

Venous ulcer healing treated with conventional therapy and adjuvant laser: is there a difference?

Cicatrização de úlceras venosas tratadas com terapia convencional e laser adjuvante: existe diferença?
Cicatrización de úlceras venosas tratadas con terapia convencional y láser adyuvante: ¿Hay alguna diferencia?

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ABSTRACT

Objectives: to evaluate the effects of venous ulcer healing in patients after six months of conventional treatment and adjuvant low-power laser therapy. **Methods:** prospective cohort study nested in a randomized clinical trial with 38 patients, allocated into an intervention group (conventional treatment and adjuvant laser therapy) and a control group (conventional treatment). Patients were followed up as outpatients, sociodemographic and clinical variables were collected, and indicators of the outcomes Wound healing: secondary intention (1103) and Tissue integrity: skin and mucous membranes (1101) of the *Nursing Outcomes Classification*. Generalized estimating equations, Kaplan-Meier tests, and robust Poisson regression were used in the analysis. **Results:** the clinical indicators Decreased wound size and Scar formation showed a statistically significant difference in the intervention group, higher number of healed wounds, lower rate, longer time to relapse. **Conclusions:** laser therapy adjuvant to conventional treatment returned better results in healing and lower recurrence rates after six months of intervention.

Descriptors: Venous Ulcer; Nursing Care; Laser; Healing; Health Care Outcome Assessment.

RESUMO

Objetivos: avaliar os efeitos da cicatrização de úlceras venosas em pacientes após seis meses de tratamento convencional e laserterapia de baixa potência adjuvante. **Métodos:** estudo de coorte prospectivo aninhado a um ensaio clínico randomizado com 38 pacientes, alocados em grupo intervenção (tratamento convencional e laserterapia adjuvante) e grupo controle (tratamento convencional). Os pacientes foram acompanhados em consulta ambulatorial; e foram coletadas variáveis sociodemográficas, clínicas, indicadores dos resultados Cicatrização de feridas: segunda intenção (1103) e Integridade tissular: pele e mucosas (1101) da *Nursing Outcomes Classification*. Na análise, utilizaram-se equações de estimativas generalizadas, testes de Kaplan-Meier e regressão de Poisson robusta. **Resultados:** os indicadores clínicos Tamanho da ferida diminuído e Formação de cicatriz apresentaram diferença estatisticamente significante no grupo-intervenção, maior número de feridas cicatrizadas, menor taxa, maior tempo para recidivas. **Conclusões:** a laserterapia adjuvante ao tratamento convencional retornou melhores resultados na cicatrização e menores índices de recidiva após seis meses da intervenção.

Descritores: Úlcera Venosa; Cuidados de Enfermagem; Laser; Cicatrização; Avaliação de Resultados em Cuidados de Saúde.

RESUMEN

Objetivos: evaluar efectos de cicatrización de úlceras venosas en pacientes tras seis meses de tratamiento convencional y laserterapia de baja potencia adyuvante. **Métodos:** estudio de cohorte prospectiva anidada a un ensayo clínico randomizado con 38 pacientes, alocados en equipo de intervención (tratamiento convencional y laserterapia adyuvante) y equipo de control (tratamiento convencional). Pacientes acompañados en consulta ambulatoria; y recogidas variables sociodemográficas, clínicas, indicadores de resultados Cicatrización de heridas: segunda intención (1103) e Integridad tisular: piel y mucosas (1101) de *Nursing Outcomes Classification*. En análisis, utilizaron ecuaciones de estimativas generalizadas, testes de Kaplan-Meier y regresión de Poisson robusta. **Resultados:** indicadores clínicos Tamaño de herida disminuido y Formación de cicatriz presentaron diferencia estadísticamente significativa en equipo de intervención, mayor número de heridas cicatrizadas, menor tasa, mayor tiempo para recidivas. **Conclusiones:** laserterapia adyuvante al tratamiento convencional volvió mejores resultados en la cicatrización y menores índices de recidiva tras seis meses de la intervención.

Descriptorios: Úlcera Venosa; Cuidados de Enfermería; Láser; Cicatrización; Evaluación de Resultados en Cuidados de Salud.

