic agents. Patients who used insulin had worse HRQoL for the dependence ( $p=0.0398$ ) and negative emotions ( $p=0.0441$ ) domains than patients who did not use insulin.

## DISCUSSION

HRQoL in patients with DFU was investigated for the first time using the DFS-SF instrument in this study. The results showed that the scores in the DFS-SF domains were low. These findings corroborate with other studies conducted in Poland, India, Greece and Jordanian.<sup>10,18–20</sup> In contrast, studies performed in Spain and in the north of Thailand reveal the opposite, patients in these studies have high scores in DSF-SF. One exception is for the worried about ulcer domain in the Spanish study.<sup>21</sup> The Northern Thailand study results suggest that the high HRQoL scores found are related to their education program about feet self care.<sup>22</sup>

The differences in HRQoL observed across these populations may be attributed to cultural factors, the healthcare system, severity of the ulcer, and whether patients have undergone amputation, when these data are compared with other studies.<sup>10,20,22,23</sup> A study aimed at evaluating the influence of ethnicity on HRQoL in patients with diabetes, using the SF-36 and single-index (SF-6D) in three different Asian countries, revealed that ethnicity is an important factor influencing HRQoL.<sup>24</sup> Although culture has been emphasised as a significant aspect in the context of health, the scarcity of psychometrically validated cultural instruments remains a barrier to advancing research in this area.<sup>25</sup>

The low DSF-SF scores observed in the Indian and the Polish studies were related to the ulcer severity.<sup>10,18</sup> In our investigation, there was no correlation between the DSF-SF scores and the Wagner grading, and most of the ulcers were classified as Grade 2 according to this scale. Other studies conducted in different countries that have used generic instruments to evaluate HRQoL demonstrated correlation between poor QoL and ulcer severity.<sup>4,19</sup>

The results of this study showed a negative correlation between the duration of diabetes and the negative emotions domain. Nonetheless, no correlations between schooling, HbA1c and/or BMI and the DSF-SF domains were observed. According to studies,<sup>23</sup> a holistic approach is fundamental to offer individualised care which should be planned considering health habits, the culture and sociodemographic characteristics of each patient. The relationship between HRQoL and its related factors in patients with DFUs is very divergent across studies, regardless of whether the instrument is generic for diabetic patients or specific for patients with

DFUs. One possible explanation for these different findings could be a relation with beliefs, cultural aspects, the quality of care the patients receive and the prevention program available.

The female gender has been associated with poor HRQoL, and the findings of this study corroborate with the literature.<sup>20,26–29</sup> The female perception regarding HRQoL could be related to a greater worry about their health condition and its impact on the family environment, especially in families where housekeeping is done by women.<sup>28</sup> These factors contribute to increased anxiety and depression more in women than in men living with DM.<sup>30,31</sup> Anxiety and depression were significantly associated with lower QoL,<sup>32</sup> and women with anxiety were less inclined to seek consultation with a podiatrist over time,<sup>33</sup> contributing to the risk of ulceration. For this reason, some interventions should be considered to improve QoL, such as patient education. This approach has been shown to improve QoL in patients with DFU.<sup>34</sup> Moreover, psychological stress interventions, such as relaxation with guided imagery, biofeedback-assisted relaxation, mindfulness, might help patients manage their expectations, anxieties, and fears regarding the disease, as well as contribute to wound healing.<sup>35</sup>

Studies have been showing that peripheral arterial disease (PAD) is a risk factor for poor HRQoL.<sup>29,36–39</sup> Nevertheless, a study has indicated that limb threatening ischemia and inability to stand or walk independently were the most important contributors to HRQoL.<sup>40</sup> Contrary to the literature, our findings did not demonstrate a relationship between PAD and low HRQoL. HRQoL knowledge can assist in predicting better treatment, which can aid in developing a treatment plan that is not only focused on clinical factors, but also takes into account the patient's experiences and perceptions.<sup>41</sup>

Individuals who did not follow a DM diet or physical exercises had low scores in the Dependence/Daily life and Bothered by Ulcer Care domains. These results could be related to the patient's perception between what they should follow to have a good control of DM and what they actually do. Many studies have shown that patients' daily, social and leisure activities are negatively affected by the presence of DFU.<sup>42,43</sup> Which can be associated with a mobility reduction and, in consequence, with the capacity for doing daily tasks and with dependence on others.<sup>44</sup>

Participants who used insulin showed low scores in the Dependence/Daily and Negative Emotions domains. The set behaviour, such as adherence to diet, physical activity, medication, glucose self-monitoring, and appointment keeping, led to diabetes-related distress which in turn

Table 2. Spearman correlation coefficients ( $p$  values) between the DSF-SF subdomain scores and qualitative variables ( $n=103$ ).

