

Longitudinal changes on the quality of life in caregivers of type 2 diabetes amputee patients

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Purpose: To explore changes in the quality of life of caregivers of amputees due to type 2 diabetes ten months after amputation.

Methods: This is a longitudinal study with three moments of evaluation (T1: one month after surgery, T2: 7 months, T3: 10 months). The sample comprised 110, 101, and 84 caregivers of amputated patients with type 2 diabetes. Caregivers answered a Socio-demographic questionnaire; the Self-Assessment Caregiver; the Family Disruption from Illness Scale; and the Short Form Health Survey (SF36).

Results: Stress levels were not significantly reflected in changes on mental quality of life over time, except in the caregivers who presented less stress, emphasizing the adverse role of stress when experienced on a continuous basis for ten months on the caregivers' mental well-being. Caregivers presented greater number of physical symptoms at T2 that decreased at T3.

Conclusions: According to the results, in order to promote caregivers' physical and mental quality of life, it would be important to evaluate stress levels especially in patients who presented somatic complaints.

Keywords: caregivers, stress, physical symptomatology, quality of life.

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Introduction

The American Diabetes Association reports that type 2 diabetes mellitus (T2D) is a public health problem with an epidemiological impact expressed in increased morbidity and mortality rates (1). The prevalence of diabetes in Europe has increased in the last decades, and Portugal is no exception. It is estimated that 9.2% of the population (approximately 952 000 people) suffer from this disease, predominantly men (10.7%), but women as well (7.8%), and present conditions favourable for the appearance of foot injuries (15%) (2). In Portugal, diabetes accounts for 40–60% of amputations from nontraumatic causes (2). Diabetes is often associated with complications that can lead to lower limb amputation and is considered the second major cause of amputation (3). Diabetic foot includes infection, ulceration or destruction of foot tissues due to a major vascular complication of diabetes. Amputated patients, after surgery, face great physical, emotional, social and occupational challenges, which compromises their functionality (4). After amputation, only 50–60% of

patients can live alone, and 20–30% are caregiver dependent (5).

Caregiving can influence various aspects of informal caregivers' lives on a physical, psychological, family and social level, which may include deterioration of physical health and increased stress, anxiety and depression (6). The informal caregiver provides unanticipated and unpaid care to patients and may cover all or only part of their needs (7). Caregivers provide physical care, emotional support over the course of patients' disease and instrumental support (e.g. taking the patient to the hospital and medical appointments) (8). In chronic disease, caregivers are exposed, for long periods of time, to stress factors stemming from caregiving tasks, which have an impact on their physical and mental quality of life (9).

The caregiving process may be experienced as a stressful experience, since it involves many physical, social, cognitive and emotional adjustments (10). The limitations of patients receiving care, time restriction to their own needs and overwork are some of the factors that can be stressful for the caregiver (11). Stress in caring for a chronic patient may have several consequences on the caregiver's health and well-being (12). Caregivers under stress tend to report higher amounts of depressive symptoms, anxiety, greater use of psychotropic drugs, lower life satisfaction, higher number of symptoms related to

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psychological stress and worse subjective health evaluation (11).

Being a caregiver is a demanding task and caring every day for a person affected by a chronic illness may have harmful health effects in otherwise healthy relatives (12). One of the repercussions of the caregiving process includes chronic stress (11,13) and several other disorders (14), suggesting that being a caregiver is a risk factor for mortality (9,15). The role of a primary caregiver is exercised primarily by women, either wives or daughters (15). When married people find themselves in situations of dependency, either the spouse or someone who lives with the patient will inevitably provide care (15). Sixty per cent of caregivers are over 50 years and 40% over 60 years old (15). A 50-year-old woman is usually in full physical and intellectual activity, being productive, working and involved in romantic relationships (16) as well as going through pre or menopause with all the implications and changes associated on the top of their caregiving role (17).

Chronic stress leads to the weathering of the body, with the weakening of the immune system, causing diseases, physiological dysfunctions, excessive irritability, depression and low self-esteem, among others (18). A recurrent behaviour of caregivers is to neglect their own health and to consider the patient's health as more critical than their own; studies reveal that this may be one of the ways the caregiver copes with the burden caused by the need of providing constant, full-time care (19).