INTRODUCTION

Venous ulcer (VU) is the last degree of chronic venous insufficiency (CVI), resulting from venous hypertension due to valve incompetence and/or obstruction of blood return from the lower limbs. The incidence of CVI ranges from 1.5 to 3.0 per thousand people/year, with a higher prevalence among the elderly and female population⁽¹⁻³⁾. In the United Kingdom, 278,000 VU patients are treated annually at an estimated cost of 1.02 billion Euros to the public sector⁽⁴⁾. Among the characteristics of this lesion are its chronicity and high relapse rates, which may reach 70% in the first months after healing, causing patients anguish, pain, suffering, prejudice, impaired autonomy, difficulty in socializing, which may substantially affect their quality of life^(1,5-8).

Conventional treatment for VU healing includes dressings with different bandages, compression therapy, the elevation of the lower limbs, mobility, and exercises to strengthen the calf muscle, adequate nutrition, and hydration, besides the control of other chronic diseases^(3-4,7-10). After healing, care must be maintained, including compression therapy through compression stockings to prevent recurrences⁽¹¹⁻¹²⁾.

However, despite the diversity of available treatments, the VU healing process is difficult and prolonged. Therefore, laser therapy, specifically Low-Level Laser Therapy (LLLT), has been used as an adjuvant to conventional treatment to aid in wound tissue repair since it reduces the inflammatory process, favors recapillarization and neof ormation of tissue layers, besides increasing collagen and elastic fibers in the healed area⁽¹³⁻¹⁶⁾. In this perspective, some randomized studies show, through the evaluation of clinical indicators, tissue regeneration and reduction in the size of chronic lesions (vascular and diabetic) when using this type of adjuvant therapy to conventional treatment⁽¹⁷⁻¹⁹⁾.

Nevertheless, there is still a gap in knowledge about this therapy's late effects in the VU healing process. In this sense, the evaluation of the healing process of these wounds through indicators validated in clinical practice is fundamental for evidence-based care and has been little described in the literature.

In this context, different studies have shown that the *Nursing Outcomes Classification* (NOC) objectively and accurately measures outcomes of nursing interventions through clinical indicators assessed using 5 point Likert Scale, in which the lowest score is the least desirable. The highest score corresponds to the most desirable. In this taxonomy, the results Wound healing: secondary intention (1103) and Tissue integrity: skin and mucosa (1101) apply to the VU evaluation⁽²⁰⁻²¹⁾.

This research aims to answer the following guiding question: What are the effects of VU healing in patients after six months of conventional and LLLT treatment?

The relevance of this study stems from the high incidence and difficulty in the healing process of VU, the suffering of patients, and the high social costs, as well as the lack of knowledge about the late effects of LLLT as an adjuvant treatment.

OBJECTIVES

To evaluate the effects of venous ulcer healing in patients after six months of conventional treatment and adjuvant low-level laser therapy.

METHODS

Ethical aspects

The institution's Research Ethics Committee approved the research under Certificate of Ethical Appraisal Submission (CAAE) through a randomized clinical trial (RCT) study addendum. All participants signed the Informed Consent Form, and the right to privacy and anonymity of the participants' information was respected.

Design, period, and place of study

This is a prospective cohort study guided by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)⁽²²⁾, aligned with an RCT⁽²³⁾, conducted between April 2016 and February 2018, from which the patients for this study were derived⁽²⁴⁾. The research was conducted at the specialized wound care outpatient clinic of the General Hospital of Porto Alegre, Rio Grande do Sul, Brazil, a reference in VU treatment and assists patients from different state regions. The period of recruitment, follow-up, and patient data collection in the present study was from September 2017 to August 2018. Between September 2017 and February 2018, both studies ran simultaneously due to the gradual withdrawal of patients from the RCT.

Population and sample: criteria of inclusion and exclusion

The population was composed of patients with VU receiving treatment in the aforementioned hospital's outpatient clinic. The sample size calculation of the RCT, from which patients were derived for this study, considered the ability to detect a one-point difference in the Likert scale score of the NOC results, with 80% power and a 5% significance level⁽²³⁻²⁵⁾. Participated in the RCT 40 patients of both genders, aged 18 years or older, with current VU. Patients with girdle/circular VU, body mass index [BMI] ≥ 40 Kg/m², with the presence of infection and/or diagnosis of lymphedema of the lower limb, being treated by immunosuppressants or corticosteroids, with more than 25% necrotic tissue in the lesion and final healing process.

