Original Research Article

Comparative Clinical Study of Four Compressive Therapies for Lower Limb Venous Ulcer

ABSTRACT

Objective: To compare among four types of compression therapy (compression stockings; layered bandages; Unna's boot, and intermittent pneumatic compression) in the treatment of chronic venous ulcers of the lower limbs.
Materials/Methods: This was a prospective interventional clinical study with a 12-week follow-up, conducted at the Vascular Surgery Service of São Paulo Hospital, Muriaé - MG, approved by the CEP/SCBH, CAAE 49711121.0.0000.5138.
Results: Comparison of demographic characteristics and ulcer duration (in months) in relation to the four types of treatments used showed that age (years), BMI, and ulcer duration (months) did not present significant differences among the various treatments assessed. A higher frequency of male patients was observed in those who used layered and stocking dressings as compared to those who used Unna's boot and pneumatic treatments, in which the female gender was more prevalent and this result was significant ($p=0.045$). Lifestyle comorbidities/habits of patients in relation to the four types of dressings were evaluated in this research. Only smoking showed a significant difference ($p<0.05$), demonstrating that patients who used stockings and layered dressings smoked proportionally more (37.1% and 41.2%) compared to those who used Unna's boot or pneumatic (17.6% and 16.7%, respectively). There was no significant difference between the types of treatment and the Ulcer Healing Index and the variation from 6 to 12 weeks; there was no significant difference between the types of dressings and the Slough to Granulation Ratio (6 and 12 weeks and variation from 6 to 12 weeks), and between the Gilman index and the different types of dressings used. Compression is the gold standard in the treatment of venous ulcers to promote their healing. However, the results of this study demonstrate that there was no significant difference among the four types of compressive therapy for the treatment of chronic venous ulcers.
Conclusion: It was not possible to determine an ideal pressure range in relation to the variables studied, but compression therapy is highly recommended for venous ulcers.

Keywords:Chronic venous ulcer. Compression therapy. Lower limbs.

1. INTRODUCTION

An ulcer is any disruption in the continuity of the skin/tegument that persists for more than 30 days without complete healing. The most affected site on the body is the lower limbs, accounting for 80-90% of cases. Lower limb ulcers are categorized based on their etiology into vascular, metabolic, infectious, neoplastic, traumatic, among others. Approximately 75% of ulcers in the lower limbs are related to peripheral vascular disease, mainly due to changes in the venous system, and may also coexist with disorders of the arterial and lymphatic systems [1].

Chronic venous disease (CVD) may be localized in the deep and/or superficial venous system and may also occur due to dysfunction in the gastrocnemius muscle pump (calf

muscle). Regardless of the mechanism involved, the relapse rates are high, occurring in 50% of patients within two years and 80% after five years of the disease [2-3].

Venous ulcers (VU) affect up to 1% of the adult population, and their incidence increases with age, reaching 4% of patients over 80 years old. It is a pathology that poses a significant public health problem both nationally and globally, with healthcare costs exceeding 1 billion dollars in the United States alone. In Brazil, venous ulcers are the 14th leading cause of temporary work leave and the 32nd cause of permanent disability [4].

Venous ulcers represent a significant public health issue due to the large number of people affected, who require healthcare attention. They can result in work absenteeism or even job loss, thereby increasing public expenditure. Venous ulcers cause suffering and negatively impact the quality of life of those affected [5-6]. These ulcers go by various names, including varicose ulcers, leg venous ulcers, stasis ulcers, or ulcers due to venous insufficiency [7-8].

Venous ulcers are recurrent and disabling, significantly affecting the ambulation of those afflicted. They require long and complex treatments and are often the cause of prolonged injuries and considerable rates of morbidity and mortality [9].

Chronic venous disease (CVD) has a profound impact on patients' quality of life, as it is associated with debilitating pain, diminished sleep quality, and productivity, limitations in daily basic activities, and altered self-image [10]. Chronic pain can contribute to the onset of depression, lowered self-esteem, social isolation, and work absenteeism, further reducing productivity [11-4].

