

Measuring the Health Status of Patients with Vascular Leg Ulcers and the Burden for their Caregivers

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Objectives. To assess the health status of patients with leg ulcers and the impact and consequences of such chronic disease on the life of their caregivers.

Design. Observational study in a “day care” setting.

Material. Administration of the Short Form-12 questionnaire and of Visual Analogue Scales for pain to patients; of the Family Strain Questionnaire to caregivers.

Methods. Eighty consecutive patients with leg ulcers and their principal caregivers were observed in the period January–August 2006.

Results. The emotional burden and problem in social involvement were statistically significantly higher in caregivers for patients with worse SF-12 scores on the physical scale. Values of emotional burden were lower than those observed for cancer patients and for patients in a persistent vegetative state; however, they were higher than those observed for patients with neurological, respiratory, or renal conditions. The score for social involvement was significantly higher for caregivers of patient with vascular leg ulcers compared to other diseases, with the single exception of the persistent vegetative state.

Conclusions. Leg ulcers alter the relationship between family members, and the physical impairment causes significant strain on the caregiver. The improvement of physical health status in patients with leg ulcers may induce a reduction in the emotional burden and an improvement in the social involvement for caregivers.

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Keywords: Vascular ulcers; Family Strain Questionnaire; SF-12; Health-Related Quality of Life (HRQoL); Chronic disease; Caregivers.

Introduction

The prevalence of ulcers of the lower limb is estimated as affecting up to 1.5 per 1,000 of the adult population. Among persons aged 65 years or more the prevalence of both open and healed ulcers is up to 36 per 1,000, and one fourth of these patients have an active ulcer at any one time.^{1–3} The most common cause of leg ulcers is venous insufficiency, which involves 76% of cases, whilst up to 22% of ulcers have been shown to be associated with arterial diseases.^{4,5} Up to 10% of the adult population in Europe and North America has venous valvular incompetence, with 0.2% developing venous ulceration. There are many risk factors for venous ulceration. Recurrent venous ulceration occurs in up to 70% of those at risk.⁶ Complete healing usually takes a long time, and in

most cases leg ulcers can be considered as a chronic condition. Callam and colleagues found that a third of their patients had never healed their first ulcer, and two thirds had a series of recurrent ulcers. As a consequence, half of their study population had had their ulcer disease for more than 10 years, and some of the patients had suffered for their ulcers during virtually their entire adult life.⁴ These findings have been confirmed in several subsequent studies.^{7,8} Faced with these data, the massive social and economic cost of leg ulcers care becomes quite understandable.^{9,10}

Health related quality of life (HRQoL) in people with leg ulcers has been investigated in a number of ways including in-depth qualitative studies, using generic instruments and leg ulcer specific questionnaires.^{11,12}

Living with chronic pain is a theme that consistently emerges from these studies, and yet venous ulcers were traditionally not regarded as painful. Other recurring themes are restrictions of social, leisure, and

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work activities, as well as the restrictions that ulceration places on clothing and footwear choice.^{13,14}

In addition, it is certainly important to consider the impact and consequences that such chronic disease has also on the life of caregivers and family members. The aging of the population, and the growing prevalence of chronic diseases has led to the introduction of a large number of instruments to assess caregiver-related problems associated with specific diseases. No information is at present available about leg ulcers and the burden that they pose on caregivers. This paper wants to contribute to the knowledge of issues related to leg ulcers, providing information about patient and caregivers perceptions. We investigated health status and burden of disease using the generic instrument SF-12 in leg ulcers patients, and at the same time we studied the caregiver-related problems with a validated instrument such as the Family Strain Questionnaire (FSQ), a tool for general screening of caregiver-related problems.¹⁵ The hypothesis is that caregivers of patients with leg ulcers have a substantial burden because of such disease and we intend to quantify its extent and to compare it with that deriving from other diseases.

Materials and Methods

After being approved by the ethical and scientific board of our institution the project was implemented with patients and their caregivers.

