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Health-related quality of life of people receiving venous leg ulcer treatment with compression therapy

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Abstract

This study assessed the effects of high compression bandages and Unna's boots on health-related quality of life for venous leg ulcer treatment. A randomised clinical trial was conducted with 56 patients across 22 primary healthcare services in Brazil, between 2020 and 2023. Participants were randomly assigned to receive high compression bandages (Group A) or Unna's boots (Group B). Health-related quality of life was assessed by the six-dimensional Health State Short Form questionnaire at baseline and follow-up (venous leg ulcer healing or at 26 weeks). Descriptive analyses, and t-tests were performed. The average score change was 0.093 (± 0.09) ($p < 0.001$) in Group A and 0.06 (± 0.1) ($p = 0.007$) for Group B, with no difference between groups ($p = 0.218$). For healed ulcers, Group A experienced an increase of 0.109 (± 0.084) ($p < 0.001$) and Group B 0.113 (± 0.115) ($p < 0.01$), with no difference between groups ($p = 0.914$). For unhealed ulcers, the increases were 0.058 (± 0.098) ($p = 0.09$) in Group A and 0.028 (± 0.078) ($p = 0.182$) in Group B, with no difference between groups ($p = 0.441$). Both treatments significantly improved participants' health-related quality of life, with no significant differences between groups, suggesting that both interventions effectively enhance quality of life.

Keywords quality of life, patient-reported outcome measures, varicose ulcer, compression bandages, primary health care

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Introduction

Venous leg ulcers (VLU) are the most severe form of chronic venous disease.¹ These conditions arise due to compromised blood flow, disrupting normal physiological functions in individuals with venous insufficiency and leading to the degradation of skin tissue.² Although the exact extent of influence that associated factors have on the development of VLU remains uncertain, a systematic review has highlighted a range of risk factors that are associated with the onset of a primary VLU.³ These factors include advanced age, deep vein reflux, previous deep vein thrombosis, elevated body mass index, limited physical activity, arterial hypertension, and a family history of VLU.³

VLU are characterised by their shallow nature, tendency to exude fluid, and association with edema caused by fluid accumulation.⁴ Additionally, these ulcers are notorious for their slow healing process and elevated recurrence rate,⁵

causing a negative impact on patients' physical, social, and psychological well-being. These conditions typically result in pain, sleep disturbances, mobility issues, limitations in daily activities, diminished productivity, social isolation, and depressive symptoms.⁴⁻⁷ Furthermore, treatment necessitates frequent visits to health care services, regular dressing changes, and recurrent hospitalisations,⁴ interfering with individuals' daily routines and availability for work and leisure activities.

The primary purpose of VLU treatment is to enhance circulation, facilitating the healing process of the VLU and concurrently reducing oedema.⁴ Among the available treatments, compression therapy has been recognised for facilitating VLU healing⁸ and reducing pain.⁹ Among the compression therapies, Unna's boots stand out as the most common conventional compression therapy option within Brazilian healthcare services, and in a few facilities,

single-layer high compression bandages have also been employed. As an inelastic/short-stretch bandage, Unna's boots provide high pressure only when the muscle contracts or when a person walks, while a high-compression bandage, which is an elastic/long-stretch bandage, supplies graduated compression in a maintained way.^{5,10} In that particular setting, patients with VLU are treated in primary healthcare services (PHCs) and are referred to specialised services when the PHC system does not have appropriate materials for dressing.

In this context, the importance of assessing health-related quality of life (HRQoL) in individuals with VLU receiving treatment with compression therapy cannot be overstated. This is especially important because, in several scenarios, such as within Brazilian healthcare services, there is a lack of a well-established routine for collecting these measurements. Moreover, HRQoL can be an indicator of VLU progression by identifying the impact of VLU on patients' lives.

Studies have delved into assessing the quality of life for individuals with active VLU using disease-specific or general assessment tools¹¹ and examining the correlation between patient factors, such as socioeconomic, demographic, and clinical characteristics, and quality of life scores.^{12–13} Nevertheless, there has been a lack of investigations into the HRQoL of this population based on the final status of VLU, since the ulcer does not always heal. Furthermore, there is a gap in the research regarding how both treatments (single-layer high compression bandages and Unna's boots) impact the HRQoL of individuals receiving these treatments.

Addressing this gap presents a critical opportunity to incorporate the viewpoints of patients into the evaluation and management of health, thus amplifying the focus on patient-centred care and allowing the implementation of more accurate and efficient approaches to managing VLU based on patient HRQoL. Therefore, this study aimed to assess the effects of high compression bandages and Unna's boots on HRQoL for VLU in PHCs.