The main risk factors for the development of venous ulcers include advanced age, obesity, prior leg injuries where there is already a breach in the skin's continuity, and deep vein thrombosis [12]. Diabetes and poor quality of life also affect approximately 1.5% of the global population suffering from this chronic issue. Chronicity is considered when there is a lack of healing within a six-week period, even with appropriate treatment. This scenario reflects the substantial consumption of both public and private resources, leading to frustration among healthcare professionals and patients [13]. Venous ulcers are multifactorial in nature [8].

Diagnosis should consider family history, clinical presentation, physical examinations [12], characteristics of skin alterations, and imaging tests such as color duplex ultrasonography, plethysmography, and venography, which can differentiate from another diagnoses[14-15].

For treatment, there is still no gold standard, necessitating further clarification on the best therapy [16-17-18]. However, compressive therapy, using appropriate methods in patients with venous ulcers (Unna's boot, elastic bandages, pneumatic systems), is most recommended [8-19-20-21-22-23-24].

The prevalence and incidence of venous ulcers have been increasing due to the aging population and the rise of associated chronic conditions like systemic arterial hypertension and diabetes mellitus. Many diseases manifest as chronic ulcers, particularly those on the lower limbs, which occur below the knee and do not heal within six weeks, causing significant social and economic impact. The most common etiologies are venous, arterial, and neuropathic, accounting for 90% of causes. However, hypertensive ulcers also occur with relative frequency. Recent studies indicate that 75% of leg ulcers worldwide are venous, affecting approximately 80% to 90% of cases [19].

In Brazil, epidemiological studies on the incidence and prevalence of venous ulcers are still scarce. Some authors estimate that approximately 3% of the Brazilian population has leg ulcers, a figure that rises to 10% among people with diabetes [25-26].

Given the above, the current study aims to compare four types of compression therapy (compression stockings - single-layer elastic system; layered bandages - two-layer elastic system; Unna's boot - inelastic system) and intermittent pneumatic compression in the

treatment of chronic venous ulcers of the lower limbs. The comparison focuses on demographic characteristics and ulcer duration, comorbidities/lifestyle habits, superiority among the therapies, vascular improvement, ulcer healing index, slough-to-granulation ratio (at 6 weeks, 12 weeks, and the variation between 6 and 12 weeks), and the Gilman Index for three-dimensional assessment correlated to the prognosis of the lesion.

2. MATERIAL AND METHODS

Type of Study

This is a prospective interventional clinical study with a 12-week follow-up. The study was submitted to the Human Research Ethics Committee of Santa Casa in Belo Horizonte, Minas Gerais, and approved: CAAE: 49711121.0.0000.5138. The study was conducted at the Vascular Surgery Service of São Paulo Hospital, Muriaé, MG.

Sample Size Calculation

In accordance with the objective, the sample size was calculated to meet the proposal of the study, using the PASS 2020 software for sample calculation with 140 patients, 35 in each group. Considering possible losses in the follow-up that could occur over the 12 weeks of evaluation, it was suggested to collect 20% more than the minimum calculated, therefore 42 patients in each group, thus ensuring that the required "n" would be reached.

Conduct of the Study Groups

Patients were stratified according to the Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification recommended by the Brazilian Society of Angiology and Vascular Surgery (SBACV). All underwent Eco Color Doppler examination, as recommended by the said society, in a step-by-step, standardized manner. Candidates for this study were patients fitting into the CEAP 6 classification (active venous ulcer) and whose Doppler examination indicated no surgical intervention was required and did not fit this study.

The anticipated follow-up period was 12 weeks, without any special regimen of physical activities, oral medication, or other concurrent treatments. The patient should have had an ulcer for at least 30 consecutive days, with no maximum time limit.

Group A: Daily use of compression stockings from Monday to Friday, with compression between 20-40 mmHg (pressure indicated by the manufacturer on the product box).

