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Quality of Life in Portuguese Patients with Diabetic Foot Ulcer Before and After an Amputation Surgery

Susana Pedras[1] · **Rui Carvalho**[2] · **M. Graça Pereira**[1]

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Abstract
Purpose Diabetic foot ulcer (DFU) including amputation surgery has serious consequences for patients, the family and healthcare services. DFU affects not only the physical health-related quality of life (HRQoL) of patients but also their mental well-being. The aims of this study were to find the predictors of HRQoL after surgery, to analyse differences in HRQoL, before and after surgery, and to explore the moderating role of a first versus previous amputation(s) in the relationship between physical and mental HRQoL, before and after surgery, in patients with DFU.
Method A longitudinal study comprising 108 Portuguese patients was conducted during the period of hospitalization before the surgery and at a follow-up consultation. Participants completed a socio-demographic questionnaire and the SF-36 to assess HRQoL.
Results Physical and mental HRQoL before surgery predicted HRQoL after surgery, as well as the number of diabetes complications and having received a re-amputation. Physical HRQoL decreased after surgery, but there were no differences on mental HRQoL. Having a previous amputation was a moderator between physical and mental HRQoL before and after surgery.
Conclusion The results help to identify the most vulnerable patients at risk of having lower HRQoL after surgery, allowing interventions to be tailored to patients' needs in order to promote their quality of life.

✉ Susana Pedras
susanapedras@gmail.com

[1] School of Psychology, University of Minho, Braga, Portugal

[2] Multidisciplinary Diabetic Foot Clinic, Centro Hospitalar do Porto, Porto, Portugal

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Introduction

In Portugal, 13 % of the population suffers from diabetes. According to the Portuguese Diabetes Society [1], in 2014, there were 1863 admissions to hospitals across the country related to diabetic foot ulcers and 1835 amputations (560 major and 825 minor). Diabetic foot ulcer (DFU) implies serious consequences for patients, family and healthcare services [2, 3]. As a result, it is imperative to understand the characteristics that contribute to the health-related quality of life (HRQoL) of this target population in order to develop strategies and multidisciplinary intervention programmes.

Current literature suggests that DFU affects not only the physical HRQoL of patients, as expected, but also their mental well-being [4]. Patients with DFU present a greater impairment of HRQoL when compared with those without DFU [5–8] in social, psychological, physical and economic domains [9]. Reduced mobility and the changes in lifestyle contribute to a decrease in HRQoL in this population [10–12]. However, mental HRQoL presents some levels of impairment which are not as linear as would be expected [3, 11–20]. Some studies have shown that the impact of DFU on HRQoL and level of mobility is so strong that amputees with mobilization capacities have a higher HRQoL than patients with DFU [21, 22]. In fact, compared with a control group of patients with diabetes, patients with DFU and those who have been submitted to amputation rated their HRQoL significantly poorer for physical functioning, but the mean scores for the DFU group were lower than those who had been submitted to an amputation [23].

Previous studies have focused on the differences in HRQoL in patients with and without DFU and suggested that this issue should be further analysed as it is considered a challenge for health professionals regarding the intervention and rehabilitation plans, particularly, for patients with DFU that are going to be amputated. To our knowledge, no comprehensive description of socio-demographic and clinical data regarding Portuguese patients with DFU indicated for an amputation surgery in terms of quality of life (assessed by the Short Form Health Survey), has been provided as well as data regarding the predictors of HRQoL, after surgery. It is intuitive that patients with DFU have a compromised HRQoL. Yet, it remains unknown which are the contributors of HRQoL before the surgery besides the socio-demographic and clinical variables. Thus, the aims of this study were to study whether HRQoL before surgery contributed to HRQoL after surgery, controlling for socio-demographic and clinical variables in patients with DFU, to test differences in HRQoL before and after surgery, as well as to analyse the moderating effect of having a first amputation in HRQoL after surgery. Knowing the predictors and the moderators between HRQoL before and after surgery will help to identify patients at risk and would be valuable for tailoring psychological interventions to promote patients' quality of life.

Materials and Methods

Study Design

The data presented in this study is based on a baseline assessment of an ongoing longitudinal study that evaluates the adjustment to amputation and HRQoL in patients with DFU before being amputated and 2 years after the surgery.

