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Health-related quality of life among Spanish patients with diabetic foot ulcer according to Diabetic Foot Ulcer Scale – Short Form

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ABSTRACT

Aim: The aim of this study was to investigate the health-related quality of life of Spanish outpatients with diabetic foot ulcer using the Diabetic Foot Scale-Short Form (DFS-SF).

Materials and methods: This cross-sectional observational study included 141 outpatients with diabetic foot ulcers (DFU). The DFS-SF was applied in personal interviews conducted by a trained investigator to assess health-related quality of life (HRQoL).

Results: The domain related to "worried about ulcers" had the lowest in score [50 (27.5–65.0)], and the highest score was in the physical health domain [76 (60.0–88.0)]. There was a statistically significant difference in the ulcer type and the physical health subscale, finding the lowest values in the physical health subscale in patients with ischaemic diabetic foot ulcers [58 (39.0–70.0), $p = 0.007$]. In the multivariable analysis the domains Leisure (OR 0.98, 95% CI 0.97–0.99) and worried about ulcers/feet (OR 0.98, 95% CI 0.96–0.99) were identified as significant independent domains in patients with the experience of a previous minor amputation. A significant negative correlation was observed between the SINBAD DFU score and leisure ($r = -0.181$, $p = 0.032$), physical health ($r = -0.202$, $p = 0.016$), dependence/daily life ($r = -0.232$, $p = 0.006$), and the "bothered by ulcer care" ($r = -0.239$, $p = 0.004$) domains of the DFS-SF. The ulcer duration had a significant negative correlation with all the domains of DFS-SF.

Conclusion: The DFS-SF survey is a specific instrument that could be implemented in diabetic foot units as part of the management of patients with DFU to evaluate HRQoL. The domain of "worried about ulcers" had the lowest score in our population suggesting that clinicians should try to work on the emotional state of patients with DFU. The mean duration of DFU was the most influential factor related to worse scores followed by previous amputations. The SINBAD score had significant negative correlations suggesting that HRQoL may be related to the severity of DFU in this study population.

1. Introduction

Diabetic foot ulcer (DFU) is a devastating chronic complication that is associated with diabetes mellitus (DM) and negatively affects a patient's health [1,2]. It results in severe consequences related to psychological features [3], physical activity [4,5], and social [6] and economic functioning [7]. It is an important healthcare issue due to its rising prevalence, which is estimated as 5.1% in Europe and around 3% in Spain [8]. Patients with DM and DFU have a deteriorating health-related quality of life (HRQoL) [4,6]. Additionally, DFU has been demonstrated to have the greatest negative impact on HRQoL compared to other conditions, such as ulcers that have healed [9], amputation [10], diabetic retinopathy, end-stage renal disease, and coronary disease [11].

Previous research has demonstrated an association between several factors that reduce the standard of life. These include demographic

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characteristics like older age, type 2 DM, poor glycaemic control [4], and increased body mass index [12]. The factors also include DFU characteristics such as the mean duration, Wagner grade [13], ulcer size, and the presence of pain [12]. There are also sociodemographic features, such as living alone, low education level [4], non-White ethnicity, and not working [5].

In recent years, there have been many reports on the HRQoL of patients with DM, especially for people with DFU [5]. Information about patient's HRQoL is commonly measured using patient-reported outcome measures (PROMs). These involve several questionnaires that assess patients' perceptions of their disability and how it affects their life [14]. A recent review identified 12 questionnaires for the spectrum of diabetes-related foot disease [15].

The Diabetic Foot Scale is a disease-specific instrument for assessing patients with DFU that has demonstrated high sensitivity, but it has a relatively large number of items that could make the evaluation difficult [16]. The Diabetic Foot Ulcer Scale – Short Form (DFS-SF) provides an abbreviated version of the DSF that could be helpful, especially when time is limited [16]. It was first developed and validated in English and has been widely studied with adaptation and validation in Chinese [17], Greek [18], Korean [19], Turkish [20], Polish [21], Brazilian [22], and Dutch [23] populations. It has also been employed to assess the HRQoL in other populations like India [6], Thailand [24], or Jordanian [25] populations using the original version, showing high-quality scientific evidence with good capacity for use in populations with DFU [17–19, 26].

HRQoL assessment is essential to identify a patient's health status. To assess the HRQoL of Spanish speakers with DFU, the DFS-SF was recently translated to Spanish and validated [26]. However, to the best of our knowledge, no previous study has employed this tool since its validation in a specialized diabetic foot unit in Spain to verify its utility. Therefore, the aim of this study was to investigate the health-related quality of life of Spanish outpatients with DFU using the DFS-SF.

2. Methods

2.1. Subjects

This cross-sectional observational study included 141 outpatients with DFUs between January 2022 and September 2022. We included patients who consecutive admitted at our specialized outpatients diabetic foot unit and had type 1 or 2 DM, age greater than 18 years, and DFUs. Patients with poor cognitive level (inability to understand and cooperate in completing the questionnaire) were excluded. A data-collection form was used to collect sociodemographic data and clinical characteristics of the study population. All of the patients included in the study were informed about the objectives of the study. This study was approved by the ethics committee of our teaching hospital (code: C.P.20/738-EC_P)), and before inclusion, all patients provided written informed consent according to the principles of the Declaration of Helsinki [27].

