Original Article

FOOT COMPLICATIONS IN DIABETES: A COMPREHENSIVE EXAMINATION OF QUALITY OF LIFE FROM A SPECIALIZED CLINIC'S VIEWPOINT

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Abstract: Diabetes Mellitus (DM) is a pervasive and intricate chronic condition, imposing a significant societal, economic, and human burden globally. The incidence of DM continues to rise, leading to alarming morbidity and mortality rates. Diabetic foot complications are among the most severe and costly consequences of DM. This paper highlights the importance of comprehensive assessment, preventive measures, and multidisciplinary healthcare approaches in managing diabetic foot conditions. By adopting a multiprofessional healthcare team and providing education and prevention strategies, it is possible to substantially reduce the prevalence of foot complications and amputations related to diabetes. This comprehensive approach is crucial in curbing the devastating impact of DM on patients' quality of life and the healthcare system.

Keywords: diabetes mellitus, diabetic foot, complications, prevention, multidisciplinary care, assessment, education, amputation.

1. Introduction

Diabetes Mellitus (DM) is a chronic and complex disease with high morbidity and mortality, requiring continuous care and rigorous blood glucose control (American Diabetes Association [ADA], 2017). It can reduce life expectancy, compromise productivity, reduce family income, imposing a high social, human and economic cost, regardless of income level (International Diabetes Federation [IDF], 2017), as well as affecting health services (Vos et al., 2016). In 2017 there were some 425 million adults aged between 20 and 79 with DM worldwide, this being the equivalent of one in eleven individuals (IDF, 2017). Among the diverse complications of DM, diabetic foot is one of the most serious and costly, with average global prevalence of 6.4% (Zhang et al., 2016). Every year at least one million diabetic people lose at least part of their lower limbs as a consequence of diabetes complications, accounting for one amputation every 20 seconds (Bakker, Apelqvist, Lipsky & Van Netten, 2015). On the other hand, when a comprehensive assessment of the risk of diabetic foot is performed and care of the feet is based on prevention, education and care provided by a multiprofessional health team, reductions of up to 85% occur in feet complications and amputations (IDF, Clinical Practice Recommendation on the Diabetic Foot, 2017). Among the risk factors for feet ulcers are prior amputation, prior history of ulcers, feet deformities, peripheral neuropathy, poor glucose control, tobacco smoking, nephropathy and visual impairment (Boulton et al., 2008).

Original Article

Studies show that diabetes and its comorbidities cause negative impact on the level of quality of life of those who have this disease when compared to those who do not (Edelman, Olsen, Dudley, Harris & Oddone, 2002).
Likewise, feet ulcers affect quality of life, with repercussions on the patient's self-image and self-esteem in relation to their family and society, causing isolation and depression (Coelho, Silva & Padilha, 2009). There is, however, no consensus as to the concept of quality of life, which can vary according to the time, place and cultural context. Quality of life is generally associated with balance between factors such as satisfaction, personal achievement, perception of well-being, leisure opportunities, level of independence, social relations (Nahas, 2001), and other subjective aspects such as happiness, solidarity and freedom.
The use of evaluation instruments enables the investigation of the impact of chronic diseases on people's lives (Santos, Assumpção & Matsutani, 2006). Generic instruments are multidimensional and assess various aspects of a disease, the efficacy of health policies and programmes, and can compare two different diseases. Specific instruments provide comprehensive analysis of alterations in quality of life and assess pain, functional capacity and emotional status specifically and in depth (Aguiar, Vieira, Carvalho & Montenegro-Junior, 2008). Analysis of quality of life is based on an individual's perception of their own state of health and considers subjective aspects and aspects of the cultural setting (Ciconelli, 2003), helping with the planning of interventions that lead to greater well-being (Novato, Grossi & Kimura, 2007).
This study explores different aspects of diabetic patients, whether they have active foot ulcers or their feet are at risk. It aims to help patients, families and health teams to understand the importance of more comprehensive and effective treatment. Moreover, having a better understanding of the quality of life of a person with diabetes can reduce cultural barriers, complications and limitations, among other serious consequences, that increase demand for consultations, hospitalization and surgery as well as increasing public health system costs.

2. Objective

To evaluate the impact of diabetic foot and feet at risk on the quality of life of diabetic patients monitored at a specialized diabetic foot outpatient clinic at a large tertiary teaching hospital in southern Brazil.