Studies focused on the quality of life of caregivers show that the physical and mental health of the primary caregiver is greatly affected (20). Disorders of sleep, appetite, weight loss or increased food intake, and mood disturbances are common (21). Fatigue and somatisation are also commonly observed (22). Researchers have also noted that caregivers with diagnosed chronic diseases seem to have a deeper understanding of the rehabilitation process, particularly in terms of time and effort required, and are consequently more empathic with patients (20,21). Informal caregivers may be considered as potential patients, since being a caregiver affects several dimensions of their quality of life, as has been shown in several studies on caregiving and chronic diseases (22–24).

According to model of psychosocial adaptation to the chronic disease (25), quality of life is the result of a three-phase process of adaptation to the disease. The first phase includes antecedents, which in this study encompass the caregiver's age (25). The second phase highlights reactions to the disease, which corresponds to the stress of caregiving and to the physical symptomatology manifested by the caregiver, in the present study (25). The third phase includes the outcome variable i.e. quality of life, which, in this study, was evaluated at both physical and mental levels (25).

Given the scarcity of longitudinal studies with informal caregivers of amputated T2D patients and based on a model of psychosocial adaptation to chronic illness (25), this study aims to explore the patterns of change in the quality of life of caregivers of amputee patients due to T2D, 10 months after amputation, controlling for the associated socio-demographic variable (age) and psychological variables (stress of caregiving and physical symptomatology).

According to the reviewed literature, it is expected that higher levels of stress and physical symptomatology over time will predict lower mental quality of life and that older age, increased stress levels of caregiving and physical symptomatology over time will predict lower physical quality of life, in caregivers of amputated patients due to T2D, 10 months after amputation.

Method

Sample

One hundred and ten caregivers took part in this study 1 month after the amputation (T1), 101 were assessed 7 months (T2) and 84 were evaluated 10 months (T3) after amputation. Following approval by the ethics committees, data were collected in key hospital units in the Northern Region of Portugal. A convenience sample of caregivers of patients with T2D with diabetic foot undergoing minor or major amputation surgery was included in the sample in three distinct moments after the patient's surgery.

Procedure

This study consists of a longitudinal design with three assessment moments moment 1 (T1), 1 month after surgery; moment 2 (T2), 7 months after surgery; and moment 3 (T3) 10 months after surgery. Patients with T2D and diabetic foot who had undergone minor or major amputation surgery were identified by health professionals from the diabetic foot consultation team and invited to participate in this study. All patients agreed to contact their caregivers, who were then contacted prior to the surgery by the health team in order to obtain their consent to participate in this study, and to schedule the first postsurgical interview (T1). Caregivers were duly informed about the nature of the study, data confidentiality and voluntary participation, and asked to sign an informed consent form.

The criteria for inclusion in the sample were as follows: being a caregiver of a family member with T2D with diabetic foot; the patient having been referred for major or minor amputation surgery; and the caregiver being 18 or older and able to consent to participate in this research.

Instruments

Socio-demographic and clinic questionnaire. This instrument was developed for this study to analyse socio-demographic variables (gender, age, education, marital status, occupation and relationship with patient), variables related to caregiving (help in caregiving, type of amputation and duration/ time of care) and the caregiver's clinical variables (practice of exercise, presence of chronic diseases).

Caregiver self-assessment questionnaire. This questionnaire with 18 items is a self-report measure devised by the American Medical Association to help physicians assess the stress levels of family caregivers accompanying chronically ill adult patients to their medical visits (26,27). The questionnaire provides an overall score with high scores indicating high levels of stress symptoms due to caregiving. The original version found a Cronbach α of 0.78, while in this study the alpha was 0.82.

Family disruption from illness scale. This scale evaluates the disruption, in physical symptomatology, on family/caregivers and consists of 42 items with seven dimensions: behavioural symptoms; acute episodic symptoms; combination of gastrointestinal and urinary symptoms, along with tinnitus, dizziness and skin sores; anxiety/depression; functional/sensory-neural symptoms; symptoms that seem to announce the need for some kind of change in lifestyle; and a combination of cardiovascular and respiratory symptoms (28,29). This questionnaire provides an overall score with high scores indicating physical morbidity. In the original version, the α was 0.93, in the Portuguese version was 0.96 and in this study, was 0.88.

