

Leg ulceration in Portugal: quality of life

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ABSTRACT

This study was undertaken to examine the impact of chronic leg ulceration on patients' health-related quality of life in an audit of practice in Lisbon, Portugal, and to observe the changes following 12 weeks of treatment. A questionnaire was administered at entry into an observational study and following 12 weeks of treatment. Patients entering the study were asked to complete the Nottingham Health Profile (NHP), Euroqol and visual analogue (VA) pain questionnaires at entry and after 12 weeks. Principal analysis compared final scores with those found at baseline and compared results with Portuguese normative data. In total, 98 patients entered the study and completed the initial questionnaire, with 68 (69.3%) patients completing the follow-up questionnaire. There were significantly ($P < 0.001$) higher scores for the patients compared with normative data for all domains of the NHP (all $P < 0.001$). Improvements were noted for all NHP scores after 12 weeks, although only bodily pain showed a significant improvement [mean difference (d) = 10.5, $P = 0.003$], with significant improvement also in Euroqol ($d = 0.10$, $P = 0.027$). Energy and social isolation improved substantially in the eight (11.8%) patients whose ulcers healed, but did not achieve statistical significance, although VA pain score did ($d = 4.85$, $P < 0.001$). Patients suffering from leg ulceration show modest improvements in perceived health following 12 weeks of usual care in Portugal. Improvements in practice may enhance the magnitude of these improvements.

Key words: Chronic leg ulcer • Healing • Quality of life

Key Points

- leg ulceration has a major impact on the health services in Portugal
- the greatest burden is on the community services, with most patients being seen either in health centres or in the patients' own home
- little is known of the burden of ulceration on the patient, and how it might influence the patients' HRQoL

INTRODUCTION

While there is good evidence on health-related quality of life (HRQoL) in patients with leg ulceration using generic tools in the United Kingdom (UK) and Scandinavia, the evidence from other European countries is lacking (1–5). These studies have shown that patients with leg ulceration exhibit deficits in HRQoL compared with population normative data. Bodily pain and physical mobility are consistently poorer in the patients with ulceration

than in normative controls (1–4), with mean differences reaching around 20 units on either Nottingham Health Profile (NHP) or SF-36 scales. While other areas of HRQoL are substantially poorer in the patients with leg ulceration (social, emotional and mental), the magnitude of the effect is usually somewhat less. Studies have also shown that with appropriate management of patients with leg ulceration, HRQoL can improve, most notably in the domains of bodily pain, mobility and sleep, the greatest improvements being in patients whose ulcers heal (6,7).

Leg ulceration has a major impact on the health services in Portugal (8). Most patients have seen a specialist doctor for their ulceration, and many patients are treated within the hospital system. However, the greatest burden is on the community services, with most patients being seen either in health centres or in the patients' own home. Patients are also seen on a regular basis, on average three times per week. Little is known of the burden of

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ulceration on the patient, and how it might influence the patients' HRQoL.

Although the quality of life assessment is rare in Portugal, these analyses began to be developed in the 1970s to describe and measure the impact of different conditions on people's daily lives in various domains including emotional and social well-being as well as the patients' physical status. Studies have been mainly directed to patients with specific conditions such as cardiac failure, but there is some information on normative data in the Portuguese population. In this study, we have chosen to compare HRQoL in patients with ulceration with Portuguese normative data derived from 371 community patients (9). Moreover, we wished to examine whether follow-up of patients over a 12-week period could demonstrate similar changes to those recorded from the UK. The purpose of this study was to evaluate the deficit in HRQoL in patients with chronic leg ulceration in Portugal and to observe changes following 12 weeks of treatment prior to the development of an evidence-based leg ulcer service.

MATERIALS AND METHODS

The study was set in an area of Lisbon, which is served by five health centres, providing care for a population of 186 000. A previous study had identified 263 patients with leg ulceration being cared for by acute and community services (8). A random sample of 100 patients was drawn from this patient database, which was representative of the mix of community and acute patients. The patients who agreed to participate were questioned on their history of leg ulceration, provided demographic information and completed the quality of life questionnaires. After 12 weeks, those patients who agreed were again questioned using a similar tool.

The NHP produces scores from 0 to 100 for each of the six domains, 0 indicating no interference in life by health and 100 indicating worst possible interference (10). The baseline scores were compared with normative data from Portugal adjusted for age and gender (9). Euroqol has five questions, which allow for the determination of health status (11). It provides scores, which include death (0) and best possible health (1·0). Euroqol also allows for negative health states, which are considered to be worse than death. The visual analogue (VA)

pain scale used was derived from that included in the McGill short form pain questionnaire and consisted of a 10-cm horizontal line, allowing the patient to score between 0 (no ulcer pain) and 10 (worse possible ulcer pain) (12). Distance from the left-hand end of the line was measured. Thus, small scores indicate low pain and large scores, high pain.

