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The health–related quality of life in patients with diabetic foot ulcers in the Kingdom of Bahrain

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ABSTRACT

Aims: The aims of this study were to assess the health-related quality of life (HRQoL) of adult Bahraini patients with diabetic foot ulcers (DFU) and to explore factors associated with poor HRQoL.
Methods: Cross-sectional HRQoL data were obtained from a sample of patients in active treatment for DFU at a large public hospital in Bahrain. Patient-reported HRQOL was measured using the following instruments: DFS-SF, CWIS and EQ-5D.
Results: The patient sample included 94 patients, with a mean age of 61.8 (SD: 9.9) years, 54 (57.5%) were males, and 68 (72.3%) were native Bahrainis. Poorer HRQoL was found among patients who were unemployed, divorced/widowed, and those with a shorter duration of formal education. Additionally, patients with severe DFUs, persisting ulcers, and a longer duration of diabetes reported statistically significantly poorer HRQoL.
Conclusions: Findings from this study demonstrate a low level of HRQoL among Bahraini patients with DFUs. A longer duration of diabetes, in addition to ulcer severity and status statistically significantly influence HRQoL.

1. Background

Diabetic foot ulcers (DFUs) are a common, debilitating, and costly complication of diabetes, with negative impacts on patients' health–related quality of life (HRQoL) [1–4]. Patients with DFUs suffer from disability, reduced mobility, and difficulty in performing daily activities, all of which can have adverse physical, social, and psychological effects on their HRQoL and general well-being [1,5–8]. Patients with a DFU also experience a wide range of negative feelings including anger, fear and depression [9–11].

DFUs are associated with high mortality, indeed, patients with diabetes and DFUs have been reported to have a 2.5 times higher mortality risk than patient with diabetes but without DFUs [12]. DFUs are also associated with worries and fears for amputation and the fear for major amputation may be worse than fear of mortality [4]. Other studies report that patients with an unhealed DFU may experience poorer HRQoL than those with an amputation [13]. Even after the DFU has healed, patients live with the fear and worry [14] particularly related to the increased risk of recurrence of DFUs [15].

In Bahrain and other countries in the Middle East and North Africa region (MENA) the prevalence of diabetes is high with 12.8% of adults (55 million people) living with the disease in 2019. This figure is expected to double by 2045 [16]. Despite the high prevalence and severe consequences, research into the HRQoL of patients with diabetes has been lacking [17–19] particularly so in patients with DFUs. Furthermore, Bahrain has a high prevalence of diabetic foot ulcers (DFUs), with a reported prevalence rate of 5.9% according to a systematic review [20]. The review also identified a lack of studies specifically investigating the effect of DFU on patients' HRQoL in Bahrain. Such studies are necessary to assess the impact of this disease on patients' well-being and to help modify treatment strategies to better suit patients' experiences and perceptions [4,21,22]. T.

As part of our efforts to identify relevant literature, we conducted a systematic review on the quality of life in patients with DFUs, which helped identify prior studies that investigated the impact of DFUs on patients' HRQoL. This review served as a foundation for our current study and informed the selection of variables for our multivariate analysis. Thus, the aim of the present study was to assess the HRQoL of

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Bahrani adults with diabetic foot ulcers (DFU), and explore factors associated with poor HRQoL, specifically in patients attending Diabetic Foot Outpatient clinics at a large public hospital in the Kingdom of Bahrain.

2. Materials and methods

2.1. Research questions

1. What is the Health-Related Quality of Life (HRQoL) in patients with Diabetic Foot Ulcers (DFU) attending Diabetic Foot Outpatient clinics at a large public hospital in the Kingdom of Bahrain?
2. What factors are associated with poor HRQoL in patients with Diabetic Foot Ulcers attending Diabetic Foot Outpatient clinics at a large public hospital in the Kingdom of Bahrain?

2.2. Study setting and subjects

This cross-sectional study recruited patients attending diabetic foot outpatient clinics at the study site, between March and May 2019. Diabetic foot clinics take place four times a week and patients waiting to be examined were approached by the researcher and nurse on duty for permission and consent to participate. Patients were included if they had either an existing/ongoing DFU or a healed DFU or both. They were excluded if they were unable to consent or did not wish to participate or provide consent. Patients who agreed to participate were given a consent form to review and sign. Once the consent form was signed, patients were then given the study questionnaires to complete. Responding to the questionnaires took between 10 and 20 min. The researcher was present to answer any questions during the process and clarify when any questions were not clearly understood. Sociodemographic and DFU characteristics of the patients were collected as part of another study and were utilised in this study.

