

# Evaluation of needs and treatment benefits in outpatient care for leg ulcer patients: a pilot study

**Objective:** Leg ulcers can take a long time to heal and have a high recurrence rate. This study aims to describe the sociodemographic and medical profile, and therapeutic needs of patients with leg ulcers, and the benefits of care in a specialised leg ulcers outpatient clinic.

**Method:** This is a descriptive, cross-sectional pilot study of patients of a university hospital outpatient clinic. A sociodemographic and medical questionnaire and the Patient Benefit Index-wound (PBI-w) were used to collect data on the therapeutic needs (patient needs questionnaire, PNQ) and benefits of treatment (patient benefit questionnaire, PBQ) they received.

**Results:** A total of 32 patients with leg ulcers were recruited. Results demonstrated that a clear diagnosis and therapy, rapid wound closure and confidence in the therapy given are the most important treatment

objectives for patients. Patients mentioned that their therapy benefitted most from confidence in the treatment given, decreased pain and being able to continue living normally. The PBI-w mean score was 2.93 (standard deviation=0.75) on a scale of zero ('did not help at all') to four ('helped a lot'). The PBI-w score showed that the patients benefitted from the treatment they received.

**Conclusion:** This pilot study showed the feasibility of using the PBI-w in practice in an outpatient clinic to assess patients' needs, which could help health professionals improve treatment and care for people with leg ulcers. The study also pointed towards the benefits of care for patients who consult specialised outpatient clinics.

**Declaration of interest:** The authors have no conflict of interest to declare regarding this study.

leg ulcers • Patient Benefit Index-wound • patient's benefit • patient's needs • pilot study • quality of care

Leg ulcers, and especially venous leg ulcers (VLUs), can take a long time to heal, sometimes even years,<sup>2</sup> and have a high recurrence rate.<sup>5</sup> The aetiology of leg ulcers is primarily venous (70%), with 15% of mixed aetiology and 5% of arterial aetiology, and 10% other causes.<sup>5</sup>

The impact on quality of life (QoL) for patients with leg ulcers is well documented. Gonzales et al.<sup>8</sup> found that, as well as the physical impact, leg ulcers also impact on patients emotional state and social interaction. The most common reported symptoms of leg ulcers are pain, immobility, insomnia, exudate, and odour.<sup>9</sup> Edwards et al.<sup>10</sup> showed that 64% of patients with leg ulcers suffered from four or more symptoms.

QoL scales or symptom descriptions used in clinical practice are not always focused on patient needs. Heinen et al.<sup>11</sup> identified that 50–70% of the patients in an outpatient setting did not receive care in relation to their leg ulcer-related problems such as sleeping, having appropriate footwear or coping with compression. Green et al.<sup>12</sup> showed that patients do not always mention their concerns to a health professional. This may lead to a difference in opinion, between the treating health professional and the patient, of what treatment is required as the health professional may not have all the information they need to deliver patient-centred care.

To ensure the best possible care is available, an assessment of their leg ulcer treatment and care needs must be undertaken in conjunction with the patient.

In order to ensure the needs of patients are met and to improve treatment and care, Augustin et al.<sup>13,14</sup> developed the Patient Benefit Index-wound (PBI-w) to identify specific patient treatment and care needs, and to measure the benefit(s) of treatments they receive.

## Aims

This study aims to obtain a description of the sociodemographic and medical profile of patients with leg ulcers, and assess the benefits to patients of treatment in an outpatient clinic.

## Method

A descriptive, cross-sectional design was chosen for this pilot study. Patients were recruited from a specialised leg ulcer outpatient clinic at a university hospital in Switzerland. The following inclusion criteria were used:

- ≥18 years
- Having a leg ulcer for >4 weeks
- Living at home
- Proficiency in the French language.

The only exclusion criteria applied was if valid informed consent was not or could not be given.