Group B: Daily use of a compression mechanism composed of two layers, one elastic and another inelastic.

Group C: Daily use of Unna's boot, installed according to the manufacturer's recommendation.

Group D: Daily use of the Intermittent Pneumatic Compression System, programmed with pressures of 130 mmHg at the foot and 45 mmHg at the leg and thigh, in cycles of 11 seconds of compression and 20-60 seconds of deflation.

All groups took Saturdays and Sundays off from any type of compressive therapy, maintaining only standardized dressings. Materials were provided free of charge to all patients, along with training for home use, as per the manufacturers' instructions.

The dressing in contact with the ulcer was applied every morning for all patients, from Monday to Friday. It could be done at their home or freely at the dressing center on weekdays.

Instructions and recommendations to patients followed MS guidelines (2006), which involve washing the wound with a bottle of saline solution (500 ml) pierced by a 40x12mm needle,

applying neutral soap, and drying only the edges, preserving the moisture of the central bed. After that, a gauze containing a thin layer of pure zinc oxide was applied, followed by the above compression mechanism.

The Unna's boot used by patients in this study is a bandage soaked in pure zinc oxide. Patients in Group C used Unna's boot from Monday to Friday and followed a standardized dressing regimen on weekends, like the other groups (without any compression).

Participants were educated about identifying undesirable signs and symptoms (allergy, local inflammation, fever, myalgia, intense discomfort when performing daily activities), and how to act in these cases. Even with the dressing center closed, São Paulo Hospital provided an on-call Vascular Surgeon every day to attend to patients in case of need or emergency.

Inclusion Criteria: All patients with chronic venous ulcers in the lower limbs who met the research specifications, over 18 years of age, of both sexes.

*Exclusion Criteria:*Patients who show no interest in participating in the study.

Data Collection and Measurement

Data were collected according to specific forms after adequate training for the placement of compression systems and pressure measurement. Wound diameters were measured using a digital caliper (length and width in centimeters). For the assessment of lesion depth (three-dimensional evaluation), a sterile insulin needle cap was gently touched to the wound bed in a vertical position, enabling depth measurement in centimeters using the caliper. Images of the wounds were captured for clinical assessment of the ulcer using a 12.2-megapixel digital camera from approximately one meter away, without using zoom or flash. Frequency of ulcer size measurement and image collection will be done on D1 (first week, first day of treatment), D6 (sixth week, halfway through the treatment; day 42), and D12 (twelfth week, last day of treatment; day 84).

Two-dimensional lesion assessments were conducted using the ImageJ software through the Ulcer Healing Index and the Slough-to-Granulation Ratio, which represents the relationship between granulation and fibrin tissue present in the wound.

Statistical Methodology

To assess a significant difference in ulcer area reduction in cm^2 among the treatment groups (A, B, C, and D), the following hypotheses were considered for sample size calculation: a 5% significance level (α); a statistical test power of 80% ($1-\beta$); and a relatively "large" expected difference between the groups, known as effect size, according to the pilot study of this research.

Statistical Analysis

Data were analyzed using SPSS 14.0 for Windows, through descriptive and inferential statistics, and presented in the form of tables, figures, and/or graphs. Observed data were expressed through measures of central tendency (mean and median). Minimum and maximum values and standard deviations were calculated. Categorical data were expressed in frequency and percentile. Comparison of sociodemographic, clinical, and lesion variables among groups (A, B, C, and D) was analyzed using the student's t-test (independent samples) or Mann Whitney test for numerical data; and by Fisher's test for categorical data. The variation in ulcer area over the four time points (1st, 5th, 9th, and 13th consultations) in each group was assessed by Friedman's ANOVA and the corresponding Nemenyi multiple comparisons test (non-parametric), identifying significantly differing time points. A 5% significance level was adopted. Statistical analysis was processed using SAS 6.11 software (SAS Institute, Inc., Cary, NC).

Ethical aspects were in accordance with Resolution 466/2012 of the National Health Council (CNS).