	Schooling	Body Mass Index	Duration of Diabetes	A1C*
Leisure	-0.1250	-0.1031	-0.0526	0.0198
Physical Health	-0.1044	-0.1291	-0.1656	0.1044
Dependence	0.0050	0.1077	-0.0850	0.0585
Negative Emotions	-0.0733	-0.0333	<b>-0.1991</b>	-0.0662
Worried about ulcers/feet	-0.1764	-0.1033	-0.0657	-0.1286
Bothered by ulcer care	-0.0515	-0.0167	-0.1353	-0.1160

\*A1C: glycosylated hemoglobin. The  $p$  values were attained via the Spearman correlation coefficient test, significant values in bold.

Table 3. Comparison of qualitative variables with the median DFS-SF subdomain scores (interquartile range), n=103.

	Leisure	Physical health	Dependence /Daily life	Negative emotions	“Worried about ulcers/feet”	“Bothered by ulcer care”
<b>Sex</b>						
Female	35.00 (60.00)	35.00 (45.00)	50.00 (45.00)	33.33 (45.83)	37.50 (18.75)	56.25 (56.25)
Male	32.50 (60.00)	60.00 (45.00)	60.00 (55.00)	58.33 (60.41)	43.75 (50.00)	68.75 (46.88)
	p = 0.4503	<b>p = 0.0260</b>	<b>p = 0.0439</b>	p = 0.0529	<b>p = 0.0310</b>	p = 0.4155
<b>Hypertension</b>						
Yes (n = 86)	35.00 (60.00)	60.00 (55.00)	57.50 (55.00)	54.17 (50.00)	43.75 (43.75)	62.50 (43.75)
No (n = 17)	25.00 (45.00)	60.00 (30.00)	55.00 (50.00)	50.00 (66.67)	50.00 (62.50)	68.75 (31.25)
	p = 0.6558	p = 0.6371	p = 0.4904	p = 0.6757	p = 0.3946	p = 0.8446
<b>Dyslipidemia</b>						
Yes (n = 22)	40.00 (65.00)	65.00 (55.00)	57.50 (60.00)	50.00 (62.50)	43.75 (25.00)	56.25 (37.50)
No (n = 81)	30.00 (55.00)	60.00 (50.00)	55.00 (55.00)	54.17 (58.33)	43.75 (43.75)	68.75 (43.75)
	p = 0.3366	p = 0.9678	p = 0.6751	p = 0.6809	p = 0.7837	p = 0.4432
<b>Wagner Classification</b>						
1 (n = 27)	40.00 (65.00)	60.00 (55.00)	65.00 (65.00)	58.33 (58.33)	43.75 (43.75)	68.75 (43.75)
2 (n = 44)	32.50 (50.00)	60.00 (42.50)	55.00 (47.50)	52.08 (43.75)	40.63 (40.63)	59.38 (62.50)
4 (n = 32)	45.00 (75.00)	52.50 (52.50)	50.00 (55.00)	58.33 (68.75)	50.00 (53.13)	65.63 (31.25)
	p = 0.3060	p = 0.8000	p = 0.3829	p = 0.8892	p = 0.5474	p = 0.9964
<b>Cerebrovascular disease</b>						
Yes (n = 10)	35.00 (45.00)	62.50 (30.00)	37.50 (35.00)	37.50 (50.00)	59.38 (25.00)	46.88 (16.75)
No (n = 93)	32.50 (62.50)	60.00 (55.00)	60.00 (55.00)	54.17 (54.16)	43.75 (43.75)	68.75 (43.75)
	p = 0.8362	p = 0.8104	p = 0.0964	p = 0.3152	p = 0.2231	p = 0.1479
<b>Cardiovascular disease</b>						
Yes (n = 23)	27.50 (65.00)	60.00 (50.00)	60.00 (40.00)	62.50 (41.67)	43.75 (37.50)	56.25 (43.75)
No (n = 80)	35.00 (55.00)	60.00 (52.50)	55.00 (60.00)	50.00 (58.33)	43.75 (43.75)	60.75 (43.75)
	p = 0.9272	p = 0.8397	p = 0.7450	p = 0.2841	p = 0.3363	p = 0.3589
<b>Peripheral arterial disease</b>						
Yes (n = 32)	40.00 (67.50)	55.00 (45.00)	52.50 (47.50)	56.25 (43.75)	40.63 (46.88)	59.38 (31.25)
No (n = 71)	25.00 (55.00)	60.00 (55.00)	60.00 (60.00)	45.83 (58.33)	43.75 (43.75)	68.25 (50.00)
	p = 0.1341	p = 0.8193	p = 0.6711	p = 0.6762	p = 0.8107	p = 0.8525
<b>Smoking</b>						
No (n = 70)	27.50 (50.00)	60.00 (50.00)	55.00 (55.00)	54.17 (50.00)	43.75 (43.75)	65.63 (43.75)
Yes (n = 33)	50.00 (70.00)	60.00 (45.00)	65.00 (55.00)	54.17 (62.50)	43.75 (50.00)	62.50 (43.75)
	<b>p = 0.0121</b>	p = 0.9210	p = 0.9211	p = 0.7259	p = 0.2859	p = 0.9069
<b>Diet and physical exercise</b>						
Yes (n = 24)	37.50 (67.50)	62.50 (50.00)	82.50 (40.00)	62.50 (35.42)	50.00 (43.75)	78.13 (21.87)
No (n = 79)	30.00 (60.00)	60.00 (50.00)	50.00 (50.00)	50.00 (58.33)	43.75 (43.75)	56.25 (43.75)
	p = 0.5286	p = 0.9253	<b>p = 0.0014</b>	p = 0.2755	p = 0.7159	<b>p = 0.0117</b>
<b>Use of oral antidiabetic agents</b>						
Yes (n = 80)	35.00 (62.50)	62.50 (45.00)	60.00 (52.50)	58.33 (54.16)	43.75 (50.00)	65.63 (43.75)
No (n = 23)	35.00 (50.00)	40.00 (45.00)	35.00 (50.00)	37.50 (45.83)	43.75 (43.75)	62.50 (50.00)
	p = 0.6279	<b>p = 0.0355</b>	<b>p = 0.0195</b>	p = 0.1257	p = 0.5459	p = 0.3822
<b>Use of Insulin</b>						
Yes (n = 47)	25.00 (50.00)	50.00 (45.00)	50.00 (45.00)	41.67 (50.00)	37.50 (37.50)	56.25 (37.50)
No (n = 56)	37.50 (60.00)	65.00 (50.00)	67.50 (50.00)	66.67 (60.42)	50.00 (50.00)	75.00 (50.00)
	p = 0.4234	p = 0.1041	<b>p = 0.0398</b>	<b>p = 0.0441</b>	p = 0.0532	p = 0.0545