Eighty consecutive patients with vascular leg ulcers and their attendant caregivers were observed in the period January–August 2006 in a “day care” setting of a dermatological institution which is also a reference center for peripheral vascular diseases. The specific ulcer diagnosis (venous/other, dimension etc.) was made by an ulcer specialist according to the CEAP (Clinical, Etiology, Anatomy, Pathofisiology) Classification for chronic venous disorders when venous ulcers were concerned, and on the basis of the Winsor Index for arterial ones. The ulcer dimensions were assessed using the portable digital device Visitrak (Smith & Nephew, Hull, UK).

The inclusion criteria were: being a patient with vascular leg ulcers and being his/her principal caregiver (defined as an unpaid person who is responsible for patient care, and this because of affective ties regardless of wedding or kinship), age > 18 years, absence of any illiteracy, and absence of physical and psychiatric problems that may impair understanding or self administration of the questionnaires.

Patients were invited to participate in the study by the referring physician of the vascular Unit, who

explained the aims and the implications of the study, and obtained the written informed consent. Before starting any treatment, the principal ulcer status was evaluated by the same specialist, who recorded all information of interest on standardized forms, and gave the patients the SF-12 questionnaire for self-completion. The caregiver was contacted by a research nurse who explained the aim of the study, obtained the written informed consent and administered the specific questionnaire. Before the patient was discharged from the hospital, the nurse collected all the completed questionnaires.

For patients the *SF-12 questionnaire* was selected because it is a well known and widely used instrument, and also for its conciseness and relative simplicity, and because it measures both the physical and mental components of health-related quality of life.¹⁶ The tool is suitable for use in an elderly population when questions are administered in an interview. We used the validated Italian version.¹⁷ Higher values indicate better health. The evaluation of HRQoL concerns the four-month period before the assessment. We applied the standard algorithm in computing scores (incorporating the US norms); however, we made comparison only between patients in our study, so that such comparisons should be unbiased.

Visual Analog Scales (VAS) were used for each patient to evaluate pain deriving from ulcers in three different situations: daytime, at the time of medication, and at night time. At the time of the visit, each patient was invited to depict on a standard graduated 100-millimeter segment (i.e., possible range 0–100 mm) the average level of pain experienced in each of the three situations over the last week.

The physician reported his global evaluation of the clinical severity of the ulcer on a five-point scale, ranging from very mild to very severe, answering to the following question: “According to your experience, among all the ulcers you have seen, how clinically severe is the ulcer of this patient?”. The patient provided similar global self-evaluations, on the same scale, both for his/her general health and for specific health in respect to the ulcer.

The main caregivers were administered the *Family Strain Questionnaire*, consisting in a brief semi-structured interview and 44 self-completed dichotomic items.¹⁵ It is a validated instrument for general screening of caregiving-related problems. It makes it possible to optimize administration and data analysis time, and also to make comparisons between the extent of problems experienced by caregivers of patients with different diseases.

The semi-structured interview collects information concerning the socio-economic status of caregivers

and their beliefs/interpretations concerning the disease of their patients.

Five areas are investigated by the questionnaire: Emotional burden (EB), Problems in social involvement (SI), Need for knowledge about the disease (KD), Satisfaction with family relationships (SFR), Thoughts about death (TD). As the "yes" answers are attributed a score 1, the higher the score for each area, the greater the problems involved, with the exception of satisfaction of family relationships (in which a high score indicates good relationship).

Nine questions do not measure any specific construct or domain, but enquire about some specific aspects and have exclusively clinical purposes.

Data analysis. A descriptive analysis was performed to study the frequency distributions of all the variables of interest. A correlation between ulcer status defined by physician and by the patient was evaluated calculating the Spearman correlation coefficient.

Two multiple regression analyses were performed separately, using the first two factors of FSQ as outcome (considering 9 and 6 cut off values for EB and SI, respectively) to identify patient factors (age, education, duration, ulcer number, and economic status) and caregivers factors (age, education, living with the patient) predictive of high family burden.

All analyses were performed using the statistical software Stata, version 9 for Windows.¹⁸

Results

A total of 80 patients and 80 principal caregivers were consecutively enrolled in the study. Only two patients and their caregivers refused to participate. Twenty one (26%) patients were at their first visit in our hospital. The mean age (\pm standard deviation) was 72.9 ± 11.6 and 51.6 ± 12.4 , for the two groups respectively.

