

Observational retrospective study on the effectiveness of sequential graduated intermittent pneumatic compression therapy of lower limbs edema

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Article history

Received: September 5, 2016

Accepted: September 28, 2016

Published: September 30, 2016

Abstract

The main aim of the study is to evaluate the effectiveness of sequential graduated intermittent pneumatic compression (SGIPC) therapy of lower limbs edema, regardless of its etiology. A retrospective observational study is conducted to determine the effectiveness of a regimen of sequential gradient SGIPC in treating edema of lower limbs. The study is carried out on 90 patients affected by different stages of edema and evaluated at a Wound Care Clinic for one month. Medical records data have been collected after the first, the third, and the fifth hour-long treatment session. The inclusion criteria are: (1) presence of edema to one limb, at least, regardless of etiology, (2) presence of both pain and feeling of heaviness (or tiredness) of the limb, (3) non-use of bandages or elastic stocking/knee socks, and (4) availability of complete data about the edema size monitoring. The exclusion criteria are: (1) presence of infected wounds, (2) severe arteriosclerosis or other ischemic vascular diseases, (3) severe congestive cardiac failure, (4) known or suspected acute deep vein thrombosis (DVT), (5) thrombophlebitis or Pulmonary Embolism (PE), and (6) hypertension (Systolic Pressure greater than 170mmHg). The following parameters are considered as grade of improvement: the decrease of the limb circumference in at least two measurement points between the foot, ankle, and calf; the disappearance of at least one of the symptoms of pain and feeling of heaviness of the limb; improved mobility. A Flowtron ACS 900 system is used, for the treatment, consisting of a pump, connected to two (calf and thigh) brace with individual tubes, applying a pneumatic compression, graduated in the air chamber, with sequential cycle in three compartments (one at the calf level and two at the thigh level), at a pressure of 45mmHg, with inflation cycles intermittent alternating. Inflation time 12s, time of deflation 48s. In addition, braces corresponding to limb size have been used (automatically recognized by the system).

In a sample of 90 patients (95.6% women and 4.4% men) with edema of the lower limbs (37.8% at stage 1, 43.3% at stage 2, 15.6% at stage 3, and 3.3% at stage 4), a successful treatment has been found, from the first session. A circumference decrease greater than 3mm in at least two measuring points between the foot, ankle, and calf, of 77.8% after the first session, 90% after the third session, 90% after the fifth session, on average for both limbs. The disappearance of pain at the end of the session has been found in 85.6% of cases after the first session and 100% after the third and fifth, respectively. The feeling of heaviness of the limb has disappeared in 100% of cases at the end of the sessions. For the stages 3 and 4, it is generally observed an improvement of mobility in 58.9% of cases at the end of the first session and equal to 100% after the third and fifth session. A good compliance in patients who have rejected the manual lymph drainage has been found. Moreover, a good applicability has been found in patients with critical issues such as dermatoporosis and capillary fragility, and bariatric patients. In general, the patients have underestimated the edema, specifically only 21% of patients at a stage greater or equal to 2 have recognized the edema as a clinical problem.

Keywords: edema, lymphedema, pneumatic compression therapy, lymph drainage venous symptoms, chronic venous disease, venous insufficiency

Introduction

The Wound Care Services (WCS), nursing management, belonging to an outpatient health facility, receive patients carrying chronic wounds and/or hard to heal and patients with edema of the lower and upper limbs for dedicated therapies. The treatments are personalized and comprehensive set after a careful and specific clinical evaluation of the edema¹⁻⁷. The request that unites this group of patients correspond to the alleviation of symptoms, such as pain and feeling of heaviness of the limb, and limb functional improvement in cases of significant edema. One of the factors that contribute to the worsening of the symptoms and the specific condition is the increase of the ambient temperature in the summer and pre-summer periods, which lead to a less compliance to the application of compression bandages or therapeutic devices such as stockings, socks and sleeves. In general, the patient who does not perceive it as a clinical problem underestimates the edema. Often, more than anything else in the case of chronic edema, also in the presence of obvious (but tolerable) symptoms, the patient lives quietly without considering the cause or the consequences and without contact a health care professional for the evaluation. In a few believe that this is a risk factor for the appearance of skin lesions. Women at a young age are more concerned about the aesthetic appearance of the limb.