2.3. Study design and sample size

The study design was a cross-sectional study conducted over a period of three months, from March to May 2019. The sample size for this study was not determined a priori through a sample size calculation. Instead, post hoc calculations were conducted to ensure adequate power for the multivariable regression analysis, following the recommendation of Polit and Beck [23], which suggests a rule of thumb of having 10–20 participants per model variable.

2.4. Confidentiality and ethical permissions

All responses were provided anonymously and no linkage with other data sources were possible. Ethical approvals were obtained from The Research Ethics Committee (REC) at RCSI University of Medicine and Health Sciences and The Ministry of Health (Bahrain) (KHUH/Research/No. 199/2018, FA/SA/531/2017).

2.5. HRQOL measurement tools

HRQoL was assessed using self-administered disease-specific and generic HRQoL measurement tools [24,25]. Two disease specific tools were used namely, The Diabetic Foot Ulcer Scale–Short Form (DFS–SF) specifically designed for patients with DFUs [26,27] and The Cardiff Wound Impact Scale (CWIS) designed for patients with chronic ulcers and wounds [28] with an aim to gain both the DFU and wound related dimensions of HRQoL. The use of both disease-specific and generic QOL tools in this study is justified as they serve different purposes. Disease-specific tools, such as the DFS-SF and CWIS, provide a more focused assessment of the impact of the disease and its treatment on patients' HRQoL. In this study, the DFS-SF and CWIS were specifically chosen to capture the impact of DFUs and wounds on HRQoL, respectively. On the other hand, generic tools, such as the EQ-5D-5L, provide a broader assessment of HRQoL and can be used to compare QOL across different disease populations. To further explain the use of the EQ-5D-5L in this study, it is worth noting that this study is part of a larger research project that aims to assess the costs of diabetic foot ulcers. In such a study, it is important to use a tool that can capture the broad impact of the disease on patients' HRQoL, as this information is critical in evaluating the economic burden of the disease. By including both types of tools, this study provides a comprehensive evaluation of HRQoL in patients with DFUs and allows for comparison with other disease population.Regarding the survey length, the study used multiple HRQoL measurement tools, which may have contributed to the overall length of the survey. However, given the importance of assessing HRQoL in patients with diabetic foot ulcers, the use of multiple tools can provide a more comprehensive understanding of the impact of this condition on patients' lives.

The Diabetic Foot Ulcer Scale (DFS) is a specific questionnaire developed to evaluate the impact of DFUs and their treatment on the HRQoL in people with diabetes [26]. The DFS includes 58 items grouped into 11 domains: leisure, physical health, daily activities, emotions, noncompliance, family, friends, positive attitude, treatment, satisfaction, and financial [26]. The DFS Short Form (DFS-SF) which was used in this study, is a concise and shorter version of the DFS providing similar vigour and responsiveness to the DFS [27]. In comparison to the original version, the DFS-SF has been considered more 'user-friendly' for everyday clinical practice [27]. It includes a total of 29 items comprising six subscales: leisure, physical health, dependence/daily life, negative emotions, worries about ulcers/feet and bothered by ulcer care [27]. The DFS has demonstrated good internal consistency (Cronbach's alpha = 0.87), test-retest reliability, and content validity [26]. The DFS-SF has also shown good internal consistency (Cronbach's alpha range = 0.88–0.95), test-retest reliability, and construct validity [27].

The CWIS is a disease-specific instrument used to evaluate the effects of chronic wounds (leg ulcers and DFUs) on the HRQoL of patients [28]. This tool was developed at the Wound Healing Research Unit in Cardiff, Wales [29] and includes three domains for Well-Being, Physical Symptoms, and Daily Living and Social Life, and evaluates symptoms and the associated stress impacting patients [29]. In addition, the CWIS includes a global scale to evaluate patients' overall HRQoL and a satisfactory scale to assess patients' satisfaction with their HRQoL [29]. The CWIS has demonstrated good internal consistency (Cronbach's alpha range = 0.79–0.93), test-retest reliability, and construct validity [29].

The generic EQ-5D-5L [30,31] was used based on the recommendations by the Patient-Reported Outcome Measurement Group (2009). The EQ-5D has been developed by a multidisciplinary group of researchers [32] and has been successfully applied in a wide range of studies specific to diabetes and its complications [33,34]. For example, the multicentre Eurodiale study used the EQ-5D because of its simple and concise format [33,35]. It comprises a descriptive profile and a visual analogue scale. The descriptive measure includes five dimensions each rated at five levels of severity. The five dimensions include: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The visual analogue scale (EQ VAS) consist of a 20 cm horizontal thermoter scale where 100 denote the best imaginable health state and 0 the worst imaginable health state [30,32]. The descriptive profile was scored into a single index using the cross-walk algorithm [31].

