Endocrine and Metabolic Science 16 (2024) 100203

Contents lists available at ScienceDirect

Endocrine and Metabolic Science

journal homepage: www.elsevier.com/locate/endmts

Full Length Article

Factors associated with quality of life and functional capacity in patients with diabetic foot in the Dominican Republic

Berniza Calderón [a,b,c,*], Manuel Soto [a], Alba Beltré [a,b]

[a] Research Unit, Centro Médico de Diabetes, Obesidad y Especialidades (CEMDOE), Santo Domingo, Dominican Republic
[b] Instituto Tecnológico de Santo Domingo (INTEC), Santo Domingo, Dominican Republic
[c] Sociedad Dominicana de Endocrinología y Nutrición (SODENN), Santo Domingo, Dominican Republic

ARTICLE INFO

Keywords:
Diabetes mellitus
Diabetic foot
Diabetic foot ulcer
Quality of life
Functional capacity
SF-36
FAAM

ABSTRACT

Purpose: To evaluate the quality of life (QoL) and physical functioning of patients with diabetic foot (DF) and their associated factors.
Methods: 120 participants with DF were recruited in 5 diabetic foot clinics in Dominican Republic. QoL and physical function were measured with the SF-36 and FAAM questionnaires respectively. Multiple linear regression models were used to determine the factors associated with each of the SF-36 and FAAM dimensions.
Results: The median scores for the SF-36's dimensions were: physical functioning 30 (Interquartile range [IQR]: 40), role limitations due to physical health 0 (IQR: 25), role limitations due to emotional problems 100 (IQR: 100), vitality 55 (IQR: 30), mental health 55 (IQR: 24), social functioning 50 (IQR: 50), bodily pain 45 (IQR: 47.5), general health 50 (IQR: 30). Median scores for the FAAM's activities of daily living and sports dimensions were 39.3 (IQR: 25.7) and 28.6 (IQR: 28.6) respectively. After multiple linear regression analysis, factors associated with lower SF-36 scores were advanced Wagner grade, smoking, unemployment, female sex, time to treatment, comorbidities and microvascular complications. Factors associated to lower FAAM scores were Wagner grade and living alone.
Conclusion: Patients with DF have poor QoL and physical function, with Wagner grade being the main associated factor. Attention should be given to prevention and opportune treatment. Studies that evaluate the impact of preventive and chronic disease management programs for DF are needed.

1. Introduction

Diabetes mellitus (DM) is a noncommunicable metabolic disease with a growing prevalence worldwide (Saeedi et al., 2019). In 2021, there were approximately 537 million adults living with diabetes (International Diabetes Federation [IDF], 2021. The prevalence of DM in the Dominican Republic (D.R.) is approximately 10 % (International Diabetes Federation [IDF], 2021. Due to its multiple related complications, it represents a significant health burden for both individuals and the health sector (Pectasides and Kalva, 2011; Ducat et al., 2014).

One of the most frequent complications of diabetes is diabetic foot (DF), appearing in around 10 % of persons with diabetes (PwD) (Meijer et al., 2001; AlSadrah, 2019). Around 15 % of persons with DF develop diabetic foot ulcers (DFU) and around 15–20 % of these will eventually have a lower extremity amputation (Vadiveloo et al., 2018). The onset of a DFU leads to a series of continuous healthcare services that significantly increase the healthcare costs. Previous studies have reported that the cost of the treatment of patients with DFU is on average four times higher than in those without ulcers, being approximately $31,000 USD for the first two years of treatment (Vadiveloo et al., 2018; Raghav et al., 2018).

Another important aspect of DF is its impact on quality of life (QoL). Studies from different countries have reported a low QoL in this population, with important impairments in physical health, emotional well-being, and social functioning (Meijer et al., 2001; Boutoille et al., 2008; Hogg et al., 2012). Researchers can measure QoL and other patient reported outcomes (PRO) by using standardized questionnaires that quantify patient's experience of wellbeing and functioning (Rothman et al., 2007). One of the most frequently use PRO questionnaire is the SF-36, used to measure QoL and previously validated in PwD (Vadiveloo et al., 2018). To measure patients' physical functionality in the context of a foot disorder, the Foot and Ankle Ability Measure (FAAM) can be

* Corresponding author at: Research Unit, Centro Médico de Diabetes, Obesidad y Especialidades (CEMDOE), Santo Domingo, Dominican Republic.
E-mail address: berniza.calderon@cemdoe.com (B. Calderón).

https://doi.org/10.1016/j.endmts.2024.100203
Received 29 July 2024; Received in revised form 22 October 2024; Accepted 30 October 2024
Available online 1 November 2024

used, which has been also previously been validated for use with PwD (Vadiveloo et al., 2018; Martin et al., 2009).

