

EVALUATION OF THE TWO-COMPONENT COMPRESSION SYSTEM FOR TREATMENT OF VARICOSE ULCER

AVALIAÇÃO DO SISTEMA DE COMPRESSÃO DE DOIS COMPONENTES NO TRATAMENTO DE ÚLCERA VARICOSA

EVALUACIÓN DEL SISTEMA DE COMPRESIÓN DE DOS COMPONENTES PARA EL TRATAMIENTO DE ÚLCERA VARICOSA

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ABSTRACT

The professionals responsible for treating patients with varicose ulcer should be competent in the selection and application of compression therapy along with the patient's individual needs. For that, it is necessary to know the performance of the products. **Objective:** To evaluate the performance of two compression systems bandages in the treatment of varicose ulcer. **Methods:** descriptive case study of product evaluation with follow-up by 12 weeks of patients older than 20 years, medical diagnosis of varicose ulcers, ankle-brachial index (ABI) > 0.8 and measures of ankle circumference between 18 and 25 cm or 25 and 32 cm. The performance variables were the percentage of change in the area; leg edema; bandage slip; adverse events. **Results:** The participants were obese, older than 36 years, ABI = 1, leg edema, calf/ankle circumference ratio of 1.5, reduced range of ankle motion, ulcers with an area from 1.0 to 5.4 cm². **Conclusion:** the variables used are suitable for performance assessment of compression systems with regard to the percentage of change in the area; leg edema; bandage slip; adverse event (necrosis of the skin) and the analyzed two-component system may be an appropriate therapy for the treatment of varicose ulcer in clinical practice in Brazil.

Keywords: Varicose Ulcer; Compression Bandages; Evaluation Studies as Topic; Effectiveness.

RESUMO

Os profissionais responsáveis pelo tratamento de pacientes com úlcera varicosa devem ser competentes na escolha e aplicação de terapias de compressão em consonância com as necessidades individuais dos pacientes. Para isso, faz-se necessário conhecer a performance dos produtos. **Objetivo:** avaliar o desempenho do sistema de compressão de duas bandagens no tratamento de úlcera varicosa. **Método:** estudo de caso descritivo de avaliação de produto com seguimento por 12 semanas de pacientes com idade superior a 20 anos, diagnóstico médico de úlcera varicosa, índice de pressão tornozelo/braço (ITB) > 0,8 e medidas da circunferência do tornozelo entre 18 e 25 cm ou 25 e 32 cm. As variáveis de desempenho foram a porcentagem da alteração da área; edema da perna; deslizamento da bandagem; eventos adversos. **Resultados:** os participantes eram obesos, idade superior a 36 anos, ITB = 1, edema na perna, relação circunferência panturrilha/tornozelo de 1,5, variação reduzida do movimento do tornozelo, úlceras com área de 1,0 a 5,4 cm². **Conclusão:** as variáveis utilizadas são adequadas para avaliação do desempenho de sistemas de compressão no tocante à porcentagem da alteração da área; edema da perna; deslizamento da bandagem; evento adverso (necrose na pele) e o sistema de dois componentes avaliado pode representar uma terapia adequada para tratamento de úlcera varicosa na prática clínica, no Brasil.

Palavras-chave: Úlcera Varicosa; Bandagens Compressivas; Estudos de Avaliação como Assunto; Efetividade.