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**Table 1. Sociodemographic characteristics**

Sociodemographic characteristics (n=32)	Mean	Median	SD	Min	Max
Age	70.7	73	12.1	40	91
Female (n=13)	69.8	75	12.8	43	87
Male (n=19)	71.3	72	11.9	40	91
Sociodemographic characteristics (n=32)		n	%		
Sex					
Female		13	40.6		
Male		19	59.4		
Nationality					
Switzerland		28	87.5		
EU		4	12.5		
Civil state					
Married		17	53.1		
Single		6	18.8		
Separate		4	12.5		
Widower		5	15.6		
Household					
Flatsharing/partner		19	59.4		
Alone		13	40.6		
Children					
One or more child		21	65.6		
Without children		11	34.4		
Profession					
Retired		25	78.1		
Disability insurance		2	6.3		
Working		3	9.4		
Unemployed		1	3.1		
Housewife/housemen		1	3.1		
Level of education					
Apprenticeship		16	50.0		
Not finished standard schooling		7	21.9		
University		5	15.6		
High school		4	12.5		

SD—standard deviation; Min—minimum; Max—maximum

Nursing staff assessed patients against the inclusion and exclusion and, if inclusion was possible, invited them to participate. After obtaining informed consent, the participants were referred to the study nurse. The ethical committee of Canton Vaud approved the study in October 2014 (number 229/14).

Data collection was conducted from October 2014 until February 2015. Sociodemographic and medical data as well as data from the PBI-w were collected. The PBI-w was composed of the Patient Needs Questionnaire

(PNQ) which focuses on the individual importance of treatment needs, and the Patient Benefit Questionnaire (PBQ) which focuses on the treatment objectives.

Patients were asked to rate the importance of each goal on a five-step Likert scale from zero (not important at all) to four (very important). PBQ measures the extent to which the current therapy helped the patients to achieve their goals, again on a five-step Likert scale from zero (didn't help at all) to four (helped a lot)

A total PBI-w score was calculated for each patient by dividing the PNQ rating on the individual importance of treatment objectives by the sum of all PNQ ratings, and then multiplying it with the respective rating of the PBQ. By summing up the scores, the PBI-w can obtain values from zero (no benefit) to four (maximum benefit).

The questionnaire was used in the French version translated by the team of Augustin according to Blom et al.<sup>15</sup> The original version was translated by two bilingual speakers into French and the results compared. After that, the translated version was retranslated into the original language by two other bilingual speakers. Consensus was obtained on the final translation. After being translated, the questionnaire was proofread.

In our study, the Cronbach's Alpha for the French version was 0.74 for the PNQ scale and 0.85 for the PBQ scale.

All analyses were conducted using STATA 13 for Mac. Data were analysed using measures of central tendency and dispersion, means, median, standard deviation (SD) and frequencies.

## Results

A total of 32 patients participated, of whom 59.4% (n=19) were male and the mean age was 70.7 years (SD: 12.1; range: 40–91); 40.6% patients (n=13) lived alone, but most had one or more children (65.6%, n=21); 78.1% (n=25) were retired, 50.0% (n=16) had been an apprentice and 21.9% (n=7) had left secondary education before completing standard schooling, indicating most participants had a low level of education (71.9%, n=23) (Table 1).

Venous insufficiency was the most frequent comorbidity in patients, 96.9% (n=31), followed by obesity (37.5%, n=12) and diabetes (18.8%, n=6). Of the participants, 81.3% (n=26) of the leg ulcers had a venous aetiology, 15.6% (n=5) had a mixed aetiology, and 3.1% (n=1) had an arterial aetiology; 75% (n=24) of patients presented with one or more recurrences of their leg ulcer, and 40.6% (n=13) presented with more than three recurrences (Table 2).

The mean duration of healing time was 44.7 weeks (SD: 41.8; range: 7–200); 40.6% (n=13) had a dressing change twice a week and 34.4% (n=11) had a dressing change once a week. In 43.8% (n=14), the time needed to change a dressing was between 15 and 29 minutes (Table 2).

### Patient needs questionnaire (PNQ)

Finding a clear diagnosis and therapy (mean: 3.8,

**Table 2. Medical characteristics**

Medical characteristics (n=32)	Mean	Median	SD	Min	Max
Duration of follow-up, weeks	27.8	18.5	29.3	4	145
Duration of the healing process, weeks	44.7	30.5	41.8	7	200
		<b>n</b>		<b>%</b>	
<b>Type of ulcer</b>	Venous	26		81.3	
	Mixed	5		15.6	
	Arterial	1		3.1	
<b>Related pathology</b>	Venous insufficiency	31		96.9	
	Obesity	12		37.5	
	Diabetes	6		18.8	
<b>Recurrences</b>	None	8		25.0	
	One	9		28.1	
	Two	2		6.3	
	Three and more	13		40.6	
<b>Wounds' origin</b>	Disease	18		56.3	
	Traumatic	13		40.6	
	Disease and surgery	1		3.1	
<b>Dressings change frequency per week</b>	One	11		34.4	
	Two	13		40.6	
	Three	5		15.6	
	Seven	3		9.4	
<b>Time of dressing change, minutes</b>	0–14	6		18.8	
	15–29	14		43.8	
	30–44	4		12.5	
	45–59	3		9.38	
	≥60	5		15.6	

