

## Pain Assessment in Patients with Venous Leg Ulcer Treated by Compression Therapy with Unna's Boot

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Received date: June 20, 2016; Accepted date: June 27, 2016; Published date: June 30, 2016

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### Abstract

**Aim:** To assess pain in patients with venous leg ulcer receiving compression therapy with Unna's boot.

**Methods:** This was a clinical, analytical, descriptive study conducted from June 2010 to May 2011 with 50 patients with venous leg ulcers. The visual analog scale (VAS) and McGill Pain Questionnaire (MPQ) were used to assess pain at inclusion (baseline) and after 4, 8 and 12 months of treatment.

**Results:** The mean VAS score was 6.70 (severe pain) at baseline, 5.02 (moderate pain) at 4 months, and 0 (no pain) at 8 and 12 months, with significant difference between time points. All patients described their pain on the MPQ as sensory, affective, and miscellaneous at baseline. However, after 4 months of Unna's boot treatment, 10 (20%) patients reported sensory pain, 46 (92%) had miscellaneous pain and 44 (88%) experienced affective pain, with significant difference between time points.

**Conclusion:** Patients with venous leg ulcers reported improvement in pain following treatment with Unna's boot.

**Keywords:** Pain; Mobility limitation; Leg ulcer; Varicose ulcer; Self-esteem; Nursing care

### Highlights

- Unna's boot therapy significantly reduced pain in patients with pressure ulcers.
- About 84% of venous ulcers completely healed after a 12 month Unna's boot treatment
- Compression therapy with Unna's boot is an effective treatment of venous leg ulcers

### Introduction

Chronic wounds can be caused by diseases, genetic factors, injuries, or lifestyle factors, are associated with impaired functioning, and require long-term treatment. They affect people of all ages in the different cultural, socioeconomic and ethnic groups and show increased prevalence with aging [1]. Patients with chronic wounds experience changes in their lifestyle and have to adapt to the new condition [2].

Chronic wounds have a marked socioeconomic impact on patients, their families, and on the public health system worldwide. In the USA, more than US\$ 3 billion are spent annually in the treatment of chronic wounds, including costs with materials and formal and informal caregivers, but excluding emotional costs associated with the presence of a non-healing sore [3]. Venous ulcers are chronic wounds caused by inadequate venous blood return from the feet and legs, and associated with a number of diseases, including diabetes mellitus, peripheral vascular disease, and chronic venous insufficiency.

About 70% to 80% of venous ulcers are associated with chronic venous insufficiency [4]. Venous ulcers are the most severe complication of chronic venous insufficiency with high prevalence and recurrence rates. This results in suffering for patients and family members and creates patient dependence on health care providers, becoming a serious public health problem with important social implications [5].

Venous leg ulcers are relatively common in the adult population, with an increasing prevalence associated with the increase in life expectancy worldwide, and recurrence rates ranging from 60% to 72% [6]. The presence of a venous leg ulcer can significantly affect the patient's daily life, cause psychosocial disorders and economic and social problems, and impair quality of life [7].

Pain is a physical experience that can affect mental health, and consequently, attitudes and behaviors. Pain may be underestimated and undertreated by health professionals [8,9]. However, it should be assessed in all patients with venous leg ulcers at regular intervals. All studies in a systematic review, indicated pain as the first symptom experienced by patients with leg ulcers. These patients reported different pain qualities, such as annoying, intense, and troublesome [10]. The presence of pain affects activities of daily living and sleep pattern, and impairs mobility in patients with venous leg ulcers. VAS pain scores varying from 2.2 (mild pain) to 5.5 (moderate pain) have been reported [10]. Pain has a negative impact on the psychological functioning of patients, regardless of gender or cultural background, limiting their social, sexual, and leisure activities. Feelings of powerlessness may lead to social isolation and, in extreme cases, to a loss of identity, affecting their psychosocial balance.

Thus, the purpose of this study was to evaluate pain in patients with venous leg ulcers treated by compression therapy with Unna's boot.

## Methods

This descriptive analytic clinical study was approved by the Research Ethics Committee of the Federal University of São Paulo (UNIFESP), Brazil, approval no. 0650/10. It was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and its subsequent revisions.

A study cohort of 50 participants of both sexes was recruited from consecutive patients attending the Outpatient Wound-Care Clinic of the Sorocaba Hospital Complex (Brazil) between June 2010 and May 2011. The study was based on a convenience sample. A history was obtained and physical examination was performed on all recruited patients, including ulcer assessment (e.g. ulcer size, location, presence of granulation tissue, necrotic tissue, exudate, odor, and infection).