RESUMEN

Los profesionales encargados del tratamiento de pacientes con úlcera varicosa deben ser competentes en la selección y aplicación de la terapia de compresión de acuerdo con las necesidades individuales de los pacientes. Para tal, es necesario conocer la performance de los productos. El objetivo del presente estudio ha sido evaluar el desempeño del sistema de compresión de dos vendajes en el tratamiento de úlcera varicosa. Se trata de un estudio de caso descriptivo de evaluación del producto con un seguimiento de 12 semanas de pacientes mayores de 20 años, con diagnóstico médico de úlceras varicosas, índice de presión tobillo/brazo (ITB) > 0,8 y medidas de la circunferencia del tobillo entre 18 y 25 cm o 25 y 32 cm. Las variables de desempeño fueron el porcentaje de alteración en la zona; edema en la pierna; deslizamiento del vendaje; eventos adversos. Los participantes eran obesos, mayores de 36 años, ITB = 1, edema en la pierna, relación de la circunferencia de pantorrilla/tobillo de 1.5, reducción de la amplitud de movimiento del tobillo, úlceras con un área de 1,0 a 5,4 cm². Las variables utilizadas son apropiadas para la evaluación del rendimiento de sistemas de compresión con respecto al porcentaje de alteración en el área; edema en la pierna; deslizamiento del vendaje; evento adverso (necrosis de la piel) y el sistema de dos componentes evaluado puede ser una terapia adecuada para el tratamiento de úlcera varicosa en la práctica clínica en Brasil.

Palabras clave: Úlcera Varicosa; Vendajes de Compresión; Estudios de Evaluación como Asunto; Efectividad.

INTRODUCTION

Leg ulcer is defined as a skin injury below the knee level that persists for more than six weeks and shows no tendency to heal within three weeks. The ulcer is a common disease among adults, it causes physical pain, stigma and prejudice and that reduces social interaction and produces negative impacts on the quality of life of these people, as seen in their everyday life. It is considered a public health problem, since it is already predicted that 1% of the adult population will have leg ulcer at some point in their life. This condition affects 3.6% of people aged over 65 years.¹ This high percentage of people with ulcer, which has limiting characteristics and strongly affects the quality of life leads these people to seek assistance by health professionals, mainly in outpatient services and home care.²

In a survey study conducted with 31,619 patients with leg ulcers, it was found that in 47.6% of patients the cause of the ulcer was venous insufficiency, 14.5% was arterial insufficiency and 17.6% of patients had arterial insufficiency and venous insufficiency. Rarer causes ulcers have been identified, such as vasculitis (5.1%), exogenous factors (3.8%), pyoderma gangrenosum (3.0%), infection (1.4%), neoplasia (1.1%) calciphylaxis (1.1%), and drug-induced ulcers (1.1%).³

In a study published in 2013, it was demonstrated that the most common causes of leg ulcers were venous disease, arterial disease and neuropathy, and the less common were metabolic disorders, hematological disorders and infectious diseases.² Around 60 to 80% of leg ulcers had a venous component and its prevalence increased with age. It is noteworthy that in the UK the occurrence of varicose ulcer is small, with an estimated prevalence between 0.1 and 0.3%⁴ and in the United States the overall prevalence is approximately 1%.² Varicose ulcers are more common in women and in people aged 65 years or more and the main risk factors are deep vein thrombosis, phlebitis, previous leg injury and obesity.⁵

There are several theories that explain the formation of varicose ulcer. However, there is a consensus that the main cause is chronic long-term venous hypertension that the lower limb is exposed to. Chronic venous hypertension is caused by high pressure in the veins due to the blockage or weakness of the valves of the veins of the superficial venous system, deep or perforating or communicating veins. Generally, beyond the ineffectiveness of venous system, there is also inefficient pump of muscles which make up the calf, which facilitates reversal of the blood flow in the deep venous system to the superficial and implies valvular insufficiency of the perforating veins, resulting in increased pressure in these veins even at ambulation.⁵ The persistence of this pressure will trigger changes in the leg, for example, secondary varicose veins, edema and trophic changes involving hyperpigmentation and stasis eczema dermatosclerosis and culminates with the emergence of varicose ulcer.²

These ulcers may require a long treatment to cure and cause discomfort to patients, and the treatment is very costly to the health system. There has been consensus among the authors who claim that the main treatment for varicose ulcers is to apply firm pressure on the leg, using bandages or stockings, to assist venous return. Both in the international and domestic market there is a big number of available compression products. Some consist of a single bandage, also called component, and others require the simultaneous application of several types of bandages, also called multicomponent. In some cases, compression stockings are used as an alternative to compression bandages.⁶

It is noted that most professionals of clinical practice in this area are always searching new compression therapy options for patients with varicose ulcer; scientifically based and effective in improving the venous leg return, in addition to being safer for the patient and promote ulcer healing. However, it is frequently observed that some of these professionals do not establish objective criteria for evaluating multicomponent compression system.