SD—standard deviation; Min—minimum; Max—maximum

SD: 0.7) was of most importance to patients, followed by the need for their leg ulcers to heal (mean: 3.8, SD: 1.0) and to have confidence in the therapy (mean: 3.6, SD: 0.6). Of least importance to patients in terms of patient needs were ‘feel less depressed’, ‘be able to have more contact with other people’ and ‘be comfortable showing oneself more in public’, with a mean score of 1.9 (SD:1.7), 1.6 (SD: 1.45) and 1.2 (SD: 1.5), respectively. The item ‘be able to lead a normal working life’ obtained a high rate (65.6%) of ‘does not apply to me’,

perhaps due to the high number retired participants (78.1%). Table 3 presents the results of the patient needs questionnaire in decreasing order of importance to the patient.

**Patient benefit questionnaire (PBQ)**

For participants, the most important benefit of treatment was having confidence in the therapy (mean: 3.7, SD: 0.5), followed by being free of pain (mean: 3.4, SD: 0.9) and being able to lead a normal everyday life (mean: 3.3, SD: 0.9). Having confidence in the therapy was a concern of every participant. Of less importance was ‘being able to have more contact with other people’ (mean: 2.2, SD: 1.5), having fewer out-of-pocket treatment expenses (mean: 2.0, SD: 1.8) or ‘be comfortable showing oneself in public’ (mean: 1.7, SD: 1.5).

As in the PNQ scale, the item ‘to be able to lead a normal working life’ obtained a high rate (71.9%) of ‘did not apply to me’. Table 4 presents the results of the patient benefit questionnaire in decreasing order of importance to the patient.

**Patient Benefit Index-wound (PBI-w)**

The PBI-w index showed patients benefited from the received treatment they received (mean: 2.9, SD: 0.8). Additionally, the PBI-w showed that having confidence in healing scored highest with a mean of 3.4 (SD: 0.7). The results from the subscales are presented in Table 5.

**Discussion**

The majority of the participants in this study were male. The populations described in other studies show similar demographic data.<sup>3,16</sup> The older age of participants also corresponds with the growing prevalence of leg ulcers, and similar to other, larger studies.<sup>2,3,11,17</sup> Household composition and levels of education are also similar to the results found in the literature in European countries.<sup>11,18,19</sup> According to the literature, leg ulcers occur mostly in populations with a low financial situation and a low level of education.<sup>11</sup>

In our study, the median healing time of a VLU was similar to that described in a study by Moffat et al.<sup>17</sup> Other studies described even wider ranges in leg ulcer healing time (range: 7–200 weeks).<sup>13,16,17</sup> This can also be applied to leg ulcers recurrence, which was the case for 75% of the participants, where the literature showed a recurrence prevalence of 50% with VLUs and variable recurrence in leg ulcers of other aetiologies.<sup>2</sup>

The PNQ scale highlighted the importance of obtaining a clear diagnosis and therapy which is similar to the study by Augustin et al.<sup>14</sup> that reported a mean PNQ score of 3.8. In a second study, Augustin et al.<sup>13</sup> identified a mean of 3.5, which demonstrated that this was of less importance to patients. Patients in this study expressed a desire for wound closure, but this did not feature so highly in Augustin’s study. Both of Augustin’s studies sampled different populations. In the 2012 study, 172 patients with chronic and acute wounds