It is often abused the diagnosis of lymphedema. Most of those who report it, excluding patients with cancer or some with chronic venous insufficiency (CVI), has never performed a lymphoscintigraphy, considered instrumental examination gold-standard for diagnosis¹. In the management of edema, patients with dermatoporosis represent a major problem. For their skin fragility, often they refuse therapeutic stockings or manual lymph drainage. Moreover, they often have pain on contact, refusing even the classic pressure therapy.

The WCS initially used the sequential graduated intermittent pneumatic compression (SGIPC) as an adjuvant therapy for the reduction of edema in the treatment of skin lesions. According to the good *compliance* of patients and the excellent results obtained, considering the results reported in the literature^{8-19, 29-32}, SGIPC it was later extended to all patients with edema, regardless of its etiology who did not report contraindications.

An active compression system was used in order to deliver a simple, easy to use method of enhancing the circulation of blood in the deep veins of the legs, reducing venous stasis and helping to prevent the formation of DVT. In use, an inflatable boot, available in different sizes and

measures, encloses the limb requiring treatment, and pressure lines are connected between the boot and the air pump. When activated, the pump fills the air chambers of the boot in order to pressurize the tissues in the limb, thereby forcing fluids, such as blood and lymph, out of the pressurized area. A short time later, the pressure is reduced, allowing increased blood flow back into the limb.

Methodology

The patient records, they required and taken advantage of SGIPC therapy at WCS within a month, were analyzed to evaluate the effectiveness of therapy on edema of the lower limbs, regardless of its etiology.

The analysis relates to the period 1-30 May 2016, during which the environmental conditions have experienced temperatures over the average of the season, condition for which have been involved a greater number of patients with edema of the limbs.

The therapy was required by 304 persons for the treatment of edema of lower and upper limbs. 256 have performed the therapy for lower limbs, whereas, of the remaining, 10 have requested the therapy for upper limb and 38 were evaluated as unsuitable (for presence of infected lesions, presence of atrial fibrillation not controlled by therapy, hypertension with systolic blood pressure of 170mmHg at the time of the assessment, and presence of venous thrombosis). On 256 patients, three were withdrawn after the third session, reporting a tingling sensation to the level of the foot and/or calf following the treatment and lasted for several hours. There is no way to determine whether this event was due to the treatment or not.

At the beginning of therapy, the willingness of patients to monitoring the edema is required, by measuring the diameter of the limb at the point of greatest enlargement in the foot level, ankle, calf, below the knee, above the knee, and thigh, both before and after the delivery of therapy. At the first and last session, the measurement is imposed, whereas for the following, not everyone accepts the dual measurement preferring only the final one, in order to benefit a few more minutes of treatment. Perform the limb volume measurement would require more time, becoming burdensome for the activity, given the specific character of the service. For this reason, the measurement of the circumferences has been therefore chosen as evaluation parameter.

The folders of the patients who had recorded all measurements to the first, third, and fifth session have

been selected, excluding patients who used other devices dedicated to reducing edema, as elastic stockings or bandages, with the presence of both symptoms: pain and feeling of heaviness of the limb. The final sample is so composed: 35 with 5 therapy sessions, 35 with 3 sessions, and 20 with only 1 session.

Treatment

The measurement was performed with a flexible centimeter, at points marked with dermatological pencil to allow the detection of the value at the same point. It must be emphasized as a limit that it has not always been possible to perform an accurate measurement for the presence of arthritic deformations and fat deposits which did not allow the perfect adhesion of the limb tool. The measurements taken into account for the processing of the data were those at the level of the foot, ankle and calf since they do not have presented difficulties in measuring.

Rates of measurement: Before treatment session TIME A
After treatment session TIME B

Duration of treatment session: 1 hour

Device: two leg braces (from thigh to calf) of appropriate measures.

Therapy: treatment used simultaneously to all two legs (although the presence of edema in a single limb).

A *Flowtron ACS 900* system is used, for the treatment, consisting of a pump, connected to two (calf and thigh) braces with individual tubes, applying a pneumatic compression, graduated in the air chamber, with sequential cycle in three compartments (one at the calf level and two at the thigh level), at a pressure of 45mmHg, with inflation cycles intermittent alternating. Inflation time 12s, time of deflation 48s. In addition, braces corresponding to limb size have been used (automatically recognized by the system).