The professionals responsible for treating patients with varicose ulcer should be kept up to date and be responsible for the translation of knowledge generated by research to clinical practice, being competent in choosing and applying a compression therapy in line with individual needs of the patients. When used incorrectly, this therapy may delay ulcer healing and cause adverse events such as, for example, pain in the affected area, new lesions or even the loss of a limb. Such complications can be avoided by adopting objective criteria for desired outcomes, helping in the selection and indication of compression therapy, based on evidence. Therefore, this study aimed to establish criteria for evaluation of a compression system performance and evaluate a two-component compression system in the treatment of varicose ulcer.

METHODS

It is a descriptive case study of performance evaluation of a two-component compression therapy system carried out from September to December 2014 at an outpatient clinic of a university hospital in Belo Horizonte, MG. This service consists of providing care to patients with leg ulcers of various etiologies.

The study consisted of the testing and validation of the variables and of the monitoring and evaluation method of the evolution of the ulcers treated with a two-component compression system, also denominated a two-layer compression system or two bandages in the treatment of varicose ulcer of two patients. The goal is to support the analysis and evaluation of the therapy performance. The next phase of the study

will be conducted using of the same method and compression system, however with a larger sample and follow-up of patients with varicose ulcer.

For recording data of this research, it was used a form, filled by one of the researchers during appointments with the participants for dressing change and application of the multi-component system, every seven days. This form contains data to characterize the participant, such as initials of his/her name, sex, age, education, body mass index (BMI), calf and ankle circumference of the leg with ulcer, lengthy course of ulcer and treatment time of the same in the research field and dimensions of the injured area.

Inclusion criteria for this study were established as: being a patient over the age of 20 years, having medical diagnosis of varicose ulcer, leg ulcer with ankle-brachial index (ABI) > 0.8 and ankle circumference measures between 18 and 25 or 25 cm and 32 cm. Exclusion criteria were considered ineligible patients with diabetes mellitus, heart failure and a history of allergy to latex. If the patient had infection in the ulcer during the evaluation period, the proposed treatment was discontinued.

The main variable in this study for product performance evaluation was the leg edema, measured through the calf circumference (measured at the widest part) and ankle (measured 10 cm above the medial malleolus). Secondary variables were related to ulcer healing (percentage of change in the area assessed by tracing the wound and photographic record); the bandage slip (bandage ability to remain in the place where it was applied); and adverse event (considered in this study as necrosis of the skin resulting from improper product application). It should be noted that the slip bandage was evaluated using the initial and final measurement of the upper location of the same, having the patella as a reference. Assessments occurred at baseline and weekly, every dressing change, during the monitoring phase of patients.

The photographic record was made in an environment with natural light without the need for flash. It remained at a distance of 30 cm and 90° angle between the camera lens and the ulcer to carry out all the photos. In order to photograph them, it was placed a label on the affected limb, above the lesion, with the initials of the patient's name, date and ulcer area. Photographic documentation was developed in color and regular periods.

A French manufacturer developed the compression system evaluated in this study. It consists of a two-component compression system designed to spread pressure evenly between them. It consists of a bandage comprising a moderately elastic compression fabric composed by polyamide filler, spandex, viscose and polyester and other cohesive elastic bandage consisting of elastane, polyamide, acrylic and natural latex.⁷ The two bandages have visual markers for information stretch of 50% and correct superimposition of the layers.

The assembly of the two components carries the recommended therapeutic pressure of 40 mmHg, indicated for the treatment of uncomplicated varicose ulcers, those with ABI > 0.8 and to reduce edema caused by chronic venous insufficiency.

The monitoring time of the bandage system was different for the two patients. The first was of five weeks and the second of 12 weeks and both with weekly exchange of the system. For the topical treatment of varicose ulcer, it was used in one of the patients a calcium alginate plate as primary cover and a secondary sterile dressing cover; and the other patient used hydrocolloid board according to the institution's protocol.

