

ASSESSING THE IMPACT OF VENOUS ULCERATION ON QUALITY OF LIFE

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ABSTRACT Palfreyman, S. (2008) Assessing the impact of venous ulceration on quality of life. *Nursing Times*; 104: 41, 34–37.

Background: There can be difficulties in measuring how quality of life is affected by having a leg ulcer.

Aim: To assess the impact of venous ulceration on quality of life and to pilot a draft questionnaire for patients with venous ulcers.

Method: Questions on the impact of venous ulceration were identified through a literature review, semi-structured interviews and focus groups. A self-completed postal questionnaire containing 16 disease-specific items, EuroQol, SF-6 and life-satisfaction questions was sent to 266 people with a history of venous ulceration.

Results and discussion: A response rate of 61% (n=152) was obtained. The most frequent symptoms reported were pain (80%), exudate (75%), and depression (65%). The presence of an ulcer resulted in statistically significant lower quality-of-life and life-satisfaction scores.

Conclusion: Patients with venous ulcers experience reduced quality of life. Those with a healed ulcer also have a poorer quality of life compared with the general population.

BACKGROUND

The concept of 'quality of life' (QoL) is used in a number of disciplines, including psychology, sociology, economics, medicine and even geography. In healthcare, the term 'health-related quality of life' (HRQoL) has been coined to focus on factors specifically affected by healthcare interventions (Anderson and Burckhardt, 1999). The easiest way of determining how QoL can be affected by such interventions is to use structured questionnaires. Such a

IMPLICATIONS FOR PRACTICE

- Practitioners should be aware of the impact of venous leg ulcers on patients' quality of life.
- The study has emphasised the impact of pain and clinicians should ensure this

group is given adequate analgesia.

- It has also shown that those with a healed ulcer can still have their quality of life affected and further investigation is necessary.

questionnaire before, during and at the end of treatment can generate a profile.

There has been a huge expansion of QoL questionnaires in the last 20 years (Moons et al, 2006). These can be used in clinical practice and in economic evaluations of healthcare interventions, and can be either generic or disease-specific.

Generic questionnaires aim to measure QoL regardless of illness or condition and can be used with healthy populations (Garratt et al, 2002). The two most commonly used are the SF-36 (Ware and Sherbourne, 1992) and EuroQol (EuroQol Group, 1990).

Disease-specific questionnaires focus on the effects on QoL of a particular disease. Both types of questionnaire can be preference-based, which means they have a value (called a utility) attached to the health states they describe and can be used in economic evaluations (Neumann et al, 2000).

MEASURING QUALITY OF LIFE

Venous ulcers can have a severe impact on QoL. They affect mobility and physical and social activities (Palfreyman et al, 2007b) and can make people feel powerless and isolated (Douglas, 2001). In Briggs and Fleming's (2007) study, one of the most debilitating symptoms reported was pain.

Attempts to measure changes in QoL in people with venous leg ulcers using generic instruments have had mixed results, with some showing changes before and after healing and others showing no difference. A series of studies by Franks et al have shown improvements in scores for the Nottingham Health Profile for energy and mobility (for

example Franks and Morgan, 2003; Franks and Moffatt, 2001). However, Walters et al (1999) used the SF-36 and were unable to detect any changes pre and post healing.

Current disease-specific instruments also have a number of limitations. Some, like the Freiburger Lebensqualität Assessment Questionnaire (Augustin et al, 1997) were developed in another language and have not been validated in English. Others, such as the Cardiff Wound Impact Schedule (Price, 1999) were developed for all wound types, not specifically for venous leg ulcers. More importantly, none are preference-based and so cannot be easily used in economic evaluations of interventions.

AIM AND METHOD

This article describes the development of a new disease-specific quality of life questionnaire, the Sheffield Preference-based Venous Ulcer-5D (SPVU-5D), for people with venous leg ulcers.

The postal survey aimed to evaluate the impact of venous ulceration on QoL and to pilot the draft disease-specific questionnaire which can then be used as a basis for a preference-based instrument.

This research project forms part of a PhD study funded by the Smith and Nephew Foundation doctoral studentship. A detailed description of the study plan has already been published (Palfreyman et al, 2007a).

Developing the questionnaire

The items for inclusion in the questionnaire were identified by undertaking semi-structured interviews and focus groups with



TABLE 1. ULCER-SPECIFIC QUESTIONS

Parameter	No of items	Item description	Number of levels
Physical	6	2 pain items 2 mobility items Personal care Sleep	5
Psychological impact	2	2 mood items	5
Social impact	5	Leisure Personal relationships Social activities Social isolation Clothes	5
Ulcer impact	3	2 smell items Exudate	5

patients and clinicians. A description of this process can be found in Palfreyman et al (2007b). The results of the interviews and focus groups were analysed to identify key themes related to the impact of venous leg ulcers on QoL. A total of 16 items including physical, psychological and social effects were identified. These were incorporated into a five-point Likert scale with levels assigned to the items based on severity and frequency, with no problem being the lowest and very severe/always being the highest. The items and level are shown in Table 1.

The relevant approvals were obtained from the local ethics committee and research governance bodies.