Eligible patients were invited to take part in the study, and randomization and allocation to the intervention group (IG) or control group (CG) of the RCT occurred blinded to the researchers⁽²³⁾ through a draw, in which the patient chose an envelope containing their designation. Throughout the RCT, there were two losses by death, one in each group.

During the RCT, the patients were followed weekly for a period of 16 weeks or until healing of the lesion and received conventional treatment that included removal of the dressing, cleaning with warm 0.9% saline solution in a jet, application of different topical products, and technological dressings recommended and available at the institution (silver or calcium alginate, gauze impregnated with vaseline, medium-chain triglycerides, papain, hydrogel or solid Vaseline) according to the VU characteristic. Then, high compression therapy was applied using a specific elastic bandage. Participants received orientation regarding diet, hydration, specific exercises for calf strengthening, and lower limb elevation during each RCT visit⁽²³⁾.

In addition to these cares, the IG received a weekly application, performed by a qualified nurse, of adjuvant LLLT in the VU, through

the Aluminum Gallium Indium Phosphorus Laser - AlGaInP (Po - 30mW), from Inbramed®, with 660 nm in length and power of 30 mW. We followed all the recommendations of the phototherapy protocol, considering the scanning mode in the lesion with at least 1 centimeter away from the area; and, at the edges, the spot mode, with the laser tip touching the skin at a distance of 1 centimeter each⁽²³⁾.

In the last assistance carried out in the RCT, all patients who had healed VU were discharged and orientations to prevent recurrences, which included daily care, such as the use of compression stockings, elevation, and exercises of the lower limbs, adequate nutrition, and hydration, besides the control of chronic diseases. However, in case of VU recurrence, the patient returned to outpatient follow-up according to the institution's protocol, while those with non-healed VU remained to receive conventional treatment, in nursing consultations, at the same outpatient clinic.

Thus, the 38 patients, with a total of 78 VU, who participated in the RCT⁽²³⁾, were invited to compose the sample of this prospective cohort study after discharge from the previous study for completing 16 weeks of treatment or presenting VU healing. Inclusion criteria involved patients' willingness to participate in a reevaluation visit six months after the end of their participation in the RCT, and no exclusion criteria were established.

Study protocol

Data collection was performed by the researchers, previously trained, partly from the RCT database (last lesion evaluation during the RCT), plus information collected from the institution's electronic medical records regarding VU healing or recurrence. Besides, a nursing consultation was performed with each patient six months after participating in the previous study (RCT) to collect socio-demographic and clinical data and assess the VU healing process. The six-month follow-up period started after the patient's discharge from the RCT to identify wound healing conditions, healing date, and occurrence of recurrences. At this stage, there was no interference from the researchers.

The variables included sociodemographic aspects (gender, age, race, marital status, education, presence of a companion at consultations and identification of the person responsible for VU care) and clinical aspects (BMI, hospitalization, procedures regarding vasculopathy/ulcer, hypercholesterolemia, systemic arterial hypertension, diabetes, use of painkillers, smoking status, alcoholism, walking, exercises, and elevation of lower limbs, healing time and VU recurrence time).

The variables referring to the wound healing process's evaluation were derived from the application of the outcome indicators Wound healing: secondary intention (1103) and Tissue integrity: skin and mucous membranes (1101), described by the NOC.

For that purpose, eight indicators of the outcome of Wound healing were used: secondary intention (1103): Foul wound odor, Macerated skin, Erythema on the skin around the wound, Periwound edema, Granulation, Decreased wound size, Scar formation, Exudate. Besides, six indicators of the outcome Tissue integrity: skin and mucous membranes (1101): Abnormal pigmentation, Thickness, Necrosis, Hydration, Pain, and Itching - evaluated according to the 5 point Likert scale scores of the NOC. These scores and indicators were selected and validated by experts in previous studies, considering the VU healing process^(17,20-21,26).

Data analysis and statistics

Data were processed and stored in the Statistical Package for the Social Sciences (SPSS), version 23.0. Categorical variables were expressed as absolute and relative frequencies and continuous variables as mean and standard deviation or median and percentile.

To analyze categorical variables, Pearson's chi-square test was used to compare the two groups. For quantitative variables with normal distribution, the difference between the two groups was compared by Student's t-test. We performed the Kaplan-Meier curve to compare the time to relapse of the VU and the Poisson regression analysis with robust variances to compare the variable Healing between the groups, controlling for the influence of the variables gender and BMI⁽²⁷⁾.