Short form health survey (SF-36). This questionnaire assesses the quality of life in two dimensions: physical and mental, and consists of 11 items and 36 questions that encompass eight components: Physical Function, Physical Performance, Emotional Performance, Pain, General Health Status, Vitality, Social Function, Mental Health and one Health Perception question (30,31). High scores in the physical dimensions indicate better quality of physical life, and high scores in the mental dimension indicate better mental quality of life. In the Portuguese version, Cronbach's α was 0.92 for the physical component and 0.91 for the mental component. In this study, an α of 0.92 for the physical dimension and 0.89 for the mental dimension were found.

Data analysis

Data were checked for distribution, missing values and discrepant values following the guidelines established (32). The results were summarised in means and

standard deviations for the continuous variables and in percentage for categorical variables. The practice of physical activity, receiving help in caregiving, having a chronic disease and type of patient's amputation were coded as dichotomous variables (0 = no, 1 = yes). Age was introduced in years and the variable duration of caregiving, in the number of months the caregiver cared for the patient. Differences over time, between the three moments regarding psychological variables, were assessed by ANOVA for repeated measures.

Multilevel modelling (MLM) has been used extensively in current longitudinal studies due to its flexibility in the handling of missing data, allowing for participants to remain in the parameter estimation even if they only took part in one instance of evaluation. Additionally, MLM can estimate the variation accounted for by factors that are either time-invariant or change/covary with the outcome of interest (time varying) (33–35). MLM was used to estimate the growth trajectory of each outcome and to determine the effects of change trends over time. Models were separately fitted for each outcome using a model-building strategy recommended (32,36). A model (without predictors) was first specified to calculate the intra-class correlation coefficient, which describes the proportion of variance in the results attributable to differences between people. The unconditional growth model (time as the only predictor) was then fitted to estimate from the mean initial state (i.e. T1) and rate of change (i.e. slope) for the entire sample. The stress of caregiving and physical symptomatology were then added as predictors that vary over time (time \times stress of caregiving; time \times physical symptoms) with age as a co-variable. In terms of interaction, variables that did not predict a significant proportion of variance ($p < 0.05$) either in the initial state or in rate changes were trimmed to achieve the most parsimonious possible model. Significant interaction effects were plotted on ± 1 SD value of the predictor and moderator using the software interaction (37).

Analyses were performed using SPSS version 25 MIXED procedures (IBM Corp, Armonk, NY, USA). A strict estimate of the maximum probability was used since it provides more accurate results with smaller sample sizes (38). Taking into consideration the number of predictors and the moment with less participants, a sample size of 84 is considered acceptable for a power of 0.80. Time was coded as 1, 2 and 3. Therefore, the interception of each model represented the value of the result in the initial evaluation. Continuous predictor variables were standardised to improve the interpretation of results (37,39,40). The critical level was set at 0.05. A nonstructured covariance was assumed for each model.

Results

Sample characteristics

Caregivers' ages ranged from 19 to 82 ($M = 51.74$, $SD = 15.15$). Table 1 describes the socio-demographic

Table 1 Descriptive statistics for socio-demographic and clinical variables in the three evaluation times

