



Article

Predictors of quality of life in patients with diabetic foot ulcer: The role of anxiety, depression, and functionality

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Abstract

The goal of this study was to analyze the relationships between anxiety, depression symptoms, and functionality as predictors of quality of life, in patients with diabetic foot ulcer taking in consideration clinical variables. A sample of 202 participants indicated for a lower limb amputation surgery, were assessed before the surgery, on physical and mental quality of life, functionality, a anxiety and depression symptoms. Anxiety and depression symptoms, as well as functionality level were predictors of mental quality of life. Pain, having a first amputation, depression symptoms, and functionality were predictors of physical quality of life. In order to promote quality of life, psychological variables should be targeted, in clinical practice.

Keywords

anxiety, depression, diabetic foot ulcer, functionality, quality of life

Introduction

In Europe, 8.3 percent of the adult population has diabetes (International Diabetes Federation (IDF), 2013) and in Portugal, about 13 percent of the population (Portuguese Society of Diabetes, 2015). Diabetic foot is a complication of diabetes and diabetic foot ulcer (DFU) is the term used to name the lesions that can occur in a patient's foot. The foot of a patient with diabetes that has the potential risk of pathologic consequences, including infection, ulceration, destruction of deep tissues associated with neurologic abnormalities, several degrees of peripheral arterial disease, and metabolic complications of diabetes, in the lower limb, is called Diabetic Foot. (Frykberg et al., 2000).

The most frequent etiologies of DFU are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease (Frykberg et al., 2000).

DFU is one of the most serious complications of diabetes and affects 15 percent of patients with diabetes representing the major cause of lower limb amputation from a non-traumatic

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origin (Armstrong et al., 2001). DFU is associated with several comorbidities related with long periods of hospitalization with great impact on the individuals' life, increased economic and social costs (Apelqvist et al., 2008), and a burden for families and the health care system (Margolis et al., 2011). In fact, the negative impact of DFU on patients' health-related quality of life (HRQoL) is a major concern for health professionals.

It is well known that several factors influence the impact of DFU on HRQoL including demographic and clinical characteristics (Ribu et al., 2007), and that DFU patients have an impaired HRQoL when compared with those without DFU (Goodridge et al., 2005, 2006; Ikem et al., 2009; Madanchi et al., 2013; Ribu et al., 2007; Valensi et al., 2005; Yekta et al., 2011). In fact, DFU affects patients' physical HRQoL mainly due to pain and to the reduced level of mobility (Ashford et al., 2000; Ribu and Wahl, 2004; Siersma et al., 2013). The impact of DFU on HRQoL and level of mobility is so strong that amputees who have mobilization capacities have a higher HRQoL than patients with DFU (Carrington et al., 1995, 1996). Pain, which progressively deteriorates the HRQoL of DFU patients, is also a concern for patients and health professionals (Bengtsson et al., 2008; Bradbury and Price, 2011; Siersma et al., 2013; Vileikyte et al., 2005).

Furthermore, DFU negatively affects emotional and psychological functioning (Douglas, 2001; Price, 2004; Ribu et al., 2007; Valensi et al., 2005; Yekta et al., 2011) and the severity of the impact on mental functioning is comparable to other serious medical problems (e.g. cancer) (Armstrong et al., 2007, 2008; Nabuurs-Franssen et al., 2005). Some studies, however, found that patients with DFU showed good mental health (Fejfarová et al., 2014; Meijer et al., 2001; Siersma et al., 2013). Nonetheless, psychological morbidity (anxiety and depression symptoms) is another factor that negatively affects HRQoL in this population, mainly due to reduced mobility (Ikem et al., 2009; Siersma et al., 2013; Vileikyte et al., 2005). Patients with DFU present high levels of anxiety and

depression at levels consistent with clinical depression (Chapman et al., 2014; Ismail et al., 2007; Vileikyte et al., 2005). Having a DFU, and the reduced mobility associated with it, is related with depressive symptoms (Williams et al., 2010) which also decrease adherence to foot care behaviors (Iversen et al., 2009; Nam et al., 2011), increasing the risk of poor wound healing and wound recurrence (Monami et al., 2008). In fact, major depression is associated with a two-fold higher risk of incidence of DFU (Williams et al., 2010). The literature on anxiety, among patients with diabetes-related foot ulcers, is limited but the few existing studies reveal that anxiety symptoms are more prevalent in patients with unhealed DFU (Ragnarson-Tennvall and Apelqvist, 2000), and no differences have been found in anxiety symptoms between patients with DFU, patients who underwent an amputation or patients with diabetes (Carrington et al., 1996).