2.2. Clinical assessment

Neuropathy assessment was performed using a 10-g Semmes–Weinstein monofilament, which was applied to three plantar foot sites, and a biothesiometer (Me.Te.Da. s.r.l., Via Silvio Pellico, 4, 63074 San Benedetto del Tronto AP, Italy). Diabetic neuropathy was confirmed in the event of two out of three answers being incorrect with the monofilament or if two out of three answers were incorrect when using the biothesiometer with a vibration perception threshold >25 mV [28].

Vascular assessment was carried out based on distal pedal pulse palpation, the ankle brachial index (ABI), the toe brachial index (TBI), and transcutaneous oxygen pressure ($tcpO_2$). Peripheral arterial disease (PAD) was defined by the absence of both distal pulses or an ABI of <0.9. In patients whose ABI was >1.4 or those with uncertain diagnostic findings, the diagnosis of PAD was confirmed with a systolic ankle pressure <70 mmHg, TBI <0.7, systolic toe pressure <50 mmHg, or $tcpO_2$ values less than 25 mmHg [29]. DFUs were classified using the Site, Ischemia, Neuropathy, Bacterial Infection and Depth (SINBAD) classification system at the moment of inclusion. The system uses a total of six items scored as 0 or 1, which are added together to create a total score of 0–6 points [30].

2.3. diabetic Foot Ulcer Scale – Short Form (DFS-SF)

The DFS-SF was applied in personal interviews that were conducted by a trained investigator to assess HRQoL. The DFS-SF contains 29 items based on 6 subscales: 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.

The score of each subscale was calculated based on a scale of 0 (poorer HRQoL) to 100 (higher HRQoL). Each interview took approximately 15 min. The validated Spanish adaptation of the DFU-SF was used [26]. This final Spanish version is available in File S1 at https://www.irblleida.org/media/upload/arxius/VARIS/File%20S1_cuestionario.pdf.

2.4. Statistical analysis

Statistical analysis was performed using the software package SPSS version 25.0 (IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY, USA: IBM Corp.). Qualitative variables were described using frequency distributions and percentages. The chi-squared test and Fisher's exact test if applicable were used to calculate differences between groups for categorical variables. The Kolmogorov-Smirnov test was used to verify the normality assumption of all continuous variables. Normally distributed variables (Kolmogorov-Smirnov test with $p \geq 0.05$) are reported as means and standard deviations (SDs), and non-normally distributed variables (Kolmogorov-Smirnov $p < 0.05$) are reported as medians and interquartile ranges.

The Mann–Whitney U and Student's t-test were performed for non-normally and normally distributed quantitative variables, respectively. Spearman and Pearson correlation coefficients were used to analyse the correlation among quantitative variables that were non-normally and normally distributed, respectively. We used a logistic regression model with the experience of previous minor amputation as the dependent variable and significant domains of the DFS-SF in bivariable analyses (leisure, dependence/daily life, negative emotions, worried about ulcers/feet and bothered by ulcer care) as covariates.

Differences were considered significant at $P < 0.05$ with a 95% confidence interval. Graphics were generated using GraphPad® for Mac OS to illustrate the scores for the HRQoL in the six subscales of the DFS-SF. The sample size was adjusted to that used in the adaptation and validation of the DFU-SF in Spanish (141 subjects) [26].

3. Results

The majority of patients were men (n = 126, 89.4%), and the mean age was 65.3 ± 9.9 years. The median diabetes duration was 20 (10.5–30) years. There were 125 patients (88.7%) with type 2 diabetes. The median HbA1c was 7.2% (interquartile range: 6.3–8%). There were 82 patients (58.2%) who had neuropathic DFUs, 12 patients (8.5%) who had ischemic DFUs, and 47 patients (33.3%) who had neuroischaemic DFUs. The median duration of DFUs was 8 (4-24) weeks, and the median SINBAD score was 3 (2-4). Table 1 shows the sociodemographic and clinical characteristics of the study population.

The HRQoL scores in the six domains of the DFS-SF are shown in Fig. 1. The domain related to "worried about ulcers" had the lowest in

Table 1
Sociodemographic and clinical characteristics of the study population.

Characteristics	Study population (n = 141)
Age (years)	65.3 ± 9.9
Male (sex)	126 (89.4)
Race (White)	141 (100)
Educational level	
Less than primary	4 (2.8)
Completed primary	43 (30.5)
Secondary high school	53 (37.6)
Graduate or higher	41 (29.1)
Employed	38 (27)
Smoking	
Never	40 (28.4)
Current	17 (12.1)
Former	84 (59.6)
Type 2 diabetes	125 (88.7)
BMI (kg/m^2)	27.9 (25.05; 31.0)
HbA1c (%)	7.2 (6.3; 8.0)
Hypertension	103 (73.0)
Dyslipidaemia	94 (66.7)
Microvascular complications	
Retinopathy	53 (37.6)
Nephropathy	26 (18.4)
Neuropathy	128 (90.8)
Cardiovascular disease *	47 (33.3)
Diabetes therapy	
OAD	50 (35.5)
OAD + insulin	53 (37.6)
Insulin	38 (27)
Antiplatelet or anticoagulant agents	91 (64.5)
Dialysis	9 (6.4)
Ulcer type	
Neuropathic	82 (58.2)
Ischemic	12 (8.5)
Neuroischaemic	47 (33.3)
Infected ulcer	42 (29.8)
Previous amputation	
Minor	75 (53.2)
Major	0 (0)
Charcot foot disease	8 (5.7)

Data are shown as mean (SD) for quantitative variables distributed normally, as medians and interquartile ranges for non-normally distributed quantitative parameters or n (%) for qualitative variables. * Cardiovascular disease included cerebrovascular disease and ischemic heart disease. BMI: body mass index; HbA1c: glycated haemoglobin; OAD: oral antidiabetic agents).

score (50 (27.5–65.0)), and the highest score was in the physical health domain (76 (60.0–88.0)). There was a statistically significant difference in the ulcer type and the physical health subscale. The lowest values were in the physical health subscale in patients with ischaemic DFUs. Fig. 2 presents the distribution of the six domains based on ulcer type.