Data collection

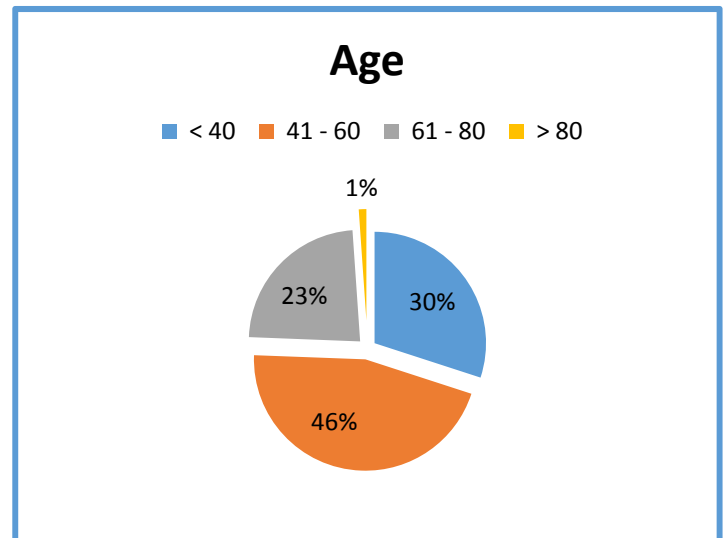
Before the start of therapy each patient was assessed globally according to the Gordon model, and an educational and personalized management plan was started. Patients were actively involved in each care plan. The data collected were based on sex, age, motivation, applicant, type of edema, edema stage, use of topical products, number of treatment sessions. In order to evaluate the treatment's effectiveness, the data regarding the decrease of the circumferences at the end of the sessions, the maintenance of the results obtained between one session and another, the decline and disappearance of

symptoms and the improvement in joint function, were analyzed.

Sample characteristics:

The sample consisted of 90 patients. 4.4% of the sample were male and 95.6% female. The patients involved were aged between 14 and 81 years. The age distribution is described in the chart below (Fig.1).

Fig.1 Age distribution



Regarding the analysis of the reasons for which it was required the treatment, there was a general underestimation of the presence of edema up at the onset of skin injuries, varicose veins or pain. Many patients claimed that they accepted it as a normal condition, especially due to old age or to a hereditary condition and they didn't consider it as a clinical problem or as a disturbing conditions. Many patients requested the treatment for the feeling of having tired legs, despite the impressive presence of edema. Few patients said that they turned to WCS for curiosity or for aesthetic reasons. Referring to motivation, the answer options were divided in: for the presence of edema, for the feeling of having tired legs and for testing. Only 21% of patients with stage ≥ 2 edema recognized the edema as a clinical problem.

The request for the treatment was carried out by a physician, especially angiologist, (24.4%) due to chronic venous insufficiency, pregnancy or trauma, or by the patient (75.6%). Any medical contrary opinion was reported.

Edema may be classified as primary or secondary. Primary edema derived from sporadic or genetic factors while the secondary one has an unclear etiology and an unknown cause. Referring to secondary edema etiology,

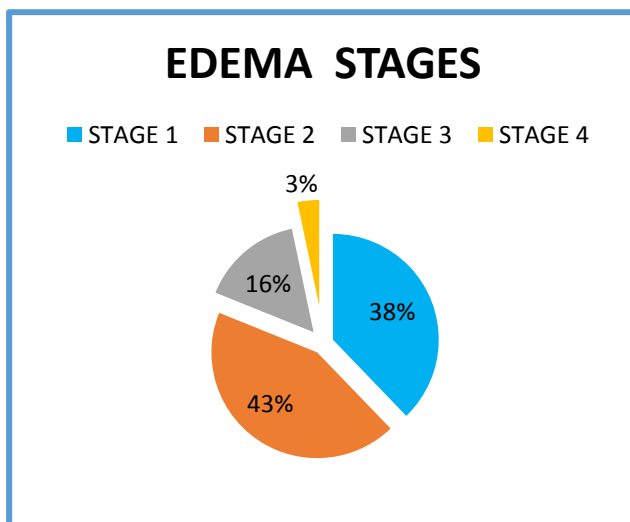
it can be divided into 4 groups: edema caused by chronic venous insufficiency (CVI), by surgery, by previous skin injury or by other reasons (Trauma, pregnancy, obesity).