A number of publications have addressed the relationship between demographic and clinical factors of HRQoL, in DFU patients (Ikem et al., 2009; Ribu et al., 2007; Valensi et al., 2005; Yekta et al., 2011). However, to our knowledge, no data is currently available regarding the HRQoL of patients with DFU indicated for amputation surgery since they make a specific group. Also, the gap in the literature lies particularly in the absence of studies that explore the impact of psychological factors besides sociodemographic and clinical variables, on HRQoL. It is of great importance to assess the impact of anxiety and depression symptoms with regard to their influence on HRQoL. It is known that the physical quality of life deteriorates more than mental health due to multimorbidity (Fortin et al., 2006). Therefore, this study also took into consideration the role of mobility difficulties as one of the most important determinants of poor HRQoL. According to the biopsychosocial model, the care of individuals with DFU should include not only the management of physical symptoms, but also a focus on the psychological and social factors (Engel, 1977), that may interfere with the effectiveness of treatments, adherence to self-care behaviors, and wound healing

(Vedhara et al., 2010). Thus, the purpose of this study was to enhance the understanding of the impact of psychological morbidity and functionality on HRQoL, in DFU patients scheduled for amputation. Knowing the predictors of mental and physical HRQoL will allow the identification of targets to promote HRQoL, in this population. It is hypothesized that DFU patients will show an impaired HRQoL and that anxiety and depression symptoms, as well as functionality, will contribute to both physical and mental HRQoL.

Methods

Procedure

This study was conducted in six hospitals, in northern Portugal, within Multidisciplinary Diabetic Foot Clinics and/or Vascular Surgery Departments. This was a cross-sectional study although it is part of an ongoing longitudinal design, and was performed between June 2013 and September 2015. Participation was voluntary and involved the signing of a written informed consent and approval by the Hospital Research Ethics Committee. Participants were assessed in the hospital after knowing they needed an amputation. Health professionals identified 277 participants that met the following inclusion criteria: having type 2 diabetes mellitus (T2DM) and DFU, be indicated for an amputation surgery, and be more than 18 years old. Exclusion criteria included a diagnosis of dementia or a psychiatric disorder. Clinical data for each patient was collected from clinical records, as well as information regarding the level of cognitive impairment (e.g. dementia) and the presence of severe psychiatric disorders (e.g. schizophrenia).

Sample

A consecutive sample, of 202 participants with T2DM and DFU scheduled for a lower limb amputation, was enrolled in the study and assessed on hospital admission. From 277 patients who were identified by health professionals to comprise the study, only 202

participated since 75 (37%), were not included due to several reasons: 39 participants had cognitive impairment; 7 refused participation, 5 had their surgeries canceled; 2 died prior to surgery; 1 patient was in the intensive care unit; 2 participants were transferred to a different hospital; 2 participants showed hearing loss, and 17 received emergency amputations and were excluded due to procedural reasons.

Instruments

Socio demographic and clinical questionnaire. This instrument included questions on gender, age, education, marital, and professional status. The clinical section asked questions concerning diabetes and DFU onset, presence of other diabetes complications other than neuropathy and vascular disease (nephropathy and nephrology), and presence of other medical conditions than diabetes and its complications, type of foot, ulcer duration and location, number of hospitalizations in the previous year, duration of the current hospital admission, body mass index (BMI), presence and duration of pain, and number of previous amputations. Pain was assessed through a question with a dichotomous answer (y/n). Type of foot was classified as neuropathic or neuroischemic. The main difference between the two types of diabetic foot lies in the absence or presence of pulses; the neuropathic foot has peripheral pulses and loss of sensation while the neuroischemic foot has no pulses (Edmonds and Foster, 2006).