Each patient had two lesions, both located in the left lower limb (LLL), totaling four injuries that were evaluated since the beginning of participation in the trial and during its development as the percentage of change in the area. The ulcers were encoded L1, L2, L3 and L4 to enable the identification of lesions. The L1 and L2 ulcers refer to the patient named "H" and L3 and L4 to patient "M". These codenames were used in the research report, with the agreement of the participants that only the initials of their names were seen in the photographic records in order to ensure their anonymity.

Data were collected, organized, submitted to descriptive analysis and presented in table format and comparative photographic record, supported by discussion in the literature concerning the topic.

The Ethics Committee of the Federal University of Minas Gerais approved this study under the number 01581612.0.0000.5149. Data were obtained after agreement and signature of Informed Consent (IC) by the patient. It is noteworthy that the study followed the national and international ethical principles as well as the terms of the National Health Council Resolution No. 466, of December 12, 2012.

RESULTS

The two patients selected for this study presents recurrent ulcers. One had varicose ulcer for four years and the other for two years. Both were obese, with a BMI of 37.0 and 35.0 kg/m²; one is male and the other female; aged 50 and 37 years, respectively. Only one patient had the disease associated with hypertension.

Early in the performance evaluation of the compression system of two components, the participants were already getting the treatment at the institution; one for two years and two months (H) and the other for six months (M). Both had ITB of 1.0 in the leg with ulcers.

Prior to the start of the evaluation of the aforementioned system performance, the patients were using an Unna boot to improve venous return and had calf circumference measures of 45.0 and 41.5 cm and 31.0 and 28 cm for ankle (Table 1).

Table 1 - Evaluation the performance of two compression systems bandages. Belo Horizonte

Variables	Evaluation	Patient H	Patient M
Calf circumference (cm)	First day	45,0	41,5
	Week 1	43,5	40,5
	Week 12	42,0	----
Ankle circumference (cm)	First day	31,0	28,0
	Week 1	29,0	26,5
	Week 12	29,0	----
Calf circumference / Ankle circumference	First day	1,5	1,5
Reduction of the calf circumference (cm)	Week 1	1,5	1,0
	Week 12	3,0	----
Reduction of the ankle circumference (cm)	Week 1	1,0	1,5
	Week 12	1,0	----
Bandage slip	During the evaluation period	Not	Not
Adverse event	During the evaluation period	Not	Not

On the first day of monitoring both patients had calf-ankle circumference ratio of 1.5 and reduced range of ankle motion. In week 1, patients showed a reduction of the measures the circumference of the calf and ankle that varied from 1.0 to 1.5 cm. For the patient who maintained the compression scheme until week 12, the reduction in the measures were 3.0 and 1.0 cm at the calf and ankle region respectively, during this period.

The two-component compression system showed ability to remain in the place where it was applied without slipping during usage period and the patients did not show necrosis of the skin.

The analyzed lesions were located in the anteromedial region (L1) and lateral (L2) in H patient; medial malleolus (L3) and lateral malleolus (L4) in the patient M. The result of the development of ulcers L1 (Figures 1 and 2), L2 (Figures 3 and 4), L3 and L4 was recorded with the camera.

Based on the examination on the first day of the study, it was found that all four ulcers of the participants were superficial, with no measurable depth, with a predominance of red granulation tissue, with drainage of serous exudate; no unpleasant odor, of moderate to intense volume. The initial area of the four ulcers ranged from 1.0 to 5.4 cm², with an average of 2.7 cm².

During the evaluation period it was found a variation in the area of ulcers. At week 5, three ulcers increased its surface, reaching the range of 10 to 227% extension and one ulcer showed a 35% reduction of the lesion area. At the end of 12 weeks of monitoring, all the ulcers exhibited notable reduction of the damaged area, wherein two had almost complete tissue healing.



Figure 1 - Ulcer L1: anteromedial region of the left leg in the first evaluation.



Figure 2 - Ulcer L1: anteromedial region of the left leg in the 12 weeks evaluation.