53,3% of patients were affected by primary edema while 46,7% by secondary edema, 74% of them had a secondary edema for a IVC condition and 26% of cases had a secondary edema for unknown reason.

Author would like to propose an edema staging system as following:

- Stage 1 spontaneous regression with nocturnal rest or declive position
- Stage 2 permanent condition regressing partially with treatment
- Stage 3 hard consistency, extended from the foot to the thigh causing limited functionality
- Stage 4 hard consistency, extended from the foot to the thigh causing functional impairment
- Stage 5 disappearance of the bony prominences

Fig.2 Edema Stages distribution



Considering the edema stage, as described in the chart above (Fig.2), 38% patients had a stage 1 edema, 43% a stage 2 edema, 16% a stage 3 edema and 3% a stage 4 edema.

At the beginning of treatment, blood pressure was detected in all patients. Patients with systolic blood pressure value > 145, pregnant women, patients with stage 3 and 4 edema were monitored and blood pressure was detected during the session and at the end. Any blood pressure increase was recorded, actually at the end of the therapy blood pressure values decreased, probably due to the patient's rest and relaxation.

Results

The main outcomes are summarized in the following: The regression of the edema entity (E) was evaluated, depending on time:

- At the end of the first session $E1 = 1A - 1B$
- At the end of the third session $E3 = 1A - 3B$
- At the end of the fifth session $E5 = 1A - 5B$

The decrease of the circumferences for anatomical area (foot, ankle, calf), divided into five groups referring to the value:

- 0 mm – 3 mm
- 4 mm – 5 mm
- 6 mm - 1 cm
- 1,1 cm – 2 cm
- > 2 cm

The values range from 0 mm to 3 mm were not considered relevant.

It was considered a successful outcome the reduction of edema greater than 4 mm in at least two measuring points.

- $E1 + = (1A - 1B) > 4\text{mm} \times 2$ measuring points
- $E3 + = (1A - 3B) > 4\text{mm} \times 2$ measuring points
- $E5 + = (1A - 5B) > 4\text{mm} \times 2$ measuring points

A positive outcome was recorded:

- At the end of the first session, as an edema reduction of 66% on the right leg and of 74% on the left leg, with an average of 77.75%,
- At the end of the third session, as an edema reduction of 85.7% on the right leg and of 94.3% on the left leg, with an average of 90%,
- At the end of the fifth session, as an edema reduction of 85.7% on the right leg and of 94.3% on the left leg, with an average of 90%.

There is a better overall response of approx. 10% of the left leg without a correlation with edema type or stage.

A greater decrease of the circumference reduction was observed in millimeters :

- The ankle after the first session, with 38.9% of cases increased to 6mm,
- Proportionate between foot and ankle after the third session, with approx. 57% of cases more than 6mm compared to the beginning of therapy,

- Proportionate between foot - ankle - calf after the fifth session, with approx. 77.2% of cases increased to 6mm compared to the beginning of therapy.

Left legs always showed better response to treatment. It can be concluded that the greater the number of sessions, better and more proportionate is the outcome.

Sequential graduated intermittent pneumatic compression therapy (SGIPC) is recognized as an adjuvant therapy in the treatment of edema. The maintenance of the results obtained, without the use of other devices (i.e. compression stockings and bandaging) was analyzed. The variation between measurements of the third and the fifth session was evaluated ($1A - 3A$; $1A - 5A$). It was considered a successful outcome the reduction of edema greater than 4 mm in at least two measuring points.

- $EPR3+ = (1A - 3A) > 4mm \times 2$ measuring points
- $EPR5+ = (1A - 5A) > 4mm \times 2$ measuring points

It was not possible to evaluate the influence of the time passed between sessions on the result because it was non homogeneous for all patients. Patients with stage 1 and 2 edema were suggested to be treated twice a week and patients with stage 3 and 4 edema were suggested to attend the WCS three times a week. These recommendations were not always respected by patients.