Literature Review

Data collection for the literature review commenced in 2020, with subsequent publications analyzed and studied. Platforms used included the Scientific Electronic Library Online (SciELO), Virtual Health Library (VHL), and the US National Library of Medicine National Institutes of Health (PubMed). Descriptors in both English and Portuguese were used: compression therapies, venous ulcer, and lower limbs.

Publications were searched by title, abstract, and results. No similar works were found, except for one study that compared different types of compression used for the treatment of chronic venous ulcers: 1) pneumatic compression, 2) multi-layer elastic system with two components, 3) multi-layer elastic system with four components, 4) single-layer elastic system (compression stocking), and 5) inelastic mechanism (Unna's boot). A total of 169 publications were selected, with 103 derived from abstracts, titles, and results. Of these, 22 were excluded for being ineligible, leaving 28 used in the text.

The results of the research are displayed through photographs of participating patients and statistical analysis, presented in indicative tables.

Results

The sample size estimate was 140 patients, with 35 patients in each group (A, B, C, D). However, some losses to follow-up were observed in each group due to various reasons, such as self-perceived healing, transportation difficulties, or unknown reasons.

Statistical Analysis

Data analysis was performed using Excel software (2013) and SPSS, version 20.0. Descriptive data analysis helped to extract relevant information from the variables and quantify the variability present in the data. Tables and graphs were formulated to present the results. For quantitative variables, measures of central tendency (mean and median), dispersion (standard deviation), and the 25th and 75th percentiles were obtained. For categorical variables, frequency and percentage corresponding to each category were calculated.

Quantitative variables were tested for normality using the Shapiro-Wilk test. Variables with a normal distribution were compared using the ANOVA test, and for those not normally distributed, the Kruskal-Wallis test was used. For categorical variables, where differences between proportions were being assessed, the chi-square test or Monte Carlo test was used, each following the necessary assumptions for their use. Associations were considered statistically significant when the p-value was less than or equal to 0.05.

3. RESULTS AND DISCUSSION

Demographic Characteristics and Ulcer Duration

Table 1 provides a comparison of demographic characteristics and ulcer duration (in months) relative to the four types of treatments used. Variables such as age, BMI, and ulcer duration did not show significant differences across the different treatment modalities.

Table 1. Comparison of Demographic Characteristics and Ulcer Duration Across 4 Types of Ulcer Treatments (Compression Stockings vs. Two-Layer System vs. Unna's Boot vs. Pneumatic Compression)

Ulcer Treatment Types	Average	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Minimum	Maximum	p-value
Age (years)								0.366a
Compression Stockings	62.57	13.98	65.00	55.00	72.00	35.00	91.00	
Two-Layer System	64.26	14.31	64.00	50.00	78.00	41.00	88.00	
Unna's Boot	68.56	14.03	68.50	58.00	79.00	37.00	93.00	
Pneumatic	65.03	14.86	64.00	53.50	74.00	39.00	98.00	
BMI								0.335b
Compression Stockings	27.74	4.95	29.00	25.00	30.00	18.00	37.00	
Two-Layer System	29.59	6.60	30.50	25.00	35.00	19.00	41.00	
Unna's Boot	30.15	5.34	29.00	26.00	35.00	22.00	41.00	
Pneumatic	28.08	5.48	28.00	24.00	33.00	19.00	40.00	
Ulcer Duration (months)								0.805b
Compression Stockings	39.97	26.85	38.00	18.00	49.00	4.00	140.00	
Two-Layer System	53.71	50.28	41.00	24.00	63.00	7.00	240.00	
Unna's Boot	43.41	35.32	37.00	18.00	60.00	9.00	200.00	
Pneumatic	44.58	33.12	39.00	28.00	55.00	6.00	200.00	
Gender	Male (n, %)	Female (n, %)						0.045c
Compression Stockings	18 (51.4%)	17 (48.6%)						
Two-Layer System	23 (67.6%)	11 (32.4%)						
Unna's Boot	14 (41.2%)	20 (58.8%)						
Pneumatic	13 (36.1%)	23 (63.9%)						

Key: SD: Standard Deviation, Q1: 1st Quartile (25%), Q3: 3rd Quartile (75%), Min: Minimum, Max: Maximum, BMI: Body Mass Index.
a: ANOVA
b: Kruskal Wallis
c: Chi-square
*Bold values indicate significant p

Interestingly, male patients were more frequently observed among those who used compression stockings and two-layer bandages. In contrast, the Unna's boot and pneumatic

compression were more commonly used among female patients. This gender difference was statistically significant (p=0.045).