In relation to response options, the EQ-5D-5L has five levels of severity for each dimension, ranging from "no problems" to "extreme problems" [31]. The total scale score is calculated by mapping the five dimensions onto a weighted health state index, with a range of −0.59 to 1, where 1 represents perfect health and 0 represents death [31]. The EQ VAS is scored by measuring the respondent's health status on a 0–100 scale [30,32]. The reliability and validity of the EQ-5D-5L have been well-established in numerous studies [36–38], including those specific to diabetes and its complications [39–41].

2.6. Statistical analysis

Data analysis was performed using the statistical software STATA/SE 16.0 for Mac (64-bit Intel). Descriptive analysis was used to evaluate sociodemographic, DFU characteristics of participants and HRQoL scores with results presented as means, standard deviation, median, minimum and maximum. Univariate analyses was used to evaluate mean score differences between groups of patients with different characteristics. Parametric 95% confidence intervals were used to identify group mean differences for sociodemographic and DFU characteristics. Graphical illustrations and Pearson's correlation coefficients were used to explore the correlation between scores from the disease specific and generic instruments. Multivariate regression analyses of HRQOL scores were used to explore the relationship between the different sociodemographic and DFU characteristics.

3. Results

A total of 106 patients consented and agreed to participate in the study. Eighty-eight % (n = 94) had completed all sets of the three questionnaires and were included in the final analysis while 11.32% (n = 11) patients had incomplete questionnaires either through missing questions (n = 7), changing their mind midway (n = 4) or leaving the clinic (n = 1). All of these were eventually excluded. A total of 23 patients refused to participate making up an overall response rate of 78%. Refusals were related to the time spent time filling out the questionnaires in the clinics or feeling ill, weak and too tired to participate. No sociodemographic or DFU characteristics were collected from the non-responders.

1. Participants' sociodemographic and DFU characteristics

The sociodemographic characteristics of the 94 participants who completed the health questionnaires are presented in Table 1. The mean age of the patients was 61.8 (sd 9.9) years (min. 34 and max. 78); 57.5% (n = 54) were males and 72.3% (n = 68) were native Bahrainis. Most of the patients were married (85.1%, n = 80), and 70.2% (n = 66) had high school or university degrees. More than half of the participants were unemployed (60.6%, n = 57).

Table 1 also shows the DFU characteristics of the included patients. Almost half of the patients (48.4%, n = 45) reported a 1–3-month duration of the ulcer. In terms of the ulcer severity, 39.4% (n = 37) of respondents had a Wagner grade 2 ulcer, 37.2% (n = 35) had a Wagner grade 1 while 23.4% (n = 22) had a Wagner grade of 3 or more. In addition, with regards to ulcer status, many patients (79.8%, n = 75) had a persisting unhealed ulcer. Further, 64.9% (n = 61) presented as not having had an amputation but had a persisting ulcer.

4. Mean overall and subscale scores of HRQoL tools

The mean scores for the DFS-SF, CWIS and EQ-5D and their relevant subscales are presented in Table 2. The mean scores were 56.8 ± 16.4, 44.6 ± 13.58 and 0.58 ± 0.29 for DFS-SF, CWIS and EQ-5D-5L, respectively. For the DFS-SF, the lowest mean subscales were, worried about ulcers/feet and, leisure (46.81 ± 16.11 and 49.87 ± 19.92 respectively), and the highest were, physical health and negative emotions (66 ± 15.53 and 67.06 ± 22.20 respectively). Similarly for the CWIS, the highest mean subscale score was for physical symptoms (49.09 ± 15.87) and the lowest was for well-being (37.08 ± 11.39).

The correlation between the disease-specific and generic instruments are illustrated in Fig. 1. The Pearson's correlation coefficients were ranging from 0.64 to 0.84 indicating high correlation. Stronger correlation was observed for the EQ-index than for EQ-VAS.

Table 1
Participants' sociodemographic and DFU characteristics.