3. Method

3.1. Design of the Study

This study has a cross-sectional design and a quantitative approach.

3.2. Sample/Participants

It was conducted at the Diabetic Foot Outpatient Clinic of a public tertiary teaching hospital located in the city of Curitiba, which serves patients from all regions of the state of Paraná. Two nurses specialized in the treatment of Diabetic Foot work at this outpatient clinic. They carry out nursing consultations and provide guidance to patients, their families or carers as to caring at home for lesions, general care of the feet and lesion prevention, in addition to care intended to promote health. Patients are referred to this clinic when they have feet ulcers or other serious problems with their feet. Once the initial problem that gave rise to the referral to the clinic has been resolved, all patients join the clinic's monitoring programme in order to prevent lesions and amputations. The interval between these consultations is based on risk stratification (International Working Group on the Diabetic Foot [IWGDF], 2011; Boulton et al., 2008). In the event of relapses or new ulcers, patients are advised to seek care as soon as they notice the problem, in order to start treatment immediately with the aim of reducing complications and amputations. The data were collected between October 2016 and March 2017. The study population was comprised of 60 adult patients of both sexes, out of a total of 125 patients who were being monitored by the Diabetic Foot outpatient clinic during the study period. They were divided into a group of 30 patients with lower limb ulceration and another group of 30 patients who did not have ulceration. Patients were selected using non-probability convenience sampling. The inclusion criteria were: patients with confirmed diagnosis of type 1 Diabetes Mellitus (DM1) or type 2 Diabetes Mellitus (DM2), aged over 18 years, of any colour/race/ethnicity/sex,

monitored by the Diabetic Foot outpatient clinic, with and without lower limb ulceration, with physical and mental ability to answer the questionnaires.

3.3. Data Collection

Two data collection instruments were used: one structured questionnaire type instrument for sociodemographic, clinical and treatment data, containing close-ended questions with answers recorded on the instrument itself, comprised of personal data such as: sex, age, schooling, family history of diabetes and comorbidities; and another instrument specifically for assessing quality of life of people with diabetes, namely the Brazilian version of the Problem Areas in Diabetes Scale (B-PAID), validated in Brazil by Gross, Scain, Scheffel, Gross and Hutz (2007), and which is being used in Brazil as an instrument to gauge the suffering to which diabetic patients may be subjected.

PAID is a specific instrument for assessing quality of life from the perspective of people with DM. It assesses the impact of diabetes and its treatment on the lives of patients. The instrument was developed by the Joslin Diabetes Center in Boston (Welch, Jacobson & Polonsky, 1997). It is comprised of 20 questions that assess a person's perception of problems faced in everyday life owing to diabetes, focusing on emotional aspects such as guilt, anger, depression, worry and fear. It has four subdimensions: food problems, social support problems, treatment problems and emotional problems. It uses a score from 0 to 100, where a high score (≥40) represents a high rate of emotional suffering (Gross et al., 2007). It uses a 5-point Likert scale, ranging from: ―Not a problem =0‖, ―Minor problem=1‖, ―Moderate problem=2‖, ―Somewhat serious problem=3‖, ―Serious problem=4‖. The total 0-100 score is calculated by adding together the scores from 0-4 in answer to the 20 B-PAID items and multiplying this total by 1.25 (Welch et al., 1997). The original version was developed by Polonsky (Welch et al, 1997) and its studied internal consistency (Cronbach's alpha) was 0.95.

3.4. Ethical Considerations

The questionnaires were read out loud by the researcher to the respondents, allowing time for each question to be understood and answered. The data were collected after the interviewees had signed a Free and Informed Consent Form. The patients' confidentiality and privacy were respected. The project was approved by the institutional ethics committee as per Submission for Ethical Evaluation Certificate 58848816.3.0000.0096 and was in accordance with National Health Council Resolution 466/2012.

3.5. Statistical Analysis

The results obtained by the study were described by mean values, standard deviations, minimum values and maximum values (quantitative variables) or by frequencies and percentages (categorical variables). The Chi-square test or Fisher's exact test was used to evaluate association between two categorical variables. Comparison of two groups in relation to quantitative variables was done using the Student's t-test for independent samples or the Mann-Whitney nonparametric test. Logistic Regression (stepwise backward) models were adjusted for multivariate analysis, including as explanatory variables those with $p<0.05$ in the univariate analysis. Following adjustment, variable significance was assessed using the Wald test. Estimated association was measured using the odds ratio (OR). P-values of <0.05 indicated statistic significance. The data were analyzed using IBM SPSS Statistics v.20.0. Armonk, NY: IBM Corp.