To the author's knowledge, there are no published articles that evaluate the QoL or physical functioning of patients with DF in the Dominican Republic (D.R). No official registry of DF cases in the country exist, however a press release states that there are around 30,000 new cases every year and approximately 7000 amputations are performed yearly due to this condition (Brujan, 2023). The aim of this study is to evaluate the QoL and physical functioning, along with its associated demographic and clinical factors, in patients with DF in the D.R.

2. Methods

2.1. Study design

A cross-sectional study was carried out from July 28, 2021 until October 18, 2021. Participants were recruited in 5 diabetic foot clinics (DFC) in Santo Domingo, D.R., from the following medical centers: Centro Médico de Diabetes, Obesidad y Especialidades (CEMDOE), Hospital Dr. Salvador Gautier, Hospital Regional Dr. Marcelino Vélez, Hospital General Dr. Vinicio Calventi, and Hospital Docente Dr. Francisco Moscoso Puello. One data collector was sent to each DFC. Data collectors were general doctors who were trained on how to properly administer the SF-36 and FAAM questionnaires and on how to properly measure blood pressure. Participants were interviewed and their medical records were retrieved to obtain essential demographic and clinical data, the SF-36 and FAAM questionnaires were used to measure their QoL and level of physical functioning respectively.

2.2. Sample size and participants

Eligible participants were those with a previous diagnosis of DF and were between 18 and 70 years old. Individuals who were pregnant, had a mental or physical disability, or were not of Dominican nationality were excluded from the study. A convenience sampling technique was employed, recruiting patients who were currently attending the DF clinics.

A total of 158 participants were interviewed. 38 participants were excluded from the final analysis due to incomplete interviews, with a final sample size of 120.

2.3. Primary outcomes

The primary outcomes measured were the level of QoL and of physical functioning measured by the scores of the SF-36 and FAAM questionnaires respectively. The RAND version of the SF-36 was used. It consists of 36 closed-ended questions that measure QoL on eight different dimensions: physical functioning (PF), role limitations due to physical difficulties (RP), bodily pain (BP), social functioning (SF), vitality (V), mental health (MH), role limitations due to emotional difficulties (RE), and general health (GH). Scores in each of these dimensions range from 0 to 100, the higher the score the higher the reported QoL (Ware Jr. et al., 1993). The scoring method of the SF-36 is described in the RAND Corporation's official website (RAND Corporation, n.d.).

Physical functioning was measured using the FAAM questionnaire. The FAAM is a 29-item questionnaire that evaluates physical function in respondents with a foot or ankle disorder in two dimensions: activities of daily living (ADL) and sports activities. Higher scores indicate higher levels of physical function. The scoring procedure for the FAAM have been described in previous studies (Saarinen et al., 2022).

Both the SF-36 and the FAAM have been previously translated and validated for use in Spanish and in patients with DM (Alonso et al., 1995; Vilagut et al., 2005; Ortega-Avila et al., 2019; Membrilla-Mesa et al., 2021).

2.4. Secondary outcomes

The secondary outcomes assessed were the presence of amputation, demographic and clinical characteristics of participants. Demographic and clinical data were collected through the participant's interview. Clinical data was validated with the participants' medical records.

The demographic variables collected were sex, age, level of education, income level, marital status, employment status, living situation (living alone or with family), and consumption of alcohol and cigarettes. Clinical variables collected were type and duration of diabetes, duration of diabetic foot, comorbidities, family history of diabetes, regular diabetes checkups, current diabetes treatment, adherence to treatment, diabetes complications, history of past DFU, history of previous amputation, location of previous amputations, presence of ulcer at the time of evaluation, number of ulcers, location of ulcers, size of ulcers, time between ulcer apparition and procurement of treatment, Wagner-Meggit grade, blood pressure, body mass index (BMI), fasting blood glucose (FBG), glycated hemoglobin (HbA1c), total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides.

2.5. Clinical and laboratory measurements

Blood pressure was measured by a qualified physician before the interview. The measurement was taken in the right arm with a manual mercury sphygmomanometer after the participant remained seated for at least fifteen minutes.

After the participants' interview, their medical records were retrieved to gather clinical data. Only laboratory results that were <6 months old were taken into account.

The cut-offs points recommended by the American Diabetes Association (ADA) for adults living with diabetes were used to classify patients result as 'Within target range' or 'Outside of target range' (American Diabetes Association, 2021). The cut-off points used were the following:

- Systolic blood pressure (SBP) < 140 mmHg and diastolic blood pressure (DBP) < 90 mmHg
- FBG < 130 mg/dl
- HbA1c < 7 %
- Total cholesterol <200 mg/dl
- LDL cholesterol <100 mg/dl
- HDL cholesterol >40 mg/dl in men and > 50 mg/dl in women
- Triglycerides <150 mg/dl

2.6. Statistical analysis

Normally distributed quantitative variables were summarized using mean (standard deviation (SD)) while median [interquartile range (IQR)] was used for skewed distributions. The normality of the distributions was assessed through visual exploration of the variables and with the Shapiro-Wilk test. Categorical variables were summarized using their absolute frequencies and proportions (%).