Methods

Study design and setting

A prospective randomised open-blinded endpoint study called the VENOS trial was performed; people assisted in 22 PHC services in Porto Alegre, which is the capital of the southernmost state of Brazil. The trial was conducted between 2020 and 2023 and had as its primary objective to compare the effectiveness of two compression therapies: a single-layer high compression bandage and Unna's boot. The trial was approved by the Research Ethics Committee (CAEE 16087119.2.0000.5327) and registered on the Clinical Trials platform (NCT04703569). A comprehensive protocol for the trial is available.¹⁴

Participants and sample

The study included participants with VLU, 18 years or older,

who had an ankle-brachial index ranging from 0.8 to 1.2, had palpable pedal and tibial pulses, had at least 18cm of ankle circumference, were able to walk and were not in treatment with compression therapies.

The exclusion criteria included pregnancy, mixed ulcers (with venous and arterial compromise), VLU with more than 90% epithelialisation, antibiotic treatment for infected ulcers, or allergies to the study materials. Based on the trial's primary outcome, a sample size of 100 VLU was required.

Randomisation and masking

Participants were randomly allocated into two groups: Group A received a single-layer high compression bandage (SurePress™, Convatec®), while Group B received an Unna's boot bandage (Unna Heal, Casex Innovation in Healthcare). Due to the distinctive appearance of the bandages, it was not possible to conceal the treatment from the participants or interventionist nurses. However, to minimise potential biases, the examiners responsible for assessing the outcomes were kept blind to the patients' assigned treatment groups.

Data collection

At baseline, participants completed a survey encompassing socioeconomic, clinical, and behavioural aspects of health. From baseline until the VLU was completely healed or, at a maximum of 26 weeks, a nurse performed dressing changes on a weekly basis following standardised care, as described elsewhere.¹⁴ To determine when a VLU was healed, an examiner who was unaware of the treatment measured the size of the ulcers at the start of the study and every two weeks. To prevent the examiner from being aware of the participants' treatment, the nurse was responsible for removing the bandage and discarding any traces of therapy. To assess participants' HRQoL, a blinded examiner applied the Brazilian version of the SF-6D questionnaire at the beginning of the study and on the final day of the follow-up period.

Measures

To measure the size of the ulcers, the planimetry technique was used, which entailed outlining the wound onto an acetate film, transferring this drawing to graph paper, and determining the area by tallying the total number of complete and partial squares contained within the ulcer's outline, as indicated by the tracing. A fully healed VLU was characterised by the presence of a fully formed epithelial layer without any scabbing.

The SF-6D is a brief version of the 36-Item Short Form Survey (SF-36) and comprises six domains: physical functioning, role limitation, social functioning, pain, mental health, and vitality.¹⁵ Each domain has four to six response levels, where one means the best answer and the last level (four, five or six, depending on the domain) means the worst condition, resulting in the potential to describe 18,000 distinct health states.¹⁶ Each of these health states is associated with a specific utility index, anchored at zero (representing dead)

and one (representing perfect health).¹⁶ In this study, we used the Brazilian version of the SF-6D, previously validated for internal consistency, which was measured with a Cronbach's alpha of 0.86 and an intraclass correlation coefficient of 0.92.¹⁷ Given that preference weights for assessing health status tend to vary across different cultures, the utility value adopted for this study is derived from the southern Brazilian population.¹⁶

Statistical analysis

Of the 56 participants, nine withdrew before achieving healing (five in Group A and three in Group B). In these cases, we employed an imputation strategy of carrying the last value forward. Participants in both treatment groups were classified into two categories based on their VLU status at the end of the follow-up: 'healed', indicating complete resolution of the VLU, and 'unhealed', indicating that the VLU remained open.

A descriptive analysis was performed to summarise the patient characteristics and SF-6D scores. This included presenting means and standard deviations, median and interquartile ranges, or counts and percentages as appropriate.

To interpret changes in the SF-6D score, a minimal important difference (MID) of 0.041 was used.¹⁸ Essentially, this value represents the extent of enhancement that holds clinical significance.¹⁹ The SF-6D provides a comprehensive score that encompasses all domains, precluding the assessment of individual domain indices. To observe changes in the domains, we analysed the percentage of participants' responses at the levels of each domain. Additionally, we

conducted paired and two-sample t-tests to compare the differences in SF-6D scores among participants over the follow-up period and between groups. A p-value of less than 0.05 was considered statistically significant. The statistical analyses were conducted in R (v4.3.3).²⁰

Results

A total of 61 participants and 110 VLU were enrolled in the trial. However, for this study, four participants were classified as lost due to having only the first assessment. Additionally, one participant who failed to complete the SF-6D questionnaire at baseline was excluded from the study's analysis. Thus, a total of 56 participants were included: 32 participants in Group A and 24 participants in Group B. Thirty-one participants (22 from Group A; 9 from Group B) had their VLU healed within the study timeframe, while 25 participants (10 from Group A; 15 from Group B) still had open VLUs at the end of the trial. Table 1 summarises the sociodemographic, clinical, and health-behavioural characteristics of the participants at baseline.