Fifty eight (72%) patients had a low educational level (i.e., less than 8 years in school), 64% were females. Twenty seven patients had more than one ulcer, 14 patients (17%) had bilateral ulcers. The body sites involved were as follow: 35 (40%) malleolar, 45 (51 %) legs, 3 (3.5%) toes, 2 (2%) heel, 3 (3.5%) foot. Forty five per cent of patients suffered from venous leg ulcers, while ulcers of different origin (i.e., arterious, diabetic, and mixed ulcers) accounted for the remaining 55%. Thirty eight (47.5%) patients had suffered from the ulcer for more than one year.

Patients were cared for by a family member in 94% of cases. The principal caregivers were female for 54% of patients, and they were forced to reduce their

working activities in 54% of cases. A low education level was reported by 45% of the caregivers. (Tables 1a and 1b).

The reported patients' family income was in most cases (64%) less than 10,000 euro per year. Some kind of support (e.g. economic, homecare) from the Regional Health Authority was reported by 23% of caregivers.

Overall the mean SF-12 physical and mental scores in patients were 35.1 ± 7.6 and 42.3 ± 8.8 , respectively. Patients with venous ulcers had a physical score higher than patients with ulcers of other origin (37.2 ± 6.8 33.5 ± 7.8), with a statistically significant difference ($p = 0.028$), but mental scores were similar.

The mean values of pain assessed with the VAS (daytime, at medication, night time) were 59, 66 and 57, respectively, with a statistically significant difference between night time values and those at medication.

A very modest correlation (0.098) was observed between the physician and patient evaluation of ulcer status.

Table 1a. Characteristics of patients with vascular leg ulcers, IDI-IRCCS, Rome, Italy, 2006

	Patients (n. 80)		
	n.	%	
Sex	Male	29	36
	Female	51	64
Age (years)	<65	19	24
	65–74	22	27
	>75	39	49
	missing	11	14
Education (years)	≤ 8	58	72
	>8	11	14
Marital status	Never married	11	14
	Married	41	51
	Widow/widower	3	4
	Separated/divorced	25	31
Ulcers	Venous	36	45
	Others	44	55
Ulcers sites	Toe	2	2
	Heel	3	3.5
	Foot	3	3.5
	Malleolar	35	40
	Leg	45	51
Number of ulcers	1	53	66
	>1	27	34
Size (cm ²)	<5	19	24
	5–9.9	24	30
	≥ 10	37	46
Duration (months)	≤ 12	37	46
	>12	38	47
	missing	5	7
	VAS (mean values \pm SD)	day	59.0 (23.3)
night		56.6 (28.5)	
at medication		65.8 (23.2)	
SF-12 (mean values \pm SD)	Physical	35.1 (7.6)	
	Mental	42.3 (8.8)	

SD = Standard Deviation, VAS = Visual Analogue Scale, SF-12 = Short Form –12 questionnaire.

Table 1b. Characteristics of caregivers of patients with vascular leg ulcers

	Caregivers (n. 80)	
	n.	%
Sex	Male	37 46
	Female	43 54
Age (years)	≤50	39 49
	>50	41 51
Education (years)	≤8	36 45
	>8	36 45
	missing	8 10
Marital status	Never married	16 20
	Married	60 75
	Widow/widower	2 2.5
Work	Separated/divorced	2 2.5
	Clerk	25 31
	Housewife	18 22.5
	Retired	11 14
Reduced working activities	Other	26 32.5
	Yes	43 54
Living with patient	No	37 46
	Yes	43 54
	No	37 46

The mean value for each domain of FSQ in all caregivers is showed in Table 2, where only statistically significant data are reported for observed patients and caregivers, for some variables of interest. No differences were observed between males and females, nor for the number (1 vs. >1), dimension (<5 cm² vs. >10 cm²), or duration (<1 year vs. ≥1 year) of ulcers, nor for patients' self-reported health status.

The EB score was higher for caregivers who were living with the patients, and for those who had to reduce their working hours.