Participants and Procedure

A sample of 108 participants with type 2 diabetes mellitus and DFU indicated for an amputation surgery were assessed during hospitalization before surgery (81 % of the sample was assessed on the day of the surgery) and after surgery, during a follow-up consultation at the hospital, approximately 1 month after.

Health professionals (nurses and physicians), in the hospitals where the research was being conducted, identified the participants who were hospitalized with indication for an amputation surgery. Patients were invited by the researchers to participate in the study. Participants were hospitalized for a mean of 9.17 days (SD = 9.84). The amputation was due to a neuropathic or neuroischaemic ulcer, which defines the foot as a neuropathic or neuroischaemic foot [24].

The study was conducted between June 2013 and April 2015 in six hospitals at the diabetic foot multidisciplinary clinics and two vascular surgery departments. Assessment interviews were performed by a health psychologist. The inclusion criteria were having type 2 diabetes and DFU, being indicated for an amputation surgery, having no diagnosed psychiatric disorder, being more than 18 years old and being able to understand written information and provide verbal answers. The study was approved by the ethical committees of the hospitals where data collection took place, and all participants were previously informed about the study. Participation was voluntary and involved the signing of an informed consent form. The following instruments were used:

Socio-demographic questionnaire. This questionnaire included questions on age, gender, educational level, marital and professional status.

Clinical questionnaire. This questionnaire included questions concerning the duration of diabetes and DFU diagnostic, active ulcer duration, number of diabetes complications and previous amputations, presence of other chronic diseases, insulin therapy, HbA1c value, BMI, presence of cardiovascular risk factors and re-amputation. Re-amputation occurs when patients have to be submitted to another amputation beyond the first scheduled amputation during the same hospitalization stay.

Short Form Health Survey [25, 26]. This scale assesses two summary measures of quality of life: the physical component score (PCS) and the mental component score (MCS) and comprises eight scales: physical functioning, role limitation due to physical health, bodily pain problems, general health perception, vitality, social functioning, role limitation due to emotional functioning and mental health. The first four scales reflect the perception of physical health status, and the remaining four the perception of psychological well-being. The instrument includes 11 items and 36 questions with a subscore for each subscale. The scores in each domain are transformed into scales of 0 to 100 and a high score indicates a good HRQoL in PCS and MCS. The Cronbach's alpha in this study for both summary components score was .89. The original version has good reliability proprieties and the coefficient's median of reliability applied through test-retest equals or exceeds .80, with the exception of the social function scale of .76, which reveals a good reliability. Also, the correlations between each item and the scale equals and exceed the cut-off point of .40, leading to a good general rate of internal consistency [27].

Statistical Analysis

Analyses were conducted using SPSS version 22 [28]. To characterize socio-demographic and clinical variables, all continuous variables are presented either as

mean and standard deviation, while categorical data, as numeric and percentages. In order to meet the first goal, two regression analyses to predict outcome PCS or MCS after surgery were conducted. In the first block, the socio-demographic variables (age and gender) were introduced; in the second block, the clinical variables (number of previous amputations, ulcer duration, number of complications and re-amputation); and finally, in the third block, the baseline PCS and MCS were added in order to know the contribution of HRQoL before surgery to HRQoL after surgery. The predictor variables included in the models were those that in previous studies have shown to influence significantly the outcomes under analysis [7, 8, 16, 18]. 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. A paired *t* test was performed to test for differences in HRQoL before and after surgery. Finally, a moderation analysis was performed with a Process macro for SPSS [29].

Results

Sample Characterization

Two hundred and twenty patients having an amputation surgery were identified to collaborate in the first time of assessment. Of these, 175 gave their informed consent and 45 patients were unable to collaborate for a number of reasons: 25 patients presented cognitive impairment, 9 were in an emergency situation, 5 patients refused, 1 patient was unexpectedly transferred to another hospital and 1 patient died before the surgery, 3 patients had their surgery cancelled and 1 was in an intensive unit care. Of those 175 participants who agreed to participate, from the first assessment (before the surgery) to the second assessment (after the surgery), 67 participants withdrew, leaving a sample of 108 participants who collaborated in the two times of assessment, before and after surgery (experimental mortality from the first to second assessment was 37 %). The causes for participants' withdrawal were as follows: surgery cancellation (29), post-surgical complications and re-hospitalization in a different hospital (2), death (5), not attending the vascular or diabetic foot follow-up consultation (3), refusal to participate (6), cognitive impairment after surgery and (3) not having a vascular or diabetic foot consultation follow-up after 1 month (19). These 67 participants did not differ significantly from the remaining 108 in terms of baseline characteristics (socio-demographic and clinical variables: gender, age, previous amputations, type of foot, diabetes and diabetic foot duration, number of hospitalizations in the previous year) unless on ulcer duration, i.e. participants that did not participate in the second assessment had a longer ulcer duration.