Table 2 presents the average SF-6D score at baseline and at the last assessment, along with the average changes in the SF-6D score from the initial to the final assessment for the overall sample, as well as by VLU status and treatment group. Both groups showed an improvement in the SF-6D score that surpassed the MID threshold, except for Group B participants whose VLUs remained unhealed. The increase in SF-6D score was statistically significant within participants over the follow-up period for the entire sample and for those whose VLU healed. No statistically significant differences were observed between the treatment groups.

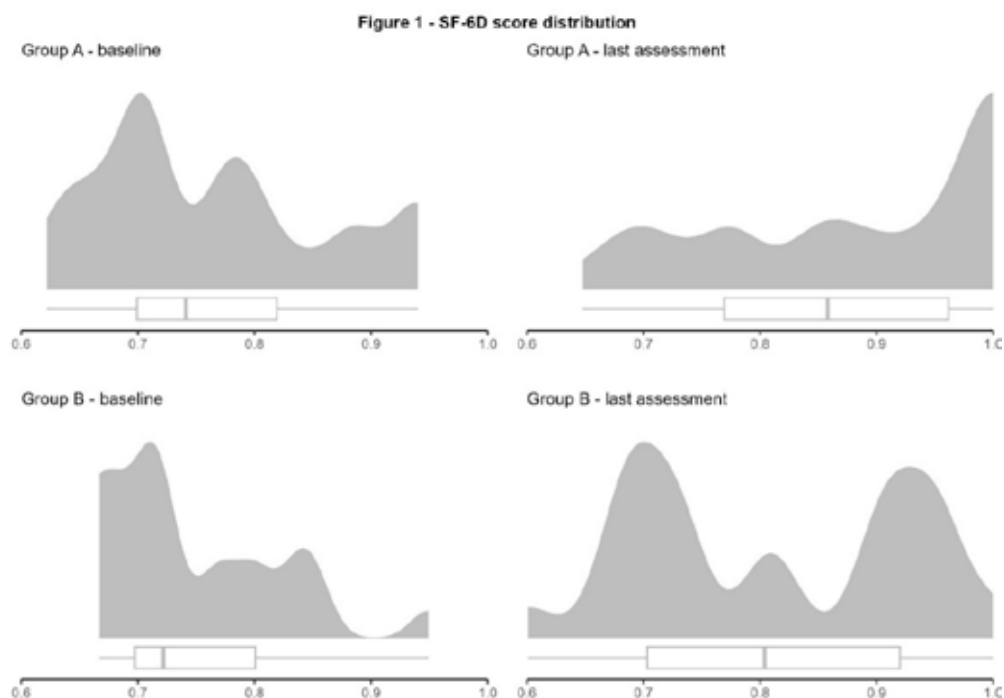


Figure 1. The distribution of SF-6D scores for Groups A and B at baseline and the last assessment.

Regardless of the treatment group, 100% of participants reported some level of problems in some domain at the baseline assessment. However, at follow-up, a 21.9% reduction in the proportion of participants reporting problems was observed in Group A, whereas a 4.2% reduction was observed in Group B. Figure 2 shows the proportion of participants reporting problems, that is, those who chose level 2 or higher as an answer in each domain of the SF-6D questionnaire at baseline and at the end of the follow-up period according to the treatment group.

Analysing the sample by treatment group and final VLU status, we observed a decrease in the proportion of participants reporting problems (level 2 or higher) across all domains of the SF-6D questionnaire at follow-up in those whose VLU had healed, in both treatment groups. The only exception

was Group A, where no change was observed in the vitality domain.

Similarly, there was a decrease in the proportion of participants reporting problems among those whose VLU did not heal. However, an increase was observed in the social functioning domain in Group B. The most significant improvements were observed in the pain domain, where the proportion of participants reporting pain decreased by 43.8% in Group A and 33.3% in Group B, as illustrated in Table 3.