Inclusion criteria were age  $\geq 18$  years, presence of a venous leg ulcer for more than one year not previously treated with Unna's boot, Doppler ankle-brachial pressure index (ABPI), ranging from 0.8-1.0 for exclusion of peripheral arterial disease (PAD) and clinical signs, including irregular shallow ulcers in the ankle region, mid-calf, and medial leg, and above the medial malleolus, swelling of the legs that is worse at the end of the day and that can be relieved by elevation, hyperpigmentation of the legs, and lipodermatosclerosis.

Exclusion criteria were skin lesions other than venous leg ulcers, neuropathic pain detected during the physical examination, ABPI $<0.8$ , and clinical signs of PAD, including round, deep ulcers in the ankle or malleolus.

Written informed consent was obtained from all participants prior to their inclusion in the study and after the objectives and relevance of the study had been fully explained. The participants were also informed that they were free to leave the study at any time and that they would continue to receive treatment as usual. Patient anonymity was assured.

It was also explained to the patients in a simple and clear language that Unna's boot creates a high counter-pressure during walking and has a low resting pressure; it increases venous return and provides topical treatment and environmental protection to the skin [11]. All of the patient's questions were answered before the informed consent was obtained. All patients who met the study criteria were included and none refused to take part in the study.

All participants were treated with wound dressings and Unna's boot. The dressings were chosen according to stage of healing, level of exudate, and amount of necrotic tissue. The ulcers were assessed weekly for size, presence of granulation tissue, necrotic tissue, exudate, odor and infection during dressing changes.

The interviews were conducted by the same investigator and took place in a private room for the patient to feel at ease and comfortable.

Patients were assessed for pain using the visual analog scale (VAS) and the McGill Pain Questionnaire (MPQ) [12-15] at inclusion (baseline) and after 4, 8 and 12 months of treatment.

The VAS rates pain intensity on a scale from 0 to 10, where 0=no pain and 10=worst possible pain [12,13]. Patients were asked to rate pain intensity by placing a mark on a 10 cm line printed on paper. The VAS was horizontally positioned with the extremes labelled "least possible pain" and "worst possible pain". The level of pain intensity of each patient was then measured using a mm ruler.

MPQ is a tool to assess pain quality consisting of word descriptors used by patients to describe subjective pain experience [12-15]. The word descriptors are organized into four major classes and 20 subclasses, as follows: sensory-descriptive (sub-classes 1-10), motivational-affective (sub-classes 11-15), cognitive-evaluative (sub-class 16), and miscellaneous (sub-classes 17-20). The sensory-descriptive class describes pain experience in terms of mechanical, thermal, pressure and spatial properties; the motivational-affective class is related to affective qualities of pain, including tension, fear and autonomic properties; the descriptors in the cognitive-evaluative class describe the subjective global experience of pain; and the miscellaneous class represents miscellaneous pain qualities. Each subclass contains 2 to 6 word descriptors qualitatively similar that vary in intensity and provide subtle differences or nuances. A numerical value representing pain intensity is assigned to each descriptor [12-15].

The MPQ provides two measures: the "number of words chosen" and the "pain rating index". The "number of words chosen" refers to the words chosen by the patient to describe the experienced pain. Its maximum possible value is 20 because the patient is allowed to choose a maximum of one word per subclass. The "pain rating index" is obtained by the sum of the intensity values of the words chosen, with a maximum possible value of 78. These measures yield an overall score and scores on the four classes: sensory, affective, evaluative, and miscellaneous.

All patients who reported pain were referred to a physician and received analgesia according to their needs and were instructed to rest with legs elevated. After 8 months of treatment, the patients were not under pain medication when responding to the questionnaires.

Variables	Participants (n=50)		P-value
	n	%	
Age group (years)			
20-40	2	4	
41-60	15	30	0.0045
>60	33	66	
Gender			
Women	26	52	0.0657
Men	24	48	
Occupational status			
Retired	33	66	
Unemployed	13	26	0.0045
Other	4	8	
Ulcer recurrence			
Yes	46	92	0.001
No	4	8	
Chi-square test of independence (P<0.05)			

**Table 1:** Demographic and clinical characteristics of patients with venous leg ulcers treated with Unna's boot therapy.

Statistical analysis was carried out with Student's t-test, the Kruskal-Wallis test and Chi-square test of independence. All statistical tests were performed at a significance level of 0.05 ( $P < 0.05$ ). The Statistical Package for the Social Sciences (SPSS) 15.0 for Windows (SPSS Inc., Chicago, IL, USA) and Microsoft Office Excel software (Microsoft Corp., Redmond, WA, USA) were used for data analysis.

## Results

All 50 patients completed the study period of one year of compression therapy with Unna's boot (treatment adherence rate=100%).

Twenty-six (52%) patients were women and 33 (66%) were aged 60 years or older and retired, with significant differences in number of patients ( $P=0.0045$ ) among age groups and occupational status. In addition, 46 (92%) patients reported ulcer recurrence (Table 1).

