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RESEARCH

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Assessment of the Effects of Low-Frequency Ultrasound Irradiation Applied to Venous Ulcer Treatment

Avaliação dos Efeitos da Irradiação Ultrassônica de Baixa Frequência no Tratamento de Úlcera Venosa

Evaluación de los Efectos de la Irradiación Ultrasonica de Baja Frecuencia en el Tratamiento de Úlcera Venosa

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ABSTRACT

Objective: The study's purpose has been to assess the effects of low-frequency ultrasound irradiation in the treatment of venous ulcer. **Methods:** It is a health technology application study, which was performed with individuals bearing venous lesions. The research was carried out over 2017 from April to August, using a structured form for data collection, where such data was analyzed in the Excel program and represented through tables and descriptive statistics. **Results:** Five patients have participated, being three women within the age group from 65 to 88 years old. The participants had five venous ulcers, predominantly located in the leg's lower portion. There was a reduction in the lesion area ranging from 2.5% (minimum) to 35.8% (maximum). One participant achieved 100% epithelization, and the others showed granulation tissue greater or equal to 70.0%. There was a maximum reduction of 10 points in the Pressure Ulcer Scale for Healing (PUSH), and a minimum reduction of 2 points. **Conclusion:** The low-frequency ultrasound therapy produces positive aspects to the tissue healing process.

Descriptors: Wounds, Venous Ulcer, Ultrasound, Treatment, Nursing.

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RESUMO

Objetivo: Avaliar os efeitos da irradiação ultrassônica de baixa frequência no tratamento de úlcera venosa. **Método:** Estudo de aplicação de tecnologia em saúde, realizado com indivíduos com lesões venosas, no ano de 2017 entre os meses de abril a agosto, utilizando formulário estruturado para coleta, analisados no programa Excel e representados em tabela e estatística descritiva. **Resultados:** Participaram cinco pacientes, três mulheres entre 65 e 88 anos de idade. Os participantes apresentaram cinco úlceras venosas, maioria localizada na porção inferior da perna. Houve redução mínima de 2,5% e máxima de 35,8% sobre a área das lesões. Um participante apresentou 100,0% de epitelização e os demais apresentaram tecido de granulação maior ou igual a 70,0%. Encontrou-se redução máxima de 10 pontos na PUSH, redução mínima de 2 pontos. **Conclusão:** A terapia ultrassônica traz aspectos positivos para o processo de reparação tecidual.

Descritores: Feridas, Úlcera Venosa, Ultrassom, Tratamento, Enfermagem.

RESUMEN

Objetivo: Evaluar los efectos de la irradiación ultrasónica de baja frecuencia en el tratamiento de úlcera venosa. **Método:** Estudio de aplicación de tecnología en salud, realizado con individuos con lesiones venosas, en el año 2017 entre los meses abril a agosto, utilizado formulario estructurado para recolección, analizados en el programa Excel y representados en tabla y estadística descriptiva. **Resultados:** Participaron cinco pacientes, tres mujeres entre 65 y 88 años de edad. Presentaron cinco úlceras venosas, mayoría localizada en la porción inferior de la pierna. Se observó una reducción mínima del 2,5% y una máxima del 35,8% sobre el área de las lesiones. Un participante presentó 100,0% de epitelización y los demás presentaron tejido de granulación mayor o igual al 70,0%. Se encontró reducción máxima de 10 puntos en la PUSH, reducción mínima de 2 puntos. **Conclusión:** La terapia ultrasónica trae aspectos positivos para el proceso de reparación del tejido. **Descriptores:** Heridas, Úlcera Venosa, El ultrasonido, Tratamiento, Enfermería.