Figure 3 - Ulcer L2: lateral malleolus of the left leg in the first evaluation.



Figure 4 - Ulcer L2: lateral malleolus of the left leg to the trial ends.

DISCUSSION

Considering the experience of the authors of the present study and the accessed clinical studies, it was possible to enumerate and confirm the objective criteria for expected outcomes for the evaluation of the effectiveness of the compression system of one or more components, for the treatment of varicose ulcers, such as the ability of the product in improving venous return, characterized by the reduction of leg edema or preventing the formation thereof; the increase of the ulcer healing rate; bandage not slipping during use; the ease application of the adequate pressure provided by the reference marks contained in each of the banding system while avoiding the occurrence of an adverse event like, for example, necrosis.

Compression therapy has been used in various forms for more than 400 years.⁸ For the treatment of varicose ulcer, the professionals of the field use different kinds of therapies. In the United States, the Unna boot is the most accepted, whereas in the UK the multilayer elastic compression is widely adopted and in the continental Europe, short stretch bandage is the standard practice.⁹ However, all kinds of therapy, even with all the advantages they possess, can have some drawbacks that limit patient adherence to treatment, and therefore, there is no “perfect” therapy.

The compression therapy mechanism of action in treating varicose ulcers is still not fully elucidated. In accordance with various studies, the application of external pressure on the calf muscle causes changes that are able to positively affect the treatment, such as elevated interstitial pressure, which results in an increase of deep venous return, reducing reflux during walking, increasing stroke volume during activation of the calf muscles and tissue pressure, favoring the reabsorption of edema and improving lymphatic drainage.¹⁰⁻¹² Consequently, the changes triggered by the action of pressure facilitate the healing of varicose ulcer. Among the aforementioned changes, the absorption of edema was confirmed in the present study aimed at evaluating performance of the two-component compression therapy since patients had reduction in circumference of the calf and the ankle.

Diversity is found in the publications on varicose ulcer healing rates obtained with compression therapy of various types, ranging widely 40-95%.¹⁰⁻¹² Although the study participants do not present clinical infection, diabetes mellitus, severe arterial disease, total venous obstruction, as well as the small size of the ulcer and the use of high quality bandage on the wound, these factors may also play an important role in the outcome to be achieved by the use of compression therapy.¹³

The difference between the healing rates may be related to the risk factors correlated to the inefficiency in the heal-

ing of varicose ulcers, even using compression therapy, such as long time preexisting ulcer; large extension area of ulcerated surface; deposition of fibrin necrotic tissue surface > 50% of the wound and ABI index <0,85.¹⁴ These factors were confirmed in a prospective study of 189 patients with varicose ulcers treated with high compression multi-component system for 52 weeks. The authors concluded that an area < 20 cm² is a favorable prognostic factor to healing the ulcer, as well as starting the treatment prior to 12 months since the disease's appearance and obtaining a decrease of calf circumference by more than 3 cm during the first 50 days of treatment. Regarding slow healing, the following factors could be identified: BMI >33 kg/m², walking short distances during the day (<200 m), history of wound debridement of ulcers and deeper presentation (>2 cm). The independent parameters associated with non-healing were: the fixed ankle joint, the reduced ankle motion range and calf circumference ratio/ankle <1,3.⁸ This data can justify the lack of reduction in the area of an ulcer of one of the study participants, since it comprised some prognostic factors for the slow cure and no cure, for example, BMI 35,0 kg/m² circle calf/ankle of 1.5 cm and reduced variation of ankle motion.

There are scientific evidences that compression therapy aims to promote venous return, reduce venous pressure and prevent venous stasis. To achieve these aims, it is applied to the legs either bandages or compression stockings, which are evidenced based in scientific knowledge, in order for the results and effectiveness to be guaranteed to the patient with varicose ulcer during treatment. When elastic bandages are applied with the same gauge, it can be reached a graduated compression in a leg of normal proportions, with the greatest magnitude of compression at the ankle, decreasing towards the calf.¹⁵ The pressure in the ankle region must be maintained around 35 to 40 mmHg, which is considered high pressure, and end in the region below the patella from 12 to 17 mmHg to allow the healing of the ulcer.