In the bivariable analysis, significant differences were found in the domains of physical health and "worried about ulcers" depending on the educational level. Dyslipidaemia was associated with lower scores in the domains of "worried about ulcers" and "bothered by ulcer care." Significant differences were found in the leisure, dependence/daily life, negative emotions, "worried about ulcers/feet," and "bothered by ulcer care" domains according to the experience of a previous minor amputation. Table 2 shows the distributions of the six domains of the DFS-SF based on qualitative variables.

In the multivariable analysis the domains Leisure (OR 0.98, 95% CI 0.97–0.99) and worried about ulcers/feet (OR 0.98, 95% CI 0.96–0.99) were identified as significant independent domains in patients with the experience of a previous minor amputation.

A significant negative correlation was observed between the SINBAD DFU score and four domains of the DFS-SF (leisure (r = -0.181, p = 0.032), physical health (r = -0.202, p = 0.016), dependence/daily life (r = -0.232, p = 0.006), and "bothered by ulcer care" (r = -0.239, p = 0.004)). The ulcer duration had a significant negative correlation with all the domains of DFS-SF (leisure (r = -0.278, p < 0.001), physical health (r = -0.200, p = 0.017), dependence/daily life (r = -0.329, p < 0.001), negative emotions (r = -0.247, p = 0.003), "worried about ulcers/feet" (r = -0.167, p = 0.048), and "bothered by ulcer care" (r = -0.281, p < 0.001)). Table 3 shows the correlation between the domains of the DFS-SF and quantitative variables.

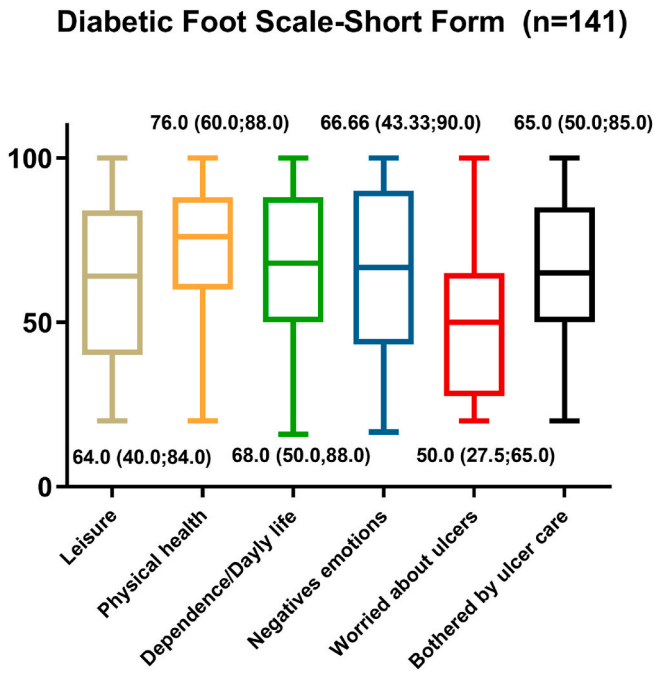

Fig. 1. Scores for the HRQoL in the six domains of the DFS-SF. Data are shown as medians and interquartile ranges. DFS-SF: Diabetic Foot Scale – Short Form).

4. Discussion

In this study, we observed that the DFS-SF domain of "worried about ulcers" had the lowest score in our study population. This result is in concordance with the study by Khunkaew et al. [24] at a tertiary hospital in Northern Thailand and that by Kontodimopoulos et al. [18] in a general hospital in Athens, Greece, involving subjects with DFU. These results suggest that patients with DFU often experience emotional uncertainty about when the ulcer will heal and whether new lesions will appear on their feet, and it may be that clinicians have to devote more attention to this domain.

In studies carried out in India [6] and Poland [21], when applying the DFS-SF, very poor scores were found in all six domains, suggesting that the scores may be related to the severity of the DFU of the population studied. In this regard, we observed that the SINBAD DFU score had a significant negative correlation with the leisure, physical health, dependence/daily life, and "bothered by ulcer care" subscales. Valensi et al. [13] used the DFS survey with French subjects who had DFU and confirmed that a more severe Wagner grade correlated with poorer HRQoL. Similar results have also been found in the study by Kontodimopoulos et al. al. [18], where lower scores of the 6 domains of the DFS-SF correlated with higher scores on the University of Texas wound classification system for DFUs.

Previous studies have found that diabetic foot is associated with severely impaired HRQoL in both physical and mental-health aspects [5,6,21]. We observed that patients with ischemic DFU had significantly lower scores in the physical health domain. A meta-analysis by Khunkaew et al. al [24]. found that an Ankle Brachial Index <0.9 was associated with poorer HRQoL among people with DFUs. Kontodimopoulos et al. [18] found lower scores in all domains of the DFS-SF among patients with vascular stenosis greater than 50%.