Comorbidities and Lifestyle Choices

Table 2 displays the comorbidities and lifestyle habits of patients in relation to the four types of dressings evaluated in this research. Only smoking showed a significant difference (p<0.05), revealing that patients using compression stockings and two-layer bandages were proportionally more likely to be smokers (37.1% and 41.2%) compared to those using Unna's boot or pneumatic compression (17.6% and 16.7%, respectively).

Table 2. Comparison of Comorbidities/Lifestyle Habits Across 4 Types of Ulcer Treatments (Compression Stockings vs. Two-Layer System vs. Unna's Boot vs. Pneumatic Compression)

Evaluated Variables	Compression Stockings	Two-Layer System	Unna's Boot	Pneumatic Compression	p-value
Hypertension					0.363a
No	13 (37.1%)	9 (26.5%)	15 (44.1%)	10 (27.8%)	
Yes	22 (62.9%)	25 (73.5%)	19 (55.9%)	26 (72.2%)	
Diabetes Mellitus					0.249a
No	24 (68.6%)	26 (76.5%)	30 (88.2%)	29 (80.6%)	
Yes	11 (31.4%)	8 (23.5%)	4 (11.8%)	7 (19.4%)	
Kidney Disease					0.309b
No	33 (94.3%)	29 (85.3%)	27 (79.4%)	32 (88.9%)	
Yes	2 (5.7%)	5 (14.7%)	7 (20.6%)	4 (11.1%)	
Smoking					0.037a
No	22 (62.9%)	20 (58.8%)	28 (82.4%)	30 (83.3%)	
Yes	13 (37.1%)	14 (41.2%)	6 (17.6%)	6 (16.7%)	

Key: *Chi-square; *Monte Carlo; *Bold values indicate significance in p-value

The p-values in the table are used to assess the statistical significance of the differences between the four groups for each variable. In this case, the only variable that shows a statistically significant difference between the four treatment groups is smoking, with a p-value of 0.037a.

For hypertension, diabetes mellitus, and kidney disease, the p-values are above the commonly accepted significance threshold of 0.05, suggesting that the variations among the four treatment groups may not be statistically significant for these variables.

This kind of information is invaluable in a clinical context. For instance, it can guide healthcare providers in making more personalized treatment choices, considering not only the type of ulcer but also the patient's comorbidities and lifestyle habits.

Ulcer Healing Index and Slough-to-Granulation Ratio

Table 3 indicates that there was no significant difference between the types of treatment and the Ulcer Healing Index (UHI) at 6 and 12 weeks, or the variation between these two periods.

Table 3. Comparison of Ulcer Healing Index at 6 Weeks, 12 Weeks, and Variation from 6 to 12 Weeks Among 4 Types of Ulcer Treatments (Compression Stockings vs. Two-Layer System vs. Unna's Boot vs. Pneumatic Compression)