At baseline, 30 ulcers (60%) had a surface area ranging from 16 to 20 cm<sup>2</sup> and after 12 months of Unna's boot treatment, ulcers were completely healed in 42 (84%) patients (Table 2).

Ulcer surface area (cm <sup>2</sup> )	Within treatment assessments				
	Baseline	4 months	8 months	12 months	P-value
	n (%)	n (%)	n (%)	n (%)	
Completely healed	0 (0)	0 (0)	4 (8)	42 (84)	0.0001
10-Jan	4 (8)	5 (10)	29 (58)	4 (8)	0.0367
15-Nov	10 (20)	20 (40)	7 (14)	2 (4)	0.067
16-20	30 (60)	15 (30)	5 (10)	2 (4)	0.0568
>21	6 (12)	10 (20)	5 (10)	0 (0)	0.654

**Table 2:** Wound surface area in patients with venous leg ulcers (n=50) treated with Unna's boot therapy at the four time points.

The mean VAS score was 6.70, corresponding to severe pain; 30 (60%) patients reported VAS scores between 6 and 7 at baseline. However, 4 months after treatment with Unna's boot, the mean VAS scores was 5.02 and 30 (60%) patients reported VAS scores between 0 and 3. All patients reported no pain (VAS score=0) at 8 and 12 months of treatment, with significant differences ( $P=0.0001$ ) between time points (Table 3).

Patients described their pain on the MPQ as sensory, affective, and miscellaneous at baseline, but reported no pain after 8 months of Unna's boot treatment, with significant differences ( $P=0.0001$ ) between time points (Table 4).

## Discussion

Population aging leads to an increase in the prevalence of chronic diseases and results in changes in the structure of public health services. Health status is no longer measured by the presence or absence of diseases, but instead by the level of functional ability of the individual [16].

Many patients with venous leg ulcers have chronic diseases and feel pain, which interfere with their ability to perform daily life activities.

In the present study, most patients were women, aged 60 years and older, and retired. An increased incidence of venous leg ulcers has been observed in women older than 61 years of age. The presence of a venous ulcer affects the patient's social and occupational functioning, and may lead to early retirement [17-23].

VAS scores	pain	Baseline	4 months	8 months	12 months	P-value
		n (%)	n (%)	n (%)	n (%)	
0		0 (0)	14 (28)	50 (100)	50 (100)	
1		1 (2)	6 (12)	0 (0)	0 (0)	
2 Jan		1 (2)	5 (10)	0 (0)	0 (0)	
3 Jan		2 (4)	5 (10)	0 (0)	0 (0)	
4		3 (6)	8 (16)	0 (0)	0 (0)	0.002
5		2 (4)	12 (24)	0 (0)	0 (0)	
6		20 (40)	0 (0)	0 (0)	0 (0)	
7		10 (20)	0 (0)	0 (0)	0 (0)	
8		4 (8)	0 (0)	0 (0)	0 (0)	
9		4 (8)	0 (0)	0 (0)	0 (0)	
10		3 (6)	0 (0)	0 (0)	0 (0)	
Total		50 (100)	50 (100)	50 (100)	50 (100)	
Mean		6.7	5.05	0	0	0.0001
SD		2.41	2.33	0	0	
Student's t-test and Kruskal-Wallis test						

**Table 3:** Total and mean scores on the visual analog scale (VAS) for pain assessed in patients with venous leg ulcers treated with Unna's boot therapy.

Classes of Word Descriptors	Sensory	Affective	Evaluative	Miscellaneous	P-value
	n (%)	n (%)	n (%)	n (%)	
Baseline	50 (100)	50 (100)	49 (98)	50 (100)	0.0001
4 months of treatment	10 (20)	44 (88)	18 (36)	46 (92)	0.0001
8 months of treatment	0 (0)	0 (0)	0 (0)	0 (0)	0.0001
12 months of treatment	0 (0)	0 (0)	0 (0)	0 (0)	0.0001
Student t-test and Kruskal Wallis test					

**Table 4:** Distribution by MPQ Classes of word descriptors used by patients to describe subjective pain experience at different time points during Unna's boot treatment.

Most ulcers had a surface area ranging from 16 to 20 cm<sup>2</sup> at baseline; however, ulcers were completely healed in 42 (84%) patients after 12 months of compression therapy with Unna's boot. This is a strong indication of the efficacy of Unna's boot treatment in the healing of venous leg ulcers. The dressings were chosen according to stage of healing, level of exudate, and amount of necrotic tissue. There

are several options of dressings in the market. The selection of a proper dressing should be based on a cost-benefit analysis, duration of treatment, and wound characteristics, including condition of the periwound skin, ulcer surface area, ulcer location, exudate and type of wound tissue [24-26].