The p values were attained via the Mann–Whitney test, significant values in bold.

linked to poor treatment adherence and low quality of life.<sup>45</sup> Another study discusses the influence of insulin on emotional behaviours. However, this is not yet firmly established.

Nevertheless, these findings underline the need for a holistic approach to diabetes treatment that addresses the emotional and psychological aspects.<sup>46</sup>

The low scores in HRQoL in patients who do not smoke or who do not take oral antidiabetics in the subscales are unexpected results. The relationship between the challenges of controlling diabetes and psychological and social factors is complex and may involve potential confounding variables not detected in the sample, which could be influencing these results. As reported in other studies, smoking is associated with foot ulcers and gangrene, which increases the risk that people with DFUs have poorer HRQoL in the physical, financial, and psychological domains.<sup>22</sup>

Strengths of this study include its pioneering nature in assessing HRQoL among patients with DFUs using the Diabetic Foot Scale-Short Form. However, it is important to recognise some limitations. This study was conducted in a single outpatient clinic of a tertiary-care facility, where the most severe DM cases are followed up, which may not be representative of the broader population. This can limit the generalisability of study findings to other settings. Furthermore, it was a cross-sectional study that used self-reported instruments, so recall bias could affect the answers obtained. To mitigate this limitation, studies with different designs should be performed in order to get a widest HRQoL assessment. Furthermore, cross-sectional studies limit the ability to make causal inferences between HRQoL and its associated factors. Therefore, longitudinal studies should be conducted to better understand these relationships.

## CONCLUSION

The results of this cross-sectional study confirmed that the patients analysed with diabetic foot ulcers experience poor HRQoL. The most important factors associated with these results were female sex, lack of physical exercise, poor diet, insulin use, no smoking habits, no use of antidiabetic oral agents. Further studies using specific instruments are necessary to evaluate all variables that could impact the quality of life of patients with DFUs. Comprehending what influences a poor QoL can contribute to improving patients' self-care behavior and health beliefs. As a consequence, it may lead to better metabolic control and clinical outcomes.

## IMPLICATIONS FOR CLINICAL PRACTICE

Our findings suggest that healthcare providers should be encouraged to routinely ask about negative emotions in people with diabetes, since negative emotions affect patients' quality of life, self-management abilities, medication compliance and blood sugar control, and increase the risk of cardiovascular events and mortality.<sup>47</sup>

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## CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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## ETHICAL ASPECTS

The study was approved by the local institutional review board (IRB, CAAE: 36413020.0.0000.5404). All of the patients included in the study were informed about the objectives and nature of the study. So, a written informed consent was obtained.

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