Treatment Types	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
ICU 6 Weeks								0.746a
Compression	0.37	0.19	0.32	0.21	0.51	0.12	0.79	
Two-Layer	0.38	0.20	0.37	0.21	0.55	0.12	0.84	
Unna's Boot	0.40	0.16	0.38	0.28	0.49	0.12	0.75	
Pneumatic	0.39	0.16	0.35	0.27	0.54	0.13	0.75	
ICU 12 Weeks								0.560a
Compression	0.57	0.27	0.53	0.35	0.81	0.19	0.96	
Two-Layer	0.56	0.25	0.62	0.35	0.78	0.18	0.97	
Unna's Boot	0.64	0.23	0.73	0.36	0.79	0.26	0.99	
Pneumatic	0.62	0.25	0.65	0.39	0.89	0.21	0.96	
Variation 6-12 Weeks								0.275a
Compression	0.20	0.14	0.15	0.08	0.32	0.04	0.53	
Two-Layer	0.18	0.11	0.16	0.10	0.30	0.04	0.46	
Unna's Boot	0.24	0.13	0.24	0.16	0.30	-0.05	0.61	
Pneumatic	0.23	0.15	0.21	0.12	0.33	0.04	0.63	

Key: a: Kruskal Wallis Test

The p-values indicate that there is no statistically significant difference in the healing rates among the four treatments at either the 6-week or 12-week time points, nor in the variation from 6 to 12 weeks. All p-values are above the conventional significance level of 0.05.

In a clinical setting, this data could imply that the choice of treatment may not significantly impact the rate of ulcer healing as measured by the ICU. Thus, other factors such as patient comfort, cost, or ease of application might be considered when choosing a treatment. However, it is also crucial to remember that the ICU is just one measure of success, and other outcomes might still be influenced by the choice of treatment.

Similarly, Table 4 shows no significant difference between the types of dressings and the Slough-to-Granulation Ratio at 6 and 12 weeks, and the variation between these periods.

Table 4. Comparison of Slough to Granulation Ratio at 6 Weeks, 12 Weeks, and Variation from 6 to 12 Weeks Among 4 Types of Ulcer Treatments (Compression Stockings vs. Two-Layer System vs. Unna's Boot vs. Pneumatic Compression)

Types of Ulcer Treatments	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
REG 6 Weeks								0.911a
Compression	0.85	0.10	0.87	0.76	0.95	0.68	0.98	
Two-Layer	0.84	0.10	0.82	0.76	0.91	0.63	0.98	
Unna's Boot	0.84	0.10	0.84	0.79	0.92	0.53	0.98	
Pneumatic	0.85	0.09	0.87	0.79	0.91	0.67	0.98	
REG 12 Weeks								0.635a
Compression	0.52	0.21	0.54	0.31	0.71	0.15	0.93	

Types of Ulcer Treatments	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
Two-Layer	0.54	0.22	0.55	0.36	0.73	0.17	0.88	
Unna's Boot	0.50	0.20	0.46	0.35	0.66	0.15	0.88	
Pneumatic	0.48	0.21	0.44	0.30	0.65	0.15	0.87	
Variation 6-12 Weeks								0.470a
Compression	-0.33	0.20	-0.29	-0.50	-0.17	-0.83	-0.02	
Two-Layer	-0.30	0.20	-0.23	-0.48	-0.12	-0.77	-0.05	
Unna's Boot	-0.34	0.18	-0.33	-0.44	-0.17	-0.78	-0.07	
Pneumatic	-0.37	0.21	-0.32	-0.54	-0.18	-0.76	-0.07	

Key: *Kruskal Wallis Test

The p-values suggest that there is no statistically significant difference in the Slough to Granulation Ratio (REG) among the four types of treatments at the 6-week and 12-week marks, or in the variation between these two time points. All p-values are considerably above the conventional 0.05 level, indicating that the treatments are equally effective based on this specific measure.

This is incredibly enlightening because it suggests that the choice of treatment modality might not significantly influence the tissue characteristics of the ulcer in terms of the slough to granulation ratio. This allows clinicians to potentially focus on other aspects like cost-effectiveness, patient compliance, or side-effects when choosing a treatment strategy. However, the nuances are crucial. The REG is just one facet of wound healing, and other parameters might still vary significantly depending on the chosen treatment.

Gilman Index

Table 5 reveals no significant difference between the Gilman Index and the different types of dressings used.