The final sample included 108 participants with DFU. Some participants had already been submitted to an amputation ($n = 72$) and the remaining were indicated for a first lower limb amputation ($n = 103$). Current location of the ulcer was prevalent in the toes (69.4 %), followed by foot (22.2 %), heel (3.7 %) and leg (4.6 %). All patients were taking oral agents. Sample socio-demographic characteristics and clinical variables are presented in Table 1.

Predictors of HRQoL After Surgery

The multiple regression analysis showed that in the first block, socio-demographic variables explained 1 % of the variance of HRQoL after surgery, and only age appeared as a significant predictor. In the second block, only the re-amputation and number of complications, along with age, emerged as significant clinical predictors, accounting for an additional 13 % of the variance. In the final model, baseline PCS along with re-amputation, explained an additional 29 % of the variance of PCS after surgery. The final regression model explained 51 % of the variance of PCS after surgery (R^2 adj = .48, $p < .001$; $F(7, 100) = 15.05$, $p < .001$) (see Table 2).

In the PCS model, the first block with socio-demographic variables was not significant and explained 5 % of the variance. In the second block, only the number of complications emerged as a significant predictor of MCS and explained 17 % of the variance. In the final model, baseline MCS along with the number of diabetes complications were the significant predictors of mental HRQoL after surgery explaining an additional 18 % of the variance. The final regression model explained 40 % of the variance of MCS after surgery (R^2 adj = .35, $p < .001$; $F(7, 100) = 9.37$, $p < .001$) (see Table 2).

Differences on HRQoL Before and After Surgery

Physical HRQoL (PCS) decreased significantly from before surgery to after surgery ($t(107) = 3.238$, $p > .001$), in contrast to mental HRQoL (MCS) where there were no significant differences.

Moderation Analysis

Two moderated regression analyses examined whether having a first amputation moderated the relationship between PCS and MCS before and after surgery. The moderating effect of having a first amputation in the relationship between PCS before and after the surgery was tested. The model was significant, $F(3, 104) = 28.33$, $p < .001$, $b = -.327$, 95 % CI

Table 1 Baseline characteristics of the sample ($N = 108$)

Variable	Mean	SD	Min	Max
Gender (male) (%)	72.2			
Marital status (with partner) (%)	73.1			
Professional status (retired) (%)	75.0			
Age (years)	65.7	11.1	36	90
Educational level (years)	4.61	2.93	0	12
Duration of diabetes (months)	218.6	137.8	1	636
Duration of diabetic foot (months)	42.6	51.1	1	228
Ulcer duration: median/mean (weeks)	8/15.8	18.02	1	96
HbA1c ($n = 56$, ≥7.6 %) (%)	44.4		6.20	13.10
Type of foot: neuroischaemic (%)	74.1			
Number of complications (≥3) (%)	64.4			
Other chronic disease: no (%)	76.9			
Insulin therapy: yes (%)	66.3			
Cardiovascular risk factors: HTA: yes (%)	88.9			
Dyslipidemia: yes (%)	82.4			
Current smoker: no (%)	89.8			
Ex-smokers: yes (%)	56.5			
Alcohol consumption: no (%)	63.9			
Previous amputation: yes (%)	53.7		0	8
Re-amputation: yes (%)	14			
BMI (kg/m^2)	27.24	4.99	17.67	46.28

Table 2 Predictors of quality of life ($N = 108$)