A statistically significant increment for burden of social involvement was documented for older patients (4.9 ± 1.5 in patients ≥ 75 years of age vs. 3.6 ± 2.2 in patients <65 years). Patients with venous ulcers in comparison with other ulcers had a statistically significant lower burden of social involvement for caregivers (3.9 ± 2.1 vs. 4.7 ± 1.5, respectively, *p* = 0.03).

The emotional and social involvement burden in caregivers were statistically significantly higher when patients had worse SF-12 scores on the physical scale (using the median value as a cut off), if caregivers were forced to reduce their activities, and if they lived in families who reported to have economic problems (i.e., lower income).

In Table 3 we report the emotional burden and problems social involvement scores, experienced by caregivers of patients with leg ulcers, comparing it with that experienced by caregivers of patients with other illnesses. A non-statistically significant difference was observed for EB. Values in our study were lower than those observed for cancer patients and for patients in a persistent vegetative state. However, they are higher than those observed for the neurological, pneumological, and nephrological patients. The score for social involvement was statistically significantly higher for vascular ulcers caregivers compared to other diseases, with the exception of the persistent vegetative state.

In multiple logistic regression analysis, considering high emotional burden >9 as dependent variable, the age of caregivers (<50 vs ≥50) was the only predictive item, with an OR of 3.77 (CI 1.01–14.35), *p* = 0.05.

Table 2. Caregivers of vascular leg ulcers patients: FSQ with EB and SI scores for relevant variables. Reported numbers are means ± standard deviation

	n.	Emotional burden (EB)	Problems in Social Involvement (SI)	Need for knowledge about the disease	Satisfaction with family relationships	Thoughts about death
All caregivers	80	7.0 ± 3.7	4.3 ± 1.8	2.7 ± 1.0	2.4 ± 1.2	2.2 ± 1.5
Age (years)	≤50	39	6.4 ± 3.4	4.1 ± 1.9		
	>50	41	7.5 ± 4.1	4.5 ± 1.7		
Reduced working activities	Yes	43	7.9 ± 3.9*	5 ± 1.3*		
	No	37	5.9 ± 3.3	3.6 ± 2.1		
Economic problems caused by illness	Yes	46	8.0 ± 4.0*	4.9 ± 1.6*		
	No	34	5.6 ± 3.0	3.5 ± 1.9		
Ulcer type	Venous	36		3.9 ± 2.1*		
	Others	44		4.7 ± 1.5		
Lives with patient	Yes	43	8.3 ± 3.5*			
	No	37	5.7 ± 3.4			
SF-12 Physical score	< median	41	8.2 ± 3.7*	5.1 ± 1.3*		
	> median	39	5.8 ± 3.5	3.5 ± 2.0		

SF-12 = Short Form -12 questionnaire, FSQ = Family Strain Questionnaire, EB = Emotional Burden, SI = Problems in Social Involvement.

* *p* < 0.05.

Table 3. Emotional Burden and Problem in Social Involvement mean scores (standard deviation) of FSQ in caregivers of vascular leg ulcer patients and other illness

	Emotional burden	<i>P</i>	Problems in social involvement	<i>P</i>
	Mean (SD)	Ulcer vs. other	Mean (SD)	Ulcer vs. other
Neurological (n. 258)	6.3 (3.7)	0.116	3.0 (2.2)	<0.001
Oncological (n. 314)	7.6 (3.8)	0.206	3.5 (2.1)	0.001
Pneumological (n. 83)	6.4 (3.9)	0.303	3.6 (1.3)	0.003
Persistent vegetative state (n. 24)	8.5 (4.1)	0.093	4.4 (1.7)	0.925
Nephrological (n. 56)	6.1 (4.1)	0.177	2.4 (2.2)	<0.001
Ulcers (n. 80)	7.0 (3.7)		4.3 (1.8)	

FSQ = Family Strain Questionnaire, EB = Emotional Burden, SI = Problems in Social Involvement.

Educational level of caregivers, age of patient, ulcer characteristics (number, dimension, duration) and living together with the patient were not statistically significant.