Table 5. Comparison of the Gilman Index Among 4 Types of Ulcer Treatments (Compression Stockings vs. Two-Layer System vs. Unna's Boot vs. Pneumatic Compression)

Types of Ulcer Treatments	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
Gilman Index								0.394a
Compression Stockings	0.87	0.09	0.89	0.81	0.93	0.61	0.99	
Two-Layer System	0.82	0.11	0.82	0.75	0.92	0.61	0.98	
Unna's Boot	0.85	0.09	0.87	0.79	0.91	0.63	0.99	
Pneumatic Compression	0.85	0.09	0.84	0.79	0.93	0.67	0.98	

Key: *Kruskal Wallis Test

The p-value of 0.394, which is above the commonly accepted threshold of 0.05, indicates that there's no statistically significant difference in the Gilman Index between the four types of treatments. In other words, each treatment appears to be equally effective when evaluated through the lens of the Gilman Index.

What makes this data intriguing is that the Gilman Index, like any other composite score, encapsulates a variety of parameters that could be clinically relevant. Yet, no matter the treatment type, the outcomes seem to be statistically indifferent. This could be a liberating revelation for clinicians, as it allows them to look beyond this index when choosing the most suitable treatment for their patients. It could also open the door for research into why this index doesn't discern between these treatments and what other metrics might.

So, while the Gilman Index might be a useful metric for other purposes, it doesn't seem to offer a decisive advantage for any of these four treatments over the others. This could allow for greater flexibility in treatment selection, focusing on other factors like patient comfort, cost, or the presence of other medical conditions.

Sociodemographic Profile of the Patients

Regarding the sociodemographic profile of the participating patients, both men and women, white and black, aged between 65 and 98, predominantly low-income and with low educational levels, were represented. Moreover, these patients likely face challenges in diagnosis, access, and transportation, especially those residing in distant rural areas. These factors, combined with work conditions and lack of disease awareness, could further hinder access to treatment, leading to chronicity of infections. Notably, lower limb infections are notoriously the most difficult to cure as they often require prolonged and complex treatments.

Indeterminate Healing Time

It's challenging to pinpoint the exact time required for an ulcer to heal, as this depends on individual factors such as the ulcer's size, depth, and the patient's personal healing timeline.

Gender and Smoking Patterns

Interestingly, our study diverged from general trends in venous ulcer demographics. While venous ulcers (UVs) are more common among elderly women, the majority of patients in our study were male [7]. The gender difference, however, does not seem to introduce a significant bias in interpreting the results, given that the course of chronic venous ulcers appears to be similar for both men and women.

Additionally, our study found a higher incidence of smoking among male patients treated with compression stockings and two-layer systems. While this could potentially influence wound healing, it did not appear to introduce a significant bias in the overall interpretation of the therapeutic efficacy.

Healing Indices and Therapeutic Approaches

Our study found no significant difference among the four types of compression therapies when evaluated using the Ulcer Healing Index (UHI) at both 6 and 12 weeks. Likewise, there were no significant differences in the Slough-to-Granulation ratio or the Gilman Index across the treatment groups. These findings suggest that no single compression therapy proved superior to others in promoting favorable or unfavorable ulcer evolution, as shown in Figures 1, 2, 3, and 4 for groups A(P1), B(P1), C(P1), and D(P1).

Fig. 1: Group A: Use of Compression Socks (Monolayer Elastic System)P1: 12th week with maintenance of granulation, but without improvement in chronic signs of venous disease, such as ocher dermatitis (darkening of the skin).

Fig. 2: Group B: Double bandage (elastic system with two layers) P1: 12th week of treatment with intense granulation, but still with stable edges and without considerable progress in epithelialization.

Fig. 3: Group C: Unna Boot (inelastic system).P1: 12th week of treatment.

Fig. 4: Group D: Intermittent Pneumatic Compression. P1: 12th week of treatment with apparent stability of the lesion and stagnation.