**Table 3. Patients' description of treatment needs**

Treatment need (n=32)	Mean	SD	Very important (%)	Did not apply to me (%)
<b>Find a clear diagnosis and therapy</b>	<b>3.8</b>	<b>0.7</b>	<b>87.5</b>	<b>00.0</b>
<b>Be healed from lesion(s)</b>	<b>3.8</b>	<b>1.0</b>	<b>93.8</b>	<b>00.0</b>
<b>Have confidence in the therapy</b>	<b>3.6</b>	<b>0.6</b>	<b>65.6</b>	<b>00.0</b>
Have no discharge from the lesion	3.4	0.9	65.6	00.0
Be able to engage in normal leisure activities	3.2	1.1	53.1	3.12
Be able to lead a normal everyday life	3.2	1.4	65.6	00.0
Be free of pain	3.2	1.2	46.9	12.5
Not have an unpleasant smell from the lesion	3.1	1.5	56.3	12.5
Experience a greater enjoyment of life	3.0	1.5	53.1	15.6
Have no fear that the disease will become worse	3.0	1.4	56.3	00.0
Be less dependent on doctor and clinic visits	3.0	1.3	46.9	00.0
Be able to have a normal working life	2.8	1.5	15.6	65.6
Be less of a burden to relatives and friends	2.8	1.7	46.9	15.6
Be more productive in everyday life	2.7	1.2	21.9	21.9
Be able to sleep better	2.6	1.5	37.5	12.5
Have fewer out-of-pocket treatment expenses	2.6	1.7	43.8	9.4
Have fewer side effects	2.5	1.6	40.6	6.3
Need less time for daily treatment	2.3	1.7	37.5	00.0
Be less burdened in partnership	2.1	1.5	9.4	56.3
<b>Feel less depressed</b>	<b>1.9</b>	<b>1.7</b>	<b>18.8</b>	<b>43.8</b>
<b>Be able to have more contact with other people</b>	<b>1.6</b>	<b>1.5</b>	<b>9.4</b>	<b>12.5</b>
<b>Be comfortable showing yourself more in public</b>	<b>1.2</b>	<b>1.5</b>	<b>12.5</b>	<b>9.4</b>

0=not important at all; 1=somewhat important; 2=moderately important; 3=quite important; 4=very important; . = did not apply to me; SD—standard deviation

were included, using negative wound pressure therapy, whereas in the 2009 study, psychometrics were measured on a much broader dermatological population.

Morgan and Moffat<sup>21</sup> reported the need for nurses to focus not only on wound closure but also on patient needs. These results could not be verified in our study because the participating patients gave a high level of importance to being healed of their wounds (mean: 3.8). However, participant confidence in the therapy obtained a high score in this study and in that of Augustin et al.<sup>13</sup>

The PBQ scale showed that patients regarded having confidence in the therapy to be the most important benefit, which is in line with Austin et al.<sup>13</sup> This confidence within our study population may be attributable to the outpatient clinic where they were treated being a specialised inter-professional wound care centre.

The second benefit was to be pain free; however, almost one fifth of participants did not prioritise this item. In Augustin et al.'s<sup>13</sup> study, the second benefit was

to find a clear diagnosis and therapy; this item scored a mean of 3.3 at the outpatient clinic and was in 4th place among the participants' concerns. The third benefit was the ability to lead a normal everyday life, which scored a mean of 3.3 in our study and obtained a mean of 2.5 in the Augustin et al.<sup>13</sup> study.

The PBI-w showed a high benefit index, mean PBI of 2.9, in this study compared with a mean of 2.75 in the study of Augustin et al.<sup>13</sup>

For participants in our study, the importance of obtaining 'a diagnosis and therapy' seemed to be the major outcome, followed by the need for all 'wounds to be healed' and 'have confidence in the therapy given'. These findings raise the question of the need for a possible paradigm shift in the care and treatment of people with leg ulcers, one that focuses on needs management and not just wound healing.<sup>20</sup>

This approach also highlights the important issue of 'patient hope' with regards to obtaining a cure in the