Categorical measure	T1 (N = 110)	T2 (N = 101)	T3 (N = 84)	
	n (%)	n (%)	n (%)	
Gender				
Female	94 (85.5)	86 (85.1)	70 (83.3)	
Male	16 (14.5)	15 (14.9)	14 (16.7)	
Level of education				
Without education	7 (6.4)	8 (8.1)	5 (6.0)	
4 years	46 (41.8)	36 (36.4)	32 (38.6)	
6 years	17 (15.5)	14 (14.1)	14 (16.9)	
9 years	15 (13.6)	20 (20.2)	11 (13.3)	
12–15 years	18 (16.4)	15 (15.2)	16 (19.3)	
Graduate	7 (6.4)	6 (6.1)	5 (6.0)	
Occupation				
Employed	34 (30.9)	32 (32.0)	27 (30.3)	
Unemployed	44 (40.0)	39 (39.0)	38 (42.7)	
Retired	29 (26.4)	27 (27.0)	21 (23.6)	
Sick leave	3 (2.7)	2 (2.0)	3 (3.4)	
Marital status				
Single	15 (15.0)	15 (15.0)	14 (16.9)	
Married or cohabitant	89 (80.9)	79 (79.9)	65 (78.3)	
Divorced	5 (4.5)	5 (5.0)	3 (3.6)	
Widower	–	–	1 (1.2)	
Relationship with patient				
Husband	51 (46.4)	47 (47.0)	41 (46.6)	
Offspring	38 (34.5)	48 (48.0)	30 (34.1)	
In law	9 (8.2)	2 (2.0)	7 (8.0)	
Parent	6 (5.5)	2 (2.0)	5 (5.7)	
Others	6 (5.5)	1 (1.1)	4 (4.5)	
Exercise				
Yes	30 (27.3)	36 (36.6)	26 (31.6)	
No	80 (72.7)	65 (64.4)	57 (67.9)	
Chronic diseases				
Yes	59 (53.6)	55 (54.5)	44 (52.4)	
No	51 (46.4)	46 (45.5)	40 (47.6)	
Help in caregiving				
Yes	54 (49.1)	51 (50.5)	46 (54.8)	
No	56 (50.9)	50 (49.5)	38 (45.2)	
Type of amputation				
Minor	81 (73.6)	75 (74.3)	64 (76.2)	
Major	29 (26.4)	26 (25.7)	20 (23.8)	
<i>Continuous measure</i>	<i>Min–Max</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>
Age	19–82	51.74 (15.1)	51.54 (15.3)	50.74 (14.6)
Duration/ time of care	1–720	69.28 (105.9)	62.58 (102.2)	76.87 (112.5)

%, percentage; M, mean; N, frequency; SD, standard deviation.

and clinical characterisation of the sample: mainly female, with 4 years of education, unemployed or retired and married or living in cohabitation; mostly are wives' patients, do not exercise and have chronic diseases. Half of the sample reported having no support in caregiving. The average duration of care was 69 months.

Preliminary analyses

Of the 110 caregivers who took part in T1, 101 continued through T2 (91.81%) and 84 through T3 (83.16%). However, only 74 took part in the three evaluation moments (67.27%). The main causes of missing data were as follows: caregiver did not attend the consultation with the patient, the patient was not amputated, the patient did not authorise the caregiver's participation in the study and the patient died (Fig. 1).

Table 2 presents Cronbach's alphas, means and standard deviations for the predictive and outcome measures. The analysis of means and standard deviations (SDs) showed a significant decrease over time in stress and on caregiver's mental quality of life, and a slightly increase on the physical quality of life 7 months after surgery but followed by a decrease 10 months after surgery. No significant differences were found regarding age and physical symptoms, over time.

Multilevel models

Estimates of fixed effects for the multilevel model predicting mental QoL and physical QoL are presented in Tables 3 and 4. Intra-class correlation coefficients indicated that 15.3% of total variation in mental quality of life, and 36.1% in physical quality of life were attributable to differences between participants.

The unconditional growth model for mental quality of life revealed an average initial status of 50.328 ($SE = 0.952$, $p < 0.001$). The average growth trajectory was negative, indicating a decrease of 2.60 points ($SE = 1.098$, $p = 0.001$) in mental quality of life per assessment. For physical quality of life, the average initial status was 71.722 ($SE = 1.074$, $p < 0.001$). The average growth trajectory was negative, with physical quality of life scores increasing by 7.857 points per assessment ($SE = 1.107$, $p < 0.001$; Tables 3 and 4).

Growth model for stress of caregiving on mental quality of life

Regarding the predictive variable of *caregiving stress*, caregivers with lower stress showed higher levels of quality