4. Results

The study population was comprised of 60 individuals, 30 of whom had lower limb ulceration and 30 of whom did not. Of the total, 39 (65%) were men and 21 (35%) were women.

Mean age was 65.2 years, ranging from 41 to 83 years. The predominant sociodemographic characteristics were: 46 (76.7%) White; 41 (68.3%) married; 34 (56.7%) had not finished their elementary education and 32 (53.3%) had monthly income of between one and three minimum wages. Approximately 16.7% had family income of up to one minimum wage (Table 1).

Original Article

Table 1 – Diabetic patient sociodemographic variables in the total sample (N= 60)

Variable	Classification	Group		Total	P-value*
		Without ulcer (n=30)	**With ulcer (n=30)**		
Age	(years)	64.2 ± 6.8 (53 - 82)	66.1 ± 8.3 (41 - 83)	65.2 ± 7.9 (41 - 83)	0.365
Sex	Female	12 (40.0)	9 (30.0)	21 (35.0)	
	Male	18 (60.0)	21 (70.0)	39 (65.0)	0.589
Ethnicity	Black	0 (0)	2 (6.7)	2 (3.3)	
	White	25 (83.3)	21 (70.0)	46 (76.7)	
	Brown	5 (16.7)	7 (23.3)	12 (20.0)	0.262
Marital status	Married	19 (63.3)	22 (73.3)	41 (68.3)	
	Divorced	5 (16.7)	2 (6.7)	7 (11.7)	
	Widowed	6 (20.0)	5 (16.7)	11 (18.3)	
	Single	0 (0)	1 (3.3)	1 (1.7)	
Family income	Friends help	1 (3.3)	0 (0)	1 (1.7)	
	< 1 min. wage	6 (20.0)	4 (13.3)	10 (16.7)	
	1-3 min. wages	13 (43.3)	19 (63.3)	32 (53.3)	
	> 3 min. wages	10 (33.3)	7 (23.3)	17 (28.3)	
Schooling	Incomplete Elementary	17 (56.7)	17 (56.7)	34 (56.7)	
	Complete Elementary	1 (3.3)	5 (16.7)	6 (10.0)	
	High School	10 (33.3)	6 (20.0)	16 (26.6)	
	University	2 (6.7)	2 (6.7)	4 (6.7)	

Results described by mean ± standard deviation (minimum – maximum) or by frequency (percentage) *Student's t-test for independent samples (age); Chi-square test (ethnicity); $p<0.05$ (-) Test not applicable

With regard to lifestyle, 33 individuals (55.0%) were found to practice physical activity, even when they had lower limb ulceration, 54 (90.0%) denied smoking and 55 (91.7%) denied alcohol use. Predominating among associated diseases were systemic arterial hypertension (SAH) in 51 (85.0%) and dyslipidemia in 49 (81.7%). Sixteen (26.7%) cases reported myocardial infarction, seven (11.7%) reported cerebrovascular accident (CVA), 13 (21.7%) reported kidney disease and 24 (40.0%) reported arterial insufficiency. There was statistical significance between the groups with and without ulcers with regard to kidney disease ($p=0.01$) and arterial insufficiency ($p=0.003$). Out of 10 (16.7%) individuals with sight problems such as amaurosis, glaucoma, cataract and retinopathy, three (10%) patients belonged to the group without ulcers and seven (23.3%) to the group with ulcers, 55% of patients also reported other comorbidities (Table 2).

Original Article

Table 2 – Diabetic patient lifestyle and comorbidities in the total sample (N= 60)