Generalized estimating equation analysis was used to compare scores across NOC outcome indicators. Values were considered statistically significant if $p < 0,05$.

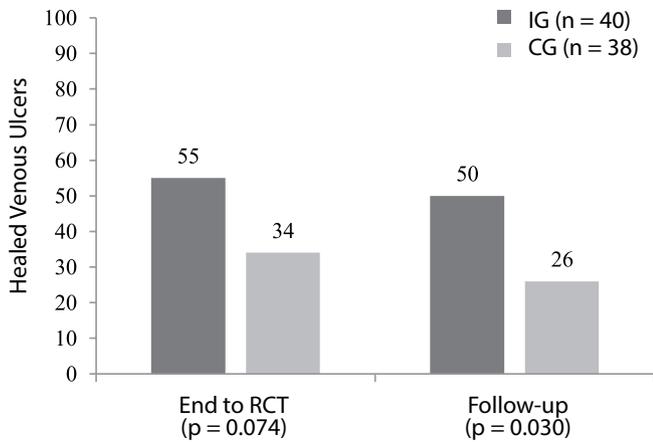
RESULTS

Participated in the study 38 patients from the RCT^(17,23), 19 from IG with 40 VU, and 19 from CG with 38 VU. The sample was homogeneous for most variables, showing that it was composed of individuals over 60 years of age, Caucasian, married, with up to eight years of education, who performed their own wound care and attended consultations alone. The most prevalent comorbidity was systemic arterial hypertension. Most participants reported that during the six-month follow-up, they regularly walked, did isometric exercises, and raised lower limbs. There was a statistically significant difference between groups (IG and CG) only regarding gender ($p = 0.038$), BMI ($p = 0.049$) and use of analgesics ($p = 0.038$) (Table 1).

Table 1 - Sociodemographic and clinical characteristics of patients with venous ulcers, Porto Alegre, Rio Grande do Sul, Brazil, 2018

Variables*	IG n = 19 (100%)	CG n = 19 (100%)	p value
Sociodemographic characteristics			
Female gender	16(84.2)	9(47.4)	0.038
Age (years)**	63.79±11.49	62.96±12.58	0.895
Caucasians	16(84.2)	15(78.9)	0.999
Marital status (married)	13(68.4)	10(52.6)	0.508
Education (up to eight years of study)	14(73.7)	12(66.7)	0.728
Accompanied in the consultation	5(26.3)	6(31.6)	0.999
Venous Ulcer Care - by:			
Patients themselves	14(73.7)	11(57.9)	
Family Members	2(10.5)	3(15.8)	0.634
Basic Health Care Unit	3(15.8)	5(26.3)	
Clinical features			
Walking	9(47.4)	10(52.6)	0.999
Isometric exercises	15(78.9)	16(82.2)	0.999
Elevation of lower limbs	17(89.5)	19(100)	0.999
Body Mass Index **	33.01±4.57	29.67±6.31	0.049
Hospital admission	3(15.8)	2(10.5)	0.999
Vasculopathy/ulcer	2(66.6)	2(66.6)	1.000
Systemic arterial hypertension	13(68.4)	11(57.9)	0.737
Hipercholesterolemia	7(36.8)	5(26.3)	0.728
Diabetes Mellitus	2(10.5)	4(21.1)	0.660
Ulcer duration (1 to 5 years)	8(42.1)	8(42.1)	0.900
Use of painkillers	16(84.2)	9(47.4)	0.038
Active smoking and abstinence	6(31.6)	7(36.8)	0.999
Alcoholism	1(5.3)	2(10.5)	0.999

Note: * Data with values expressed as absolute and percentage frequency, Fisher's exact test; IG - intervention group; CG - control group; n - number of patients; ** Data with values expressed as mean and standard deviation, Student's t test.



Note: IG – intervention group; CG – control group; RCT: randomized clinical trial.

Figure 1 - Percentage of venous ulcers healed at the last evaluation of the randomized clinical trial and during the six-month follow-up, Porto Alegre, Rio Grande do Sul, Brazil, 2018

The VU was evaluated comparing the healing condition at the time of the last RCT evaluation and six months follow-up. At the end of the RCT, the patients in IG had 22 (55%) wounds healed, and the patients in CG had 13 (34.2%) wounds healed, however, without statistical difference between the groups. In the evaluation of the follow-up period, we found 20 (50%) healed wounds in the patients from IG, while in the patients from CG, there were 10 (26.3%), showing a statistically significant difference ($p = 0.030$) (Figure 1).