n (%)	Total	Males	Females	P-value
	94 (100.0)	54 (57.4)	40 (42.6)	
Age group, n (%)				
<60 yrs	37 (39.4)	22 (40.7)	15 (37.5)	
>60 yrs	57 (60.6)	32 (59.3)	25 (62.5)	0.75
Nationality, n (%)				
Bahraini	68 (72.3)	42 (77.8)	26 (65.0)	
Non-Bahraini	26 (27.7)	12 (22.2)	14 (35.0)	0.17
Marital status, n (%)				
Married	80 (85.1)	44 (81.5)	36 (90.0)	
Single/divorce/widowed	14 (14.9)	10 (18.5)	4 (10.0)	0.25
Educational status, n (%)				
≤high school	66 (70.2)	43 (79.6)	23 (57.5)	
>high school	28 (29.8)	11 (20.4)	17 (42.5)	0.02
Employment status, n (%)				
Employed	37 (39.4)	21 (38.9)	16 (40.0)	
Unemployed	57 (60.6)	33 (61.1)	24 (60.0)	0.91
Years with diabetes, n (%)				
<1 year	19 (20.4)	10 (18.9)	9 (22.5)	
1–5 years	33 (35.5)	18 (34.0)	15 (37.5)	
>5 years	41 (44.1)	25 (47.2)	16 (40.0)	0.78
Duration of the ulcer, n (%)				
<2 weeks	18 (19.4)	12 (22.6)	6 (15.0)	
2 weeks-3 mths	45 (48.4)	23 (43.4)	22 (55.0)	
3–6 mths	18 (19.4)	11 (20.8)	7 (17.5)	
>6 mths	12 (12.9)	7 (13.2)	5 (12.5)	0.69
Wagner grading system, n (%)				
Grade 1	35 (37.2)	24 (44.4)	11 (27.5)	
Grade 2	37 (39.4)	20 (37.0)	17 (42.5)	
Grade 3-5	22 (23.4)	10 (18.5)	12 (30.0)	0.20
Ulcer status, n (%)				
Persisting unhealed	75 (79.8)	43 (79.6)	32 (80.0)	
Healed/amputation	19 (20.2)	11 (20.4)	8 (20.0)	0.96
Amputation status, n (%)				
No amputation, persisting	61 (64.9)	33 (61.1)	28 (70.0)	
No amputation, ulcer healed	19 (20.2)	13 (24.1)	6 (15.0)	
With amputation	14 (14.9)	8 (14.8)	6 (15.0)	0.54

P-values are based on Chi-squared test.

Table 2
Mean scores for DFS-SF, CWIS and EQ-5D/VAS scales and subscales.

	Mean	SD	Median	Minimum	Maximum
Diabetic Foot Ulcer Scale - Short Form					
Total score	56.9	16.4	53	26	92
Leisure	49.9	19.9	46	20	100
Physical health	66.0	15.5	68	32	96
Dependence/daily life	53.3	17.8	52	24	96
Negative emotions	67.1	22.2	65	27	100
Worried about ulcers/feet	46.8	16.1	45	20	80
Bothered by ulcer care	58.1	17.0	55	30	95
Cardiff Wound Impact Scale					
Total score	44.6	13.6	43	17	78
Physical symptoms and everyday living	49.1	15.9	48	23	92
Social life	47.5	17.0	49	11	91
Well-being	37.1	11.4	36	14	71
Global HRQoL	5.1	1.3	5	2	8
Satisfaction with HRQoL	5.0	1.4	5	1	9
EQ-5D					
EQ-index	0.575	0.285	0.644	−0.161	1.000
EQ-VAS	48.2	14.7	50	10	80

5. Relationship between HRQoL and sociodemographic characteristics

The associations between sociodemographic characteristics and the DFS-SF, CWIS and EQ-5D are presented in Table 3. The CWIS and EQ-5D showed that single/divorced/widowed patients had a significantly

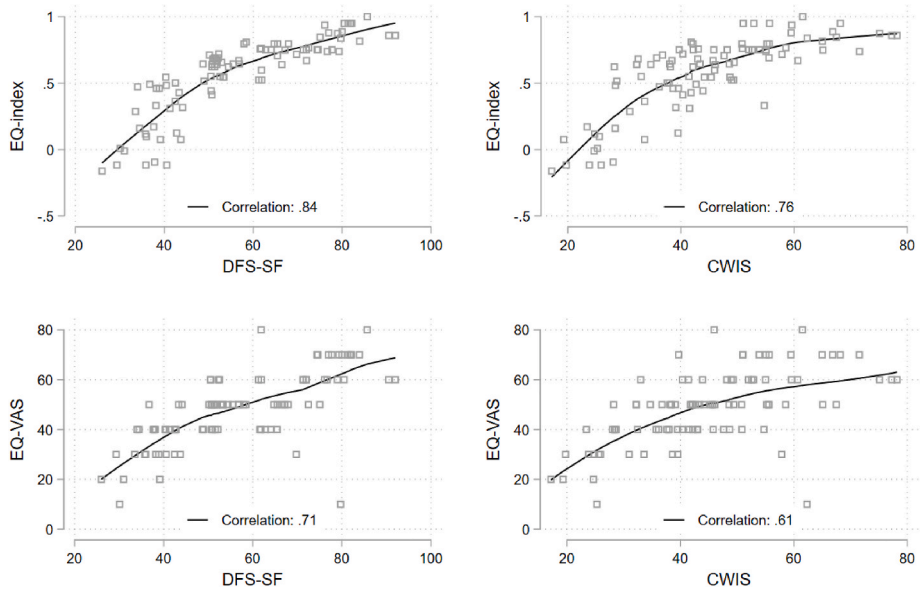

Fig. 1. Correlation between the two disease-specific HRQoL instruments (DFS-SF, CWIS) and the generic instrument (EQ-5D/EQ-VAS).