Dyslipidaemia was associated with lower scores in the domains of "worried about ulcers" and "bothered by ulcer care". In a study by Al

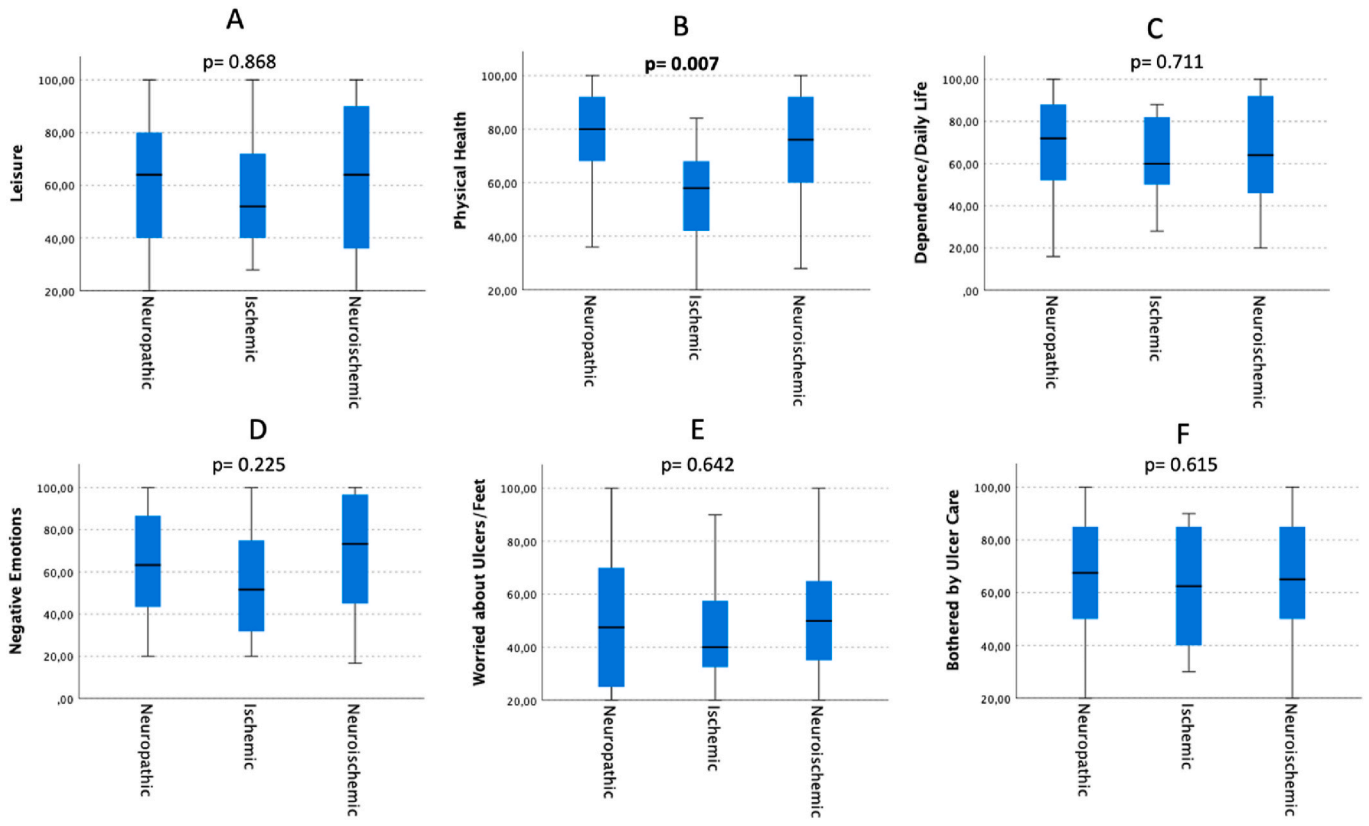

Fig. 2. Scores for HRQoL in the six domains of the DFS-SF based on ulcer type. DFS-SF: Diabetic Foot Scale – Short Form. (A) Leisure, (B) Physical health, (C) Dependence/daily life, (D) Negative emotions, (E) "Worried about ulcers/feet," (F) "Bothered by ulcer care."

Ayed et al. [31], the emotional health of patients was affected by dyslipidaemia according to the Arabic version of the 36-item Short-Form (SF-36) survey, highlighting the importance of managing comorbidities for these patients. The mean duration of diabetic foot was the main aspect of ulcers that had a negative correlation with all the domains of the DFS-SF observed in the present study. Valensi et al. [13] confirmed that a longer duration of the DFU may be related to the duration of the care process and is associated with a worse HRQoL with regard to physical health, side effects, treatment, and financial burden according the original form of the DFS.

Previous amputation events were the second most influential factor related to worse scores in more domains in our results. Prior studies have recognized that a history of amputations is associated with decreased HRQoL scores, especially in terms of depression, anxiety, and social isolation [32,33]. Furthermore, it has been shown that patients who had had a previous amputation experienced greater deterioration in the domains of daily activities, leisure, side effects, emotions, family life, and friends according to the DFS questionnaire [13].