Discussion

The results demonstrated an improvement in HRQoL for participants receiving either compression therapy. This trend was observed in the entire study sample and in participants whose VLU either healed or remained unhealed. Notably,

Table 1. Sociodemographic, clinical, and health-behavioural characteristics of participants at baseline by VLU status

| | Group A = 32 participants | Group B = 24 participants | Overall = 56 participants |
|---|---------------------------|---------------------------|---------------------------|
| Sex: N (%) | | | |
| Male | 21 (65.6) | 14 (58.3) | 35 (62.5) |
| Age in years: mean (SD) | 65.5 (±9.2) | 61.3 (±14.6) | 63.7 (±11.9) |
| Education in years of study: median (interquartile range) | 8 (5–11.5) | 7 (5–10.5) | 7.5 (5–11) |
| Income: N (%) | | | |
| Less than 1 minimum wage* | 0 (0) | 2 (8.3) | 2 (3.6) |
| 1 to 2 minimum wages* | 14 (43.8) | 13 (54.2) | 27 (48.2) |
| 2 to 3 minimum wages* | 8 (25) | 5 (20.8) | 13 (23.2) |
| 3 to 4 minimum wages* | 4 (12.5) | 3 (12.5) | 7 (12.5) |
| More than 4 minimum wages* | 6 (18.7) | 1 (4.2) | 9 (12.5) |
| Self-reported race: N (%) | | | |
| White | 18 (56.3) | 11 (45.8) | 29 (51.8) |
| Black | 8 (25) | 9 (37.5) | 17 (30.4) |
| Brown | 6 (18.8) | 3 (12.5) | 9 (16.1) |
| Yellow | 0 (0) | 1 (4.2) | 1 (1.8) |
| Comorbidity: N (%) | | | |
| Hypertension | 23 (71.9) | 14 (58.3) | 37 (66.1) |
| DM | 7 (21.9) | 4 (16.7) | 11 (19.6) |
| DVT | 1 (3.1) | 2 (8.3) | 3 (5.4) |
| Family history of VU: N (%) | 11 (34.4) | 17 (70.8) | 28 (50) |
| Consuming alcohol: N (%) | 11 (34.4) | 8 (33.3) | 19 (33.9) |
| Smoking: N (%) | | | |
| Current | 1 (3.1) | 5 (20.8) | 6 (10.7) |
| Previous | 12 (37.5) | 10 (41.7) | 22 (39.3) |
| BMI: median (interquartile range) | 29.6 (25.5–33.7) | 30.9 (27.2–35.8) | 30 (26–34.1) |
| Physical limitation: N (%) | 2 (6.3) | 5 (20.8) | 7 (12.5) |
| Physical activity: N (%) | 10 (31.3) | 9 (37.5) | 19 (33.9) |

VU: venous ulcer; SD: standard deviation; DM: diabetes mellitus; DVT: deep venous thrombosis; BMI: body mass index; *Minimum wage in Brazil in 2023: R\$1.320,00 (I\$521.74)

these improvements surpassed the MID threshold and were statistically significant for the entire sample and those whose VLU healed. No statistically significant differences were identified between the treatment groups. These findings reinforce the hypothesis that the presence of VLU has a negative impact on HRQoL. However, we found it difficult to locate any studies that utilised the SF-6D to evaluate HRQoL in individuals with VLU, analysed by the final status of the VLU and by the SF-6D domains to compare our findings.

Our results revealed greater improvements in HRQoL than those of a study involving individuals with VLU who used compression stockings in the U.S.²¹ In that study, the SF-6D score improved by only 0.02 (±0.09) when considering the entire sample, which included individuals across the spectrum of venous diseases, from the initial stages to the most severe. However, when specifically analysing patients with active VLU, the improvement was notably lower, at 0.01 (±0.15).²¹ In China, another study with Unna's boot identified a significant improvement in the SF-36 score after

three months of treatment compared to the baseline, when 91.11% of ulcers healed.²² Similarly, in a study conducted in Serbia comparing the effects of moderate and high compression bandages, both groups showed improvements in quality of life scores after 24 weeks of treatment, while pain reduction and improvement in the psychological domain were only statistically significant among participants who used high compression bandages, the group with the highest number of healed ulcers.²³

Initially, the domain most affected by all participants was pain, which improved by the end of follow-up, regardless of the treatment group. These findings are like those of a study conducted in the Netherlands on the effect of hyperbaric oxygen therapy on VLU healing. At the end of the treatment, there was less pain in both the healed and unhealed groups.²⁴ Moreover, a systematic review revealed a pooled prevalence of 80% pain in individuals with VLU (95% CI 65–92).²⁵ Additionally, these findings align with similar studies involving individuals with VLU who assessed