Hospital Anxiety and Depression Scale. This scale assesses psychological morbidity (depression and anxiety) on a 14-item scale: seven items for anxiety (e.g. "I feel tense or wound up"; "Worrying thoughts go through my mind") and seven items for depression (e.g. "I enjoy the things I used to enjoy"; "I have lost interest in my appearance") (Zigmond and Snaith, 1983; Portuguese adapted Version of Pais-Ribeiro et al., 2007). The score for each scale ranges from 0 to 21 and each item has a choice of four response statements (scored 0–3). Higher scores indicate higher levels of anxiety

and depressive symptoms, respectively. The Portuguese validation included an inspection for lexical equivalence and content validity, cognitive debriefing, exploratory and confirmatory factor analysis, as well as sensibility. The Portuguese adaptation showed metric properties similar to those in international studies, suggesting that the constructs are measured the same way as the original HADS. A score above 11 is the cutoff for the presence of clinical depressive and anxiety symptoms or a mood disorder in the Portuguese validation (Pais-Ribeiro et al., 2007). In this study, Cronbach's alpha for the anxiety scale was .85 and .88 for the depression scale.

Barthel Index. This scale assesses the functionality level for activities of daily living (ADLs), such as the functionality to transfer, mobility, bladder and bowel control, grooming, dressing, feeding, bathing, toilet use, and stair climbing (Mahoney and Barthel, 1965; Portuguese Version of Araújo et al., 2007). The scale comprises 10 items. Typical Barthel Index (BI) items are as follows: feeding, 0: "unable"; 1: "needs help cutting"; 2: "independent." Responses range from: 0 to 3 or 0 to 2, according to the number of items with the total possible scores ranging from 0 to 20. Lower scores indicate increased disability and higher scores indicate higher levels of functionality and independence. In this study, Cronbach's alpha for the scale was .87. According to the adapted Portuguese version, the cutoff scores are as follows: 0–8: "dependency"; 9–12: "severe dependency"; 13–19: "mild dependency"; and 20: "independency" (Araújo et al., 2007).

Short-Form Health Survey 36. This scale assesses quality of life and comprises 11 items, 36 questions, and two summary measures that aggregate eight scales (Ware et al., 1993; Portuguese adapted version of Ferreira et al., 2012). The scale has a self-evaluated health transition item with five response categories ranging from "much better" to "much worse," which is not used in scoring the scales or

summary measures. The Physical Component Score (PCS) comprises 21 items and includes four scales: Physical Functioning, Role Physical, General Health, and Bodily Pain scales (e.g. "During the past 4 weeks, how often have you experienced any of the following problems with your work or other regular daily activities as a result of your physical health?"; "During the past 4 weeks, how much has pain interfered with your normal work (including both work outside the home and housework)?" Responses, in the Likert scale ranged from, "all of the time=1," "most of the time=2," "sometime=3," "a little of the time=4," and "none of the time=5" and "not at all=1," "a little bit=2," "moderately=3," "quite a bit=4," and "extremely=5," respectively. The Mental Component Score (MCS) comprises 14 items and includes four scales: Vitality, Social Functioning, Emotional Role and Mental Health. Typical MCS items are as follows: "During the past 4 weeks, how long have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?" and "Have you been very nervous?" Responses in the Likert scale, ranged from, "all of the time," "most of the time," "some time," "a little of the time," and "none of the time." In this study, only the two summary components were used. Total possible scores range from 21 to 87 in the PCS and from 14 to 70 in MCS, with a higher score indicating a higher HRQoL. The scores in both summary measures were transformed into a scale of 0–100 (raw score) following the instrument's guidelines and results were analyzed in terms of being above or below the 50th percentile. The Cronbach's alpha in this study, .89 for both PCS and MCS.

Data analysis

Analyses were conducted using SPSS version 22 (IBM Corporation, 2013). Descriptive sociodemographic clinical data and psychosocial variables are presented as means and standard deviations (SDs). The cutoff points

Table 1. Sample demographic and clinical characteristics (N=202).