In our results, those with previous amputation showed significant differences in five of the six analysed domains: leisure, dependence/daily life, negative emotions, "worried about ulcers/feet," and "bothered by ulcer care." Moreover, we found that the domains leisure (OR 0.98, 95% CI 0.97–0.99) and worried about ulcers/feet (OR 0.98, 95% CI 0.96–0.99) were identified as significant independent domains in patients with the experience of a previous minor amputation. Similar results were obtained when the history of amputation was analysed with other PROMs. Al Ayer et al. [31] demonstrated a particular impact on emotional health measured by the Arabic version of the SF-36 survey in relation to prior amputations. Similarly, Perrin et al. [5] reported higher mean scores of bodily pain among patients with a history of amputation compared to those without such a history using the same questionnaire.

In the present study, the main sociodemographic features that correlated with a lower HRQoL score were a lower educational level and BMI, which is consistent with previous research. Our findings showed that patients with a higher level of education had significantly higher scores in the domains of "worried about ulcers" and physical health. In the same way, Yekta et al. [4] showed a relationship between low educational level and differences in the physical component of patients with DFU compared to those without DFU according to SF-36. Other studies also reported a relation between damage in social standing and education level [31].

Elevated BMI had a negative correlation with the HRQoL scores regarding the items of "worried about ulcers" and "bothered by ulcer care" in our study. It is well known that obesity is a common problem among patients with DM and DFU, especially in regard to lower mental component scores [4,31]. It is also related to physical functions [31], vitality, and bodily pain among patients who have high risk of developing DFU [5].

SF-36 has been considered the most thoroughly tested and accepted PROM to assess HRQoL among such patients [14]. For this reason, most of the available literature has analysed factors related to HRQoL with this tool. Most studies referring to the DFS-SF have focused on validation and translation to different languages. To our knowledge, this is the first study that has evaluated HRQoL among patients with DFU in Spain using the DFS-SF. The results show that this specific instrument could be implemented in diabetic foot units as part of the management of patients with DFU to evaluate HRQoL.

A previous meta-analysis investigated HRQoL among adults with DFUs [24], and only one of the examined studies used a specific tool for DFU (the large form of the DFS). The advantage of using the DFS-SF is that it takes less than 15 min in daily clinical practice. Thus, more studies should be carried out to determine the clinical utility of this instrument in daily clinical practice for patients with DFU.

Table 2
Distribution of six domains of the DFS-SF based on qualitative variables.