Quantitative variables were explored visually and with descriptive statistics to detect outliers. Outliers resulting from data entry errors were corrected with their true value by revision of patient case report form whenever possible. Missing values were replaced with the mean of non-missing values of the evaluated variable in cases were less tan 10 % of values were missing. In cases were >10 % of the values were missing a complete case analysis was performed. Variables with >50 % missing values were dropped.

Statistical tests were used to establish associations between the scores of the SF-36 and FAAM with sociodemographic and clinical variables. A *P*-value was stablished to determine statistical significance. The Chi-square test was used to evaluate association between categorical variables. To assess the association between categorical and quantitative variables the *T*-Test and One-Way ANOVA was used in the case of normal distributions; for skewed distributions the Mann-Whitney U

and Kruskal-Wallis tests were used. Spearman and Pearson tests were used to evaluate the correlations between the scores of the different dimensions of the SF-36 and FAAM questionnaires.

To adjust for potential cofounders, stepwise multivariate linear regression models were fitted to evaluate the association of test scores with sociodemographic and clinical factors. A model for each of the dimensions of the SF-36 and FAAM questionnaires was created, using the dimensions' score as dependent variable and demographical and clinical characteristics as independent variables. The initial models included the following variables: male sex, age, civil status, education level, employment status, living situation, presence of comorbidities, alcohol intake, smoking status, regular diabetes checkup, time with DF, time to treatment (of DF), Wagner grade, presence of previous amputation, microvascular complications, and insulin use. After the initial model, stepwise regression based on the Akaike Information Criterion (AIC) was used to determine the least biased models. All statistical analysis were performed using the Python programming language on Jupyter Notebook version 8.5.0.

2.7. Ethics approval and informed consent

The study was designed and developed in accordance to established ethical principles and to the principles of the Declaration of Helsinki. This is an observational study. The research ethics committee of the Hospital Pediátrico Dr. Hugo Mendoza granted approval to the study protocol. Informed consent was obtained from each participant prior to their participation.

3. Results

A total of 120 participants were interviewed. There were no missing values in social and demographical variables. However, there were 97 (80.3 %) participants with missing values for HbA1c, 74 (61.7 %) for LDL cholesterol, 77 (64.2 %) for HDL cholesterol and 111 (92.5 %) for BMI, thus these variables were dropped from the analysis. There were 54 (45 %) missing values for BP, 28 (23.3 %) for FBG, 55 (45.8 %) for total cholesterol and 59 (49.2 %) for triglycerides; complete case analysis was done for these variables but were not included in regression models due to high probability of introducing bias.

Social and demographical characteristics of the participants are summarized in Table 1. Of the included participants, 66 (55 %) were male with a median age of 58 (IQR = 12) years. 92 (76.7 %) of the participants reported being unemployed at the time of the interview, with 63 (55.8 %) reporting not having a fixed source of income and being dependent on their family. There were statistically significant differences by sex, with more men reporting being married or in a domestic partnership in comparison to women ($P = 0.003$) and also reporting living alone more frequently than women ($P = 0.02$).

Clinical and ulcer characteristics are summarized in Table 2 and Table 3 respectively. 86 (71.7 %) of the participants had type 2 diabetes and 30 (25 %) reported not knowing which type of diabetes they had and the information was missing from their medical record. The median duration of diabetes and DF were 10 years [IQR = 12] and 1 year [IQR = 3.75] respectively. Hypertension was the most frequent comorbidity (50 %) and the most frequent diabetes complication was neuropathy (81.7 %). 70 (58.3 %) of participants were being treated with insulin alone.

At the moment of the interview, 116 (96.7 %) participants had an active DFU and 72 (60 %) reported having an ulcer in the past. Of the participants with an active DFU, 38 (32.8 %) had more than one ulcer. History of previous amputation was reported by 49 (40.8 %) participants. Men had a significantly higher rate of amputations in comparison to women (53 % vs. 25.9 %, $P = 0.002$). Moreover, the median time to seek treatment for DFU was 1 [2.6] weeks in men and 0.9 [1.71] weeks in women ($P = 0.037$).

Regarding laboratory measurements, 70 % of participants were within the target range for total cholesterol, triglycerides and BP. In contrast, only 29.3 % of participants were within the target range for FBG.