Principal analysis for all comparisons was by paired *t*-test analysis, with 95% confidence intervals generated for each sub-score of the NHP, Euroqol and VA pain scale. The Euroqol scale goes in the opposite direction to the other scores, that is higher scores indicate better health with Euroqol. To ensure consistency, the mean difference scores presented in the tables indicate health gain for all scores. Thus, a positive difference indicates a health gain, while a negative score indicates a health deficit.

RESULTS

In total, 98 patients were entered into the study, of which 63 (63·3%) were women (Table 1). The mean (SD) age was 71·9 (10·6) years. Of the 118 ulcerated limbs, the majority suffered from large ulcers of greater than 10 cm² (70/116, 60·3%) in size, with long ulcer duration (median = 15·5 months). Diabetes (16·3%) and history of deep vein thrombosis (22·4%) were common in this patient group. Just over half of all patients were able to walk outside their home without need of a mobility aid. Patients were treated with a wide variety of dressings, but only two received compression bandaging.

As expected, the majority of patients were retired (88·8%) (Table 2). One half were married, the remainder being mainly widowed (35·7%). Half lived with a partner, although one quarter (23·3%) lived alone. Most patients saw relatives and friends on either a daily or a weekly basis, although there were a sizeable minority who saw them less often (36, 36·8%).

Patients with ulceration in this study had poor HRQoL as assessed by the NHP. There was strong evidence that Portuguese patients experienced greater deficits in HRQoL than the general population in Portugal (Table 3). There were significantly higher scores for the NHP (worse perceived health) in all domains of the NHP, the largest mean differences being for bodily pain [difference (*d*) = 33·2, *P* < 0·001], energy (*d* = 24·2, *P* < 0·001) and physical mobility (*d* = 22·8, *P* < 0·001).

Key Points

- the purpose of this study was to evaluate the deficit in HRQoL in patients with chronic leg ulceration in Portugal and to observe changes following 12 weeks of treatment prior to the development of an evidence-based leg ulcer service
- there was strong evidence that Portuguese patients experienced greater deficits in HRQoL than the general population in Portugal
- after 12 weeks of the treatment, there was evidence of some improvements in the patient's perceived health
- there was a significant improvement in bodily pain and a significant improvement in health status

Key Points

- changes to the patients' mobility and social contacts between the two time periods were evaluated
- while there was similar mobility experienced before and after the 12-week treatment cycle, there was some evidence that social contacts might have improved, although, the difference was small

Table 1 Baseline clinical details of 98 patients with ulceration

Sex, <i>n</i> (%)	
Male	36 (36.7)
Female	62 (63.3)
Age, mean (SD)	71.9 (10.6)
Number of ulcers	118
Ulcer size (<i>n</i> = 116), <i>n</i> (%)	
≤ 10 cm ²	46 (39.7)
> 10 cm ²	70 (60.3)
Ulcer duration (months)	
Median (range)	15.5 (0.25–264)
Hypertension, <i>n</i> (%)	
Yes	40 (40.8)
No	54 (55.1)
Unknown	4 (4.1)
Deep vein thrombosis, <i>n</i> (%)	
Yes	22 (22.4)
No	54 (55.1)
Unknown	22 (22.4)
Diabetes, <i>n</i> (%)	
Yes	16 (16.3)
No	75 (76.5)
Unknown	7 (7.1)
Diagnosis made by, <i>n</i> (%)	
Clinical alone	44 (45.4)
Ankle brachial pressure index Doppler	14 (14.4)
Other vascular test	11 (11.3)
Unknown	28 (28.9)
Dressings, <i>n</i> (%)	
Gauze	47 (47.9)
Hydrocolloids	10 (10.2)
Charcoal	10 (10.2)
Alginates	8 (8.2)
Iodine paste	7 (7.1)
Foam	5 (5.1)
NA	3 (3.1)
Other	24 (24.4)
Bandages, <i>n</i> (%)	
Crepe	39 (39.9)
Zinc	10 (10.2)
Cotton wool	5 (5.1)
Compression	2 (2.0)
Mobility, <i>n</i> (%)	
Bed	5 (5.1)
Chair	8 (8.2)
Walk with aid	21 (21.4)
Walk without aid indoors only	8 (8.2)
Walk freely	56 (57.1)

