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

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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-weeks 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. In the study, male patients were more commonly associated with the use of layered and stocking dressings, while female patients predominated in groups treated with Unna's boot and pneumatic compression, and it was statistically significant with a p-value of 0.045. 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. Ulcers affecting the lower limbs have various etiological categories, such as vascular, metabolic, infectious, neoplastic, and traumatic causes. Notably, about 75% of these ulcers happens because peripheral vascular disease, stemming from venous system abnormalities. These ulcers may also co-occur with complications in the arterial and lymphatic systems. [1].

Chronic venous disease (CVD) happens 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 one 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 and 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].

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 inadequate quality of life also affect approximately 1.5% of the global population suffering from this chronic issue. 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 [8-19-20-21-22-23-24-29].

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. Chronic ulcers, particularly those on the lower limbs, which occur below the knee and do not heal within six weeks, causes 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 80% to 90% of cases [19].

In Brazil, epidemiological studies on the incidence and prevalence of venous ulcers are still scarce. Authors estimate that 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 [33].

2. MATERIAL AND METHODS

Type of Study

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

Sample Size Calculation

Using the PASS 2020 software for sample calculation: 140 patients minimum for scientific relevance.

Conduct of the Study Groups

According to the Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification recommended by the Brazilian Society of Angiology and Vascular Surgery (SBACV), we had patients' class 6 (active ulcer). 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 when surgical intervention is the best treatment, and the patient 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 thirty 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. The patients had no costs in this study, received training for all devices home use, as per the manufacturers' instructions and were free to quit the research.

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 ended the dressing, 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 knew 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 help 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

Trained professionals collected data using specific forms, following proper instruction on compression system placement and pressure measurement. A digital caliper served to gauge wound diameters, capturing both length and width in centimeters. To evaluate lesion depth in a three-dimensional context, a sterile insulin needle cap delicately touched the wound bed in a vertical position, facilitating depth measurement via the caliper. A 12.2-megapixel digital camera captured wound images from about one meter away, without the use of zoom or flash, for clinical ulcer assessment. Ulcer size measurements and image collections will occur 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).

Professionals conducted two-dimensional lesion assessments using ImageJ software to calculate both the Ulcer Healing Index and the Slough-to-Granulation Ratio, representing the relationship between granulation and fibrin tissue 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 underwent analysis with SPSS 14.0 for Windows, employing both descriptive and inferential statistical methods, and took shape in tables, figures, and/or graphs. The team expressed observed data through central tendency measures such as mean and median, along with calculated minimum and maximum values and standard deviations. They also presented categorical data in terms of frequency and percentile. For comparing sociodemographic, clinical, and lesion variables among groups (A, B, C, and D), the team used the student's t-test (independent samples) or Mann Whitney test for numerical data, and Fisher's test for categorical data. They assessed the variation in ulcer area at four time points (1st, 5th, 9th, and 13th consultations) within each group using Friedman's ANOVA and the corresponding Nemenyi multiple comparisons test (non-parametric) to identify time points with significant differences. The team adopted a 5% significance level for the analysis and processed it with 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). These are the descriptors used: compression therapies, venous ulcer, and lower limbs.

The search strategy focused on titles, abstracts, 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). It has a total of 169 publications, with 103 derived from abstracts, titles, and results. Of these, twenty-two were not eligible, leaving twenty-eight used in the text.

Results

The sample size estimate was 140 patients, with thirty-five patients in each group (A, B, C, D). However, losses to follow-up happened in each group, such as self-perceived healing, transportation difficulties, or unknown reasons.

Statistical Analysis

Excel software (2013) and SPSS, version 20.0 did the data analysis. Descriptive data analysis helped to extract relevant information from the variables and quantify the variability present in the data. Measures of central tendency (mean and median), dispersion (standard deviation), and the 25th and 75th percentiles came out for quantitative variables. Frequency and percentage corresponding to each category received calculation for categorical variables.

The Shapiro-Wilk test evaluated quantitative variables. The ANOVA test compared variables with a normal distribution, while the Kruskal-Wallis's test served for variables that did not follow a normal distribution. The chi-square test or Monte Carlo test assessed differences between proportions for categorical variables, each adhering to the necessary prerequisites for application. The team considered associations statistically significant when the p-value equaled or fell below 0.05.

3. RESULTS

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	

Ulcer Treatment Types	Average	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Minimum	Maximum	p-value
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, more women used the Unna's boot and pneumatic compression. 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 assessed 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	

Treatment Types	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
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 are relevant when choosing a treatment. However, it is also crucial to remember that the ICU is just one measure of success.

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	
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	

Types of Ulcer Treatments	Mean	Standard Deviation (SD)	Median	1st Quartile (Q1)	3rd Quartile (Q3)	Min	Max	p-value
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 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 distinct 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 is no statistically significant difference in the Gilman Index between the four types of treatments. In other words, each treatment is 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 are 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 does not discern between these treatments and what other metrics might.

So, while the Gilman Index might be a useful metric for other purposes, it does not 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, low-income and with low educational levels. Moreover, these patients 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 is 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, most 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 is 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.

4. DISCUSSION

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 the gold standard for promoting venous ulcer healing.

Considering these findings, it is reasonable to assert that while compression therapy is crucial for venous ulcer healing and the choice between types considers 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 [39-40].

Informed Clinical Decisions

Adding to this, De Carvalho et al. [24] stressed that the choice of compression system is 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 [38].

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, particularly in patients with venous ulcers (UVs) [30].

Pneumatic Compression as a Rescue Option

Nelson et al [28] have posited that pneumatic compression helps 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 to help a larger number of patients [31-32-34].

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 and inelastic compression system achieved their goal somehow, they are not useless. While it does provide necessary compression to diseased veins, its

complex application involving multiple layers and potentially excessive cost for prolonged treatment can be restrictive [35-36].

Individual Specificities

Our study could not assess if certain patients benefit more from one type of therapy over others based on individual factors like smoking or hypertension. Healing has a variable course for each person, more influenced by individual physiological factors than by any specific comorbidity or therapy. Therefore, future studies will clarify more personalized investigation [37].

5. CONCLUSION

Our study adds to the understanding of the complexities involved in the management of venous ulcers. The decision must consider 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.

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COMPETING INTERESTS

There is no conflict of interest in this study.

AUTHORS' CONTRIBUTIONS

Author 1. Research, data collection, textual writing, and general reviews.
Author 2. Review, guidance and accompaniment of the entire study, final review.

CONSENT

AS PER INTERNATIONAL STANDARDS OR UNIVERSITY STANDARDS, PATIENT(S) WRITTEN CONSENT HAS BEEN COLLECTED AND PRESERVED BY THE AUTHOR(S).

ETHICAL APPROVAL

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

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