Variable	Classification	Group		Total	P-value*
		Without ulcer (n=30)	**With ulcer (n=30)**		
Physical activity	No	13 (43.3)	14 (46.7)	27 (45.0)	
	Yes	17 (56.7)	16 (53.3)	33 (55.0)	1
Alcohol	No	27 (90.0)	28 (93.3)	55 (91.7)	
	Yes	3 (10.0)	2 (6.7)	5 (8.3)	1
Tobacco smoking	No	27 (90.0)	27 (90.0)	54 (90.0)	
	Yes	3 (10.0)	3 (10.0)	6 (10.0)	1
Systemic arterial hypertension	No	6 (20.0)	3 (10.0)	9 (15.0)	
	Yes	24 (80.0)	27 (90.0)	51 (85.0)	0.472
Dyslipidemia	No	5 (16.7)	6 (20.0)	11 (18.3)	
	Yes	25 (83.3)	24 (80.0)	49 (81.7)	1
Myocardial infarction	No	22 (73.3)	22 (73.3)	44 (73.3)	
	Yes	8 (26.7)	8 (26.7)	16 (26.7)	1
Cerebrovascular accident	No	27 (90.0)	26 (86.7)	53 (88.3)	
	Yes	3 (10.0)	4 (13.3)	7 (11.7)	1
Kidney disease	No	28 (93.3)	19 (63.3)	47 (78.3)	
	Yes	2 (6.7)	11 (36.7)	13 (21.7)	0.010*
Arterial insufficiency	No	24 (80.0)	12 (40.0)	36 (60.0)	
	Yes	6 (20.0)	18 (60.0)	24 (40.0)	0.003*
Sight problems (glaucoma, amaurosis, cataract, retinopathy)	No	27 (90.0)	23 (76.7)	50 (83.3)	
	Yes	3 (10)	7 (23.3)	10 (16.7)	0.299

Original Article

Other comorbidities	No	14 (46.7)	13 (43.3)	27 (45.0)
	Yes	16 (53.3)	17 (56.7)	33 (55.0)	1

Results described by frequency (percentage)
* Fisher's exact test, p<0.05

When analyzing the characteristics of diabetes, five (8.3%) patients were found to have DM1 and 55 (91.7%) had DM2, with mean length of time of diagnosis of 23.3 years, varying between 3 and 45 years. Forty-seven (78.3%) patients had been monitored by the diabetic foot outpatient clinic for more than 24 months and mean self-reported capillary glycaemia was 141.2 mg/dl, ranging between 62 and 318mg/dl. With regard to risk classification, 53 (88.3%) patients had level 3 risk, meaning that they have a history of prior ulceration and/or amputation (p=0.01), and 46 (76.7%) were taking insulin (Table 3).

Table 3 – Diabetes Mellitus characteristics and insulin use in the total sample (N= 60)

Variable	Classification	Group		Total	Pvalue*
		Without ulcer (n=30)	**With ulcer (n=30)**		
Type of DM	1	3 (10.0)	2 (6.7)	5 (8.3)	
	2	27 (90.0)	28 (93.3)	55 (91.7)	1
Glycaemia (self-reported)	(mg/dL)	139.6 ± 40.4 (75 - 280)	142.8 ± 60.7 (62 - 318)	141.2±51.1 (62 - 318)	0.813
Diagnosed how long ago	(years)	22.3 ±9.5 (3 - 42)	24.2 ± 9.4 (8 - 45)	23.3 ± 9.4 (3 - 45)	0.447
Outpatient clinic monitoring for how long (months)	< 3	2 (6.7)	2 (6.7)	4 (6.7)	
	3-6	1 (3.3)	2 (6.7)	3 (5.0)	
	7-12	2 (6.7)	2 (6.7)	4 (6.7)	
	12-24	2 (6.7)	0 (0)	2 (3.3)	
	> 24	23 (76.7)	24 (80.0)	47 (78.3)	
Risk classification	1	7 (23.3)	0 (0)	7 (11.7)	
	3	23 (76.7)	30 (100)	53 (88.3)	0.011*
Insulin use	No	7 (23.3)	7 (23.3)	14 (23.3)	
	Yes	23 (76.7)	23 (76.7)	46 (76.7)	1

Results described by mean ± standard deviation (minimum – maximum) or by frequency (percentage) *Student's t-test for independent samples (glycaemia and length of time of diagnosis); Chi-square test (categorical variables); p<0.05 (-) Test not applicable

Trauma was referred to as the cause of 80% of ulcers. With regard to the presence of lower limb alterations and non-ulcerated lesions, 54 (90.0%) had nail dystrophy, 37 (61.7%) had hyperkeratosis and 46 (76.7%) had deformities due to neuropathy or due to lesion scar tissue sequels, with similar results between the ulceration and

nonulceration groups. The presence of atrophic scars was statistically significant and was found in seven (23.3%) patients without lesions and in 17 (56.7%) with lesions (p=0.01).