Table 2. SF-6D score at baseline and the last assessment stratified by VLU status and treatment group

| | SF-6D score baseline ^a | SF-6D score end ^a | p-value ^b | Difference ^a | p-value ^c |
|---------------------|-----------------------------------|------------------------------|----------------------|-------------------------|----------------------|
| Total sample | | | | | 0.218 |
| Group A, N=32 | 0.764 (±0.095) | 0.856 (±0.096) | < 0.001 | 0.093 (±0.09) | |
| Group B, N=24 | 0.750 (±0.07) | 0.810 (±0.071) | 0.007 | 0.06 (±0.1) | |
| Healed VLU | | | | | 0.914 |
| Group A, N=22 | 0.786 (±0.09) | 0.894 (±0.095) | < 0.001 | 0.109 (±0.084) | |
| Group B, N=9 | 0.759 (±0.097) | 0.873 (±0.097) | 0.01 | 0.113 (±0.115) | |
| Unhealed VLU | | | | | 0.441 |
| Group A, N=10 | 0.786 (±0.095) | 0.894 (±0.095) | 0.09 | 0.058 (±0.098) | |
| Group B, N =15 | 0.759 (±0.097) | 0.873 (±0.097) | 0.182 | 0.028 (±0.078) | |

^aMean (standard deviation)

^bPaired t-test.

^cTwo-sample t-test

Table 3. Proportion of participants who reported problems using the SF-6D questionnaire by treatment group and final VLU status

| | Physical functioning | | | | Role limitation | | | | Social functioning | | | |
|----------|----------------------|-------|----------|-------|-----------------|-------|----------|-------|--------------------|-------|----------|-------|
| | Group A | | Group B | | Group A | | Group B | | Group A | | Group B | |
| | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final |
| Healed | 72.7 | 40.9 | 88.9 | 55.6 | 72.7 | 36.4 | 88.9 | 33.3 | 50 | 36.4 | 66.7 | 33.3 |
| Unhealed | 90 | 70 | 86.7 | 80 | 80 | 60 | 73.3 | 66.7 | 90 | 70 | 73.3 | 80 |
| | Pain | | | | Mental health | | | | Vitality | | | |
| | Group A | | Group B | | Group A | | Group B | | Group A | | Group B | |
| | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final | Baseline | Final |
| Healed | 95.5 | 36.4 | 88.9 | 44.4 | 72.7 | 31.8 | 77.8 | 44.4 | 45.5 | 45.5 | 66.7 | 44.4 |
| Unhealed | 90 | 80 | 100 | 73.3 | 80 | 70 | 86.7 | 66.7 | 90 | 80 | 73.3 | 53.3 |

their quality of life using disease-specific instruments, revealing a significant proportion of patients reporting pain at baseline.^{12,25} Furthermore, pain has been associated with poorer quality of life,¹²⁻¹³ as it has the potential to interfere with other factors, such as sleep, mobility, and the ability to perform daily activities.²⁶⁻²⁷

Nevertheless, it is crucial to emphasise that a substantial number of participants, despite the healing of their VLU, reported persistent pain at the conclusion of the follow-up period in both treatment groups. This enduring pain post-VLU healing can be attributed to various factors, including nerve damage in the affected area, residual inflammation in the tissues surrounding the healed ulcer site, skin alterations, muscle weakness, circulatory problems, or psychological influences.²⁸ This outcome underscores the complexity of VLU management and emphasises the need for ongoing care even after the ulcer has closed.

Another critical consideration is that patients with VLU often experience a greater incidence of depressive symptoms than healthy individuals and even mild depressive symptoms have been linked to a reduced quality of life.¹³ Coping with chronic wounds can take an emotional toll, leading to feelings of frustration, anxiety, depression, and diminished self-esteem, largely due to the restrictions they impose.²⁷ In this context, it becomes evident that at the conclusion of the treatment, there was a notable reduction in the proportion of participants reporting issues related to mental health among those whose VLU had healed in both treatment groups. This finding suggested that these interventions had a positive influence on overall well-being. Similarly, in another study conducted in China, participants who underwent a three-month treatment with Unna's boots for their VLUs experienced a fourfold increase in their SF-36 scores for social communication, 'role-emotional' (social activity time given up by patients), and mental health.²²

On the other hand, the relationship between mental health and VLU status can be viewed as a two-way street. While an unhealed VLU can disrupt psychological processes, it is essential to recognise the significant interplay between mental health and the wound-healing process. Stress, for instance, can have a detrimental impact on wound healing, as occurs in various systemic diseases, by disrupting the regulation of endocrine hormones.²⁹ Furthermore, adherence to treatment plays a crucial role in achieving better outcomes in the wound healing process.³⁰ This aspect is intricately linked to an individual's mental health condition, as motivation is often required to diligently follow a treatment regimen. Nutrition also plays a role in healing,²⁹ and an individual's mental health can influence their willingness to maintain an appropriate nutritional state. Moreover, factors such as pain can impact the functional status of individuals with VLU, which can, in turn, affect their mental health. Thus, the relationship between mental health and wound healing is multifaceted and interconnected, encompassing various aspects of the healing process.