Table 1
Sociodemographic characteristics of the sample ($N = 120$)*

Variables	No. (%)	Men ($N = 66$)	Women ($N = 54$)	P-Value
Sex				
Men	66 (55)			
Women	54(45)			
Age (Years)*	58[12]	55[15]	58[9]	0.11
35–50	22(18.3)	16(24.2)	6(11.1)	
51–60	50(41.7)	25(37.9)	25(46.3)	
>60	48(40)	25(37.9)	23(42.6)	
Marital status				**0.003**
Single	60(50)	31(47)	29(53.7)	
Married	23(19.2)	16(24.2)	7(13)	
Divorced	2(1.7)	1(1.5)	1(1.8)	
Widowed	9(7.5)	0(0)	9(16.7)	
Domestic partnership	26(21.7)	18(27.3)	8(14.8)	
Education level				0.98
None	11(9.2)	6(9.1)	5(9.3)	
Primary, not completed	36(30)	21(31.8)	15(27.8)	
Primary, completed	35(29.2)	18(27.3)	17(31.5)	
Secondary	28(23.3)	15(22.7)	13(24.1)	
Superior education	10(8.3)	6(9.1)	4(7.4)	
Occupational status				0.26
Employed	28(23.3)	18(27.3)	10(18.5)	
Unemployed	92(76.7)	48(72.7)	44(81.5)	
Income (RD$)($N = 50$)*	9750 [11,750.0]	10,000 [10,500]	6000 [14,375]	0.25
Economically dependent	69(57.5)	33(50)	36(66.7)	0.07
Living alone	34(28.3)	26(39.4)	8(14.8)	**0.002**
Lifestyle habits				
Current smoker	3(2.5)	2(3)	1(1.9)	0.68
Current alcohol intake	10(8.3)	8(12.1)	2(3.7)	0.09

* Quantitative variables are expressed as mean (standard deviation) or median [interquartile range].

3.1. SF-36 and FAAM scores

The scores for the SF-36 and FAAM are summarized in Table 4. In general, almost all dimensions of the SF-36 were affected, with median scores of <60. The exceptions were the RE and MH dimension with median scores of 100 and 72 respectively. Men had statistically higher median scores in these two dimensions ($P = 0.001$ and $P = 0.005$ respectively). Participants that had not completed primary education had lower scores in the mental health dimensions ($P = 0.017$). Those who were unemployed had lower scores in the emotional role ($P = 0.01$), vitality ($P = 0.006$), and mental health dimensions ($P = 0.01$). Furthermore, participants that reported adhering to their treatment had higher scores in the vitality ($P = 0.001$) and general health ($P = 0.03$) dimensions.

In regards to the FAAM, both dimensions where severely affected with a median score of 39.3 [IQR = 25.7] and 28.6 [IQR = 28.6] for the ADL and sports dimensions respectively.

There was a significant positive correlation between the ADL scale of the FAAM and all the dimensions of the SF-36, the strongest found with pain scale (Spearman's $R = 0.5$, $P < 0.001$). In a similar way, there was a significant positive correlation between the sports scale and all the SF-36 dimensions except the vitality and RE dimensions, with the strongest correlation found with the physical function scale (Spearman's $R = 0.56$, $P < 0.001$).

After stepwise linear regression, the variables that were associated to lower scores of the SF-36 were Wagner stage, smoking, presence of comorbidities, presence of microvascular complications, and a longer

Table 2
Clinical characteristics of the sample ($N = 120$)*

Variables	No. (%)	Men (N = 66)	Women (N = 54)	P-Value
Type of Diabetes				0.41
Type 1	4(3.3)	1(1.5)	3(5.6)	
Type 2	86 (71.7)	47(71.2)	39(72.2)	
Unspecified	30(25)	18(27.3)	12(22.2)	
Time with diabetes (years)	10[12]	10.5[12.25]	10[11.75]	0.18
Comorbidities				
Hypertension	60(50)	29(43.9)	31(57.4)	0.14
Dyslipidemia	36(30)	18(27.3)	18(33.3)	0.47
Chronic Kidney Disease	13 (10.8)	7(10.6)	6(11.1)	0.93
Sleep apnea	12(10)	8(12.1)	4(7.4)	0.39
Diabetes treatment				0.72
Oral antidiabetics	28 (23.3)	15(22.7)	13(24.1)	
Insulin	70 (58.3)	41(62.1)	29(53.7)	
Oral antidiabetics + insulin	14 (11.7)	6(9.1)	8(14.8)	
No pharmacological treatment	8(6.7)	4(6.1)	4(7.4)	
Treatment adherence	97 (81.5)	57(86.4)	40(75.5)	0.13
Regular diabetes checkup	80 (66.7)	43(65.2)	37(68.5)	0.7
Diabetes complications				
Retinopathy	37 (30.8)	18(27.3)	19(35.2)	0.35
Neuropathy	98 (81.7)	53(80.3)	45(83.3)	0.67
Kidney disease	13 (10.8)	7(10.6)	6(11.1)	0.92
Angina	16 (13.3)	10(15.2)	6(11.1)	0.51
Coronary Heart Disease	6(5)	4(6.1)	2(3.7)	0.56
Stroke	10(8.3)	6(9.1)	4(7.4)	0.74
Peripheral vascular disease	13 (10.8)	6(9.1)	7(13)	0.5
Heart Failure	2(1.7)	2(3)	0(0)	0.2

* Quantitative variables are expressed as mean (standard deviation) or median [interquartile range].