The number of amputated patients differed between the two groups, with four (13.3%) in the group without ulcers and 11 (36.7%) in the group with ulcers (p=0.72). Of the 15 patients who had suffered amputation, only two (13.3%) were cases of larger amputations, defined as amputations above the ankle, while 13 (86.7%) were smaller amputations, defined as those restricted to the toes of the feet or the foot (Kolossváry et al., 2015). It is noteworthy that only three of these amputations occurred after these patients began to be monitored at the diabetic foot outpatient clinic and all three were smaller amputations (toes of the feet).

With regard to mobility, eight (13.3%) patients needed assistance in order to walk, one from the group without ulcers and seven from the group with ulcers (p=0.05); seven (11.7%) patients used crutches, of whom one was from the group without ulcers and six from the group with ulcers; three (5%) used lower limb prostheses all of whom were from the group with ulcers; there was one wheelchair user, also from the group with ulcers. Only 15 (25%) patients had foot ware adapted for diabetics, five of whom were from the group without ulcers and ten from the group with ulcers, despite adapted foot ware use being recommended for all patients with neuropathy, vasculopathy, deformities, prior sores or amputations and/or Charcot arthropathy (Brazilian Diabetes Society [BDS] (2017). B-PAID scores were found to be higher (≥40) in individuals with ulcers (mean score of 47), in contrast to those without ulceration (mean score of 34.3) (p=0.05).

When analyzing Spearman's correlation coefficients, the results of the group without ulcers indicated significant correlation between the number of comorbidities, total B-PAID score and the emotional and treatment subdimensions, while the results of the group with ulcers showed significant correlation between the number of comorbidities, total B-PAID score and all B-PAID subdimensions (Table 4).

Table 4 – Correlation between number of comorbidities and B-PAID results in total sample (N=60)

Group	Variables	n	Spearman's correlation coef.	P-value
Without ulcer	Number of comorbidities vs. B-PAID (Total)	30	0.39	0.034*
	Number of comorbidities vs. Emotional_total	30	0.42	0.021*
	Number of comorbidities vs. Treatment_total	30	0.44	0.014*
	Number of comorbidities vs. Food_total	30	0.34	0.069
	Number of comorbidities vs. Social support_total	30	-0.05	0.779
With ulcer	Number of comorbidities vs. B-PAID (Total)	30	0.56	0.001*
	Number of comorbidities vs. Emotional_total	30	0.54	0.002*
	Number of comorbidities vs. Treatment_total	30	0.46	0.010*
	Number of comorbidities vs. Food_total	30	0.47	0.009*
	Number of comorbidities vs. Social support_total	30	0.4	0.027*

*Spearman's correlation coefficient, $p<0.05$
B-PAID- Brazilian Version of the Problem Areas in Diabetes Scale
When comparing the groups defined by B-PAID score (<40 or ≥40) in relation to the number of comorbidities, statistical difference ($p<0.001$) was found between the groups, with an average of 5 comorbidities in the group with a B-PAID score <40 (range of 2-8) and an average of 6.8 in the group with a B-PAID score ≥40 (range of 2-11), representing greater emotional suffering in patients with a greater number of comorbidities.
In the multivariate analysis of the relationship between B-PAID score (≥ 40) and each of the variables tested, the results of the final model show significant correlations with the female sex ($p=0.020$), absence of physical activity ($p= 0.049$), presence of obesity ($p= 0.032$), presence of kidney disease ($p= 0.027$) and number of comorbidities ($p<0.01$).

