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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.*

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 caregivier-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