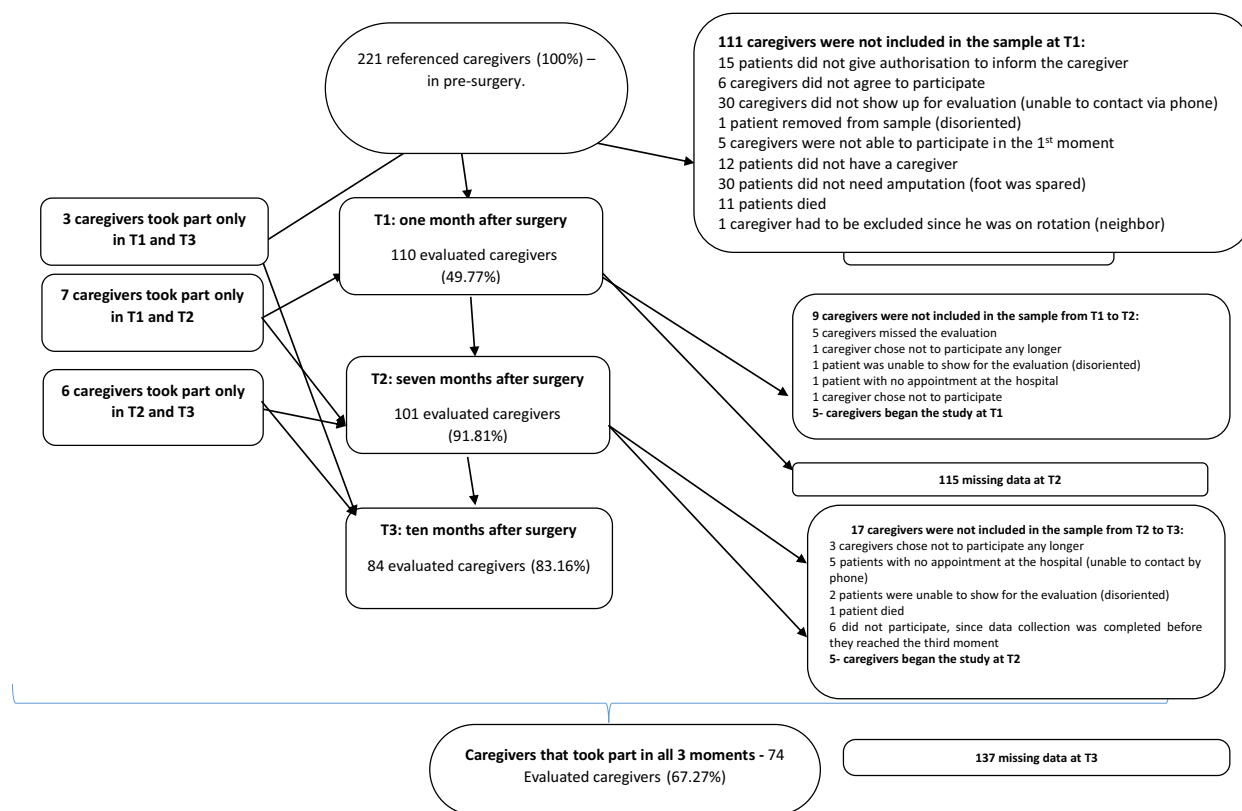


Figure 1 Case flow and data collection.

of mental life, although there was variation over time (lower quality of mental life) only in those who presented less stress (Fig. 2).

Growth model for stress of caregiving on physical quality of life

Concerning the predictive variable of caregiving stress, caregivers with high levels of stress showed low levels of physical quality of life over time, statistically significant in both conditions, although changes in physical quality

of life over time (decrease in physical quality of life) occurred in caregivers with higher levels of stress (Fig. 3).

Growth model of symptomatology on physical quality of life

Regarding the predictor variable, caregivers with lower scores of physical symptomatology showed better mental quality of life, although this variation over time (lower mental quality of life) occurred only in those with lower scores of symptomatology. In this study, no significant

Table 2 Descriptive statistics for predictor and outcome variables at each time point

Variables	Range	T1 (N = 110)		T2 (N = 101)		T3 (N = 84)		χ^2 / F	p	η^2
		M ± SD	α	M ± SD	α	M ± SD	α			
Predictor variables										
Age	19–82	51.74 ± 15.15	–	51.54 ± 15.33	–	50.84 ± 14.90	–	0.263	0.608	–
Stress from caring	1–16	7.96 ± 5.93	0.81	6.06 ± 4.22	0.85	5.96 ± 4.43	0.88	81.471	0.000	0.53
Physical symptoms	1–168	11.09 ± 13.02	0.88	12.98 ± 17.02	0.92	10.65 ± 14.71	0.92	0.014	0.906	0.00
Outcome variables										
Mental quality of life	27–70	50.40 ± 10.63	0.92	50.29 ± 10.78	0.89	47.85 ± 3.68	0.94	7.435	0.008	0.13
Physical quality of life	32–87	72.12 ± 12.50	0.89	72.53 ± 13.01	0.92	64.87 ± 6.81	0.94	36.020	<0.001	0.33

F, ANOVA for repeated measures; M, mean; p, p value; SD, standard deviation; α , alpha' Cronbach; η^2 , partial eta squared effect size; χ^2 , chi-square. (Bold results are statistically significant).