INTRODUCTION

The advancement of the incorporation of new technologies in health raises the need to establish an evaluation strategy that allows understanding if these resources employed are in fact resulting in the best benefits for the society. The Health Technology Assessment is a comprehensive process of investigating the clinical, economic and social consequences of using existing or emerging health technologies.¹

Considering the treatment of wounds, the technologies for recovering the injured area involve factors related to healing time, patient comorbidities, presence of infection in the lesion, areas affected and the individual's adherence to the treatment.^{2,3} In turn, chronic wounds are a problem that has been frequent in the context of public health. This type of lesion usually results from chronic venous insufficiency, from 80.0 to 85.0%, and from arterial disease (5.0 to 10.0%), with the remainder of neuropathic origin, usually diabetic, or even mixed.⁴

In this scenario we highlight the venous ulcers, characterized by late complications of chronic venous insufficiency, which may arise by trauma or spontaneously.

Chronic venous insufficiency has an influence on the treatment of wounds by provoking obstruction or reflux of venous return, which causes venous hypertension and subsequently edema and lipodermatosclerosis.⁵

In Brazil, it is estimated that 3.0% of the population has a venous ulcer and about 70% present a recurrence.⁶ In the United States, venous ulcers correspond to 70.0% to 90.0% of leg ulcers. Worldwide, it is estimated that the prevalence of the lesion is 0.5% to 2% of the population.⁷ People of different age groups have venous ulcers, but the elderly, especially females, are the most affected.⁸

Therefore, compressive therapy is indicated as the standard therapy for the treatment of venous ulcers, but it requires the patient to be followed up by specialists and the cost of treatment when it is not available free of charge by the health service.⁷ In this framework, topical therapy has been the most widely used because of its easy handling and access. Nevertheless, the search for technological resources to assist in the treatment of skin lesions has shown favorable results in studies that analyzed bactericidal coatings, biophotonic interventions and biological agents.^{3,4}

Among the advances, the effects of low-frequency ultrasound in the treatment of skin lesions and chronic wounds are highlighted. The use of ultrasound therapy has been advocated in the wound healing process because its predominant physiological effects act on the tissues at all stages of the wound repair process.³

A study developed in the United States assessed the efficacy of low-frequency (< 100 kHz) and low-intensity (< 100 mW/cm²) ultrasound in the treatment of venous ulcers. The results indicated that ultrasound of 20 kHz at 100 mW/cm² caused an average of 32% increase in metabolism (p < 0.05) and 40% of cell proliferation (p < 0.01) after 24 hours of the onset of treatment when compared to the control group.⁹

An inpatient pilot study was conducted in Germany that investigated the role of low-frequency ultrasound therapy in the microcirculation of venous ulcers. It was concluded that ultrasound therapy at 34 kHz was well tolerated, increasing the oxygen saturation values in hemoglobin and the number of hemoglobin after a single application.¹⁰

Hence, the use of low-frequency ultrasound can become an associated procedure in the treatment of venous ulcers. Given the aforementioned, the goal of this study was to assess the effects of low-frequency ultrasound irradiation in the treatment of venous ulcer of patients assisted in Primary Health Care Units.

METHODS

This was an evaluation study of the effects of a health technology related to intervention with low-intensity ultrasound irradiation. The study was carried out in Primary Health Care Units of *Baturité* city, *Ceará* State, Brazil,

which had people undergoing treatment for venous ulcers. The study population consisted of primary care users who had a medical diagnosis of chronic venous insufficiency and venous ulcer skin lesions. Therefore, the study data included five users, who were randomly selected according to the medical diagnosis, availability to integrate the research and compliance with the eligibility criteria for performing the ultrasound experiment.

The criteria for sample selection were as follows: individuals over 18 years of age, presenting a venous ulcer wound, and attending the health unit on pre-established days for at least 15 days after the intervention. The exclusion criteria were as follows: to present three or more criteria that hamper healing (nutritional disorders, chronic diseases such as Diabetes Mellitus, use of drugs such as corticosteroids and smoking) and present necrotic tissue with the indication of limb amputation.