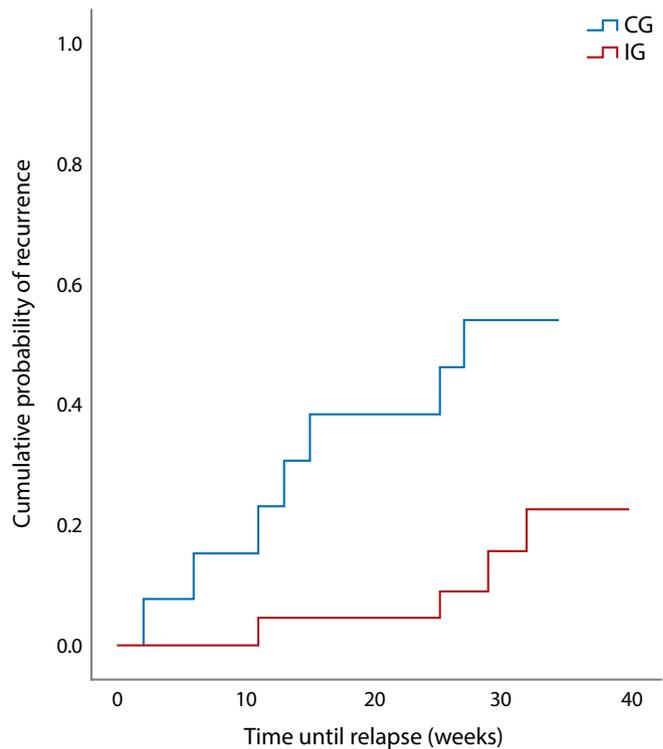
To better understand the results, patients who had at least one healed wound were paired using the multiple Poisson regression test adjusted for gender and BMI. This test showed that the CG had a relative risk of 2.20 (95% confidence interval: 1.11 to 4.37) of having no healed VU compared with the IG ($p = 0.024$).

During the follow-up, 4 (18.2%) recurrences were identified out of 22 wounds healed in patients in IG, and 7 (53.8%) out of 13 lesions that healed in patients in CG, with a significance between the groups of $p = 0.057$. The first recurrence identified in the follow-up in patients of the IG occurred at the 12th week after healing, while the last recurrence was at the 32nd week. In the CG, the first recurrence occurred at the 2nd week of follow-up, and the last one, at the 27th week.

The Kaplan-Meier curve was used to evaluate the distribution of time to recurrence between groups, which showed a statistically significant difference ($p = 0.014$), i.e., the mean time of recurrence in IG was 36 weeks (median 32), while in CG, it was 23 weeks (median 27). It is observed that by the 15th week of follow-up, IG had only one relapse, while CG had five relapses.

It should be noted that VU healing occurred in different weeks in the

same patient during the RCT since some patients had more than one lesion. Thus, the counting of weeks for relapses identified in this study considered the date of the patient's first healed VU in the previous study (Figure 2)



Note: CG – control group; IG – intervention group.

Figure 2 - Kaplan-Meier curve considering the time (in weeks) of venous ulcer relapse of patients in the control group and intervention group during follow-up, Porto Alegre, Rio Grande do Sul, Brazil, 2018

Table 2 - Mean scores of the outcomes Wound Healing: secondary intention (1103) and Tissue Integrity: skin and mucous membranes (1101) and their indicators in the evaluation of venous ulcers of the intervention group and control group in the last evaluation of the randomized clinical trial and after six months, Porto Alegre, Rio Grande do Sul, Brazil, 2018