	Leisure	Physical health	Dependence/daily life	Negative emotions	"Worried about ulcers/feet"	"Bothered by ulcer care"
Male (n = 126)	68.0 (52.0-80.0)	64.0 (44.0-92.0)	60.0 (44.0-88.0)	53.33 (40.0-73.33)	40.0 (25.0-65.0)	65.0 (50.0-80.0)
Female (n = 15)	64.0 (36.0-84.0)	76.0 (63.0-88.0)	68.0 (51.0-88.0)	70.0 (43.33-90.0)	50.0 (30.0-66.25)	67.5 (50.0-85.0)
	p = 0.459	p = 0.537	p = 0.654	p = 0.164	p = 0.338	p = 0.732
Type of Diabetes						
Type 1 (n = 16)	56.0 (41.0-87.0)	78.0 (53.0-92.0)	68.0 (43.0-84.0)	65.0 (46.66-94.26)	42.5 (26.25-60.0)	62.5 (46.25-80.0)
Type 2 (n = 125)	64.0 (40.0-84.0)	76.0 (60.0-88.0)	68.0 (50.0-88.0)	70.0 (43.33-90.0)	50.0 (27.5-65.0)	70.0 (50.0-85.0)
	p = 0.853	p = 0.837	p = 0.720	p = 0.800	p = 0.585	p = 0.523
Educational level: Graduate or higher						
No (n = 100)	68.0 (40.0-87.0)	74.0 (56.0-87.0)	64.0 (45.0-92.0)	66.66 (36.66-90.0)	45.0 (25.0-65.0)	65.0 (45.0-85.0)
Yes (n = 41)	52.0 (38.0-72.0)	80.0 (68.0-94.0)	72.0 (54.0-84.0)	70.0 (53.33-88.33)	55.0 (45.0-75.0)	70.0 (57.5-85.0)
	p = 0.126	*p = 0.027	p = 0.599	p = 0.368	*p = 0.021	p = 0.279
Smoking:						
Never (n = 40)	60.0 (37.0-80.0)	80.0 (57.0-92.0)	66.0 (41.0-92.0)	65.0 (37.5-86.66)	42.5 (25.0-60.0)	62.5 (40.0-75.0)
Current (n = 17)	48.0 (32.0-78.0)	76.0 (54.0-82.0)	80.0 (46.0-94.0)	66.66 (45.0-90.0)	60.0 (45.0-72.5)	60.0 (45.0-87.5)
Former (n = 84)	64.0 (40.0-87.0)	76.0 (61.0-88.0)	68.0 (52.0-84.0)	70.0 (44.16-89.16)	47.5 (25.0-68.75)	70.0 (55.0-90.0)
	p = 0.438	p = 0.623	p = 0.564	p = 0.726	p = 0.228	p = 0.053
Employed:						
No (n = 103)	64.0 (40.0-84.0)	76.0 (60.0-92.0)	68.0 (48.0-88.0)	70.0 (40.0-90.0)	50.0 (25.0-70.0)	65.0 (45.0-85.0)
Yes (n = 38)	56.0 (36.0-84.0)	76.0 (67.0-88.0)	70.0 (52.0-85.0)	60.0 (46.66-84.16)	45.0 (28.75-65.0)	65.0 (55.0-85.0)
	p = 0.981	p = 0.678	p = 0.617	p = 0.568	p = 0.924	p = 0.640
Hypertension:						
No (n = 38)	64.0 (43.0-84.0)	84.0 (68.0-92.0)	72.0 (60.0-92.0)	73.33 (55.83-90.83)	50.0 (35.0-70.0)	70.0 (53.75-90.0)
Yes (n = 103)	60.0 (36.0-84.0)	76.0 (60.0-88.0)	68.0 (48.0-84.0)	60.66 (36.66-86.66)	50.0 (25.0-65.0)	65.0 (50.0-80.0)
	p = 0.405	p = 0.095	p = 0.263	p = 0.131	p = 0.330	p = 0.197
Dyslipidaemia:						
No (n = 47)	68.0 (44.0-84.0)	80.0 (68.0-92.0)	76.0 (52.0-92.0)	73.33 (46.66-93.33)	60.0 (35.0-70.0)	75.0 (55.0-90.0)
Yes (n = 94)	60.0 (36.0-84.0)	72.0 (56.0-88.0)	68.0 (47.0-84.0)	65.0 (39.16-86.66)	45.0 (25.0-60.0)	65.0 (45.0-80.0)
	p = 0.464	p = 0.071	p = 0.087	p = 0.184	*p = 0.022	*p = 0.010
Retinopathy:						
No (n = 88)	64.0 (40.0-84.0)	76.0 (64.0-88.0)	66.0 (48.0-84.0)	68.33 (43.33-86.66)	47.5 (30.0-70.0)	65.0 (50.0-80.0)
Yes (n = 53)	64.0 (38.0-84.0)	72.0 (54.0-90.0)	76.0 (52.0-92.0)	66.66 (43.33-90.0)	50.0 (25.0-65.0)	70.0 (47.5-87.5)
	p = 0.998	p = 0.480	p = 0.267	p = 0.572	p = 0.866	p = 0.628
Cardiovascular disease:						
No (n = 94)	62.0 (39.0-81.0)	80.0 (60.0-92.0)	68.0 (48.0-92.0)	68.33 (43.33-90.0)	45.0 (28.75-65.0)	65.0 (50.0-81.25)
Yes (n = 47)	64.0 (40.0-84.0)	72.0 (56.0-88.0)	64.0 (52.0-80.0)	66.6 (36.66-86.66)	52.5 (25.0-65.0)	70.0 (50.0-90.0)
	p = 0.587	p = 0.175	p = 0.236	p = 0.657	p = 0.753	p = 0.457
Nephropathy:						
No (n = 115)	64.0 (36.0-84.0)	76.0 (60.0-88.0)	68.0 (48.0-88.0)	66.66 (40.0-90.0)	50.0 (25.0-65.0)	65.0 (50.0-85.0)
Yes (n = 26)	64.0 (44.0-78.0)	68.0 (52.0-92.0)	64.0 (52.0-84.0)	70.0 (46.66-87.50)	52.5 (35.0-65.0)	67.5 (57.5-90.0)
	p = 0.972	p = 0.298	p = 0.763	p = 0.423	p = 0.456	p = 0.297
Dialysis:						
No (n = 132)	64.0 (37.0-84.0)	76.0 (60.0-88.0)	68.0 (48.0-88.0)	68.33 (43.33-90.0)	50.0 (25.0-68.75)	67.5 (50.0-85.0)
Yes (n = 9)	64.0 (56.0-70.0)	68.0 (52.0-84.0)	64.0 (56.0-84.0)	66.66 (35.0-78.33)	50.0 (35.0-55.0)	65.0 (47.5-75.0)
	p = 0.764	p = 0.359	p = 0.902	p = 0.398	p = 0.754	p = 0.368
Charcot foot disease:						
No (n = 133)	64.0 (40.0-84.0)	76.0 (60.0-88.0)	68.0 (50.0-88.0)	70.0 (43.33-90.0)	50.0 (30.0-65.0)	70.0 (50.0-85.0)
Yes (n = 8)	64.0 (31.0-77.0)	86.0 (68.0-100.0)	78.0 (37.0-91.0)	55.0 (36.66-69.16)	35.0 (20.0-66.25)	62.5 (43.75-68.75)
	p = 0.655	p = 0.138	p = 0.639	p = 0.203	p = 0.305	p = 0.401
Previous minor amputation:						
No (n = 66)	68.0 (47.0-92.0)	80.0 (60-80)	78.0 (59.0-92.0)	73.33 (56.66-90.0)	55.0 (40.0-75.0)	70.0 (55.0-90.0)
Yes (n = 75)	56.0 (28.0-76.0)	76.0 (60.0–88,0)	60.0 (40.0-84.0)	56.66 (36.66-86.66)	35.0 (20.0-55.0)	60.0 (45.0-80.0)
	*p = 0.002	p = 0.258	*p = 0.004	*p = 0.022	*p < 0.001	*p = 0.032
Clinical sign of infection						
No (n = 99)	64.0 (40.0-84.0)	76.0 (60.0-92.0)	68.0 (48.0-88.0)	70.0 (43.33-86.66)	50.0(25.0-65.0)	70.0 (55.0-85.0)
Yes (n = 42)	64.0 (31.0-85.0)	76.0 (60.0-88.0)	66.0 (52.0-84.0)	61.66 (39.16-93.33)	50.0 (30.0-71.25)	60.0 (45.0-90.0)
	p = 0.792	p = 0.658	p = 0.993	p = 0.850	p = 0.408	p = 0.408

Data are shown as medians and interquartile ranges. * ($p < 0.05$).