For data collection that occurred from April to August 2017, a structured form formulated by the authors was adopted, addressing epidemiological and clinical aspects of the study participants, such as: age, gender, skin color, education, marital status, occupation, income, medical diagnoses, medications in use, record of Systemic Arterial Pressure (SAP) and characteristics of the lesion. The use of the Pressure Ulcer Scale for Healing (PUSH), which compiles data about the lesion area (cm^2), amount of exudate and type of tissue, was chosen to measure wound healing. This scale allows for a continuous, pragmatic and systematic assessment, contributing to the quality of patient care.¹¹ Photographic records were stored and analyzed by ImageJ Software version 1.40 (Research Services Branch, U.S. National Institute of Health, Bethesda, MD, USA). This software processed and analyzed images in computers that have JAVA and allowed to perform the delimitation and quantification of the total area of the lesion, the areas of granulation and dead tissue. After data collection, the information was tabulated and quantified. The method of descriptive statistical analysis with percentage and average calculation was used.

The main steps of Low-Frequency Ultrasound Therapy

The wound was cleaned with sterile gauze and 0.9% saline solution; a PVC film was applied over the area of the wound, being considered a margin of safety in the edges; the ultrasound transducer was also protected with the PVC film, never in direct contact with the lesion; an acoustic impedance agent was applied to the transducer or wound area, in which case a water-based gel was used.

The low-frequency ultrasound was applied punctually, initially at the edges and then in the wound spot, following a 1 cm margin between the application areas. Traversing the entire area of the lesion. In the case of infected wounds, the application followed the least contaminated to the most contaminated. Three minutes remained in each

area, followed by the edges and then the wound spots. The application time was defined using the effective radiation area measure, where $\text{TIME} = \text{AREA}/\text{ERA}$. TIME is the unit to be defined, AREA is the length x width measured through a tape measure before each application and ERA is the Effective Radiation Area, in other words, where there is the emission of sound waves also measured with a measuring tape leading in the diameter of the transducer and defined as 4 cm^2 .¹²

It was defined based on another study already performed that the ultrasound device would respect the following definitions: frequency of 3 MHz, with energy density of 0.5 Watts/ cm^2 that is relative to 3.5 Watts of emission, with cycle of 100 Hz pulse rate, 50% pulse rate, and pulsatile type emission.² The ultrasound was smoothly applied in a "8" shape over the semi-static area with minimal amplitude movements applied in clockwise as indicated by physiotherapy professionals. Photographic registration and notes about the injury were performed. At the end of the application, the PVC film was removed and the dressing was standardized by the health unit. In some cases, a new coverage was indicated by the researchers, such as when the wound had lesions requiring enzymatic-type coverage or even when the wound spot was found to be viable tissue requiring hydration coverage. The use of Personal Protective Equipment occurred throughout the process. The discomfort or pain was evaluated during the procedure, based on the report of the Visual Analogue Scale (VAS) participants. The periodicity of the application occurred every 48 hours. A maximum total of 15 applications was established, since it is perceived that the use of low-intensity radiation loses efficacy according to the number of subsequent sessions.³

The study complied with the formal requirements contained in the national and international norms regulating research involving human beings, with a positive appreciation of the Research Ethics Committee from the *Universidade da Integração Internacional da Lusofonia Afro-Brasileira (UNILAB)* under the Legal Opinion No. 1.049.373.

RESULTS AND DISCUSSION

Among the five participants, three were women and two men. These included a total of five lesions of the venous ulcer type. The participants were within the age group from 65 to 88 years old. Of these individuals, four were considered brown and one white. As for schooling, four had incomplete elementary education and one was illiterate.

With regards to the occupation of study participants, all five were retired. The family income of two individuals corresponded to a minimum wage, and of the others was more than two minimum wages. Taking into account the minimum salary at the time of the research, R\$ 880.00, a maximum family income of approximately 2.3 minimum wages was then verified.

In addition to chronic venous insufficiency, these patients may present other diseases that interfere with the healing process. In the individuals submitted to ultrasound therapy, it was identified that Systemic Arterial Hypertension (SAH) and Diabetes Mellitus (DM) were among the basic diseases most associated with venous insufficiency. In addition to these morbidities, there was also the presence of leprosy. Such pathologies can hinder the healing process, which leads to the need for a more complete therapeutic apparatus.