Most of patients were treated twice a week, depending on WCS availability and personal reasons. Treatment session timing remains a matter to be explored. The use of topical products (i.e. creams, sprays) during therapy, demonstrated no effect on the results.

Other two symptoms, pain and the feeling of tired legs were considered as outcome indicators. The decrease or disappearance of at least one of the two was considered as a positive outcome.

Pain

Pain symptom was evaluated by NRS (Numeric Rating Scale) at the beginning and end of the treating

session, as referred by patients. It was observed that the pain disappeared at the end of the session in:

- 85.6% - after the first session
- 100% - after the third session
- 100% after the fifth session

Feeling of tired legs

This symptom was reported if present or not. All patients, without exception, reported that unpleasant feeling was replaced by the feeling of lightness and ease of movement.

Functionality

The improvement of the limb functionality and the joint mobility was evaluated in patients with stage 3 and 4 edema. The evaluation was performed based on clinical observation and patients records after walking immediately after the treatment session. There was an improvement in 58.9% of cases after the first session and in 100% of cases after the third and fifth session.

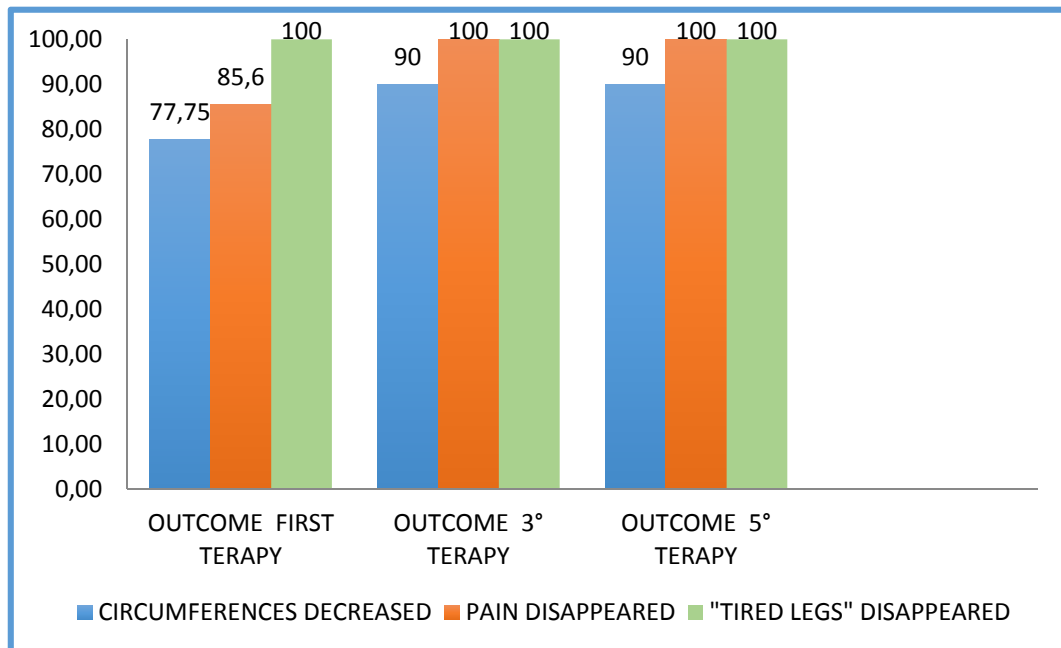
Conclusion

Sequential graduated intermittent pneumatic compression (SGIPC) therapy is a remarkable support in the treatment of edema in the lower limbs, regardless of its etiology. The effectiveness of the combined therapy using SGIPC and other devices such as bandages and stockings need to be investigated. The use of a brace with graduated sequential air chamber located on the back of the limb acting on the deep venous circulation leads to a better outcome, in terms of immediate response and acceptance of therapy. Patients with increased sensitivity on shin, dermatoporosis and capillary fragility showed a better compliance.

An improvement of communication skills and educational plans about risks and clinical implications of edema, is an essential step to avoid potential complications and to improve nursing care.

It is worth considering the launching of activities for the effective communication of issues arising from the chronic edema and patient education to its management.

Fig.3 Treatment Outcomes



Conflict of Interests

The author declare that there is no conflict of interests regarding the publication of this paper.

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