After 12 weeks of the treatment, there was evidence of some improvements in the patient's perceived health (Table 4). There was a significant improvement in bodily pain ($d = 10.5$, $P = 0.003$) and a significant improvement in health status as given by the Euroqol questionnaire ($d = 0.10$, $P = 0.027$). Other domains of the

Table 2 Socio-demographic details of the 98 patients

Socio-demographic details	<i>n</i> (%)
Employment status	
Employed full time	6 (6.1)
Retired	87 (88.8)
Looking after home	1 (1.0)
Not working because of illness	3 (3.1)
Other	1 (1.0)
Marital status	
Single (never married)	12 (12.2)
Married	48 (49.0)
Widowed	35 (35.7)
Divorced/separated	3 (3.1)
Living	
Alone	23 (23.5)
With partner	48 (49.0)
With other relative	23 (23.5)
With friend	2 (2.0)
Other	1 (1.0)
Contact with family and friends	
Every day	23 (23.5)
Every week	39 (39.8)
Every month	13 (13.3)
Less often	23 (23.5)

NHP showed some evidence of improvement, but none approached statistical significance.

Improvements in the scores were compared between patients whose ulcers healed ($n = 8$) and those that failed to heal ($n = 60$) (Table 5). While there were greater improvements in the patients with healed ulceration for social isolation ($d = 17.2$), sleep ($d = 13.6$) and energy ($d = 10.9$), none of these achieved statistical significance because of the small number of patients in the healed group. VA ulcer pain reduced by 4.75 in the healed patients compared with a slight increase (0.1) in the patients with unhealed ulceration, the difference achieving a high level of statistical significance ($P < 0.001$).

Finally, we evaluated changes to the patients' mobility and social contacts between the two time periods (Table 6). While there was similar mobility experienced before and after the 12-week treatment cycle, there was some evidence that social contacts might have improved, although, the difference was small (25% improved, 17.6% deteriorated).

DISCUSSION

HRQoL is an important outcome measure in studies of patients suffering from chronic leg

Table 3 Age- and gender-adjusted comparison of NHP scores between patients with leg ulceration in Portugal and age and gender normative values from Portugal. Values given are mean scores, with statistical analysis by paired *t*-test. A high score indicates a deficit in perceived health

	<i>n</i>	Leg ulcer mean	Normative mean	Mean difference	95% confidence intervals	<i>P</i> value
Energy	98	50.3	26.1	24.2	15.7 to 32.7	<0.001
Bodily pain	98	60.9	27.7	33.2	26.3 to 40.1	<0.001
Emotional reactions	96	41.4	22.7	18.7	11.8 to 25.6	<0.001
Sleep	98	49.0	33.7	15.3	7.8 to 22.8	<0.001
Social isolation	97	34.9	21.2	13.6	7.1 to 20.2	<0.001
Physical mobility	96	48.1	25.3	22.8	16.8 to 28.8	<0.001

NHP, Nottingham Health Profile.

ulceration. The application of effective care, particularly high-compression bandaging, showed substantial improvements in HRQoL. The first study to examine HRQoL as an outcome measure appeared in the Riverside leg ulcer project using the symptom rating test to evaluate the changes in psychiatric morbidity following 12 weeks of treatment in nurse-led community leg ulcer clinics (13). This study demonstrated improvements in depression, hostility and anxiety following a treatment period of 12 weeks. In addition, patients whose ulcers healed had significantly greater improvements than those patients whose ulcers remained open in the domains of depression and hostility. This implied that healing the ulceration improved the patients' psychiatric states.

Recently, Charles (14) studied 65 ambulatory patients with venous leg ulcers and showed that patients with leg ulcers have lower SF-36 values (poorer HRQoL), except for general health, compared with equivalent norms. During treatment, there was a significant improvement in the SF-36 domains of bodily pain, health transition, mental health and

social functioning for all 65 patients. Patients whose ulcers healed also showed a statistically significant improvement in the vitality domain. Patients whose ulcers did not heal had statistically significant improved scores for bodily pain and health transition.

The results of randomised trials using the NHP in venous ulcer care also show significant improvements during periods of treatment using high compression. (5,6,15,16). The present study has shown improvements in bodily pain over 12 week but failed to show improvements in any other domain of the NHP. This is probably a consequence of the current care being offered to patients, which does not include the use of compression bandaging. As a consequence of this, just 8/68 (11.8%) had achieved healing after 12 weeks of treatment.