Nursing Results*	End of RCT		6-month follow-up		P value
	IG (UV = 40)	CG (UV = 38)	IG (UV = 40)	CG (UV = 38)	
Wound Healing: Secondary intention (1103)	4.41(0.04)	4.30(0.09)	4.22(0.10)	3.85(0.13)	0.111
Indicators					
Foul wound odor (110317)	4.85(0.71)	4.82(0.06)	4.66(0.10)	4.86(0.05)	0.073
Macerated skin (110311)	4.58(0.12)	4.58(0.09)	4.50(0.18)	4.40(0.21)	0.732
Erythema on the skin around the wound (110307)	4.36(0.18)	3.96(0.26)	4.16(0.25)	3.68(0.33)	0.840
Peri wound edema (110308)	4.62(0.11)	4.34(0.24)	3.96(0.32)	3.48(0.25)	0.699
Granulation (110301)	4.81(0.08)	4.62(0.10)	4.84(0.06)	4.74(0.10)	0.541
Decreased wound size (110321)	3.58(0.16)	3.58(0.07)	3.39(0.27)	2.46(0.23)	0.010
Scar formation (110320)	4.28(0.09)	4.31(0.07)	4.07(0.13)	3.34(0.19)	0.002
Exudate**	4.33(0.08)	4.26(0.07)	4.25(0.11)	3.98(0.12)	0.224
Tissue integrity: skin and mucous membranes (1101)	4.32(0.06)	4.29(0.08)	4.38(0.09)	4.12(0.10)	0.419
Indicators					
Abnormal pigmentation (110105)	3.10(0.19)	3.48(0.20)	3.36(0.18)	3.24(0.19)	0.061
Thickness (110109)	4.53(0.02)	4.50(0.02)	4.46(0.04)	4.33(0.05)	0.162
Necrosis (110123)	5.00(0.00)	4.98(0.02)	4.98(0.02)	5.00(0.00)	0.128
Hydration (110104)	4.52(0.10)	4.45(0.11)	4.63(0.13)	4.57(0.10)	0.960
Pain***	4.34(0.22)	3.98(0.29)	4.38(0.28)	3.43(0.35)	0.246
Itching***	4.45(0.87)	4.40(0.13)	4.50(0.16)	4.24(0.21)	0.430

Note: Group means at the end of the RCT and after 6 months were compared with each other; RCT – randomized clinical trial; IG – intervention group; CG – control group; VU – venous ulcer; * Equation of generalized estimates are with values expressed as mean (standard error); ** Derived from the union of the indicators Purulent drainage (110303), Serous drainage (110304), Blood drainage (110305) and Serosanguinous drainage (110306) of the same outcome^(17,21-23); *** The indicators are part of the outcome Tissue integrity: skin and mucous membranes (1101) based on previous research^(17,23).

About the indicators of the outcome Wound Healing: secondary intention (1103), we observed better averages in evaluating patients who were part of IG, but without statistically significant difference. However, in the individual evaluation of the scores of two indicators of this outcome - decreased wound size ($p = 0.010$) and scar formation ($p = 0.002$) - a statistically significant difference was found between groups, with better results in IG. The outcome Tissue integrity: skin and mucous membranes (1101), the indicators Thickness, Hydration, Pain and Itching also maintained better mean scores in IG, but without statistically significant difference (Table 2).

DISCUSSION

This is a study that looked at VU healing using NOC outcomes as an evaluation tool at a six-month follow-up after patients received conventional treatment or LLLT adjunctively to conventional treatment in an RCT^(17,23-24).

The data show that six months after the intervention performed in the RCT, the VU of patients who received treatment with adjuvant LLLT maintained better mean scores in the outcomes Wound Healing: secondary intention (1103) and Tissue Integrity: skin and mucosa (1101), with a statistically significant difference with the indicators, Decreased wound size and Scar formation. In line with this, a randomized study conducted in France on 24 patients with VU, which also evaluated healing and local pain during the 12-week treatment period, demonstrated that although there was no statistically significant difference in total wound healing, patients who received LLLT had decreased wound size and pain compared to the control group⁽¹⁹⁾. These results reiterate that LLLT generates benefits in the VU healing process, and this is promising because it is a wound that has slow evolution and a high probability of complications and recurrences.

Other indicators evaluated, such as erythema on the skin around the wound, periwound edema, and exudate, are related to the clinical characteristics of the active and chronic inflammatory process of these lesions⁽²⁸⁾ and showed no statistically significant difference between groups. However, the group that received adjuvant LLLT showed better scores, from which we infer that there was a clinical improvement with benefits to healing, following the literature⁽²⁹⁾.

Regarding the Pain indicator, it was observed that the CG showed lower scores, even after six months, but with no statistically significant difference between the groups. However, this group showed a statistical difference in painkillers' use, normally observed in this clinical picture⁽²⁹⁾. The results suggest that patients who received adjuvant LLLT benefited from the analgesic effects provided by the treatment and showed a higher number of healed lesions, in line with previous studies⁽²⁹⁻³¹⁾.