In this context, PHC professionals can play a significant role in ensuring patient adherence to treatment and enhancing their self-management skills. This approach has the potential to yield improvements in both clinical and patient-centred outcomes, as supported by a systematic review comprising 58 randomised clinical trials that assessed self-management support interventions in PHC on health outcomes compared to usual care involving individuals with various medical conditions.³¹ Moreover, in Brazil, where individuals are connected to PHC services based on their residential proximity, the effectiveness of treatment adherence can be significantly influenced by the availability of adequate resources within PHC facilities. When these resources are sufficient to manage patients without necessitating referrals to distant specialised services, they can play a pivotal role in ensuring treatment adherence.

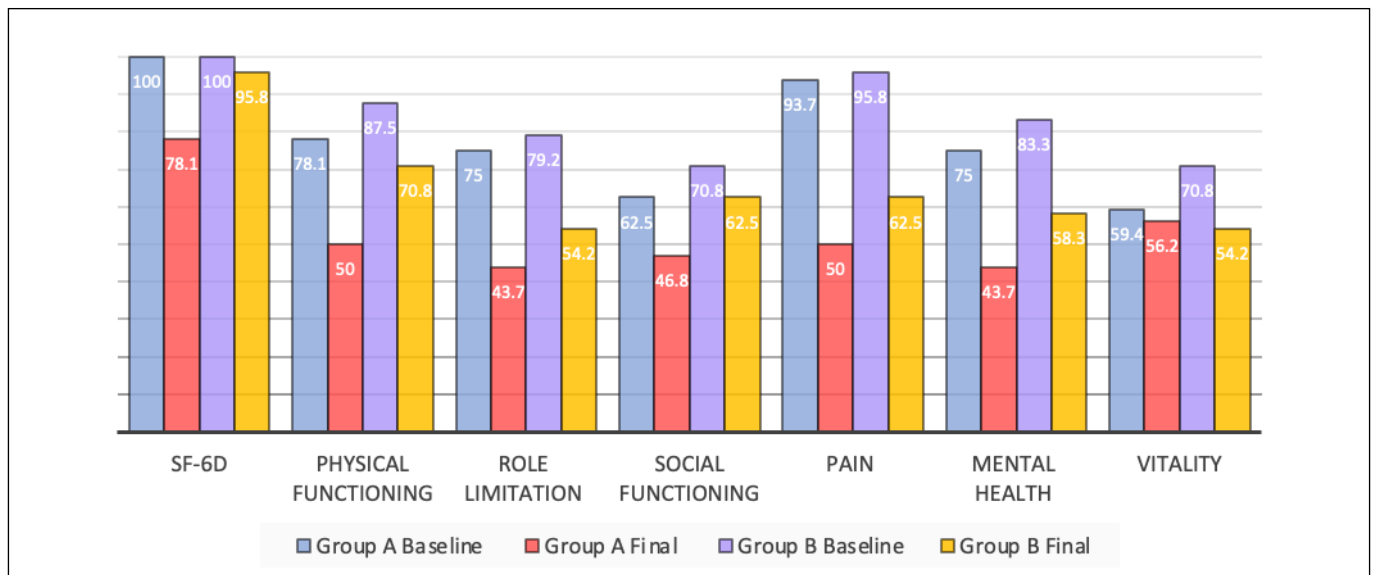


Figure 2. Proportion of participants who chose a score of two or higher on the SF-6D according to treatment group

While it may not be the most severely affected aspect, a significant number of participants reported issues related to the domain of social functioning, regardless of the treatment group. Alongside the direct repercussions of the wound, such as exudate, odour, pain, reduced mobility, and the time-consuming nature of the treatment, these challenges could result in limitations in various activities and withdrawal from social interactions, which may, consequently, elevate the risk of self-isolation and feelings of loneliness.³²

As the impact of VLU on every aspect of HRQoL in patients and individuals living with this condition for a prolonged period continues to increase, it becomes increasingly important to gain a deeper understanding of the effect of available treatments for VLU on people's HRQoL. By doing so, we can enhance the accuracy and effectiveness of VLU management, aligning it better with patients' needs. This approach leads to improvements in HRQoL and facilitates the adoption of a patient-centred approach to healthcare, as VLU management requires a more holistic approach encompassing pain management, physical functioning, mental health, and social aspect support.