The questionnaire was piloted by asking five patients and five clinicians to comment on the structure and relevance of the questions. The final questionnaire consisted of two generic health questionnaires – the SF-6D (Brazier and Roberts, 2004) and EuroQol (EuroQol Group, 1990), 16 disease-specific questions, and clinical and

demographic questions. The questionnaires were sent with a covering letter explaining the project and a stamped addressed envelope. A repeat questionnaire with a reminder was sent three weeks later.

Sample

The sample was identified from a locally held database of patients who had received care from the tissue viability service. The sample consisted of people who had a current ulcer and those with a history of ulceration but whose ulcer had healed.

RESULTS

Out of 266 questionnaires sent, 162 were returned. However, one was unopened with no questions completed, two participants had moved house, six were returned as incorrect address and one with a note stating the person had died. The response rate was therefore 61% (n=152). For full details on respondents' demographic characteristics, see nursingtimes.net.

A total of 92 (61%) had a current ulcer, and the remainder had an ulcer that had healed. The mean age was 66.6 years (range 27–104, median 70). This was reflected in the number of respondents who were retired (n=96, 64%) and who stated they had other illnesses, such as arthritis (n=88, 59%).

The majority of respondents had a history of previous ulceration (80%), while 36% had an ulcer present for over 12 months

and 32% had a newly diagnosed ulcer.

Cronbach's alpha, which measures the reliability of questionnaires, was calculated. For all 16 items it was high at 0.934. This value is above 0.7, which is the recommended lower limit. Therefore the questionnaire can be considered reliable for the sample (Norris and Aroian, 2004).

The first 16 questions focused on the impact of having an ulcer. Table 2, p36, shows the responses to the Likert-scale items. Ten respondents with no current ulcer ignored these questions completely but answered those related to general health. The item asking about personal relationships had a non-completion rate of 18%, with 74% who did answer the question stating they had no problems.

The non-completion rate for all items (range 18–28%) for those who did not have an ulcer was significantly higher. This could indicate the items were not completed because respondents did not think the question applied to them. One illustration of this was that the item with the highest non-completion rate for those without an ulcer was the exudate item (28%).

The most frequent symptoms experienced by respondents with ulceration were: pain (80%); exudate (75%); depression (65%); insomnia (65%); and adverse smell (56%). The Chi-square test was used to examine whether there were differences between people with a current ulcer and those with a healed ulcer. This found statistically significant ($p < 0.05$) differences for the items asking about pain, smell, exudate, mobility and mood. No differences between the groups were found for items asking about clothes, social isolation and personal relationship.

Quality-of-life scores

The questionnaire contained two widely used generic QoL instruments – the SF-6D and the EuroQol, and questions about life satisfaction. A utility score, which is a value between zero and one (with one being equal to full health and zero death), can be calculated for the health states described by these questionnaires. The average health state value for respondents can then be compared with the general population to see whether there are any differences.

The utility values for the SF-6D were calculated using the Brazier algorithm

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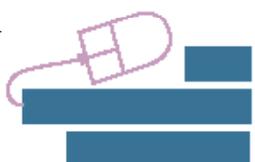


TABLE 2. LIKERT-SCALE ITEMS RELATED TO ULCERATION

Item	Presence of ulcer	No problems (%)	Very occasionally/mild problem (%)	Occasional/moderate problem (%)	Nearly always/severe problem (%)	Always/very severe problem
Pain 1	Ulcer	20.9	26.4	25.3	19.8	7.7
	No ulcer	66.7	17.6	7.8	5.9	2.0
Pain 2	Ulcer	15.4	22.0	30.8	25.3	6.6
	No ulcer	62.7	17.6	11.8	5.9	2.0
Smell 1	Ulcer	46.2	16.5	15.4	15.4	6.6
	No ulcer	83.3	1.7	0.0	0.0	0.0
Smell 2	Ulcer	46.2	19.8	19.8	9.9	4.4
	No ulcer	96.1	3.9	0.0	0.0	0.0
Sleep	Ulcer	34.8	25.0	22.8	9.8	7.6
	No ulcer	72.5	15.7	7.8	3.9	0.0
Mood 1	Ulcer	33.7	34.8	22.8	6.5	2.2
	No ulcer	80.4	15.7	2.0	2.0	0.0
Mood 2	Ulcer	28.3	35.9	25.0	8.7	2.2
	No ulcer	67.3	28.6	4.1	0.0	0.0
Mobility 1	Ulcer	25.0	27.2	23.9	23.9	0.0
	No ulcer	52.1	29.2	10.4	8.3	0.0
Mobility 2	Ulcer	26.4	18.7	16.5	28.6	9.9
	No ulcer	51.1	25.5	6.4	12.8	4.3
Exudate	Ulcer	28.6	20.9	19.8	25.3	5.5
	No ulcer	93.6	4.3	2.1	0.0	0.0
Leisure	Ulcer	27.8	14.4	14.4	23.3	20.0
	No ulcer	50.0	24.0	8.0	14.0	4.0
Clothes	Ulcer	41.3	19.6	17.4	10.9	10.9
	No ulcer	61.2	16.3	8.2	10.2	4.1
Social isolation	Ulcer	48.9	22.8	15.2	8.7	4.3
	No ulcer	69.4	24.5	6.1	0.0	0.0
Social 2	Ulcer	33.7	28.1	12.4	15.7	10.1
	No ulcer	49.0	28.6	14.3	6.1	2.0
Personal relationships	Ulcer	65.4	18.5	6.2	4.9	4.9
	No ulcer	87.5	6.3	2.1	4.2	0.0
Personal care	Ulcer	68.5	13.0	9.8	4.3	4.3
	No ulcer	85.7	12.2	2.0	0.0	0.0

(Brazier and Roberts, 2004) and for EQ-5D using the Dolan algorithm (Dolan, 1997).