Table 3 Estimates of fixed effects for the multilevel model predicting mental quality of life

Parameters	Estimates	SE	p
Intercept	50.328	0.952	<0.001
Time	-2.602	1.098	0.020

Parameters	Estimates	SE	p
Intercept	51.100	0.728	<0.001
Time	-3.727	0.943	<0.001
Stress from caring	-0.731	0.122	<0.001
Physical symptoms	-0.220	0.052	<0.001
Time × Stress from caring	0.386	0.182	0.037
Time × Physical symptoms	0.189	0.070	0.008

p, p value; SE, standard error.

evidence was found for an interaction between time and physical quality of life for physical symptomatology (Fig. 4).

Discussion

This study's goal was to explore patterns of change in mental and physical quality of life in informal caregivers of amputee patients due to T2D during the first 10 months following amputation. The results showed that the mean score of caregiving stress and mental and physical quality of life decreased over time. Although physical quality of life increased 7 months after surgery, 10 months after surgery a decrease was observed.

As proposed (25) in the model of adjustment to a chronic illness/disability, age was considered an antecedent that showed a discrete increase over the course of 10 months. The second phase of the model contemplates reactions to the disease and, as the literature indicates, caregiving tasks impacts the caregiver's quality of life (6,9,22,24). However, even though chronic diseases interfere with patient's mental and physical quality of life and their families, individual characteristics and different lifestyles change the impact of the disease in different individuals, and often this impact does not correlate with the severity or prognosis of the disease itself (41,42). In

Table 4 Estimates of fixed effects for the multilevel model predicting physical quality of life

Parameters	Estimates	SE	p
Intercept	81.615	2.113	<0.001
Time	-7.649	0.968	<0.001
Physical symptoms	-0.458	0.058	<0.001
Time × Stress from caring	0.379	0.076	<0.001
Age	-0.191	0.038	<0.001

p, p value; SE, standard error.

this study, stress levels were not significantly reflected in changes on mental quality of life over time, except in caregivers with lower levels of stress. Understandably, caregivers showed more physical symptoms 7 months after the patient's surgery, emphasising the need to provide greater support to the caregiver during this time, when demands were greater. Ten months after surgery, the physical symptomatology decreased, which indicates that caregivers may have adapted to their caregiving situation.

Caregiving exposes the informal caregiver to a number of unexpected and stressful situations that require changes in their lifestyles (6,7). Other perspectives point out that not all caregivers develop illnesses or stress exhaustion, suggesting that individuals show variability in responses to changes, that differ from individual to individual and over time (43,44). In this study, caregivers with low levels of stress showed higher levels of mental quality of life over time, thus emphasising the adverse role of continuous stress. Several studies have shown that caregiving for long periods of time can be extremely difficult and exhausting for informal caregivers in several areas of their lives (8,45). In addition, the extended duration of caregiving exposes caregivers to challenging and constantly unexpected experiences, leading them to develop coping strategies to better deal with the caregiving context that clearly impacts their quality of life (10,11,46,47).

Regarding the predictive variable physical symptomatology, caregivers who presented high levels of physical symptomatology showed low levels of mental quality of life over time, although this variation was not statistically significant. Also, caregivers who exhibited low levels of physical symptomatology showed a statistically significant increase on mental quality of life over time. The health condition of the caregiver is an important factor, which is often not evaluated, or valued by health professionals. In fact, Livneh's model (25) contemplates the different levels of reactions and responses to the process of adjustment to a chronic illness or incapacity, and the studies (48) with caregivers have shown that caregivers report several chronic diseases, during the period of caregiving. The results showed high levels of physical symptomatology that may indicate the presence of the caregiver's physical exhaustion as a result of all activities required to care for patients with reduced mobility. Chronic stress leads to frequent psychological manifestations such as dissatisfaction, anxiety, anguish, a desire to flee, isolation, moodiness, fear, inability to control emotions and aggressiveness (49). At the physical level, caregivers may present disorders such as hypertension, increased cholesterol, angina and digestive ulcers, among others (11,13,14,18). The psychological, physical and functional conditions as a result of caregiving, seriously compromise their quality of life (50).