poorer HRQoL (48 ± 12.9 and 0.70 ± 0.11, respectively; $p < 0.5$), than married patients. In addition, those who had an educational level of high school or more had a significantly higher HRQoL (59 ± 16.5 and 46.6 ± 13.09; $p < 0.005$), compared to those with a lower educational level on the DFS-SF and CWIS, respectively. Moreover, employed patients showed a better HRQoL on the DFS-SF, CWIS and EQ-5D-5L (60.7 ± 16.02, 47.9 ± 13.11 and 0.66 ± 0.25, respectively; $p < 0.05$) than unemployed respondents.

6. Relationship between HRQoL and DFU characteristics

The relationship between DFU characteristics and the three instruments are also presented in Table 3. Participants diagnosed with diabetes from 1 to 5 years had a more satisfactory HRQoL (48.0 ± 12.5, $p < 0.05$) than those diagnosed from 5 to 20 years, or more than 20 years, on the CWIS. In contrast, participants diagnosed less than one year had a significantly higher HRQoL (0.69 ± 0.21, $p < 0.05$) than those diagnosed from 1 to 5 years, 5–20 years, or more than 20 years, on the EQ-5D-5L.

Patients with advanced Wagner grades, thus greater severity of ulcer, had significantly lower HRQoL scores on the EQ-5D-5L (0.28 ± 0.31, $p < 0.05$). Conversely, there were no statistical differences between groups noted on the DFS-SF or CWIS. Consistently, patients with healed ulcers exhibited better HRQoL (0.78 ± 0.15, $p < 0.05$) than those with persisting ulcers, as assessed using the EQ-5D-5L but not on the DFS-SF or CWIS. In terms of amputation, those who had an ulcer resolved after amputation scored higher on the CWIS than those who had an ulcer resolved without amputation (52.58 ± 9.75 vs. 48.68 ± 12.48, $p < 0.05$), and much higher than those with persisting ulcers, either with or without amputation (26.02 ± 5.68, 23.45 ± 2.67, $p < 0.05$).

7. Multivariate analysis of characteristics associated with HRQoL

The sociodemographic and DFU characteristics associated with the HRQoL instruments are shown in Table 4. In the multivariate analysis, none of the sociodemographic details remained statistically significantly associated with any of the HRQoL instruments. As for the DFU characteristics, the severity of the ulcer, according to Wagner grading, remained statistically significant ($p < 0.005$) for both the DFS-SF and EQ-5D-5L, but not for CWIS ($p < 0.054$). However, with the CWIS, after linear progression, participants with healed ulcers exhibited statistically significantly better HRQoL ($p < 0.05$) than those with persisting ulcers. Patients with amputations, but were ulcer free, also had significantly higher HRQoL than those with persisting ulcers with or without amputations with the CWIS.

8. Discussion

The findings from this study demonstrate that the strongest predictor for HRQoL in patients with DFUs was the severity of the ulcer according to Wagner's grading, even after controlling for confounding factors on the DFS-SF and EQ-5D instrument. Conversely, healing of DFUs was associated with better HRQoL on the CWIS. In addition, patients with amputations, but were ulcer free, also had significantly higher HRQoL than those with persisting ulcers with or without amputations as measured by the CWIS. These findings imply that the impact of worsening severity of DFUs can be detected by the DFS-SF and EQ-5D whilst the CWIS is best at detecting changes in HRQoL between healed and persisting DFUs. In contrast this study revealed that none of sociodemographic factors were independent predictors of HRQoL in patients with DFUs, however the univariate analysis revealed higher HRQoL in patients who were employed, had a higher education level and were single.

The results of this study are consistent with those reported from previous studies. For example, similar findings in relation to ulcer severity and HRQoL have been found in recent studies [42–44]. [42] utilizing the SF-36 instrument, found ulcer severity based on Wagner's classification was the main determinant of HRQoL suggesting that this could be a successful tool in monitoring and assessing patients with DFUs with the aim of preventing further deterioration in HRQoL scores [42]. However, as with the present study, Jaksa et al. (2010) found that study subjects with more severe ulcers did not display lower HRQoL on the CWIS instrument [28].