Table 3
Diabetic foot ulcer characteristics (N = 120)*

Variables	No. (%)	Men (N = 66)	Women (N = 54)	P-Value
Active ulcer	116 (96.7)	64(97)	52(96.3)	0.84
Time between appearance of the ulcer and seeking treatment (weeks)*	1[2]	1[2.6]	0.9[1.71]	**0.02**
Number of ulcers ($N = 116$)				
1	78 (67.2)	42(63.6)	36(66.7)	0.66
≥2	38 (32.8)	22(33.3)	16(29.6)	
Location				
Forefoot	41 (34.2)	21(31.8)	20(37)	0.55
Midfoot	21 (17.5)	10(15.2)	11(20.4)	0.45
Hindfoot	17 (14.2)	9(13.6)	8(14.8)	0.85
Back of the foot	33 (27.5)	15(22.7)	18(33.3)	0.2
Toes	41 (34.2)	25(37.9)	16(29.6)	0.34
Other	19 (15.8)	10(15.2)	9(16.7)	0.82
Wagner stage				0.5
0	4(3.3)	2(3)	2(3.7)	
1	26 (21.7)	13(19.7)	13(24.1)	
2	54(45)	33(50)	21(38.9)	
3	20 (16.7)	13(19.7)	7(13)	
4	7(5.8)	2(3)	5(9.3)	
5	5(4.2)	2(3)	3(5.6)	
Undetermined	4(3.6)	1(1.5)	3(5.6)	
Size of the ulcer (cm, $N = 84$)*	3[3.75]	4[3.5]	3[3]	0.11
Previous amputation				**0.002**
0	71 (59.2)	31(47)	40(74.1)	
1	34 (28.3)	25(37.9)	9(16.7)	
≥2	15 (12.5)	10(15.2)	5(9.3)	

* Quantitative variables are expressed as mean (standard deviation) or median [interquartile range].

time to seek treatment. Wagner stage was the variable with greater impact in QoL, being associated with lower score in 6 out of the 8 dimensions of the SF-36, with Beta coefficients ranging from −7.91 to −3.35. Smoking also had a significant effect, associated with lower scores in 4 of the 8 dimensions (Beta coefficients from −10.62 to −5.73). A higher education level was associated with a lower score in the RP dimension, but with a higher score in the Vitality dimension. Furthermore, being employed was associated with a higher QoL in the PF, RE, and Vitality dimensions (Beta coefficients from 9.55 to 18.98). Similarly, being male was associated with higher QoL in the RE and MH dimensions (Beta coefficients 25.24 and 9.53 respectively). Regarding the FAAM questionnaire, a higher Wagner stage was also associated with lower physical functioning in both of its ADL and sports dimensions. Living alone was associated with lower functioning in the sports scale. The results and details of the regression model can be seen in Table 5.

4. Discussion

The majority of participants of the study had mild to moderate disease, considering that 66.7 % had a Wagner stage of 1 or 2. This is consistent with the results of previous studies where the majority of participants had a Wagner stage of <3 (AlSadrah, 2019; Polikandrioti et al., 2020). Although there were few participants with the most severe form of the condition (Wagner grade > 3), the majority of the study sample was unemployed similar to a previous study (Vileikyte, 2001). This is suggestive of the great impact that DFU can have on person's life by severely limiting their capacity to work even in early stages.

The amputation rate of the sample was 40.8 %, similar to the amputation rate found in Bonilla et al.'s study (47.2 %) which was also developed in the Dominican Republic (Bonilla et al., 2019). However, in their study, women had a significantly higher amputation rate compared to men, unlike the present study in which men had a higher amputation rate. Other studies have also reported the male sex as a risk factor for amputation (Bruun et al., 2013; Rossboth et al., 2021).

It is important to mention that these amputation rates (Bonilla et al.'s and the present study's) are considerably larger than the ones reported in other studies of countries of Latin America which report amputation rates that oscillate around 10 % (Parisi et al., 2016; Seguel, 2013). In addition, the International Working Group on Diabetic Foot guidelines recommend that glycemic control should be optimized in patients with DF, if necessary with insulin (IWGDF, 2019). However, in our study only 58 % of participants were treated with insulin and almost 7 % reported having no treatment for diabetes. This could be suggestive of a deficiency in the quality of service offered in diabetic foot clinics in the Dominican Republic. Moreover, there appears to be a lack of focus on prevention due to the very low number of patients with Wagner grade 0 (3.3 %). However, more studies are needed to test these hypotheses.