Chronic venous insufficiency is mainly caused by incompetence of the superficial venous system with or without associated valvular incompetence or obstruction of the deep venous system. This condition makes it difficult for the blood to return from the lower extremities to the heart, leading to blood stagnation in the legs, which results in an inflammatory process and consequent ulcer development. The clinical treatment of venous ulcers is based on local care with the use of wound dressings and compression therapy, which improves the venous return, facilitates oxygen transport to the skin and subcutaneous tissue, reduces edema and inflammation, and thus helps the healing process [17,27-29]. This can be achieved through leg elevation and compression therapy with elastic or inelastic bandaging [30].

Compression therapy is essential for an effective treatment of venous leg ulcers. It reduces venous hypertension and is commonly delivered with graduate compression stockings, elastic bandages, or Unna's boot. The intensity of external compression applied to the legs should decrease from ankle to knee in order to revert the effect of prolonged orthostasis, which increases intravascular hydrostatic pressure [31]. In the present study, Unna's boot therapy resulted in complete healing in 84% of patients after 12 months of treatment. This is in agreement with the findings of other studies, in which compression therapy in patients with venous leg ulcers led to complete healing in 40% to 95% of cases, improving the quality of life and functional status of this population [32-34].

All patients described their pain on the MPQ as sensory, affective, and miscellaneous at baseline, but chose no word descriptor for pain at 8 and 12 months of treatment. With regard to pain intensity, the mean VAS pain score was 6.70 at baseline, corresponding to severe pain and 0 (no pain) at 8 and 12 months of treatment. After 8 months of Unna's boot therapy, even patients with venous leg ulcers reported no pain and had a marked reduction of the edema. Patients were not under pain medication when responding to the questionnaires at 8 and 12 months of treatment. This indicates that compression therapy with Unna's boot is efficient in promoting pain control and wound healing. In a study on pain in chronic leg ulcers, 63% of the patients described their pain as sensory, including pinching, throbbing, pricking, burning, and pinching, and reported a mean VAS pain score of 3.1, a mean "worst pain of the week" of 7.56, and mean "best pain of the week" of 2.05 [35]. A study using the Wound Associated Pain model (a foot and leg care model) on 111 venous ulcer patients reported VAS pain scores of 6.3 (moderate pain) at baseline and 2.8 (mild pain) after 4 weeks of treatment [36]. Another study assessed the impact of pain in 30 patients with venous ulcers and 90% of them reported a VAS pain score of 6.9 (severe pain); 83% described their pain as sensory and 16.75% as evaluative [37].

Pain is a complex and personal experience involving a number of components, including the sensory, affective, cognitive, social, behavioral aspects. The multidimensional aspects of pain make its assessment difficult by health professionals [38]. Pain may lead patients with venous leg ulcers to depression, anxiety, and consequent social isolation, reduced sleep quality, mood changes, agitation, aggressiveness, feelings of powerlessness, decline in cognitive function, functional disability, and impaired quality of life, resulting in

functional dependence to perform activities of daily living and increased social service costs [35,39-42]. Thus, pain assessment is an essential part of the nursing care process, specialized or not in patients with chronic wounds [43].

Several studies have reported that venous leg ulcers are painful and lead to impaired mobility and reduced quality of life [35,44-47]. Elderly people, who suffer from pain, and especially those with venous leg ulcers, may experience progressive social isolation, have a tendency for sedentary lifestyle, loss of self-esteem, and neglect self-care. They may also show limited functional ability and physical and mental dependence on caregivers to perform complex tasks of daily living, such as housekeeping, buy groceries, leisure activities, and walk [48-51].

The use of convenience sampling and a small sample size were the major limitations of this study. Further studies with a larger number of patients and involving multiple centers are necessary extend our results. It is also important to investigate the effects of this treatment on long-term recurrence of venous leg ulcers, pain control, wellbeing, spirituality, and hope of cure by assessing patients either receiving or not receiving (control group) compression therapy with Unna's boot.

The understanding of the severity of pain in patients with venous leg ulcers is of fundamental importance for the development of strategies not only for the prevention and treatment of the condition, but also to improve quality of life and promote the wellbeing of this population [11,52,53].

It is also important to highlight the need for government incentives in Brazil, such as grants and tax breaks, to increase the number of outpatient wound care clinics for the treatment of patients with chronic wounds, including venous leg ulcers. Patients with chronic wounds should have access to the new technologies found on the market, because the healing of the ulcer improves the pain, functional status, and quality of life of these patients, while reducing health care costs.

## Conclusion

In this study, all patients with venous leg ulcers experienced a reduction in pain after receiving compression therapy with Unna's boot.

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