Variables	Predictors of physical quality of life				Predictors of mental quality of life			
	R^2 (ΔR^2 adj)	F	β	t	R^2 (ΔR^2 adj)	F	β	t
Block 1	.09 (.07)	$F(2, 105) = 4.847$**			.05 (.04)	$F(2, 105) = 2.968$***		
Age			−.265	−2.830**			−.181	−1.900
Gender			−.106	−1.128			−.134	−1.410
Block 2	.22 (.17)	$F(6, 101) = 4.677$***			.22 (.17)	$F(6, 101) = 4.713$***		
Age			−.254	−2.814**			−.164	−1.812
Gender			−.118	−1.313			−.110	−1.226
Number of previous amputations			−.092	−.972			.106	1.125
Ulcer duration			.077	.861			.097	1.085
Re-amputation[a]			−.240	−2.688***			−.136	−1.529
Number of complications			−.218	−2.341*			−.384	−4.119***
Block 3	.51 (.48)	$F(7, 100) = 15.05$***			.40 (.35)	$F(7, 100) = 9.37$***		
Age			−.067	−.886			−.050	−.606
Gender			.080	1.053			.018	.222
Number of previous amputations			.043	.562			.108	1.290
Ulcer duration			.137	1.928			.123	1.563
Re-amputation[a]			−.256	−3.624***			−.100	−1.270
Number of diabetes complications			−.078	−1.021			−.272	−3.214**
PCS baseline			.645	7.792***			.474	5.423***

*$p < .05$; **$p < .01$; ***$p < .001$

[a] Yes = 1/no = 0

[−.577, −.077], $t = -2.59$, $p = .011$, explaining 45 % of the variance. These results showed that PCS before surgery was associated with PCS after surgery. Specifically, this association was found to be stronger for those patients who had already been submitted to previous amputations ($b = .720$, 95 % CI [.543, .896], $t = 8.08$, $p < .001$) (see Fig. 1a). In patients without previous amputations, the relationship between PCS before and after surgery was also significant ($b = .393$, 95 % CI [.215, .569], $t = 4.40$, $p < .001$) but weaker (see Fig. 1a).

In terms of the relationship between MCS before and after surgery, the moderating effect of having a first amputation versus previous amputation was also analysed. The model was significant, $F(3, 104) = 17.07$, $p < .001$, $b = -.333$, 95 % CI [−.666, −.001], $t = -1.99$, $p = .049$, explaining 33 % of the variance. These results showed that MCS before surgery was associated with MCS after surgery; specifically, this association was found to be stronger for those patients who had already been submitted to previous amputations ($b = .739$, 95 % CI [.506, .972], $t = 6.30$, $p < .001$.), (see Fig. 1b). In patients without previous amputation, a significant relationship between MCS before and after surgery was also significant ($b = .405$, 95 % CI [.168, .643], $t = 3.39$, $p < .01$) but weaker (see Fig. 1b).

Discussion

One purpose of this study was to find whether HRQoL before surgery contributed to HRQoL after surgery after controlling for socio-demographic and clinical variables, since several studies suggest that these variables are established predictors of HRQoL [7, 8, 16, 18] as well as morbidity and mortality in patients with DFU [30]. Thus, according to the results of the current study, after controlling for socio-demographic and clinical variables, physical HRQoL after surgery was predicted by physical quality of life before surgery and by re-amputation (during the same hospitalization stay). None of the other socio-demographic and clinical variables contributed significantly to HRQoL after surgery in the final model, although several studies emphasize their importance on the patients' quality of life [5–8, 13–15]. The only significant clinical variable, in the final model, was re-amputation in the same inpatient stay. Having a scheduled amputation is a rescue and inevitable procedure when no other solutions are possible, but having a re-amputation is an uncontrollable event that the patient was not expecting and, therefore, it comes as no surprise that there is a great impact on HRQoL after surgery, since it may be quite difficult to accept and cope. In fact, studies suggest that health professionals should deliver bad news in a clear manner, explaining the diagnosis and prognosis, facilitating patient's understanding, adjustment and acceptance; otherwise, the patient's process of coping may be hindered resulting in increased anxiety and depressive symptoms [31–34].

With regard to mental HRQoL after surgery, this was predicted by mental HRQoL before the surgery and number of complications. It is thus logical that these complications are associated to a longer duration of the disease, and it is possible that the psychological burden associated not only to the care of diabetic foot ulcers but also with the care of other complications reduces and affects the mental quality of life. The results of the present study emphasize the perceptions of HRQoL before surgery as fundamental predictors of HRQoL after surgery. In the Eurodiale study [30], it was found that a low HRQoL was predictive of major amputation and death. However, interestingly, a high HRQoL did not increase DFU healing.