The degree of compression produced by any bandage system over a period of time is determined by complex interactions between four major factors: the characteristics of the bandage; the size and shape of the patient's leg in which the bandage is applied; the technical skills of the professional that applies the system and by the nature of any physical activity undertaken by the patient.¹⁶

Patients who participated in the evaluation of the two-component compression system performance had benefits in reducing the leg circumference since the first week of product use, due to the reversal of edema brought about by the high pressure of 40 mmHg. It is noteworthy that before starting the study patients were already in use for several months of containment therapy, represented by the use of the Unna boot. For these patients, the multicomponent system was superior

to Unna boot with respect to the ability to force the reabsorption of edema, which corroborates the assertion of Wound, Ostomy and Continence Nurses Society (WOCN)¹⁶, among others, that "the compression therapy can reduce the pressure on the venous system when used properly, resulting in regression of leg edema and also the ability to promote ulcer healing".

It can also be found in literature another important study regarding the use of compression for healing of varicose ulcers published by The Cochrane Collaboration, whose conclusions were that: a compression increases the ulcer healing rates compared to cases where no compression technique is used; the multi-component systems are more effective than single component systems; the multicomponent systems containing an elastic bandage appear to be more effective than those composed primarily of non elastic components.⁶ However, high compression bandage application also requires that this product be safe for the patient.

These studies reaffirm the principles and guiding scientific paths, as well as the preliminary results obtained in this study, concerning the increased possibility of healing of varicose ulcers by compression multicomponent system.

It should be noted that, as in all scientific technical procedure in the event of malpractice, the use of compression bandages could cause tissue damage, if given or applied incorrectly. We must consider with the use of criteria the relationship between the circumference and pressure on the limb may help explain the occurrence of damage from pressure on bony prominences or tendon in the lower limb. The legs have an irregular shape in cross section and the curves that provide their irregular shape can be thought of as being part of a series of imaginary circles. For areas of the member corresponding to the smaller circles, the pressure produced by the compression therapy system will be higher. This could explain why the tibia crest, prominence of the anterior edge of the tibia throughout the length of the leg, is particularly vulnerable to damage caused by pressure. The tibia crest is more sharply curved than the posterior muscles of the leg, which has a flatter curve; therefore, the pressure is higher on the tibia crest. Likewise, due to the appearance of the lateral and medial malleoli, which have small radius of curvature, but no tissue immediately behind, the bandage exerts high pressure on these points.¹⁷

In this study, one patient exhibited in the early applications of two-component system, small lacerations in the epithelialized areas, which are fragile because they are in the remodeling phase of healing process and without sufficient tensile strength to withstand the pressure. In the following weeks, with the continuation of the study, the lacerations no longer occurred due to the increase in tissue resistance. The risk of this type of injury can be minimized by using a compression system wherein the first layer has the function to protect fragile tissue, and the bony prominences, since these do not have sub-

cutaneous tissue as protection. It is worth to notice that the adoption of a high-compression system (40 mmHg) requires the training of professionals who will apply it in patients.

It is worth noting that when the bandages are applied with the same tension along the leg, the pressure will be greatest at the ankle and will gradually decrease toward the patella effect known as graduated compression. The circumference of the limb inversely affects the pressure under the bandage (interface pressure). The smaller the area of the radius of curvature (bony prominence), the greater the likelihood of pressure damages. Application of a compression bandage to the leg of great width needs to be performed with high blood pressure; however, care is needed when applying bandages on one leg of reduced dimensions to prevent damage from improper pressure used in the bandage.¹⁷

The two-component compression system, whose performance was evaluated in the present study, also had its therapeutic efficacy, tolerability and acceptance in the treatment of varicose ulcers evaluated in a clinical study. This study was conducted with 42 patients with ulcers lasting one to 24 months, with at least 50% of granulation tissue, area 2 to 20 cm², circumference of the ankle inferior to 28 cm and no history of deep venous thrombosis in the three months prior to baseline. The authors concluded that the two-component compression system was considered safe and well accepted by patients.⁷