5. Limitations

The main limitation of this study is that despite DFS-SF is a validated instrument, the HRQoL measurements could be influenced by the comorbidities present in our patients. Nonetheless, in the in the Spanish validation of this instrument authors report good psychometric properties of this questionnaire used in patients with DFU.

6. Conclusions

The DFS-SF survey is a specific instrument that could be implemented in diabetic foot units as part of the management of patients with DFU to evaluate HRQoL. The domain of "worried about ulcers" had the lowest score in our study population, suggesting that clinicians should try to work on the emotional state of patients with DFU. The mean duration of diabetic foot was the most influential factor related to worse scores in the majority of the domains of DFS-SF, followed by previous amputations. The SINBAD DFU score had significant negative correlations with leisure, physical health, dependence/daily life, and the "bothered by ulcer care" domain, suggesting that HRQoL may be related to the severity of DFU in this study population.

Authors' contribution

FJAA, MGM and JLLM designed the study. FJAA, MGM, EGM, RJMB, MLM, and JLLM conducted the study. FJAA, MGM, EGM, MLM, RJMB JLLM were involved in sample processing and analysis. FJAA performed the statistical analyses. FJAA drafted the manuscript and MGM and

Table 3
Correlation between the domains of DFS-SF and quantitative variables.

	Leisure	Physical health	Dependence/daily life	Negative emotions	"Worried about ulcers/feet"	"Bothered by ulcer care"
Age (years)	r = 0.233	r = 0.099	r = 0.095	r = 0.121	r = 0.230	r = 0.136
	*p = 0.005	p = 0.242	p = 0.261	p = 0.154	*p = 0.006	p = 0.107
SINBAD Score	r = -0.181	r = -0.202	r = -0.232	r = -0.159	r = -0.097	r = -0.239
	*p = 0.032	*p = 0.016	*p = 0.006	p = 0.060	p = 0.254	*p = 0.004
BMI (kg/m^2)	r = -0.031	r = 0.020	r = -0.112	r = -0.165	r = -0.175	r = -0.208
	p = 0.719	p = 0.818	p = 0.186	p = 0.051	*p = 0.037	*p = 0.013
Diabetes duration (years)	r = 0.093	r = -0.085	r = -0.017	r = -0.037	r = -0.014	r = -0.119
	p = 0.270	p = 0.317	p = 0.844	p = 0.663	p = 0.870	p = 0.158
HbA1c (%)	r = -0.188	r = -0.185	r = -0.127	r = -0.060	r = -0.117	r = -0.076
	*p = 0.025	*p = 0.028	p = 0.133	p = 0.479	p = 0.169	p = 0.372
Ulcer duration (weeks)	r = -0.278	r = -0.200	r = -0.329	r = -0.247	r = -0.167	r = -0.281
	*p < 0.001	*p = 0.017	*p < 0.001	*p = 0.003	*p = 0.048	*p < 0.001

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Declaration of competing interest

There are no relevant conflicts of interest to disclose.