In addition, differences in HRQoL in patients with DFU before and after an amputation surgery were found, particularly on physical HRQoL, which decreased instead of mental HRQoL that did not change. Given the decrease in mobility due to the cicatrisation process and taking into consideration what the patient needs to do after surgery to promote stump healing (e.g. rest and not putting a load on the foot), it is understandable why physical HRQoL decreased after surgery [21, 22]. Regarding mental quality of life, in a Portuguese sample of amputees, Dias [35] found that patients were moderately satisfied with their lives and that the physical HRQoL domains were more compromised than the mental domains. One may hypothesize that, over time, the psychological functioning may deteriorate and compromise more the mental quality of life but not right after the surgery. We may also hypothesize that the burden associated with a diabetic foot ulcer, the intensive treatments such as daily dressing changes, trips to healthcare centres and the suffering/distress regarding the outcome are so negative to the patient's physical HRQoL that may explain why this dimension is more affected than the emotional HRQoL [3, 12, 36–38]. In fact, according to Armstrong and collaborators [37], patients with DFU have severely impaired physical and mental functioning, comparable to those with other serious medical conditions (e.g. cancer). However, other variables such as social support, presence of a caregiver or family functioning should be studied as potential moderators or mediators in the relationship between HRQoL before and after surgery. The third goal of this study was to explore the role of previous amputation versus having a first amputation as a moderator between physical and mental quality of life before and after surgery. Results have revealed that having a previous amputation was a moderator in the relationship between HRQoL before and after surgery. Thus, it seems that having a previous amputation had a stronger effect in the relationship between HRQoL before and after surgery which is an interesting result. The emerging hypothesis is that patients already amputated