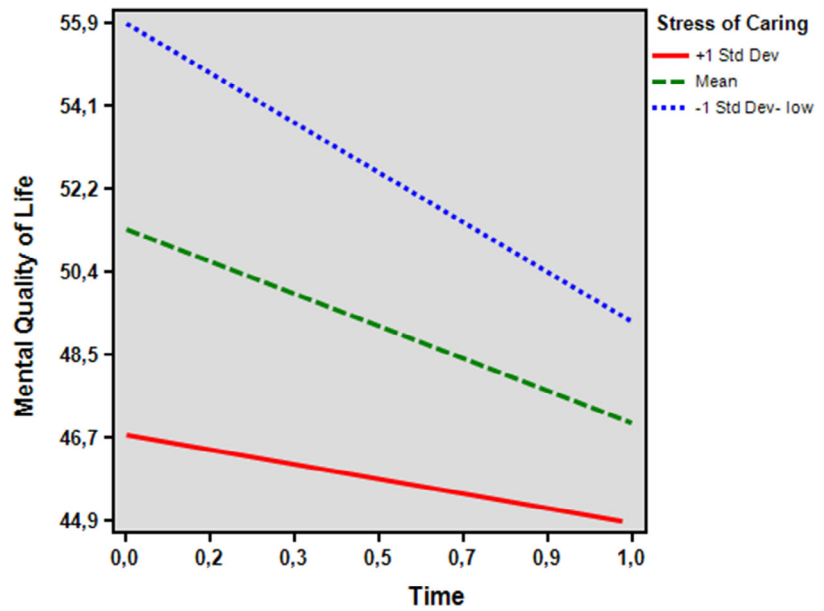


Figure 2 Plot of interaction between time and mental quality of life for stress of caring.

Regarding the predictive variable of caregiving, caregivers who presented low levels of caregiving stress, showed high levels of physical quality of life over time. However, contrary to expectations, in this study no significant evidence was found in the interaction between time and physical quality of life for age (antecedent variable) and physical symptomatology (reaction to disease). The caregiving process may be a stressful experience, since caregiving involves several physical, social, cognitive and emotional adaptations, as mentioned before. Stressed caregivers tend to report higher rates of depressive symptoms, anxiety, greater use of psychotropic

drugs, lower satisfaction with life, more symptoms related to psychological stress and worse subjective health evaluations (10,11). Consistent with the model (25), the relationship of symptoms, over time, is significant for both high and low levels of stress, although the relationship is stronger for higher levels of stress. The relationship between caregiving, stress and health can be further intensified by factors such as the amount of care requested by the patient, type of family relationship, cognitive processes of stress assessment and coping, as well as individual, social and cultural characteristics. For example, caregivers with disabled partners exhibit double

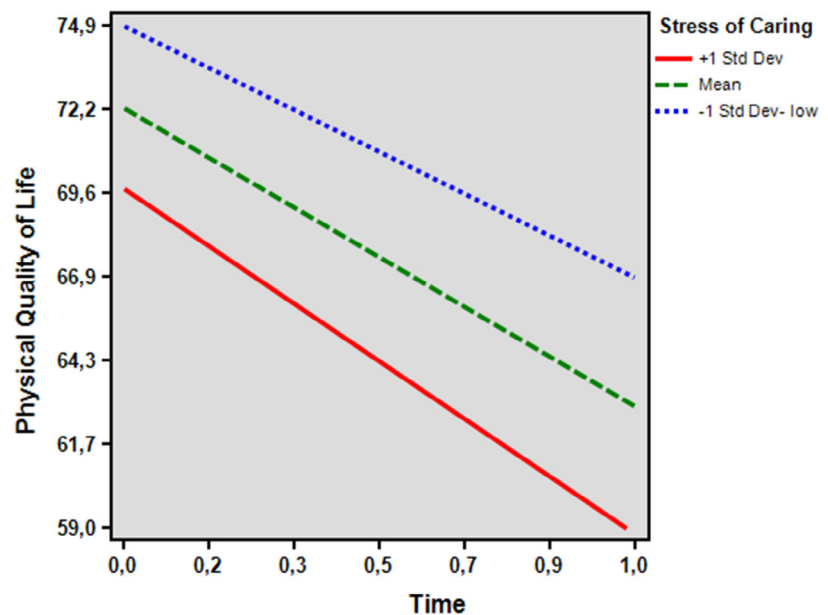


Figure 3 Plot of interaction between time and physical quality of life for stress of caring.