Considering the five wounds studied, most were in the malleolar region. The chronicity of these wounds was observed, reaching a higher evolution five years ago. Three of the five venous ulcers had superficial depth and drained either purulent or bloody-serum exudate. Considering those, most drained from large to medium quantities.

Upon observing the wound spot, it was observed that three had granulation tissue associated with dead tissue. As the edges of the two ulcers were epithelialized, two macerated, one with hyperemia and friable. The skin around the lesions was mostly hyperpigmented, dry and scaly. In regards to the products used in the wound spot, it was observed the predominance of essential fatty acids and silver sulfadiazine (Table 1).

Table 1 - Clinical profile of the patients/lesions undergoing the low-frequency ultrasound therapy. Baturité city, Ceará State, Brazil, 2017. (n = 05)

Patient	Associated disease	Anatomic region of the lesion	Evolution time of the lesion	Depth	Characteristics of the edges	Topical Therapy
01	Venous Insufficiency + Leprosy	Malleolar region	< 1 year	Superficial	Macerated; hyperpigmented; dry and scaly	Silver sulfadiazine
02	Venous Insufficiency + Leprosy	Malleolar region	> 5 years	Superficial	Epithelialized; hyperpigmented	Collagenase
03	Venous Insufficiency + SAH	Malleolar region	> 2 years	Deep	Epithelialized; hyperpigmented; erythematous and hydrated	Essential fatty acids
04	Venous Insufficiency + DM	Malleolar region	> 2 years	Deep	Hyperemia; friable; hyperpigmented; erythematous and hydrated	Essential fatty acids
05	Venous Insufficiency + SAH and DM	Foot	< 1 year	Superficial	Macerated; hypopigmented; dry and scaly	Silver sulfadiazine

Table 2 shows the parameters of the lesions before and after the application of the low-frequency ultrasound therapy from the PUSH score, where the three dimensions that this scale addresses are identified: area in cm² (length x width), (none, sparse, moderate, abundant) and type of tissue (healing tissue, epithelization, granulation, devitalized, necrotic).

The mean reduction was greater than 15% in the lesions evaluated. It is also verified that the effect of the low-frequency ultrasound therapy is potentiated when the lesion presents a smaller diameter and a viable tissue (in the present study, the lesion with a smaller diameter at the beginning of the therapy obtained a reduction of 20% of its total area).

Table 2 – The effects of low-frequency ultrasound irradiation on the treatment of venous ulcers. Baturité city, Ceará State, Brazil, 2017. (n = 05)

Venous Ulcer (n = 05)	Days of use	PUSH initial	PUSH final	Initial area (cm ²)	Final area (cm ²)	Initial characteristics	Final characteristics	Pain reduction	Area reduction (%)
1	15	13	3	105	91	Epithelization 80% + Granulation 15% + dead tissue 5%	Epithelization 100%	Yes	13.3
2	15	13	10	12.5	10	Granulation 80% + dead tissue 20%	Granulation 95% + dead tissue 5%	No	20
3	12	14	12	56	52.5	Granulation 85% + dead tissue 15%	Granulation 100%	Yes	6.5
4	13	15	13	221.3	215.7	Granulation 40% + dead tissue 40% + Necrose 20%	Granulation 75% + dead tissue 25%	Yes	2.5
5	12	15	12	135	86.6	Granulation 50% + dead tissue 50%	Granulation 70% + dead tissue 30%	Yes	35.8

In the first lesion, a larger reduction in the PUSH score and the predominance of epithelial tissue were observed, evidencing wound healing after low-frequency ultrasound therapy. In the fifth wound, we observed a difference of three points in the scale, reduction of the dead tissue and reduction of 35.8% of the ulcer total area, the largest reduction in the area of the lesion observed among the study subjects. While the fourth lesion presented a minimal reduction in the lesion area (2.5%), however, although it did not achieve a significant reduction, it presented an increase in the granulation rate of 35% with a reduction of the dead tissue and absence of necrosis, as well as relief of pain symptoms. In addition to the reduction in the PUSH score, wound area and increase in viable tissue, there has been also a reduction in pain reported after the application of ultrasound therapy in most individuals undergoing low-frequency ultrasound therapy (Table 2).