Similar to the findings from the current study, previous studies have demonstrated improved HRQoL in patients with healed DFUs [1,33,45,46]. However, in contrast to the current study [33], detected these changes using the EQ-5D [33]. Moreover, results from other work showed patients with unhealed DFUs had poorer HRQoL scores even than those who had healed with amputation [47] consistent with findings from the current study where patients with a resolved ulcer following amputation had better HRQoL than patients without an amputation and an unhealed ulcer as measured by the CWIS instrument. Another study [33] showed higher HRQoL scores in patients with

Table 3
Mean scores for DFS-SF, CWIS and EQ-5D/VAS scales by subgroups of participants.

	DFS-SF	CWIS	EQ-index	EQ-VAS
Gender				
Males	59.3 (54.7–63.8)	45.6 (41.7–49.5)	0.607 (0.529–0.685)	49.3 (44.8–53.7)
Females	53.6 (48.7–58.5)	43.1 (39.3–46.9)	0.532 (0.445–0.620)	46.8 (43.1–50.4)
Age group				
<60 yrs	61.4 (56.3–66.6)	48.1 (44.1–52.0)	0.671 (0.590–0.752)	48.4 (44.0–52.8)
>60 yrs	53.9 (49.6–58.2)	42.3 (38.6–46.0)	0.513 (0.436–0.590)	48.1 (44.0–52.2)
Nationality				
Bahraini	57.2 (53.1–61.2)	44.7 (41.4–47.9)	0.585 (0.518–0.652)	49.0 (45.5–52.4)
Non-Bahraini	56.1 (49.9–62.3)	44.3 (38.6–50.0)	0.550 (0.430–0.669)	46.2 (40.0–52.3)
Marital status				
Married	58.0 (54.2–61.7)	45.5 (42.4–48.6)	0.583 (0.517–0.650)	49.6 (46.4–52.9)
Single/ divorce/ widowed	50.6 (43.5–57.7)	39.2 (33.5–44.9)	0.530 (0.431–0.629)	40.0 (33.1–46.9)
Educational status				
≤high school	59.0 (55.0–63.0)	46.6 (43.4–49.8)	0.603 (0.535–0.671)	48.8 (45.2–52.4)
>high school	51.8 (46.1–57.6)	39.8 (34.6–45.0)	0.510 (0.398–0.621)	46.8 (41.3–52.3)
Employment status				
Employed	60.7 (55.5–66.0)	47.9 (43.7–52.2)	0.664 (0.583–0.745)	48.1 (43.8–52.4)
Unemployed	54.3 (50.0–58.6)	42.4 (38.8–45.9)	0.518 (0.440–0.595)	48.2 (44.1–52.4)
Years with diabetes				
<1 year	59.6 (51.2–68.1)	46.1 (41.2–51.1)	0.690 (0.596–0.785)	47.9 (39.9–55.9)
1–5 years	62.1 (57.0–67.2)	48.2 (43.8–52.6)	0.684 (0.617–0.751)	51.2 (47.2–55.2)
>5 years	51.5 (46.6–56.3)	40.9 (36.3–45.4)	0.435 (0.335–0.535)	45.9 (41.0–50.7)
Duration of the ulcer				
<2 weeks	57.7 (51.1–64.4)	42.4 (37.2–47.7)	0.609 (0.484–0.734)	47.2 (40.8–53.6)
2 weeks-3 mths	61.7 (57.1–66.2)	49.5 (46.3–52.8)	0.684 (0.628–0.740)	52.7 (48.7–56.7)
3–6 mths	55.7 (47.6–63.8)	44.9 (37.7–52.0)	0.552 (0.424–0.680)	47.8 (40.9–54.7)
>6 mths	37.9 (33.3–42.5)	27.3 (22.8–31.8)	0.143 (−0.001–0.287)	32.5 (27.0–38.0)
Wagner grading system				
Grade 1	65.1 (60.4–69.8)	47.7 (43.6–51.8)	0.728 (0.661–0.795)	55.1 (50.2–60.1)
Grade 2	57.2 (52.5–62.0)	48.8 (45.2–52.3)	0.609 (0.546–0.672)	49.5 (46.0–52.9)
Grade 3-5	43.1 (37.0–49.2)	32.4 (26.9–37.9)	0.275 (0.144–0.407)	35.0 (29.8–40.2)
Ulcer status				
Persisting unhealed	54.8 (51.0–58.5)	43.4 (40.2–46.6)	0.522 (0.456–0.588)	45.9 (42.6–49.1)
Healed/ amputation	65.1 (58.6–71.6)	49.1 (43.6–54.6)	0.783 (0.715–0.852)	57.4 (51.5–63.2)
Amputation status				
No amputation, persisting	58.0 (54.0–61.9)	46.8 (43.8–49.9)	0.595 (0.538–0.651)	48.2 (44.9–51.5)
No amputation, ulcer healed	64.6 (58.0–71.2)	48.7 (43.0–54.4)	0.771 (0.694–0.849)	57.4 (51.7–63.0)
With amputation	41.5 (34.2–48.7)	29.1 (23.1–35.1)	0.224 (0.036–0.412)	35.7 (27.0–44.5)

Table 4
Multivariate regression analysis.