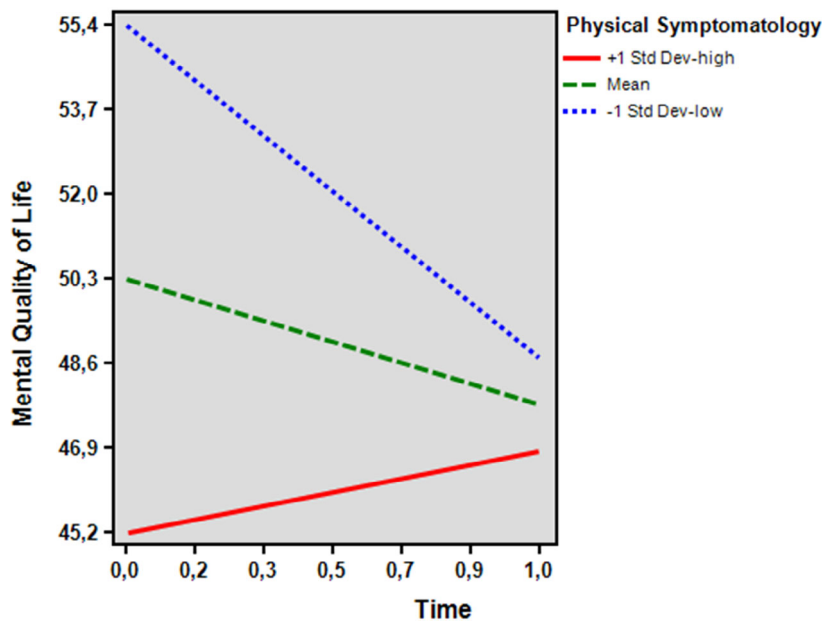


Figure 4 Plot of interaction between time and mental quality of life for physical symptomatology.

the mortality risk of those with healthy partners (9), thus emphasising the need to intervene preemptively in this population.

The results of the present study are crucial for intervention programs in order to promote physical and psychological health in informal caregivers. Health professionals should focus on assessing caregiver's mental and physical functioning, and health interventions should be oriented towards promoting psychosocial as well as physical health (51). A successful adaptation to chronic illness incorporates a wide variety of criteria with a range of interactive responses that include quality of life indicators, successful community integration, vocational/professional achievements and successful leisure activities (52).

Limitations

The limitations of this study include the exclusive use of self-report instruments and the fact that only caregivers who accompanied the patient to the hospital, were included in the study. Also, the fact that the sample is quite heterogeneous requires caution in the interpretation of the results.

Conclusion

According to our results, it is vital to evaluate the physical health and stress levels of informal caregivers, especially those with somatic complaints. The period between 1 and 7 months after surgery appears critical, given the increase in physical symptoms, and thus,

this is the moment where support to caregivers is more crucial. Psychological counselling focused on strategies to deal with stress, and on coping mechanisms to deal with the demands of caregiving is extremely important since caregivers with low stress levels showed higher levels of mental and physical quality of life over time, and those with low levels of physical symptomatology also reported higher levels of mental quality of life.

According to results, it is therefore important to intervene in the dyad patient-caregiver, early on during the caregiving process and develop health policies that help caregivers live with the uncertainties and limitations imposed by the patient's disease. Health services for caregivers of patients with amputated diabetic foot should offer professional training and social support towards the caregiver role in order to promote caregiver's physical and mental quality of life and, indirectly, patient's quality of life as well.

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from the Service of Vascular Surgery at the Hospital of Braga.

Conflict of interest

The authors declare that they have no conflict of interest.

Author contributions

M. Suely Costa was responsible for data acquisition, manuscript preparation, data interpretation, manuscript review and editing. José C. Machado was responsible for data analysis and data interpretation. M. Graça Pereira was responsible for the study design, data interpretation, manuscript review and editing, revising it critically for important intellectual content.

Ethical approval

Research involving Human Participants: All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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