This same two-component system also had its efficacy, tolerance and acceptance in the management of varicose ulcers, compared with a four-component system widely used in Europe. This was a randomized controlled study conducted in 37 centers in three countries (France, UK and Germany) and included 187 adult participants. Of these, 93 were treated with two-component compression system and 93 received the four components compression system. Patients that reported a level of ABI > 0.8, had ulcers predominantly of venous origin, not infected, with surface from 2 to 50 cm² and duration from one to 24 months. Patients were followed every two weeks for 12 weeks or until complete wound closure. The evaluation of the system in question included traces of the injured area and photographic records. The authors concluded that the two systems were effective in treating varicose ulcer. Furthermore, the two-component system was considered to be the simplest to be applied.¹⁸

The ideal multi-component compression therapy system must have the following characteristics: have elastic and inelastic component; be formable, which means, to produce good anatomical adjustment; allow full functionality and movement; be comfortable with the leg at rest or activity; have ease application and adapt to a variety of sizes and shapes of members; must be non allergenic and have a certain durability.¹⁷ These

qualities can also interfere with the patient's preference for a particular type of compression therapy.

The evaluation of the two-component compression system performance identified that participants who used this product did not exhibit the bandage slip and this finding may influence the decision of patients to accept this compression system. A similar result was obtained with the use of other two-component compression systems (Coban™ 2 Layer) and four components (Profore™) treatment of 81 patients with varicose ulcer. It is an open clinical randomized trial, follow-up of eight weeks involving 10 treatment centers. At the end of this study, it was found that the two-component compression system had less slippage, which did not influence the wounds healing.¹⁹

Another comparative study with a sample of 675 patients in the UK clinical practice evaluated clinical outcomes and cost-effectiveness of multi-component compression system of two layers (Coban™ 2 Layer) as compared to other two-layer system (Ktwo™) and a four-layer compression system (Profore™) for the treatment of varicose ulcers. It was concluded that of the three systems evaluated, the Coban™ 2 Layer proved to be more efficient in the use of resources of the National Health Service of that country, as it has resulted in high rate of healing, improved quality of life and reduced globally cost.²⁰

In addition to the healing rate analysis, cost-effectiveness and types of compression system, one has to consider that psychological and psychosocial aspects permeate the reality experienced by people with varicose ulcers. Concerning one of those aspects – self-esteem – a study, which used the Rosenberg Self-Esteem Scale was conducted and obtained gradual improvement of self-esteem of patients who used the Unna boot along with the dressing application in the ulcer.²¹

Professionals need to substantiate their knowledge of clinical practice on scientific evidence to establish protocols²² to ensure the effectiveness of the treatment as well as better quality of life for patients. The results must be measured by using tools such as, Pressure Ulcer Healing Scale (PUSH) instrument, used for the evaluation of the healing process.²³

The results of the study can be considered restricted because it is a case study without a previous sample size calculation, which does not allow the generalization of the findings. However, it offers relevant contribution as the findings indicate that the two-component compression therapy is effective and that the clinical benefits include reducing the circumference of the lower limbs as a result of reabsorption of the edema and the area of most ulcers. It was considered that the participants were already using containment therapy system (Unna boot) before inclusion in this study. Also, it is emphasized that in this research the existing type of marker in one of the system components used is important and guaranteed

the offer of 40 mmHg pressure in the ankle region, as scientific evidence recommends.

The next step of this work will be developed using the same method and the same compression system, however with a larger sample and follow-up of patients with varicose ulcer.

CONCLUSION

At this stage of research it was possible to establish the criteria for evaluating compression system performance: percentage change in area; leg edema; slip bandage and adverse events (skin necrosis). One can also evaluate a compression two-component system for the treatment of varicose ulcer, based on established criteria.

Regarding the two-component compression system, it was concluded that this is a suitable alternative therapy for improving venous return in the treatment of varicose ulcer. Thus, it is presented as a contribution to the clinical practice of Brazilian professionals.

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