References

[1] Garcia-Morales E, Lazaro-Martinez JL, Martinez-Hernandez D, Aragon-Sanchez J, Beneit-Montesinos JV, Gonzalez-Jurado MA. Impact of diabetic foot related complications on the Health Related Quality of Life (HRQol) of patients–a regional study in Spain. Int J Low Extrem Wounds 2011;10(1):6–11.
[2] Palomo-Lopez P, Losa-Iglesias ME, Becerro-de-Bengoa-Vallejo R, Lopez-Lopez D, Rodriguez-Sanz D, Romero-Morales C, et al. Specific foot health-related quality-of-life impairment in patients with type II versus type I diabetes. Int Wound J 2019;16(1):47–51.
[3] Fejfarova V, Jirkovska A, Dragomirecka E, Game F, Bem R, Dubsky M, et al. Does the diabetic foot have a significant impact on selected psychological or social characteristics of patients with diabetes mellitus? J Diabetes Res 2014;2014:371938.
[4] Yekta Z, Pourali R, Ghasemi-Rad M. Comparison of demographic and clinical characteristics influencing health-related quality of life in patients with diabetic foot ulcers and those without foot ulcers. Diabetes Metab Syndr Obes 2011;4:393–9.
[5] Perrin BM, van Netten JJ, Aan de Stegge WB, Busch-Westbroek TE, Bus SA. Health-related quality of life and associated factors in people with diabetes at high risk of foot ulceration. J Foot Ankle Res 2022;15(1):83.
[6] Sekhar MS, Thomas RR, Unnikrishnan MK, Vijayanarayana K, Rodrigues GS. Impact of diabetic foot ulcer on health-related quality of life: a cross-sectional study. Semin Vasc Surg 2015;28(3–4):165–71.
[7] Hopkins RB, Burke N, Harlock J, Jegathisawaran J, Goeree R. Economic burden of illness associated with diabetic foot ulcers in Canada. BMC Health Serv Res 2015;15:13.
[8] Zhang P, Lu J, Jing Y, Tang S, Zhu D, Bi Y. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis (dagger). Ann Med 2017;49(2):106–16.
[9] Ragnarson Tennvall G, Apelqvist J. Health-related quality of life in patients with diabetes mellitus and foot ulcers. J Diabet Complicat 2000;14(5):235–41.
[10] Boutoille D, Feraille A, Maulaz D, Krempf M. Quality of life with diabetes-associated foot complications: comparison between lower-limb amputation and chronic foot ulceration. Foot Ankle Int 2008;29(11):1074–8.
[11] Sothornwit J, Srisawasdi G, Suwannakin A, Sriwijitkamol A. Decreased health-related quality of life in patients with diabetic foot problems. Diabetes Metab Syndr Obes 2018;11:35–43.
[12] Khunkaew S, Fernandez R, Sim J. Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis. Qual Life Res 2019;28(6):1413–27.
[13] Valensi P, Girod I, Baron F, Moreau-Defarges T, Guillon P. Quality of life and clinical correlates in patients with diabetic foot ulcers. Diabetes Metab 2005;31(3 Pt 1):263–71.
[14] Hogg FR, Peach G, Price P, Thompson MM, Hinchliffe RJ. Measures of health-related quality of life in diabetes-related foot disease: a systematic review. Diabetologia 2012;55(3):552–65.
[15] Perez-Panero AJ, Ruiz-Munoz M, Fernandez-Torres R, Formosa C, Gatt A, Gonzalez-Sanchez M. Diabetic foot disease: a systematic literature review of patient-reported outcome measures. Qual Life Res 2021;30(12):3395–405.
[16] Bann CM, Fehnel SE, Gagnon DD. Development and validation of the diabetic foot ulcer scale-short form (DFS-SF). Pharmacoeconomics 2003;21(17):1277–90.
[17] Ma L, Ma W, Lin S, Li Y, Ran X. Adaptation and validation of the diabetic foot ulcer scale-short form scale for Chinese diabetic foot ulcers individuals. Int J Environ Res Publ Health 2022;19(21).
[18] Kontodimopoulos N, Veniou A, Tentolouris N, Niakas D. Validity and reliability of the Greek version of the diabetic foot ulcer scale - short form (DFS-SF). Hormones (Basel) 2016;15(3):394–403.
[19] Lee YN. Translation and validation of the Korean version of the diabetic foot ulcer scale-short form. Int Wound J 2019;16(Suppl 1):3–12. Suppl 1.
[20] Toygar I, Hancerlioglu S, Gul S, Utku T, Simsir IY, Cetinkalp S. Turkish adaptation of diabetic foot ulcer scale-short form. Int J Low Extrem Wounds 2020;19(3):269–74.
[21] Macioch T, Sobol E, Krakowiecki A, Mrozikiewicz-Rakowska B, Kasprowicz M, Hermanowski T. Health related quality of life in patients with diabetic foot ulceration - translation and Polish adaptation of Diabetic Foot Ulcer Scale short form. Health Qual Life Outcome 2017;15(1):15.
[22] de Oliveira Kaizer UA, Alexandre NMC, Rodrigues RCM, Cornelio ME, de Melo Lima MH, Sao-Joao TM. Measurement properties and factor analysis of the diabetic foot ulcer scale-short form (DFS-SF). Int Wound J 2020;17(3):670–82.
[23] Rezaie W, Lusendi F, Doggen K, Matricali G, Nobels F. Health-related quality of life in patients with diabetic foot ulceration: study protocol for adaptation and validation of patient-reported outcome measurements (PROMs) in Dutch-speaking patients. BMJ Open 2019;9(12):e034491.
[24] Khunkaew S, Fernandez R, Sim J. Health-related quality of life and self-care management among people with diabetic foot ulcers in northern Thailand, 5. SAGE Open Nurs; 2019, 2377960819825751.
[25] Alrub AA, Hyassat D, Khader YS, Bani-Mustafa R, Younes N, Ajlouni K. Factors associated with health-related quality of life among Jordanian patients with diabetic foot ulcer. J Diabetes Res 2019;2019:4706720.
[26] Martinez-Gonzalez D, Doria M, Martinez-Alonso M, Alcubierre N, Valls J, Verdu-Soriano J, et al. Correction: martinez-Gonzalez et al. Adaptation and Validation of the Diabetic Foot Ulcer Scale-Short Form in Spanish Subjects. J Clin Med 2022;11(19). J. Clin. Med. 2020, 9, 2497.
[27] World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310(20):2191–4.
[28] Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ, Lipsky BA. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes Metab Res Rev 2020;36(Suppl 1):e3266.
[29] Hinchliffe RJ, Forsythe RO, Apelqvist J, Boyko EJ, Fitridge R, Hong JP, et al. Guidelines on diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers and diabetes (IWGDF 2019 update). Diabetes Metab Res Rev 2020;36(Suppl 1):e3276.
[30] Monteiro-Soares M, Russell D, Boyko EJ, Jeffcoate W, Mills JL, Morbach S, et al. Guidelines on the classification of diabetic foot ulcers (IWGDF 2019). Diabetes Metab Res Rev 2020;36(Suppl 1):e3273.
[31] Al Ayed M, Ababneh M, Alwin Robert A, Al Misfer N, Cruz M, Austria HC, et al. Factors associated with health-related quality of life in patients with diabetic foot ulcer: a cross-sectional study from Saudi arabia. Cureus 2020;12(6):e8658.
[32] Meijer JW, Trip J, Jaegers SM, Links TP, Smits AJ, Groothoff JW, et al. Quality of life in patients with diabetic foot ulcers. Disabil Rehabil 2001;23(8):336–40.
[33] Carrington AL, Abbott CA, Griffiths J, Jackson N, Johnson SR, Kulkarni J, et al. A foot care program for diabetic unilateral lower-limb amputees. Diabetes Care 2001;24(2):216–21.