This work allowed to identify the socioeconomic characteristics of individuals with venous ulcers, as well as the clinical profile of the lesions and the effects of low-frequency ultrasound irradiation on the treatment of these ulcers.

The use of this technology in health is indicated as another resource for the treatment of skin lesions, this therapy provides a reduction in the time of wound epithelialization.

The lesions most frequently seen in primary health care units are vascular ulcers, corresponding to the epidemiological panorama of the northeastern region of the country.¹³ These skin lesions have increased in incidence and are closely related to the aging process that currently occurs the Brazilian population, thus demanding special assistance, considering the chronic character, secondary to a basic disease and its repercussions on the quality of life of the client and their relatives.⁴

Venous ulcers are lesions that predominantly affect the female sex and this is confirmed in the findings of the research. Venous ulcers are more prevalent in the elderly, older than 65 years old, especially in women, which manifest beyond the wound, reduction of daily activities and chronic-degenerative diseases.^{8,14}

It is observed that in the present study the population presented low schooling and low family income. This fact converges with other studies that indicate low levels of schooling and income among individuals with venous ulcers.^{8,15} Low socioeconomic status has a negative influence on the understanding of the care needed to treat the lesions, as well as health care in general, as well as hampering access to health services and material resources.¹⁴

So, it is necessary to identify the economic and educational profile of the lesion sufferers, so that the health professional can better plan their interventions aiming at not only the cutaneous lesion but also the bearer with its characteristics and needs.

Concerning the occupation, it is observed that the five individuals in the study are retired, this fact can be justified because they are older than 60 years. Nonetheless, venous ulcers can compromise the ability to work, generating high numbers of early retirements, unemployment and medical leave.¹⁵

It is common for patients with venous ulcers to present other associated diseases, in addition to chronic venous insufficiency, which may interfere with tissue healing. Systemic Arterial Hypertension and Diabetes Mellitus, both of which interfere negatively with tissue repair, cause changes in the circulatory system, making the healing process deficient, which may increase the risk of infections.^{8,16} Such basic diseases were present in three of the subjects of the present study.

Lesions of venous etiology usually present in the lower portion of the leg near the malleolar region. They rarely occur in the upper portion of the calf and feet.^{2,9} These data corroborate the findings of the present study, whereof the five lesions, four are located in the malleolar region.

Venous ulcers are lesions characterized by their chronicity and recurrence. 40 to 50% of lower extremity ulcers remain active or open for more than six months and 10% remain unhealed for more than five years. And a third of the healed ulcers recur during the twelve months after healing.¹⁷

Venous ulcers are generally superficial and deep when they are more painful, especially those located near the malleolus.² This data is in line with the results obtained in the research, where three of the individuals submitted to ultrasound therapy have superficial venous ulcers.

The presence of exudate in the wound spot is a physiological process being frequent in the inflammatory phase due to extravasation of plasma. From the evaluation of the volume, odor, and color, one can consider the presence or not of infection. Serous exudate is usually related to clean wounds, whereas purulent exudate is often associated with infectious processes, and the bloody-serum exudate often indicates the presence of vascular injury that affects the new fragile vessels.⁸

When assessing the wound spot, it is important to identify the viability of the present tissue, as this may define the healing stage or complications that may be present. The viable tissue is that formed in the healing process, aiming at

the epithelial reconstitution, it is the granulation tissue and epithelialization tissue. The infeasible one is necrotic tissue, made up of different organic materials.⁸

Some of the studied wounds have edges with epithelial tissue, which is characterized by its fine pinkish aspect that grows toward the center of the lesion, providing its closure.⁸ While another is macerated, this may occur due to inadequate use of coatings that stimulate the excessive exudation of the wound, which hinders the migration of keratinocytes, thus avoiding epithelialization.¹⁷ There is also an injury involving the fibrous edge represented by a tissue of yellow or white color, which adheres to the wound spot and presents as thick cords or crusts.^{8,17}