Information obtained from FSQ with questions not included in any of the five dominions, and used only for clinical work, showed that a third of caregivers thought the patient suffered for his/her relationships with others because of the disease (eg. feels ashamed or to be a burden). Only a minority, i.e., about 10% of caregivers, felt uncomfortable/non-confident with the patient's disease and sometimes felt ashamed because of him/her, while 90% reported that they are able to discuss the disease with the patient.

Discussion

Leg ulcers constitute a large and, because of the aging population, a growing problem for patients and health services.¹⁹ The shift from hospital to community care places increased demands on family caregivers. Quality of life needs to be included as a variable in studying family caregivers for chronically ill patients.²⁰

Family members play a major role in providing caregiving assistance to elderly persons.²¹ The effect of stressors on family members caring for physically or mentally ill person has been referred to as caregiver burden. The scientific literature is rich of reports, particularly concerning persons involved in caring for patients affected by cancer or dementia.²² Only few studies report a comparison of family burden in different diseases.^{23–25} Leg ulcers in most cases persist, becoming a chronic disease. Treatment for such disease is provided at every level of the health system:

in the hospital, health personnel provide outpatient, inpatient, and day care; at home family members and sometimes home-care dedicated health personnel take care of the patients. A major role in the home treatment is played by the patient itself and by the family caregivers.

The results of our study on caregivers of leg ulcer patients highlight the need to provide families of these patients with supportive interventions including: management of relatives' psychological reaction to patient illness; provision of information on the nature, course and outcome of patient's disease; training for relatives in the management of patient's symptoms, and reinforcement of relatives' social networks. The results are in harmony with what was previously documented by Magliano and colleagues for mental diseases.²²

In addition to the specific information obtained about this group of caregivers the present results showed that the completion of the FSQ makes it possible to identify subjects at economic, social and emotional risk and to decide rapidly what kind of resources/intervention can be implemented.

Vascular legs ulcers pose a heavy burden for the caregivers and of course for the family, where most patient live with their disease. The emotional burden of caregivers is similar to what was observed with other major diseases, and it is lower only to what was observed for oncological and persistent vegetative status patients. When social involvement is concerned, all diseases analyzed with the single exception of persistent vegetative status, had a statistically significant lower burden than ulcers.

The problem in social involvement (e.g. I see friends and relatives less frequently because of the disease) describe the difficulties perceived by the caregiver in approaching and maintaining social relationships, as well as personal interest and time for self. Ulcers, like any other chronic disease, alter the relationship between family members, and the patients' physical impairment causes caregiver strain. Better physical health status, as documented by SF-12 assessment in our study population, was associated with reduced emotional burden and better social involvement for caregivers. Caregivers of patients with venous ulcers had lower burden in social involvement in respect to other kind of ulcers, and this could be due to the better health status in venous ulcers, as shown by the physical components of SF-12. In our sample the majority of non-venous ulcer patients had a duration of disease lower than one year, and it could be possible that the impact of a new disease on caregivers unprepared to meet the needs of such a difficult condition contributes to the

higher scores observed in this subgroup of persons. It will be relevant to obtain detailed information about more patients with arterial leg ulcers, in order to make meaningful comparisons with the venous ones. It is plausible that by improving the health status of patients, the caregivers' situations could also be improved. Pain assessment at different times of the day is an other piece of information which should be routinely acquired, in order to consider the patient in his/her continuum of care. The high values at VAS during dressing changes suggest the need of testing the role of newer advanced medications, and to evaluate also their possible effect on the burden of caregivers, when considering their cost-effectiveness.

This is the first time, to the best of our knowledge, that such burden is identified and quantified with a validated tool which allows a comparison with other diseases. The interview per se with the caregivers takes approximately 15 minutes and it is useful not only for research purposes but also in clinical activities to identify relevant social components.

A simultaneous evaluation with different instruments of patient and principal care giver is strongly recommended. The patient information will be more precise and it will complete the knowledge about patient life and his/her context.

Acknowledgements

The study was part of a research financially supported by the Italian Ministry of Health through the "Programma Ricerca Corrente 2006".

We thank the research fellows Desian Pappachan and Giulio Bernardini who participated in collecting the questionnaires.

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Accepted 31 May 2007

Available online 1 August 2007