Strengths and limitations

This study applied utilities derived from a sample within the same region of Brazil where the study was conducted; this method is considerably more appropriate than using utilities sourced from other countries with disparate socioeconomic and cultural traits. However, it is important to acknowledge that this approach may limit the generalisability of the results.

Furthermore, it is worth noting that the MID employed in this study was estimated from research conducted in diverse contexts using the SF-6D questionnaire, not exclusively for individuals with VLU. Another limitation that we can mention is that the sample size was determined primarily for the main objective of the trial and not specifically tailored to the objective of this study. Additionally, the data from participants who withdrew before achieving healing and required the use of an imputation strategy can be considered another limitation.

The small sample size prevented the application of different statistical analyses. On the other hand, this allowed us to evaluate in more detail the distribution of HRQoL according to the different final statuses of VLU.

Conclusions

Both treatments examined in this study, a single-layer high compression bandage and Unna's boots, had comparable positive effects on participants' HRQoL. The average improvements in the SF-6D scores were substantial, exceeding the typical MID, and statistically significant for the entire sample and those whose VLU healed during follow-up, with no statistically significant difference between treatment groups. Moreover, the results underscore the significant influence of VLU status on HRQoL, with treatments that led to the healing of VLU showing enhancements in various

aspects of HRQoL, particularly in terms of pain relief, role limitation, and mental health.

These findings highlight the multifaceted nature of VLU and the complexity involved in its management. They emphasise the importance of implementing comprehensive wound care strategies to enhance the overall quality of life for individuals dealing with VLU. Additionally, these results demonstrate that treatments promoting VLU healing can significantly improve HRQoL. Furthermore, the role of PHC teams is crucial in involving patients in wound treatment and achieving better health outcomes, particularly in terms of HRQoL.

Author contribution

ACF, FPC and LMGP conceptualised and designed the study. ACF and FPC collected the data. ACF analysed and interpreted the data and drafted the paper. All authors contributed to writing the manuscript, read and approved the final version.

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Conflict of interest

The authors declare no conflicts of interest. The compression therapy Unna's boots were donated by the company Casex Innovation in Healthcare which had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Ethics statement

The study received ethical approval from the Research Ethics Committee, Porto Alegre/Brazil (CAEE 16087119.2.0000.5327), following Resolution No. 466/2012 of the National Health Council of the Brazilian Ministry of Health, which focusses on research involving human beings. Informed consent was obtained from all individual participants included in the study.

References

1. Nicolaidis AN. The most severe stage of chronic venous disease: an update on the management of patients with venous leg ulcers. *Adv Ther.* 2020;37(S1):19–24.
2. Nicolaidis A, Kakkos S, Baekgaard N, Comerota A, de Maeseneer M, Eklof B, et al. Management of chronic venous disorders of the lower limbs. Guidelines according to scientific evidence. Part I. *Int Angiol.* 2018;37(3):181–254.
3. Meulendijks AM, de Vries FMC, van Dooren AA, Schuurmans MJ, Neumann HAM. A systematic review on risk factors in developing a first-time venous leg ulcer. *J Eurn Acad Dermatol Venereol.* 2019;33(7):1241–1248.
4. Millan SB, Gan R, Townsend PE. Venous ulcers: diagnosis and treatment. *American Family Physician.* 2019;100(5):298–305.