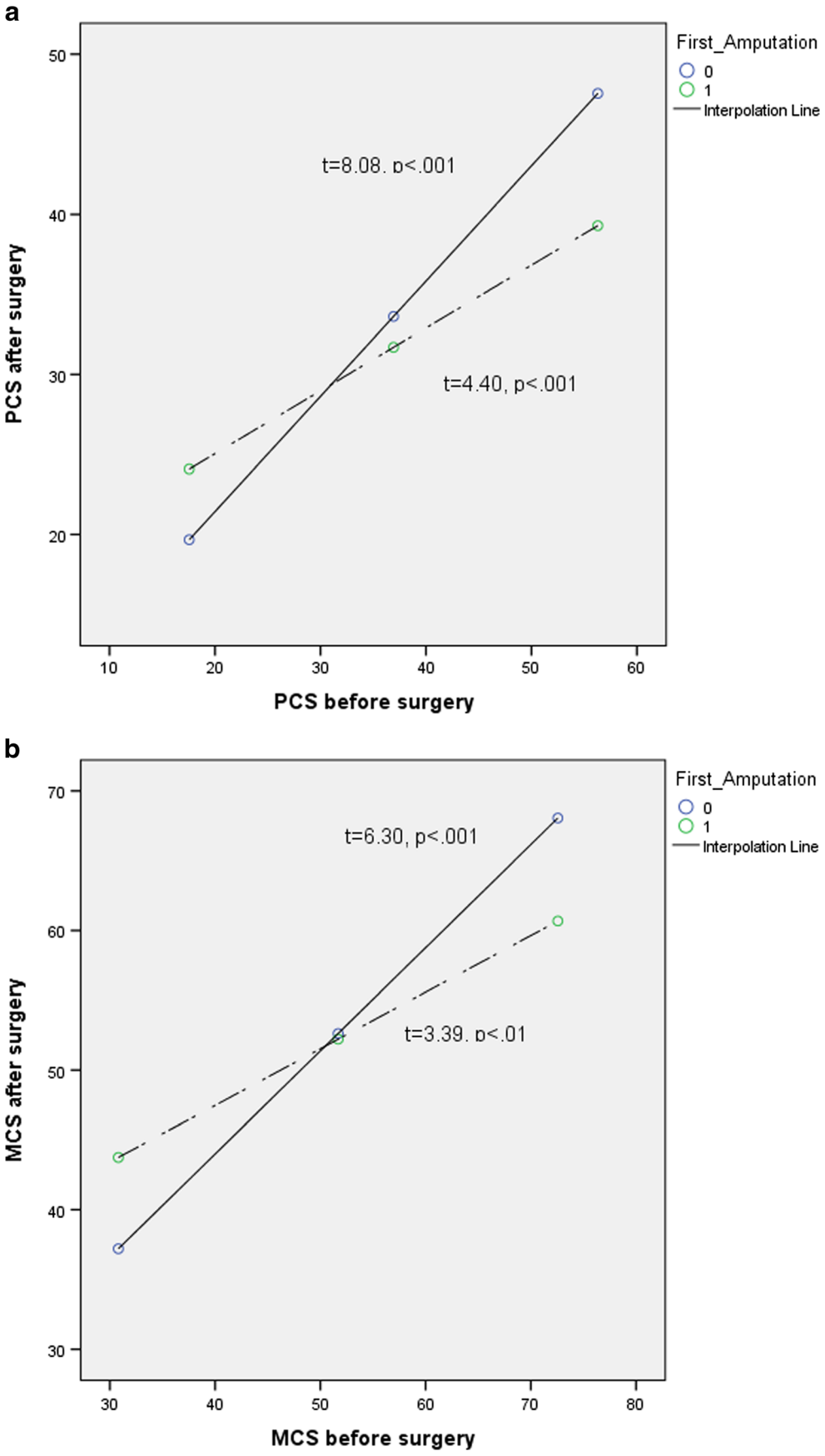

Fig. 1 **a** Graphical representations of the interaction effects of having a first amputation between PCS before surgery and PCS after surgery. **b** Graphical representations of the interaction effects of having a first amputation between MCS before surgery and MCS after surgery

are more resilient and may have more coping mechanisms to deal with another amputation than those who are going to be amputated for the first time. Furthermore, the negative effects of an amputation on HRQoL increase significantly, as the amputation becomes more proximal [39]. Future longitudinal analysis should therefore assess the moderator role of the level of amputation, on HRQoL, over time.

This study has several implications for practice regarding HRQoL in patients with DFU. Thus, the importance and utility of HRQoL assessment in patients with DFU in clinical settings is undeniable, particularly for those who are indicated for an amputation surgery due to the future possibility of a significant reduction in HRQoL, at post-surgery. However, among patients with DFU, different instruments have been used by health professionals, some more disease-specific and others more global. On one hand, a disease-specific instrument may capture the problems posed by diabetic foot complications specifically, allowing to compare results before and after surgery, and the analysis of the differences between treatments or changes along a medical and/or psychological intervention. On the other hand, a generic instrument allows the comparison of results between patients with DFU and control groups. Therefore, the choice of a specific or global instrument to assess DFU patients' HRQoL, should be focused on the provider's need of information.

The early detection of patients with a reduced HRQoL (e.g. domains more impaired) will help the health professional to identify patients that may need a detailed psychological evaluation and a tailored psychological intervention that meets the patients' needs. This clinical individualized approach will be helpful in preventing future poor outcomes. In addition, assessing patients' HRQoL may help identify subgroups of patients with DFU and which characteristics may distinguish patients who have better versus worse HRQoL.

This study has a limitation regarding the limited number of participants. It will also be important to compare the results of the present study with a control group of patients with type 2 diabetes but without DFU or amputation.

Conclusion

These results emphasize the relevance of assessing HRQoL in patients with DFU indicated for amputation, taking into account the predictive value of baseline HRQoL after surgery. In addition, in this sample, none of the socio-demographic variables were important to predict HRQoL, but two clinical variables were, although they were different for physical and mental HRQoL. In addition, physical quality of life, in patients with DFU to be submitted to an amputation surgery, decreases after surgery. However, in mental quality of life there were no changes Also, being amputated is not so harmful to the patient's quality of life after surgery, as one might think. Therefore, the results of this study are important to identify significant variables in predicting HRQoL after surgery and are valuable to tailor psychological interventions to promote patients' quality of life that take into account not only the clinical and socio-demographic characteristics but also the patients' perceptions of HRQoL.

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Compliance with Ethical Standards The authors report that the current study conformed to the Helsinki Declaration concerning human rights and informed consent and followed correct procedures concerning the treatment of humans and animals in research.

Conflict of Interest The authors declare that they have no conflict of interest.

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