	DFS-SF	CWIS	EQ-index	EQ-VAS
Gender				
Males	reference			
Females	−4.9 (−11.7 to 1.9)	−3.4 (−8.8 to 2.0)	−0.085 (−0.183 to 0.013)	0.1 (−5.7 to 5.9)
Age group				
<60 yrs	reference			
>60 yrs	−4.3 (−16.0 to 7.4)	−0.6 (−9.9 to 8.8)	−0.059 (−0.228 to 0.110)	−0.1 (−10.1 to 10.0)
Nationality				
Bahraini	reference			
Non-Bahraini	3.6 (−3.6 to 10.9)	3.5 (−2.2 to 9.3)	0.054 (−0.051 to 0.159)	0.6 (−5.7 to 6.8)
Marital status				
Married	reference			
Single/ divorce/ widowed	−5.5 (−15.1 to 4.2)	−5.8 (−13.4 to 1.9)	0.033 (−0.106 to 0.172)	−5.5 (−13.7 to 2.8)
Educational status				
≤high school	reference			
>high school	−3.0 (−10.5 to 4.4)	−3.6 (−9.5 to 2.3)	0.021 (−0.086 to 0.128)	−2.1 (−8.5 to 4.3)
Employment status				
Employed	reference			
Unemployed	2.4 (−9.6 to 14.5)	−1.3 (−10.9 to 8.3)	0.030 (−0.144 to 0.203)	5.5 (−4.8 to 15.9)
Years with diabetes				
<1 year	reference			
1–5 years	4.0 (−5.1 to 13.1)	1.6 (−5.7 to 8.9)	0.076 (−0.055 to 0.207)	7.2 (−0.6 to 15.0)
>5 years	1.7 (−8.3 to 11.7)	0.9 (−7.1 to 8.9)	−0.032 (−0.176 to 0.112)	7.7 (−0.9 to 16.2)
Duration of the ulcer				
<2 weeks	reference			
2 weeks-3 mths	6.2 (−3.2 to 15.6)	4.9 (−2.5 to 12.4)	0.093 (−0.042 to 0.228)	5.9 (−2.1 to 14.0)
3–6 mths	7.1 (−3.9 to 18.0)	6.5 (−2.2 to 15.2)	0.087 (−0.070 to 0.245)	6.3 (−3.1 to 15.7)
>6 mths	−5.3 (−20.0 to 9.3)	−4.8 (−16.5 to 6.8)	−0.181 (−0.392 to 0.030)	−3.0 (−15.5 to 9.6)
Wagner grading system				
Grade 1	reference			
Grade 2	−7.6 (−16.4 to 1.2)	1.6 (−5.4 to 8.6)	−0.048 (−0.175 to 0.078)	−6.5 (−14.0 to 1.0)
Grade 3-5	−8.6 (−21.3 to 4.0)	−0.9 (−11.0 to 9.2)	−0.122 (−0.304 to 0.060)	−14.5 (−25.3 to −3.6)
Ulcer status				
Persisting unhealed	reference			
Healed/ amputation	10.6 (−4.7 to 25.9)	12.3 (0.1–24.5)	0.283 (0.063–0.503)	6.2 (−7.0 to 19.3)
Amputation status				
No amputation, persisting	reference			
No amputation, ulcer healed	−4.6 (−19.6 to 10.3)	−8.0 (−19.9 to 3.9)	−0.100 (−0.315 to 0.115)	6.0 (−6.8 to 18.8)
With amputation	−9.5 (−21.8 to 2.8)	−14.1 (−23.9 to −4.2)	−0.209 (−0.387 to −0.031)	−3.2 (−13.8 to 7.4)
Constant	60.0 (48.8–71.2)	44.8 (35.8–53.8)	0.593 (0.431–0.755)	40.3 (30.7–50.0)
R2	0.412	0.448	0.597	0.456