This study has confirmed many of the previous observations about quality of life in patients with chronic leg ulceration. It has shown that patients in Portugal perceive that ulceration places a great burden on them compared with the general population. It has confirmed that periods of treatment can lead to reductions in perceived pain, although the

Key Points

- the application of effective care, particularly high-compression bandaging, showed substantial improvements in HRQoL
- healing the ulceration improved the patients' psychiatric states
- patients whose ulcers healed also showed a statistically significant improvement in the vitality domain

Table 4 Changes in NHP score after 12 weeks of treatment for all patients with evaluable NHP scores. Values given are mean scores, with statistical analysis by paired *t*-test. A positive mean difference for all indices indicates a health gain

	<i>n</i>	Entry mean	12-week mean	Mean difference	95% confidence intervals	<i>P</i> value
Energy	68	51.9	56.6	-4.7	-12.7 to 3.3	0.242
Bodily pain	67	61.3	50.8	10.5	3.7 to 17.3	0.003
Emotional reactions	66	45.6	41.2	4.5	-2.2 to 11.1	0.186
Sleep	68	47.3	43.0	4.3	-4.2 to 12.7	0.319
Social isolation	67	35.4	29.9	5.5	-1.6 to 12.7	0.129
Physical mobility	67	50.2	48.2	1.9	-2.6 to 6.5	0.399
Euroqol	68	0.17	0.27	0.10	0.01 to 0.18	0.027
VA pain	68	6.07	5.60	0.47	-0.38 to 1.32	0.27

NHP, Nottingham Health Profile.

Key Points

- this study has confirmed that these patients experience significant deficits in all domains of the NHP compared with the general population and has indicated some potential for improvement with treatment
- a project is currently underway to create an evidence-based leg ulcer service in this area of Lisbon
- assessment will be enhanced by the use of Doppler (21), with compression therapy used as the main treatment option for patients with venous ulceration
- it is anticipated that if this system can offer expected improvements in healing, it is also likely to benefit the patients in terms of improvements in quality of life, which we will be evaluating in the future

Table 5 Improvements in NHP scores between patients whose ulcers were open at week 12 ($n = 60$) and those that had healed ulceration ($n = 8$) after 12 weeks of treatment. Values given are mean differences, 95% confidence intervals and P values. A positive mean difference indicates a greater improvement in the patients with closed ulcers compared with those with ulcers that remained open

	Mean open	Mean closed	Mean difference	95% confidence intervals	P value
Energy	-6.0	4.9	10.9	-14.0 to 35.8	0.39
Bodily pain	10.7	9.0	-1.7	-22.9 to 19.4	0.87
Emotional reactions	3.3	12.8	9.5	-10.9 to 30.0	0.36
Sleep	2.7	16.3	13.6	-12.7 to 39.9	0.31
Social isolation	3.5	20.6	17.2	-4.6 to 39.0	0.12
Physical mobility	1.6	4.1	2.4	-7.1 to 12.0	0.73
Euroqol	0.09	0.12	0.02	-0.25 to 0.29	0.87
VA pain	-0.10	4.75	4.85	2.45 to 7.23	<0.001

NHP, Nottingham Health Profile; VA, visual analogue.

benefits in other areas of the patients' lives have failed to change substantially. This may be a consequence of less than optimal treatment, with fewer patients achieving healing during the follow-up period. In this study, we have chosen to use a generic HRQoL tool. While a number of disease-specific tools have been developed for patients with ulceration (17) or general chronic venous insufficiency (18,19), these have yet to be translated into Portuguese and validated within this population.

This study was designed to evaluate the baseline HRQoL in patients with chronic leg ulceration in Portugal prior to new service changes. It has confirmed that these patients

experience significant deficits in all domains of the NHP compared with the general population and has indicated some potential for improvement with treatment. A project is currently underway to create an evidence-based leg ulcer service in this area of Lisbon. This will provide continuity of care between hospital and community by developing and implementing wound care protocols for procedures such as wound cleansing, dressings and microbiology and nutritional advice, using a model similar to that adopted in Riverside, west London (20). Assessment will be enhanced by the use of Doppler (21), with compression therapy used as the main treatment option for patients with venous ulceration (22). It is anticipated that if this system can offer expected improvements in healing, it is also likely to benefit the patients in terms of improvements in quality of life, which we will be evaluating in the future.