Overall, the most affected QoL dimensions were the ones related to physical health and activities (PF, RP, BP and GH dimensions). In

Table 4
SF-36 and FAAM Scores ($N = 120$)*

Dimension/Scale	Overall ($N = 120$)	M ($N = 66$)	F($N = 54$)	P-Value
SF-36				
Physical functioning				
Mean (SD)	33.7 (27.9)	35.5 (27.4)	31.4 (28.6)	
Median [IQR]	30[40]	30[35]	20[55]	0.29
Role functioning/ physical				
Mean (SD)	16.3 (29.3)	15.2 (29)	17.6 (29.8)	
Median [IQR]	0[25]	0[18.8]	0[25]	0.46
Role functioning/ emotional				
Mean (SD)	61.9 (43.9)	73.2 (40.6)	48.1 (44.2)	
Median [IQR]	100[100]	100[58.3]	33.3[100]	**0.001**
Vitality				
Mean (SD)	55.3 (20.7)	57 (19.6)	53.1 (22)	0.31
Median [IQR]	55[30]	55[28.75]	50[25]	
Mental Health				
Mean (SD)	70.1 (19.2)	74.2 (20.1)	65.2 (17.1)	
Median [IQR]	72[24]	80[31]	68[19]	**0.005**
Social functioning				
Mean (SD)	52.4 (29.5)	54.7 (30.4)	49.5 (28.2)	
Median [IQR]	50[50]	50[50]	50[50]	0.34
Pain				
Mean (SD)	44.9 (30.2)	46.3 (30.8)	43.3 (29.6)	
Median [IQR]	45[47.5]	47.5 [46.8]	45[46.8]	0.57
General health				
Mean (SD)	48.6 (22.2)	51.9 (21.2)	44.6 (22.8)	0.07
Median [IQR]	50 [30]	52.5 [25]	45[33.8]	
FAAM				
Activities of Daily Living				
Mean (SD)	43 (24.5)	44.8 (24.5)	40.7 (24.6)	0.38
Median [IQR]	39.3[25.7]	47[36.3]	36.3[38 0.4]	
Sports activities				
Mean (SD)	29.9 (19)	30.1 (18.7)	29.6 (19.5)	
Median [IQR]	28.6[28.6]	28.6 [28.6]	26.8 [26.8]	0.76

* Statistical significance calculated using Student's T or Mann Whitney U correspondingly.

contrast, dimensions related to mental and emotional health were not as severely affected. This differs from AlSadrah's study were patient's with DFU had lower scores of SF-36's dimensions related to emotional and mental health in comparison to physical health dimensions AlSadrah, 2019). This might be due to cultural differences among the studies' samples and differences in the quality of healthcare services provided.

Consistent with Alrub et al.'s findings, in our study men had significantly higher scores in role emotional and mental health dimensions when compared to women (Alrub et al., 2019). This is also comparable to the results of several previous studies from different countries where men reported higher QoL in many dimensions of the SF-36 Sabbah et al., 2003; Hopman et al., 2000; Ware Jr., 1999; Jenkinson et al., 1999). This sex differences might be related to intrinsic social and biologic differences (Guallar-Castillón et al., 2005).

The sociodemographic factor that affected the most dimensions of the SF-36 was employment status, with employed participants having significantly higher scores in PF, RE, and Vitality. This is similar to Polikondroti et al.'s findings that reported lower scores in the Vitality and mental health dimensions among unemployed participants (Polikandrioti et al., 2020). This finding is of special importance as unemployment could be limiting the access to healthcare of this participants, especially considering that the majority of the study sample reported not having a fixed income and being economically dependent to their family. A previous study reported insufficient insurance coverage and financial strain as one of the main barriers to healthcare among patients with DFU (Tan et al., 2022).

Among the clinical characteristics, the Wagner grade was the variable that affected most dimensions of QoL in the regression models. A higher Wagner grade was associated with lower scores in the six of the eight dimensions of the SF-36. This is not surprising as higher Wagner grade indicates a more severe disease which inevitably affects a person's QoL. These findings are consistent with Alzharani & Sehlo's study in which participants with higher Wagner had significantly lower scores in all dimensions of the SF-36 (Alzahrani and Sehlo, 2013).

The second factor that affected most QoL dimensions was being current smoker, affecting negatively the PF, RP, MH, and GH dimensions. The negative effects of smoking on QoL and health have been studied widely (Alzahrani and Sehlo, 2013; Valensi et al., 2005; Lima et al., 2014). However, it is important to mention that smoking affects more severely patients with diabetes, as it is associated with aggravation of micro and macrovascular complications, severe DFU, insulin resistance, and is considered as an independent risk factor for T2D (Laaksonen et al., 2006; Bellido-Casado et al., 2004; Chang, 2012). Additionally, it has been shown that smoking cessation has benefits for patients with diabetes in general and for DFU healing (Jalilian et al., 2020; Campagna et al., 2019; Xia et al., 2019).