maximal minor amputations when compared to patients with current ulcers and no previous amputation. In addition, the Eurodiale study revealed that minor amputation had no negative impact on HRQoL in patients with healed ulcer in comparison to conservative treatment in patients with persisting unhealed DFUs [48]. In fact, 6–12 months after their initial visits, patients with minor amputation appeared to demonstrate improved HRQoL scores [48]. Thus, it has been suggested that a focus on conservatively managing patients in an attempt to reduce and delay amputations could lead to increased suffering and thereby lower HRQoL in patients with DFUs [49]. This position has also been supported by others who recommend that amputation trends need to be interpreted carefully together with HRQoL assessments in management strategies [13,50,51]. It is worth noting that the DFS-SF was not able to detect statistically significant differences between DFU outcomes and HRQoL as demonstrated by Bann et al. [27]. Other studies, applying the DFS to assess the HRQoL in patients with DFUs were not able to demonstrate statistically significant differences between healed and persisting ulcers [42,52].

In terms of sociodemographic factors, the mean age of patients included in the current study is comparable to other studies where the mean age was 60–61 years [45]; Ribu, Hanestad et al., 2007). Similar to results in this study, age was not found to be a predicting factor of HRQoL [53] whilst another study could not establish an association between advanced age and diabetes [54]. On the other hand, other studies have identified that advancing age has been associated with poorer HRQoL in patients with diabetes [42]; Ribu, Hanestad et al., 2007, [44,55]. It is therefore unclear whether there is a relationship between advanced age and HRQoL of patients with DFUs or if this could possibly be due to problems that are part of the ageing process rather than DFUs in isolation.

Female gender has also been associated with poorer HRQoL in several studies [55–57]. Conversely, another study [53] determined that gender was not a predicting factor of HRQoL among participants with DFU, a finding which was similar to this study. Notably, one study reported a poorer HRQoL in males [56]. Given the conflicting findings in the literature and this current study, it is reasonable to conclude that it may be difficult to establish a true relationship between gender and HRQoL as results remain contradictory.

In contrast to results from the current study, one study [44] found improved HRQoL scores with patients who were living with a partner, but others [53] could not establish a relationship between marital status and HRQoL. Prior studies support this finding, showing an association between low educational levels and poor HRQoL scores [55,58,59]. Further, in line with findings in the current study, other studies have also demonstrated poorer HRQoL scores in unemployed patients with DFU (Ribu, Hanestad et al., 2007, [55]. There is evidence that employment can be markedly affected by DFUs and where (50–79%) of patients are unemployed either due to early retirement or the inability to work with existing DFUs [60,61].

9. Limitations

The current study has several limitations. Firstly, the sample size is relatively small, the consequences of which include reduced statistical power in establishing true effects and low reproducibility. Secondly, due to the cross-sectional study design it was not possible to establish cause and effect associations between variables. A third limitation is that not all hospitals in Bahrain were included, however, it is likely that this sample population is representative of the population since the selected hospital caters for most patients with DFUs. Fourthly, non-responders are more likely to decline because they are sick and therefore may have worse outcomes and more severe DFUs, and as such, this should be borne in mind when interpreting the data. None the less, the study was still able to report a relationship between outcomes, severity and poor HRQoL in patients with DFUs. A strength of this study remains the combination of generic, diabetic foot specific and wound specific tools to evaluate the impact of HRQoL on the study participants.

10. Conclusions

Findings from this study demonstrate that patients with DFU have consistently low HRQoL scores on all three instruments (CWIS, DFS-SF and EQ-5D). The DFS-SF and EQ-5D tools demonstrated an association between severity of DFUs and HRQoL, whereas the CWIS established a relationship between ulcer outcomes and HRQoL reflecting the importance of combing generic and disease-specific tools in the HRQoL of patients These findings may assist healthcare leaders to increase focus on supportive and educational programmes aimed at improving the well-being of patients with DFU.

Recommendations for future research include studies comparing HRQoL between patients with DFUs and those with diabetes but without DFU, to highlight the burden on HRQoL specific to patients with DFUs in Bahrain. In spite of the evidence that patients with diabetes suffer from a poor HRQoL, studies show that patients with DFU have an even poorer HRQoL when compared to those with diabetes without DFUs [62]. Additionally, measuring HRQoL over time in patients with DFU will show how HRQoL changes with progress such as healing or amputation. Further, qualitative studies would also provide more detailed account of elements of HRQoL by capturing personal experiences and mechanisms of coping in patients with DFU. These could, in turn, direct management and education programmes to improve the HRQoL in patients with DFU. It is also necessary that studies include patients from both primary and secondary care facilities to provide a more accurate and overall assessment of the impact of DFUs on HRQoL of patients.

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Declaration of competing interest

The authors have no conflict of interest to declare.

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