Table 6 Changes in activity following 12 weeks of treatment ($n = 68$)

	First visit	Week 12 visit
Mobility, n (%)		
Bed	4 (5.9)	3 (4.4)
Chair	5 (7.4)	2 (2.9)
Walk with aid	16 (23.5)	25 (36.8)
Walk without aid indoors only	6 (8.8)	1 (1.5)
Walk freely	37 (54.4)	37 (54.4)
Improved mobility, n (%)	8 (11.9)	
Same mobility, n (%)	52 (76.4)	
Worsened mobility, n (%)	8 (11.9)	
Contact with family and friends, n (%)		
Every day	16 (23.5)	11 (16.2)
Every week	26 (38.2)	28 (41.2)
Every month	8 (11.8)	11 (16.2)
Less often	18 (26.5)	18 (26.5)
More contact, n (%)	17 (25.0)	
Same contact, n (%)	39 (57.4)	
Less contact, n (%)	12 (17.6)	

REFERENCES

- 1 Lindholm C, Bjellerup M, Christensen OB, Zederfeld B. Quality of life in chronic leg ulcers. *Acta Derm Venereol (Stockh)* 1993;73:440-3.
- 2 Franks PJ, Moffatt CJ. Who suffers most from leg ulceration? *J Wound Care* 1998;7:383-5.
- 3 Franks PJ, McCullagh L, Moffatt CJ. Assessing quality of life in patients with chronic leg ulceration using the Medical Outcomes Short Form 36 questionnaire. *Ostomy/Wound Manage* 2003;49:26-37.
- 4 Price P, Harding K. Measuring health-related quality of life in patients with chronic ulcers. *Wounds* 1996;8:91-4.
- 5 Walters SJ, Morrell CJ, Dixon S. Measuring health-related quality of life in patients with venous ulcers. *Qual Life Res* 1999;8:327-36.

- 6 Franks PJ, Moody M, Moffatt CJ, Patton J, Bradley L, Chaloner D, Stevens J, Lewis C. Quality of life in a trial of short stretch versus four layer bandaging in the management of chronic venous ulceration. *Phlebology* 2004;19:87–91.
- 7 Franks PJ, Moffatt CJ. Health related quality of life in patients with venous ulceration: use of the Nottingham health profile. *Qual Life Res* 2001;10: 693–700.
- 8 Pina E, Furtado K, Franks PJ, Moffatt CJ. Leg ulceration in Portugal: prevalence and clinical history. *Eur J Vasc Surg* 2005;29:549–553.
- 9 Coelho R, Ramos E, Prata J, Barros H. Psychological indexes and cardiovascular risk factors in a community sample. *Psychother Psychosom* 2000;69: 261–74.
- 10 Hunt SM, McEwan J, McKenna SP. Measuring health status. London: Croom Helm, 1986.
- 11 The Euroqol Group. Euroqol – a facility for the measurement of health related quality of life. *Health Policy* 1990;16:199–207.
- 12 Melzak R. The short form McGill pain questionnaire. *Pain* 1987;30:191–7.
- 13 Franks PJ, Moffatt CJ, Connolly M, Bosanquet N, Oldroyd M, Greenhalgh RM, McCollum CN. Community leg ulcer clinics: effect on quality of life. *Phlebology* 1994;9:83–6.
- 14 Charles H. Does leg ulcer treatment improve patients' quality of life? *J Wound Care* 2004;6:209–13.
- 15 Franks PJ, Moffatt CJ, Connolly M, Fielden S, Ellison DA, Groarke L, McCollum CN. Quality of life in a randomised trial in venous leg ulceration. *Phlebology* 1999;14:95–9.
- 16 Franks PJ, Bosanquet N, Brown D, Straub J, Harper DR, Ruckley CV. Perceived health in a randomised trial of treatment for chronic venous ulceration. *Eur J Vasc Endovasc Surg* 1999;17: 155–9.
- 17 Smith JJ, Guest MG, Greenhalgh RM, Davies AH. Measuring the quality of life in patients with venous ulcers. *J Vasc Surg* 2000;31:642–9.
- 18 Launois R, Reboul-Marty J, Henry B. Construction and validation of a quality of life questionnaire in chronic lower limb venous insufficiency (CIVIQ). *Qual Life Res* 1999;5:539–54.
- 19 Klysz T, Junger M, Schanz S, Janz M, Rassner G, Kohnen R. Quality of life with chronic venous insufficiency (CVI). *Hautarzt* 1998;49:372–81.
- 20 Moffatt CJ, Franks PJ, Oldroyd M, Bosanquet N, Brown P, Greenhalgh RM, McCollum CN. Community leg ulcer clinics and impact on ulcer healing. *BMJ* 1992;305:1389–92.
- 21 Moffatt CJ, Oldroyd M, Greenhalgh RM, Franks PJ. Palpating ankle pulses is insufficient in detecting arterial insufficiency in patients with leg ulceration. *Phlebology* 1994;9:170–2.
- 22 Moffatt CJ, Franks PJ. Implementation of a leg ulcer strategy. *Br J Dermatol* 2004;151:857–67.