Other factors that significantly affected less SF-36 dimensions were education level, time to seek treatment, living alone, presence of comorbidities, and microvascular complications. Of these variables, the ones with larger negative effect on reported QoL were the presence of comorbidities in the PF dimension and microvascular complications in the SF dimension. There is copious amount of evidence that show that socioeconocomic factors and comorbidities have an additive negative impact in QoL (Wang et al., 2016a, 2016b; Pati et al., 2020; Adriaanse et al., 2016; Laiteerapong et al., 2011). The findings of the present and previous studies suggest that diabetes management would benefit from multidisciplinary approach and treatment of comorbidities. However, multiple studies have reported that care provided for patients with diabetes with comorbid conditions are incomplete, inefficient and ineffective (Adriaanse et al., 2016; Laiteerapong et al., 2011).

Wagner grade was also the factor most significantly associated with lower scores in both of the FAAM's dimensions in the regression models, being the only factor associated significantly with the ADL dimension score. This contrasts with AlSadrah's findings were no significant association between Wagner grade and FAAM scores were found. However, this might be due to the majority of ulcers being of a similar Wagner grade in AlSadrah's study (77 % being Wagner grade 2), as significant differences in FAAM score according to clinical outcomes were found (Patients with and without healed ulcers) (AlSadrah, 2019). Considering the potential effect of the severity on functionality and QoL, attention should be given to the importance of opportune treatment and prevention for the preservation of QoL in patients with DF.

To the authors' knowledge, this is the first study that studies both QoL, physical functionality and their associated factors in patients with DF in the Dominican Republic. The findings provide useful information for the development of future health promotion strategies to help reduce the burden of DF on the QoL and physical functioning in Dominicans with diabetes.

4.1. Limitations

There were some important limitations in the development of the study. Due to lack of access to an appropriate sampling frame in the DFCs included in the study, a convenience non-randomized sampling was used, in which patients that were attending the DFC to receive

Table 5
Variables associated with SF-36 and FAAM dimensions scores. Multivariate linear regression analysis.

	Method	Adjusted R^2	Coefficient B (SE)	CI 95 %	t	P-Value
Model I	WLS	0.58				**<0.001**
Dependent variable						
Physical Functioning (SF-36)						
Independent variables						
Age			0.42 (0.26)	(−0.09; 0.93)	1.64	0.105
Currently employed			11.65 (5.77)	(0.22; 23.09)	2.02	**0.046**
Comorbidities			−14.83 (5.18)	(−25.1; −4.56)	−2.86	**0.005**
Current smoker			−10.62 (2.5)	(−15.57; −5.67)	−4.25	**<0.001**
Wagner stage			−7.91 (1.29)	(−10.47; −5.35)	−6.12	**<0.001**
Model II	WLS	0.12				**<0.001**
Dependent variable						
Role Physical (SF-36)						
Independent variables						
Education level			−2.98 (0.84)	(−4.64, −1.31)	−3.54	**0.001**
Current smoker			−9.72 (3.4)	(16.45, −2.98)	−2.86	**0.005**
Wagner stage			−3.35 (1.47)	(−6.26, −0.43)	−2.74	**0.025**
Insulin use			−8.88 (4.82)	(−18.43, 0.67)	−1.84	0.068
Model III	WLS	0.26				**<0.001**
Dependent variable						
Role emotional (SF-36)						
Independent variables						
Male			25.24 (7.45)	(10.48; 40.01)	3.39	**0.001**
Age			−0.50 (0.39)	(−1.28; 0.27)	−1.3	0.197
Currently employed			18.98 (7.53)	(4.06; 33.91)	2.52	**0.013**
Time to treatment			−0.40 (0.17)	(−0.73; −0.07)	−2.39	**0.019**
Wagner stage			−7.53 (3.04)	(−13.56; −1.50)	−2.43	**0.015**
Amputation			−12.04 (7.54)	(−26.98; 2.89)	−1.6	0.113
Microvascular complications			−17.89 (9.45)	(−36.62; 0.84)	−1.89	0.061
Model IV	OLS	0.14				**<0.001**
Dependent variable						
Vitality (SF-36)						
Independent variables						
Education level			2.55 (1.08)	(0.41; 4.67)	2.36	**0.02**
Currently employed			9.55 (4.35)	(0.94; 18.17)	2.19	**0.03**
Living alone			11.44 (4.15)	(3.22; 19.65)	2.76	**0.007**
Current smoker			−5.08 (3.22)	(−11.45; 1.30)	−1.58	0.117
Wagner stage			−2.27 (1.54)	(−5.31; 0.77)	−1.48	0.142
Microvascular complications			−8.54 (4.95)	(−18.34; 1.25)	−1.73	0.087
Model V	OLS	0.22				**<0.001**
Dependent variable						
Mental Health (SF-36)						
Independent variables						
Male			9.53 (3.15)	(3.29; 15.78)	3.03	**0.003**
Education level			1.56 (0.96)	(−0.34; 3.46)	1.63	0.11
Currently employed			7.12 (3.81)	(−0.43; 14.67)	1.87	0.06
Current smoker			−5.73 (2.82)	(−11.31; −0.14)	−2.03	**0.045**
Time to treatment			−0.32 (0.11)	(−0.54; −0.11)	−3.02	**0.003**
Wagner stage			−2.50 (1.33)	(−5.12; 0.13)	−1.88	0.062
Microvascular complications			−6.31 (4.34)	(−14.92; 2.29)	−1.45	0.149
Insulin use			−6.12 (3.47)	(−13.0; 0.75)	−1.77	0.08
Model VI	OLS	0.07				**0.007**
Dependent variable						
Social Functioning (SF-36)						
Independent variables						
Wagner stage			−4.89 (2.22)	(−9.29; −0.49)	−2.2	**0.03**
Microvascular complications			−17.83 (7.14)	(−31.97; −3.70)	−2.5	**0.014**
Model VII	OLS	0.03				**0.032**
Dependent variable						
Bodily Pain (SF-36)						
Independent variables						
Wagner stage			−5.0 (2.32)	(−9.59; −0.42)	−2.16	**0.033**
Model VIII	OLS	0.12				**0.002**
Dependent variable						
General Health (SF-36)						
Independent variables						
Male			7.70 (3.89)	(−0.01; 15.4)	1.98	0.05
Age			0.51 (0.23)	(0.05; 0.97)	2.2	**0.03**
Comorbidities			−6.40 (4.32)	(−14.96; 2.15)	−1.48	0.141
Current smoker			−8.92 (3.44)	(−15.73; −2.10)	−2.59	**0.011**
Wagner stage			−4.79 (1.65)	(−8.05; −1.53)	−2.91	**0.004**
Model IX	OLS	0.17				**<0.001**
Dependent variable						
Activities of Daily Living (FAAM)						
Independent variables						