**Table 4. Patients' rating of treatment benefit**

Treatment benefit (n=32)	Mean	SD	Helped a lot (%)	Did not apply to me (%)
<b>Have confidence in the therapy</b>	<b>3.7</b>	<b>0.5</b>	<b>71.9</b>	<b>00.0</b>
<b>Be free of pain</b>	<b>3.4</b>	<b>0.9</b>	<b>50.0</b>	<b>18.8</b>
<b>Be able to lead a normal everyday life</b>	<b>3.3</b>	<b>0.9</b>	<b>53.1</b>	<b>6.3</b>
Find a clear diagnosis and therapy	3.3	1.2	65.5	00.0
Be able to have a normal working life	3.2	1.3	15.6	71.9
Have no discharge from the lesion	3.2	1.0	56.3	00.0
Need less time for daily treatment	3.2	1.1	53.1	6.3
Be healed from lesion(s)	3.1	1.3	59.4	00.0
Experience a greater enjoyment of life	3.1	1.3	50.0	15.6
Be less of a burden to relatives and friends	3.1	1.4	46.9	28.1
Not have an unpleasant smell from the lesion	3.0	1.5	43.8	21.9
Have no fear that the disease will become worse	3.0	1.3	53.1	00.0
Have fewer side effects	3.0	1.4	50.0	3.1
Be more productive in everyday life	2.7	1.3	21.9	28.1
Be less dependent on doctor and clinic visits	2.7	1.5	46.9	00.0
Be able to engage in normal leisure activities	2.6	1.3	28.1	12.5
Feel less depressed	2.5	1.6	25.0	46.9
Be able to sleep better	2.4	1.7	31.3	21.9
Be less burdened in partnership	2.4	1.7	12.5	65.6
<b>Be able to have more contact with other people</b>	<b>2.2</b>	<b>1.5</b>	<b>21.9</b>	<b>15.6</b>
<b>Have fewer out-of-pocket treatment expenses</b>	<b>2.0</b>	<b>1.8</b>	<b>31.3</b>	<b>12.5</b>
<b>Be comfortable showing yourself more in public</b>	<b>1.7</b>	<b>1.5</b>	<b>15.6</b>	<b>28.1</b>

0=didn't help at all; 1=somewhat helped; 2=moderately helped; 3=quite helped; 4=helped a lot; . = did not apply to me; SD—standard deviation

context of chronic disease. The extended duration of healing required for leg ulcers could lead patients to experience feelings of hopelessness.<sup>22</sup> However,

**Table 5. Total score and scores of subscales of Patient Benefit Index-wound (PBI-w)**

PBI-w (n=32)	Mean	SD
Global score PBI-w	2.9	0.8
Having confidence in healing	3.4	0.7
Reducing physical impairments	2.9	1.0
Reducing psychological impairments	2.8	1.1
Reducing impairments due to therapy	2.6	1.3
Reducing social impairments	2.4	1.4
SD—stanadr deviation		

improving patient hope could help them better cope with their LU and the symptoms.<sup>23</sup>

Persoon et al. reported the most important impact of leg ulcers on daily life are pain and sleep disorders.<sup>9</sup> However, in our study at the outpatient clinic, expectations in pain management and sleep disorders were less important. It should be noted that the large variance in age of the sample could influence the relevant individual needs obtained in this study (SD: 12.12; range: 40–91).

The consistency between patient needs and benefits were congruent. Regarding their subscales, the PNQ and PBQ have some similarities. The therapy had a more beneficial impact on the patient's physical than their psychological aspect. In the study by Green et al.<sup>12</sup> there was less focus and treatment of the emotional impact than the physical impact of VLUs.

Additionally, patient scores of >1 on the PBI-w and the subscales indicated an ability to manage their disease from the patient perspective.

### Reflective questions

- How can we better develop and implement the Patient Benefit Index-wounds (PBI-w) for use in clinical practice?
- How can we develop clinical interventions based on scores derived from patient needs questionnaires, patient benefit questionnaires and the PBI-w?
- How, if at all, does use of the PBI-w affect wound closure?

### Limitations

The small sample size did not allow a generalisation but illustrated the application of the instrument in another context and language. A cross-sectional design was used which could have an influence on the comprehension of the questionnaires and could influence the results. Although there was a strong link between the leg ulcer clinic and home care services, patients who attended the clinic may have different characteristics (age, gender, wound duration and type etc.) those who receive services at a home visit. An extension of the study will be planned to examine home care services.

Nursing and medical interventions were not taken into consideration in this study. Therefore it was difficult to identify which intervention was the most important to patients. Finally, the study did not focus

on the ease of use of the instrument which should form the premise for a future study using the French questionnaire.

### Conclusion

This study demonstrated the validity of the French version of PBI-w. More research is needed to improve nursing interventions so that their outcomes and benefits of treatments can be measured.

In terms of clinical practice, this study highlighted the most important needs of patients in an outpatient clinic. This instrument could be used to guide an assessment of patient needs assessment in order to deliver patient-centred care. Further study is needed in a larger patient and clinician population to evaluate the acceptance and ease of use of the French-translated questionnaires. **JWC**

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