5. Discussion

Diabetes Mellitus can cause many physical, emotional and social restrictions, causing profound changes to the lives of those who have the disease. Moreover, it can lead to serious complications and disabilities (Edelman et al., 2002). Research shows that the profile of people with diabetic foot includes older individuals, those who have had DM for longer periods of time, prior history of arterial hypertension, diabetic retinopathy and tobacco smoking (Zhang et al., 2016). In our study a patient profile similar to that in the literature was found, comprised of more elderly individuals, who had been diagnosed for longer, with low socioeconomic and education levels and, above all, who were found to have a high level of emotional suffering owing to living with diabetes when they had feet ulcers and a greater number of comorbidities. In our study, mean age of 65 years (41-83 years) was similar to that found in the literature (Leite et al., 2015; Pedras, Carvalho & Pereira, 2016; Bernini et al., 2017). The skin of elderly people is more fragile and, in the case of people with diabetes, may be more vulnerable to the appearance of skin lesions and slower healing.
The male predominate in 65% in the total sample and 70% on the group with ulcers. This is in agreement with the literature (Zhang et al., 2016) which indicates higher diabetic foot incidence in males (Sekhar, Thomas & Unnikrishnan, 2015; Hoban et al., 2015; Pedras, Carvalho & Pereira, 2016). Men tend to be more reluctant to seek health care, while in our study 68.3% of males were married, which permits us to deduce that they were able to count on some form of family support (Chibante, Sabóia, Teixeira & Silva, 2014; Bernini et al., 2017). In their study with 120 patients recently diagnosed as having DM2, Shi et al. (2016) found that those individuals whose family members were completely involved achieved better results for knowledge, attitudes and practices in relation to taking care of DM, as well as better quality of life, blood glucose control and weight control than those with no family involvement, indicating that the involvement of family members helps to improve health education and quality of life. 76.7% white ethnicity is compatible with racial miscegenation in the southern region of Brazil. Family income of between one and three minimum wages among 53.3% of respondents and incomplete elementary education, i.e., less than nine years schooling among 56.7% demonstrated low socio-economic and educational status in this population, this being a characteristic common to users of the Brazilian Unified Health System (SUS) (Chibante et al., 2014; Leite et al., 2015; Souza & Almeida, 2016). This low level of education may impact the understanding these individuals have of their disease, its complications and also about the care needed to treat it. Furthermore, low schooling has been indicated as a risk factor for the appearance of acute and chronic DM complications. It is noteworthy that ten (16.7%) patients lived off a monthly family income of less than one minimum wage, which at the time the study was conducted was the equivalent of around U$ 270 (DIEESE, 2016). Considering that diabetes is a disease with high economic cost, this low family income may have a negative influence on the adequate treatment of these patients and increase the risk of complications.

Original Article

The fact that 55% of the respondents practice physical activity and that most do not drink alcohol (91.7%) or smoke tobacco (90%) is similar to the literature (Villas-Boas, Foss, Freitas & Pace, 2012; Lima Neto et al., 2017) and may indicate care taken by patients with regard to seeking a healthy lifestyle or may also result from the educational emphasis of guidance on the health of people with diabetes given by the outpatient clinic nurses.

Among comorbidities, SAH reported by 85% and dyslipidemia by 81.7% are percentages higher than the 72% found by Ribu, Hanestad, Moum, Birkeland & Rustoen (2007) in their study with 127 outpatients with diabetic foot in Norway. Kidney disease reported by 36.7% of the patients in our study and visual disorders such as amaurosis, glaucoma, cataracts and retinopathy reported by 16.7%, also differ from the 21% and 39%, respectively, found by Ribu et al. (2007). Our findings on dyslipidemia (81.7%) and kidney disease (36.7%) diverge from Souza et al. (2012) which found 48.8% dyslipidemia and 7.1% nefropathy.

Visual impairment is one of the risk factors for feet ulcers, as it may hinder or even make it impossible to perform self-care, such as examining one's feet daily, adequate hygiene, daily assessment of one's foot ware, daily use of moisturizers and correct nail cutting (Bus et al., 2016), in addition to significantly increasing risk of traumas.

The high incidence of complications found among the participants of our study may be related to the long length of time of DM diagnosis and also to late diagnosis, which often only takes place when chronic complications are present and which tend to appear after having had the illness for a long time in addition to being associated with poor metabolic control (BDS, 2017). For this reason, preventive measures and early diagnosis are the main factors for morbidity and mortality prevention and reduction.

With regard to the type of diabetes, we found five (8.3%) patients with DM1 and 55 (91.7%) with DM2. This was similar to the distribution found in the global population (IDF, 2017). The mean length of time of DM diagnosis was 23.3 years, ranging from three to 45 years. This long diagnosis time differs from the studies found in the literature consulted, in which the mean diagnosis time varied between 6.62 years (Leite et al., 2015) and 19.4 years (Gomides, Villas-Boas, Coelho & Pace, 2013).