	Mean (%)	SD	Min	Max
<i>Demographic characteristics</i>				
Gender (male)	72.3%			
Marital status (living with partner)	62.90%			
Professional status (retired)	75.30%			
Age (years)	66.2	10.94	36	90
Educational level (years)	4.56	3.18	0	17
<i>Clinical characteristics</i>				
Duration of diabetes (months)	224.4	138.2	1	636
Duration of diabetic foot (months)	43.70	56.0	1	264
Ulcer duration: median/mean (weeks)	11/18.26	22.46	1	192
Ulcer location				
Toes	62.90%			
Foot	29.20%			
Leg/heel	8%			
Type of foot: neuroischemic	74.3%			
Retinopathy	63.4%			
Nephropathy	47%			
Other chronic disease: no	77.7%			
Insulin therapy: yes	68.3%			
Pain: yes	58.90%			
Pain duration (weeks)	23.1	22.0	1	96
BMI (kg/m ²)	26.99	4.63	17.19	46.28

of the instruments were used to characterize HRQoL, clinical symptoms of anxiety and depression, and functionality level. To analyze the relationships among demographic, clinical, and psychological variables, Pearson and Point Biserial correlations were performed for interval and dichotomous variables, respectively. In order to find the best predictors of MCS and PCS, a hierarchical regression analysis was conducted. The variables correlated with MCS and PCS were included in the model as well as the variable, "having a first amputation" which was not related either with MCS or PCS but due to its relevance in the literature, was added to both models. Therefore, the first step included sociodemographic variables, the second step

Table 2. Descriptive statistics for psychosocial variables.

Measure	Min	Max	Mean	SD
PCS	21	87	45.13	12.46
MCS	14	70	43.05	11.64
Anxiety symptoms	0	21	11.46	5.14
Depressive symptoms	0	21	9.34	5.90
Functionality	0	20	15.52	3.73

included clinical variables, and the third step included all psychological variables. To control for multicollinearity, the variance inflation factor (VIF) value was established as being below 2 and the tolerance coefficient was set to be greater than .60.

Results

Sample demographic and clinical characteristics

Of the 202 patients, 57.9 percent had already been amputated, in the past. All the participants were taking oral agents. The duration of current admission was 8.98 days (SD: 9.9). Table 1 shows the sociodemographic and clinical characteristics of the sample.

Descriptive statistics for psychosocial variables

Descriptive statistics for psychosocial variables are presented in Table 2. Short-Form (SF)-36 summary scores after being transformed into a scale ranging from 0 to 100, with a mean of 50 and a SD of 10, participants scored below the percentile 50 in the PCS (36.56%) and slightly above in MCS (51.88%), that is, on average. Taking into account the cutoff score of 11, for the presence of clinical symptoms of anxiety and depression, the proportion of participants with clinical symptoms of anxiety was 59.9 percent and 37.6 percent for clinical depressive symptoms. Regarding the functionality level, only 18.3 percent showed independency, 62.4 percent reported a mild level of dependency,

14.9 percent, severe dependency, and 4.5 percent were totally dependent.

Relationships between sociodemographic, clinical, and psychosocial variables

Positive relationships were found between MCS and type of foot ($r=.168, p=.017$) and functionality ($r=.498, p<.001$). Negative relationships were found between MCS and gender ($r=-.294, p<.001$), age ($r=-.191, p=.006$), number of hospitalizations in the last year ($r=-.194, p=.006$), presence of pain ($r=-.224, p=.001$), depression ($r=-.720, p<.001$), and anxiety symptoms ($r=-.498, p<.001$).

PCS was positively associated with type of foot ($r=.255, p<.001$) and functionality ($r=.606, p<.001$) and was negatively associated with gender ($r=-.254, p<.001$), age ($r=-.307, p<.001$), number of hospitalizations in the last year ($r=-.273, p<.001$), presence of pain ($r=-.469, p<.001$), ulcer duration ($r=-.151, p=.032$), depression ($r=-.502, p<.001$), and anxiety symptoms ($r=-.267, p<.001$).