5. Jindal R, Chaudhary P, Gupta B, Kaur T, Dhillion S. Venous ulcers: review article. *Indian Journal of Surgery*. 2023;85(S1):121–132.
6. Raffetto JD, Ligi D, Maniscalco R, Khalil RA, Mannello F. Why venous leg ulcers have difficulty healing: overview on pathophysiology, clinical consequences, and treatment. *J Clin Med*. 2020;10(1):29.
7. Epstein DM, Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, et al. Cost-effectiveness analysis of a randomized clinical trial of early versus deferred endovenous ablation of superficial venous reflux in patients with venous ulceration. *Br J Surg*. 2019;106(5):555–562.
8. Patton D, Avsar P, Sayeh A, Budri A, O'Connor T, Walsh S, et al. A meta-review of the impact of compression therapy on venous leg ulcer healing. *Int Wound J*. 2023;20(2):430–447.
9. Shi C, Dumville JC, Cullum N, Connaughton E, Norman G. Compression bandages or stockings versus no compression for treating venous leg ulcers. *Cochrane Database of Syst Rev*. 2021;7(7): CD013397.
10. Bjork R. The long and short of it: Understanding compression bandaging. *Wound Care Advisor*. 2013;2(6):12–20.
11. Liu S, Team V, Qiu Y, Weller CD. Investigating quality of life instrument measurement properties for adults with active venous leg ulcers: A systematic review. *Wound Repair Regen*. 2022;30(4):468–486.
12. Folguera-Álvarez C, Garrido-Elustondo S, Rico-Blázquez M, Verdú-Soriano J. Factors associated with the quality of life of patients with venous leg ulcers in primary care: cross-sectional study. *Int J Low Extrem Wounds*. 2022;21(4):521–528.
13. Lin H, Fang C, Hung C, Fan J. Potential predictors of quality of life in patients with venous leg ulcers: a cross-sectional study in Taiwan. *Int Wound J*. 2022;19(5):1039–1050.
14. Cordova FP, Fuhrmann AC, Machado D, Mocellin D, Silva BU, Lucena A, et al. Clinical and economic analysis on compression treatment of venous leg ulcers: clinical trial protocol VENOS. *Wound Prac Res*. 2022;30(4):216–222.
15. Campolina AG, Bortoluzzo AB, Ferraz MB, Ciconelli RM. Validação da versão brasileira do questionário genérico de qualidade de vida short-form 6 dimensions (SF-6D Brasil). *Cien Saude Colet*. 2011;16(7):3103–3110.
16. Cruz LN, Camey SA, Hoffmann JF, Rowen D, Brazier JE, Fleck MP, et al. Estimating the SF-6D value set for a population-based sample of Brazilians. *Value in Health*. 2011;14(5):S108–114.
17. Campolina AG, López RVM, Nardi EP, Ferraz MB. Internal consistency of the SF-6D as a health status index in the Brazilian urban population. *Value Health Reg Issues*. 2018;17:74–80.
18. Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Quality of Life Research*. 2005;14(6):1523–1532.
19. Sedaghat AR. Understanding the minimal clinically important difference (MCID) of patient-reported outcome measures. *Otolaryngol Head Neck Surg*. 2019;161(4):551–560.
20. R Core Team. R: A Language and Environment for Statistical Computing. Online 2024. <https://www.R-project.org/>.
21. Chi YW, Durbin-Johnson B, Schul M. Short-form 6D assessment in compression module of the American College of Phlebology Patient Reported Outcome Venous Registry. *Phlebology*. 2018;33(6):425–429.
22. Zou Y, Wang S, Zhou H, Zhang L. Effect of the compression therapy guided by Unna boots on the quality of life and complications in patients with lower limb venous ulcers. *Indian J Pharm Sci*. 2020;82(5,S7):130–133.
23. Karanikolic V, Ignjatovic A, Marinkovic M, Djordjevic L. The effectiveness of two different subbandage pressure values on healing and quality of life outcomes for patients with venous leg ulcers. *Adv Dermatol Allergol*. 2023;40(1):47–53.
24. Lalieu RC, Akkerman I, van Hulst RA. Hyperbaric oxygen therapy for venous leg ulcers: a 6 year retrospective study of results of a single center. *Front Med (Lausanne)*. 2021;8:671678.
25. Leren L, Johansen E, Eide H, Falk RS, Juvet LK, Ljoså TM. Pain in persons with chronic venous leg ulcers: a systematic review and meta-analysis. *Int Wound J*. 2020;17(2):466–484.
26. Mościcka P, Cwajda-Białasik J, Szewczyk MT, Jawień A. Healing process, pain, and health-related quality of life in patients with venous leg ulcers treated with fish collagen gel: a 12-week randomized single-center study. *Int J Environ Res Public Health*. 2022;19(12):7108.
27. Fearn N, Heller-Murphy S, Kelly J, Harbor J. Placing the patient at the center of chronic wound care: a qualitative evidence synthesis. *J Tissue Viability*. 2017;26(4):254–259.
28. Cohen SP, Vase L, Hooten WM. Chronic pain: an update on burden, best practices, and new advances. *Lancet*. 2021;397(10289):2082–2097.
29. Gushiken LFS, Beserra FP, Bastos JK, Jackson CJ, Pellizzon CH. Cutaneous wound healing: an update from physiopathology to current therapies. *Life*. 2021;11(7):665.
30. Atkin L, Bučko Z, Montero EC, Cutting K, Moffatt C, Probst A, et al. Implementing TIMERS: the race against hard-to-heal wounds. *J Wound Care*. 2019;28(Sup3a):S1–50.
31. Dineen-Griffin S, Garcia-Cardenas V, Williams K, Benrimoj SJ. Helping patients help themselves: a systematic review of self-management support strategies in primary health care practice. *PLoS One*. 2019;14(8):e0220116.
32. Klein TM, Andrees V, Kirsten N, Protz K, Augustin M, Blome C. Social participation of people with chronic wounds: a systematic review. *Int Wound J*. 2021;18(3):287–311.