As for VU recurrence, CG showed 53.8%, and IG, 18.2%, ($p = 0.057$), besides delaying this event's occurrence. Studies have shown that, even though patients perform the care recommended by the guidelines, such as using compression stockings to prevent VU recurrences, it has been observed recurrence prevalence rates of up to 70%^(11-12,32-33). These findings show that LLLT, besides contributing to the healing process, acts as an ally to conventional care and in reducing recurrences.

It is noteworthy that the time of healed VU was evaluated at six-month follow-up and showed a statistically significant

difference for IG and a lower number of recurrences. Thus, the present investigation contributed to the knowledge of part of the gap related to recurrence of relapses in patients who received LLLT, a theme very little explored in current studies^(11-12,34).

The study findings also revealed that the CG had a relative risk of 2.20 of not having any healed VU compared to the IG ($p = 0.024$) during follow-up. To reach these results, the influence of the variables Female gender and BMI for obesity was controlled between the groups, evidencing that both are risk factors that create conditions for CVI pathophysiology, VU development, and difficulty in lesion tissue repair⁽³⁵⁾. Therefore, adjuvant LLLT contributes in the long term to VU patients' healing process and the prevention of recurrences.

Considering the described benefits of adjuvant LLLT to conventional treatment for VU and other chronic wounds^(17-19,29,31,36), it is essential that nursing seeks to update itself on the theme and be able to offer this technology to vulnerable patients in order to qualify care; and that professionals be qualified to apply this treatment, a fact mentioned in research that identified factors related to successful VU healing⁽³⁷⁾. Thus, it is reiterated that the improvement of wound care employing effective adjuvant therapies and the use of evaluative tools based on scientific evidence is fundamental for the improvement of clinical practice.

Finally, it is noteworthy that the results evaluated using a standardized instrument showed benefits in using LLLT as a long-term adjuvant treatment, conferring scientific legitimacy to the findings obtained.

Study limitations

This research's limitations refer to the lack of similar studies to compare results and the fact that it was carried out with patients from only one center. However, it should be noted that this is a reference institution for the treatment of wounds of this etiology and that accepts patients referred from various regions of the state.

Another point is related to the sample size; however, the study proposal was to investigate patients from an RCT, based on statistical calculations to compose its sample with accuracy, which allowed to observe statistically significant differences in the results obtained. It is noteworthy that the research did not establish monitoring of post-discharge care for the prevention of recurrences in these participants since the objective was to reflect the reality of patients after they were discharged for healing. Nevertheless, an instrument was applied after the six-month period to identify the care during the follow-up.

Contributions to the Fields of Nursing, Health or Public Policy

The current research contributes to scientific progress and the improvement of nurses' clinical practice and the quality of life of patients since treatment by LLLT helps pain relief, provides better tissue healing, and reduces the rate of long-term recurrences.

The study's findings also contribute to the inspiration of research with more strong approaches and indicate the need for public health policies that reinforce nurses' actions in the provision of new technologies such as LLLT, affecting the quality of care and well-being of patients suffering from chronic wounds. In turn, the use of the NOC collaborated to demonstrate its applicability and scientific accuracy

in the evaluation process of injuries, as well as in the positive action of the treatment instituted by nurses, corroborating its benefit for the construction of specific knowledge and organization of care that is increasingly more complex in clinical nursing practice.

CONCLUSIONS

Patients treated with adjuvant LLLT exhibited better tissue conditions in the healing process, maintained a higher number of healed VU, and had a lower recurrence rate than those who received isolated conventional treatment at a six-month follow-up.

Evaluation with NOC outcome indicators demonstrated the benefits of LLLT as adjuvant treatment in the VU healing process. The outcomes Wound Healing: secondary intention (1103) and Tissue Integrity: skin and mucosa (1101) revealed better mean scores for patients who received adjuvant LLLT and clinical and statistically significant difference according to the mean scores of the indicators Decreased wound size and Scar formation. Also,

there was reduced use of painkillers and delayed and decreased numbers of relapses over six months.

It is expected that the results of this study may contribute to the improvement of nurses' clinical practice, as well as for other institutions to consider incorporating the use of this technology to improve quality of care and to benefit patients with VU.

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