Predictors of MCS

The regression analysis showed that anxiety and depression were negative predictors and that functionality was a positive predictor of MCS. The final model explained 63 percent of the variance ($R^2_{Adj}=.61, p<.001$), $F(9,192)=35.70, p<.001$, and when psychological variables were added to the model, sociodemographic and clinical variables were no longer significant (Table 3).

Predictors of PCS

The regression analysis showed that pain and depression symptoms were negative predictors and having a first amputation as well as the level of functionality, were positive predictors of PCS. The final model explained 57 percent of the variance ($R^2_{Adj}=.54, p<.001$), $F(10,191)=25.02, p<.001$ (Table 3).

Discussion

HRQoL is an important health outcome representing the ultimate goal of health promotion interventions (World Health Organization, 2009). Thus, according to SF-36, DFU patients presented a compromised PCS since they scored below percentile 50, and an average MCS since they scored slightly above the percentile 50. Similar findings have been reported by several other studies which found HRQoL scores to be lower for patients with DFU (Ribu et al., 2007; Valensi et al., 2005; Vileikyte et al., 2003, 2005; Yekta et al., 2011). In this study MCS was higher than PCS. This result is interesting, given that the commitment to PCS is obvious and expected in patients with unhealed DFUs, yet MCS was not as compromised as we had expected it to be. However, Meijer et al. (2001) also did not find psychological complaints in patients with DFU and suggested they had accepted the disability and learned to live with their condition.

The results showed a relationship between anxiety symptoms, depression symptoms, functional level, and MCS and PCS, which are in accordance with the literature (Chapman et al., 2014; Ikem et al., 2009; Siersma et al., 2013; Vileikyte et al., 2005; Williams et al., 2010). In fact, this sample is characterized by high levels of clinical symptoms of anxiety and depression during hospitalization due to DFU although the percentage of patients with clinical symptoms of anxiety was higher than the percentage of patients with clinical symptoms of depression. This result should be read in view of the clinical status of patients since they were indicated for an amputation surgery and therefore, might have felt more anxious about their physical condition, having a pessimistic vision of their future's health and concerned whether they would be able to change their lifestyle. Also, these patients were waiting for a surgery, in the following days and, therefore, might be experiencing high levels of pre-surgery anxiety (Bally et al., 2003). Concerning functionality level, 81.7 percent of patients showed some degree of dependence on ADLs, which confirms the negative impact and

Table 3. Hierarchical multiple regression with MCS and PCS as dependent variables (N=202).

Variables	B	SE B	β	R ² _{Adj}	ΔR ²	B	SE B	β	R ² _{Adj}	ΔR ²
<i>MCS</i>						<i>PCS</i>				
1 Step				.11	.11***	1 Step			.14	.15***
Gender	-7.262	1.735	-.280***			-6.422	1.823	-.231**		
Age	-0.179	0.071	-.169*			-0.328	0.075	-.288***		
2 Step				.16	.07**	2 Step			.37	.24***
Gender	-6.881	1.705	-.265***			-5.355	1.585	-.193**		
Age	-0.135	0.074	-.127			-0.207	0.069	-.182**		
Number hospitalizations	-2.513	0.944	-.185**			-3.037	0.877	-.208**		
Presence of pain ^a	-2.940	1.638	-.125			-9.330	1.527	-.369***		
First amputation ^b	0.257	1.662	.011			3.209	1.545	.127*		
Ulcer duration	-	-	-			-0.030	0.032	-.055		
Type of foot ^c	2.500	1.785	.094			3.390	1.662	.119*		
3 Step				.61	.44***	3 Step			.54	.18***
Gender	-1.573	1.219	-.061			-2.224	1.407	-.080		
Age	0.042	0.053	.039			-0.027	0.062	-.024		
Number hospitalizations	-0.691	0.661	-.051			-1.470	0.764	-.101		
Presence of pain ^a	-0.795	1.137	-.034			-7.229	1.320	-.286***		
First amputation ^b	-0.300	1.136	-.013			2.820	1.313	.112*		
Ulcer duration	-	-	-			-0.052	0.027	-.094		
Type of foot ^c	0.511	1.224	.019			2.088	1.418	.073		
Anxiety	-0.592	0.109	-.262***			-0.247	0.126	-.102		
Depression	-1.003	0.106	-.509***			-0.357	0.123	-.169**		
Functionality	0.617	0.170	.198***			1.214	0.197	.363***		

^aYes=1/No=0.