Results were also obtained for the mean QoL (utility) scores for the SF-6D and EQ-5D (see nursingtimes.net for table). The EQ6 current index is simply a question that asks people to rate their current state of health on a line between zero and one. A t-test was used to examine if there were any differences between those with an ulcer compared with those with a healed ulcer.

Respondents with a current leg ulcer had significantly poorer perceived QoL for both the SF-6D and the EQ-5D. No statistically

significant difference was found for the EQ6 question. Those with a current ulcer were also feeling less satisfied by what they were achieving in life and life satisfaction overall.

Table 3 shows the average values of the EQ-5D scores for respondents compared with the UK general population. It can be seen that utility scores for both groups of respondents were lower than population values. The exception was the over-75s with healed ulcers, who had a higher value than the normative population. However, this could have been a result of low numbers in the survey group.

DISCUSSION

This study used a postal questionnaire in order to examine patients' QoL with a venous ulcer. The survey showed the presence of a venous ulcer has an effect on perceived QoL.

Data quality

The postal survey received a response rate of 61%, which was within the range generally accepted for these types of surveys, with 60–80% seen as generally acceptable (Edwards et al, 2002). The overall non-completion rate for the items



TABLE 3. COMPARISON OF EQ-5D SCORES WITH AGE-MATCHED GENERAL POPULATION

Current leg ulcer	Age (banded)	N	EQ-5D utility value			Population values
			Min	Max	Mean	
Yes	Under 45	11	-0.24	0.796	0.37	0.90
	46–64	26	0.02	1	0.64	0.82
	65–74	21	-0.02	1	0.52	0.78
	Over 75	33	-0.24	1	0.61	0.73
No	Under 45	2	0.06	0.73	0.39	0.90
	46–64	24	0.06	1	0.71	0.82
	65–74	19	-0.02	1	0.67	0.78
	Over 75	11	0.59	1	0.83	0.73

KEY REFERENCES

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was higher than expected at 8.5%. However, the non-completion rate was highest for respondents who did not have a current ulcer. One method of reducing this might have been to have a response category for those items specifically related to ulceration that stated respondents did not currently have an ulcer.

The percentage of missing data (non-completion of items) was greatest for the item related to personal relationships. This was included as it was thought to be a key effect of leg ulceration. In the semi-structured interviews participants said their chance of having intimate relationships was hampered by having an ulcer (Palfreyman et al, 2007b).

It could be inferred that personal relationships are not a problem for this group of patients, or it could be that the question was too personal to answer in a postal questionnaire. It may have been advisable to include an option for respondents to indicate they were unwilling to answer the question. This difference between postal surveys and interviews was highlighted in a randomised controlled trial comparing the techniques (Addington-Hall et al, 1998). This found interviews produced more complete data and more positive answers than questionnaires.

Symptoms

The symptom reported by most respondents with ulceration was pain (80%). A metasynthesis of qualitative research by Briggs and Fleming (2007) also showed pain was a particular problem for this group. This is at odds with some of the accepted wisdom

that venous ulcers are not particularly painful (London and Donnelly, 2000). Two other symptoms experienced by those who had a leg ulcer were insomnia and depression – these could be related to pain. Other studies have also highlighted the way pain can restrict physical and social activities for this group (Herber et al, 2007). Questionnaire-based studies have also highlighted the effect of pain for patients with venous ulcers (Walters et al, 1999).

No differences between the groups were found for the items on clothes and social isolation, which has been reported in studies that have used qualitative techniques (for example Lindsay, 2001).

Quality of life

QoL scores for the generic questionnaires (the EQ-5D and SF-6D) were significantly lower for respondents with a current ulcer. These scores were also lower than those for the general population. An interesting survey finding was that QoL and life satisfaction for those who have previously experienced an ulcer were also significantly lower compared with the age-matched general population. It could be speculated that long-term factors, high recurrence rate and the need for lifelong compression hosiery have an adverse impact on perceptions of QoL.

CONCLUSION

It is important to be able to demonstrate the impact of interventions on QoL, which requires validated questionnaires to measure changes. This study has shown differences in

QoL between those who have a venous ulcer and those who do not. It has also explored symptoms experienced and identified how even having an ulcer in the past can have an adverse effect on QoL.

The questionnaire needs further development to determine whether it will be able to discriminate in a prospective rather than retrospective group of patients. The next stages of the project will be to further evaluate the psychometric properties and value the health states described by the questionnaire. ■