The classic changes in the edges of the venous ulcers were identified in the evaluated participants. Erythema, hyperpigmentation, and desquamation are characteristics of the skin around venous ulcers, being aggravating factors that hinder the epithelial recovery process, besides favoring the appearance of new lesions.⁸

Regarding the products used, we observed the predominance of the use of oils based on essential fatty acids, indicated for the treatment of wounds with granulation tissue, as it promotes chemotaxis and angiogenesis, in addition to maintaining a humid environment and accelerating the tissue granulation process.^{2,4} It is also reported in the literature that patients are unaware of compression techniques such as elastic stockings and Unna boot, which are fundamental treatments for venous ulcers since they have the purpose of reducing venous hypertension.²

The findings of this study are similar to a randomized controlled trial of 90 outpatients where ultrasound was performed three times a week for twelve weeks or until the patient was cured. There was a significant improvement in wound surface, pain, and edema, as well as a reduction in the healing time of individuals undergoing ultrasound treatment when compared to a group that used standard treatment.¹⁸

The high number of venous ulcers that generate billions of dollars of spending on the health system in the United States associated with the low cure rate led to the development of a study to evaluate the efficacy of the use of ultrasound in refractory venous ulcers. After the application of ultrasound therapy, there was a significant reduction in the wound area, a decline in bacterial amounts, the expression of inflammatory cytokines when compared to basal levels, and pain assessed by the VAS.¹⁹ The reduction in lesion and pain area were found similar to those found in this study.

Among the treatment methods, ultrasound has been a supporting resource to aid in the wound healing process. The ultrasound, through its waves, causes the micro flow as a result of the unidirectional movements of the ultrasonic field and that give rise to tension forces beneficial to the treatment of the wound. Among the physiological effects of ultrasound, cell degranulation, changes in cell membrane function, increase of intracellular calcium levels, an increase of angiogenesis and vascular permeability, stimulation of

fibroblastic activity and, consequently, increase of synthesis and elastic tension of collagen.²

In a study evaluating the acceleration of tissue repair in animal models with surgical wounds, it was found that the use of ultrasound therapy as a supporting resource with the comfrey gel (*Symphytum officinale* L.) demonstrated significant tissue improvement in the healing process, quantified in 10.0% in relation to the control group that used the same treatment and did not associate the ultrasound. Histological analysis demonstrated increased cell diffusion and collagen synthesis by the physical and chemical mechanisms promoted by low-frequency ultrasound.²⁰

In the *Rio Grande do Sul* State, a study analyzed the effect of ultrasound on pressure injuries of 11 patients admitted to the intensive care unit. The researchers used therapeutic ultrasound with a frequency of 3 MHz in the pulsed form at 100 Hz, with a pulse ratio of 1:5 and a dose of 0.4 W/cm². The macroscopic analysis through photographic record indicated a decrease in lesions after 30 days of application, applied twice per week.²

The literature covers ultrasound therapy as a supporting resource in the process of wound healing. Data reported in studies declined for the feasibility of using this technology in nursing care. This technology has been used for some years in the care of wounds, mainly by professionals in the area of physiotherapy, however the nursing has been appropriating the use of this resource for a few years, which refers to the need for disclosure and understanding both by professionals and by the users of the health services so that there is greater acceptance and use of this mechanism in the therapy of skin lesions.

CONCLUSIONS

The low-frequency ultrasound therapy produces positive aspects to the tissue healing process. It causes the reduction of the lesion area, and also increases the amount of viable tissue, then stimulating faster healing, when compared to conventional dressing techniques with a more resistant cicatricial tissue.

It is worth mentioning that the results of this study might contribute to nursing practice in regards to wound bearing individuals, since, based on the findings of health professionals, particularly, the nurses can improve their interventions vis-à-vis the treatment of skin lesions. Furthermore, it is clear the need for new researches addressing larger samples in order to confirm the results obtained here.

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