^bYes=1/No=0.

^cNeuropathic foot=1/Neuroischemic foot=0.

*p<.05; **p<.001; ***p<.000.

the restrictive features of DFU, as previous studies have reported (Reiber et al., 1998). In fact, only a small part of patients were totally functional for ADLs. Given the well-known association between depressive symptoms and reduced mobility, the results found in this sample come as no surprise (Vileikyte et al., 2005). However, contrary to our expectations, a history of previous amputation was not correlated with PCS or MCS. This result should be pursued in future studies.

Regarding the predictors of PCS, the demographic variables such as male gender and being younger, as well as the clinical variables like fewer hospitalizations in the previous year, not having pain, having a neuropathic foot and a first amputation, were significant predictors of PCS, which is in accordance with previous

studies (Akca and Cinar, 2008; Mayfield et al., 2003). However, when the psychological variables were added, the variance explained by the model increased, highlighting the role of psychological variables, such as less depression and higher functionality, on PCS. The reduction in mobility and functionality, as well as the adjustment to a new lifestyle, characterized by limitations, are two major risk factors for an increase in depressive symptoms (Vileikyte et al., 2005) and a decrease in PCS (Ashford et al., 2000; Ribu and Wahl, 2004). However, absence of pain and having a first amputation remained predictors of PCS, as expected.

Regarding MCS, only the psychological variables played an important role for physical and mental well-being. As in the prediction model of PCS, the demographic and clinical variables

were significant predictors until the psychosocial variables were added to the model. As expected, less psychological morbidity and high functionality were significant predictors of MCS. Moreover, and contrary to PCS, in the MCS's prediction model, none of the demographic and clinical variables were significant predictors. Thus, the contribution of psychological variables to MCS was higher than to PCS. Future studies should analyze whether clinical variables play a role as mediators in the relationship between psychological variables and HRQoL.

The results reveal the simultaneous influence of sociodemographic, clinical, and psychological variables on MCS and PCS as the biopsychosocial model advocates. This study has several implications for clinical practice. In patients with DFU, it is important to address patients' clinical and psychological state as well as the level of functionality. In fact, DFU should be considered a lifelong condition since patients with previous ulcers are at a higher risk of developing a new ulcer (Apelqvist et al., 1993), and undergo a contralateral amputation or a re-amputation (Johannesson et al., 2009).

HRQoL should be assessed in routine medical care in order to early identify patients at risk of a reduced HRQoL. The assessment of both mental and physical quality of life should also be included in interventions designed to promote HRQoL. Since functionality level and mobility have a great impact on physical and mental health, rehabilitation programs (e.g. physiotherapy, vocational therapy) should be offered in order to enhance independence and decrease the negative impact of disability on HRQoL, in DFU patients. Finally, a multidisciplinary intervention should be mandatory especially for those patients with DFU indicated for lower limb amputation.

Limitations

The sample was collected only in hospitals in the North of the country. The nature of the study design does not allow causal relationships. Thus, in future studies, it is important to follow patients from pre-surgery to post-surgery during the rehabilitation process in order to explore

the contributions of anxiety and depression symptoms as well as functionality on HRQoL, using a longitudinal design. Future studies should also focus on which specific areas of HRQoL are most affected, in this population.

Conclusion

The results highlight the contribution of psychosocial variables for HRQoL and the need for psychological intervention, in order to decrease anxiety and depression symptoms, in patients with DFU. Results also suggest that rehabilitation programs should begin as early as possible in order to increase functionality for ADLs and promote HRQoL. According to results, the factors that determine HRQoL, in DFU patients, are not only disease specific. Treatment, therefore, should not only be focused on ulcer healing, but also based in a multidisciplinary approach that includes psychological factors.

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