In both groups, 76.7% of people take insulin. This rate is lower than that found in the study conducted by Gomides et al. (2013) and the study conducted by Villas-Boas et al. (2012), with 94.3% and 88.3% of participants taking insulin, respectively. The rate we found is however similar to that found in studies conducted by Ribu et al. (2007), Souza et al. (2012), Figueira, Villas-Boas, Freitas, Foss & Pace (2012), Sekhar et al. (2015) and Pedras et al. (2016). Taking insulin is often associated with greater psychological suffering in these patients (Santos et al., 2014), as well as with feelings of guilt, anger, fear and frustration for not having managed to achieve adequate blood sugar control without this form of treatment (Brod, Kongsø, Lessard & Christensen, 2009). In a systematic review of the literature, Gusmai, Novato & Nogueira (2015) reported that insulin use was among the main indicators of worsening quality of life in this population, whereby its use was related above all to pain during application. When evaluating quality of life using B-PAID, Ramalho, Marques, Silva & Silva (2017), found a mean score of 29.3 for those who did not use insulin and 46.1 for insulin users. In our study, 35.7% of patients who did not use insulin and 52.2% of those who did use insulin had a score ≥40, demonstrating that the use of this treatment has a negative impact on the quality of life of these patients.

Among non-ulcerated lesions and alterations to the feet, nail dystrophy was mentioned by 90%, deformities by 76.7%, hyperkeratosis by 61.7% and fissures by 41.7% of the total sample. These complications are strong predictors of ulceration (Boulton et al., 2008). Bus et al. (2016) recommend that corns be removed, that blisters be protected and drained when necessary, that bleeding and ingrown or thickened nails be treated and that patients with these complaints be assessed by a specialized team every 1-3 months in order to prevent severe complications such as infections and hospitalizations.

They also emphasize that the cost of these preventive treatments is low and that comprehensive foot care includes adequate foot ware and education on self-care. This endorses the procedures and guidance adopted at the

outpatient clinic described in this study, where patients' feet are examined, ulcerated and non-ulcerated lesions are treated and guidance on care at home is emphasized during each appointment. Furthermore, patients and their family members always receive guidance on the need to seek medical care within the first 24 hours after an ulcer appears.

When analyzing amputations among the patients in our study, we found that 15 individuals (25% of the population studied) had some degree of amputation of the lower limbs, this being lower than the result found in the study conducted by Pedras et al. (2016), 57.9% of individuals who had already been amputated. In view of the results of our study, in can be inferred that monitoring by a specialized diabetic foot outpatient clinic has collaborated with patients achieving health gains and has reduced impacts in terms of amputation rates.

The mean B-PAID score of the participants in our study was 40.7. This was higher than the score found using the same instrument in the studies conducted by Bernini et al. (2017) and by Souza et al. (2012), where mean scores were 19 and 32.5, respectively.

In the analysis of the relationship between B-PAID score (≥40) and socio demographic variables, we found significant correlation with the female sex (p= 0.014), with 71.4% of women compared to just 35.9% of men having a score ≥40. These percentages are considerably higher than those found by Silva and Almeida (2016) where only 33.3% of women and no men had a score above 40. They are also higher than those found by Gross, Gross & Goldim (2010) where only 13.2% of women and 8.5% of men had a score ≥40. The higher score among women may be related to hormonal factors and to the role of women in the family and society.

When analyzing the relationship between B-PAID score (≥40) and lifestyle variables, we found statistically significant correlation with physical activity (p= 0.019), as did Souza et al. (2012), suggesting that people with diabetes can improve their quality of life by practicing physical activities regularly.

When we assessed B-PAID score and comorbidities we found significant correlation with obesity, CVA, kidney disease, arterial insufficiency and, above all, with the number of comorbities present in each patient, resulting in greater emotional suffering in patients with these conditions. According to Ramalho et al. (2017), presence of comorbidities appears to be the main determinant in the way in which patients assess their well-being and satisfaction. The limitations of this study were its cross-sectional design, absence of a control group, sample size and sample homogeneity. Future research should be encouraged to have larger population samples, control groups, more heterogeneous populations and a longer follow-up time.

We conclude that the quality of life of the patients attending the diabetic foot outpatient clinic is impacted, above all by the presence of feet ulceration and by the number of comorbidities. Nevertheless, the focus of our work is not only on treating ulcers, but rather it is undertaken holistically and with responsibility in relation to human beings, reaffirming that nursing is directed towards care by working with prevention and treatment.

6. Final Considerations

Health education is a practice inherent to a nurse's work. It is a resource in the attempt to improve quality of life and one of the mainstays of the treatment of diabetic patients. A nurse's work is not limited to passing on information, but rather building knowledge, enabling patients to understand the causes of their illness, in search of solutions and critical analysis of the events that occur over time with DM.

We hope that this study will contribute to helping interventions that enable improved quality of life and selfcare of people with diabetes, whether or not they have ulcerations.

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