(*continued on next page*)

Table 5 (*continued*)

	Method	Adjusted R^2	Coefficient B (SE)	CI 95 %	t	P-Value
Currently employed			9.45 (4.90)	(−0.25; 19.16)	1.93	0.056
Current alcohol use			4.78 (3.18)	(−1.51; 19.16)	1.51	0.135
Wagner stage			−6.51 (1.78)	(−10.04; −2.99)	−3.66	**<0.001**
Amputation			−6.61 (4.25)	(−15.04; 1.81)	−1.56	0.123
Microvascular complications			−9.88 (5.68)	(−21.12; 1.37)	−1.74	0.084
Model X	WLS	0.2				**<0.001**
Dependent variable						
Sports (FAAM)						
Independent variables						
Age			0.44 (0.19)	(0.07; 0.81)	2.33	**0.022**
Currently employed			6.34 (3.89)	(−1.37; 14.05)	1.63	0.106
Living alone			−12.26 (3.52)	(−19.22; −5.29)	−3.49	**0.001**
Current alcohol use			7.41 (2.49)	(2.48; 12.34)	2.98	**0.004**
Wagner stage			−4.62 (1.27)	(−7.12; −2.11)	−3.65	**<0.001**

OLS: Ordinary Least Squares; WLS: Weighted Least Squares.

healthcare were recruited. This can produce a selection bias. Furthermore, the stress related to having DFU treatment could affect the SF-36 scores. On another hand, the medical records in the majority of the participating centers were very poorly kept and incomplete. Lab results, ulcer treatment plan, and ulcer size data were missing for the majority of participants and thus could not be used for inferential analysis. Lastly, no DFC clinics outside of the district of Santo Domingo were included, which makes our results probably not generalizable to other districts and rural areas of the country.

5. Conclusion

Patients with DF report low QoL and level of physical functionality. In patients with DFU, a high Wagner grade is the main factor associated with both low QoL and low level of functionality. Other factors that negatively affected QoL were smoking, unemployment, the presence of comorbidities and microvascular complications. All of these factors point towards the necessity to refocus care towards prevention of both DFU and disease progression, and the need of development a multidisciplinary patient-centered care. Patients should receive proper quality care for their comorbidities and other supportive therapies like smoking cessation should be provided.

DF is a condition that affects not only a person's physical health, but also their emotional, social, familial and financial well-being. It also represents an important economic burden to the health sector, as patients with DFU need to recurrently receive treatment in healthcare facilities. More research studies that evaluate the efficacy of preventive and multidisciplinary chronic disease management programs to improve the QoL and diminish the cost of this condition are needed.

CRediT authorship contribution statement

Berniza Calderón: Writing – review & editing, Validation, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Manuel Soto:** Writing – review & editing, Writing – original draft, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Alba Beltré:** Writing – review & editing, Writing – original draft, Investigation.

Authors' contribution

All authors contributed to the study conception and design. Material preparation and data collection were performed by Alba Beltré and Manuel Soto. Data analysis was performed by Manuel Soto. The first draft of the manuscript was written by Manuel Soto and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

This study was funded by Fundación Alivia Diabetes, a non-profit organization with the aim to reduce health inequities among vulnerable populations with diabetes. The sponsor had no involvement in the study design, analysis and interpretation of data, or writing of the report.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Berniza Calderon reports financial support was provided by Fundación ALIVIA. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

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