Individual Factors and Therapeutic Choices

The absence of a significant difference in the healing rates among different compression therapies may indicate the influence of individual patient factors, such as lifestyle or intrinsic wound healing capabilities. Literature supports the effectiveness of compression therapy for venous ulcer healing. Amsler et al. [22] posited that leg compression with stockings is clearly superior to bandages in terms of ease of use and positive impact on pain. Nair [10] echoed this, stating that compression therapy is the cornerstone for treating venous leg ulcers. Hussain's [11] study indicated that the difference in healing rates between simple and modern dressings was not statistically significant. Haesler [7] stated that compression therapy is recognized as the gold standard for promoting venous ulcer healing.

In light of these findings, it's reasonable to assert that while compression therapy is crucial for venous ulcer healing, the choice between different types may be guided more by convenience, ease of use, and cost-effectiveness rather than superior clinical efficacy. Compression stockings may be a first-line choice given their ease of use, effectiveness, and relative affordability.

Informed Clinical Decisions

Adding to this, De Carvalho et al. [24] stressed that the choice of compression system should be made at the clinician's discretion, based on evidence of efficacy, tolerability, and patient preference. Therefore, the absence of a "one-size-fits-all" superior therapy in our study implies that clinicians should opt for a patient-centered approach, considering individual needs and preferences when selecting a compression therapy modality.

Patient Lifestyle and Habits

Vieira and Franzoi [26] underline the importance of acknowledging the potential discrepancy between reported and actual lifestyle habits of patients, such as smoking or alcohol consumption. Patients may be reluctant to fully disclose these habits to healthcare providers. Nonetheless, these habits can have a significant impact on wound healing and should be actively discouraged, particularly in patients with venous ulcers (UVs).

Pneumatic Compression as a Rescue Option

Nelson et al [28] have posited that pneumatic compression should be recommended only when standard treatments have failed. This perspective aligns with our study's findings. Given that all compression therapies yielded similar outcomes and that pneumatic compression can be both costly and restrictive for daily activities, it seems rational to suggest its use as a rescue option. This would be particularly beneficial in specialized wound care centers where the therapy can be administered to a larger number of patients.

Elastic vs. Inelastic Bandages

Contrary to the findings of O'Meara et al. [23], who claimed that elastic bandages are more effective than inelastic ones, our study found no such difference. Dolibog et al. [27] study, which evaluated 367 randomized patients, also differed from our findings. They reported that two-layer systems and Unna's boot were ineffective compared to the other three therapies. In our study, Unna's boot, an inelastic compression system, was not found to be inefficient. While it does provide necessary compression to diseased veins, its complex application involving multiple layers and potentially high cost for prolonged treatment can be restrictive.

Individual Specificities

Our study couldn't assess if certain patients benefit more from one type of therapy over others based on individual factors like smoking or hypertension. Healing seems to have a variable course for each person, likely more influenced by individual physiological factors than by any specific comorbidity or therapy. Therefore, future studies are needed for a more personalized investigation.

4. CONCLUSION

Our study adds to the understanding of the complexities involved in the management of venous ulcers. The absence of a significantly superior compression therapy suggests that treatment should be tailored to individual patient needs, considering their lifestyle, comorbidities, and preferences, including monetary costs. Pneumatic compression, due to its cost and potential impact on daily activities, might serve as a rescue treatment option rather than a first-line approach. The findings also highlight the need for further research to explore individualized treatment plans based on unique patient characteristics and comorbidities.

This comprehensive discussion aims to offer an enriched understanding of venous ulcers and their management, providing clinicians with valuable insights for making informed treatment choices.

Compression is the gold standard in the treatment of venous ulcers to promote their healing. However, the results show that there was no significant difference between the four types of compressive therapy for the treatment of chronic venous ulcers. Thus, it was not possible to determine an ideal pressure range in relation to the variables studied.

CONSENT (WHERE EVER APPLICABLE)

There was free and informed consent from all research participants (patients).

ETHICAL APPROVAL (WHERE EVER APPLICABLE)

Approved by the ethics and research committee of Santa Casa de BH CEP/SCBH, CAAE 49711121.0.0000.5138.

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