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Neuromuscular bandage for the prevention of post-mastectomy seroma: a clinical trial protocol

Erica Alves Nogueira Fabro[1,*], Rejane Medeiros Costa[1], Flávia Oliveira Macedo[1], Daniele Medeiros Torres[1], Suzana Sales de Aguiar[1], Luiz Claudio Santos Thuler[2], Anke Bergmann[2]

ABSTRACT

Introduction: Seroma is the most common early complication after breast cancer surgery and is associated with other complications and adjuvant therapy delays. A potential hypothesis for its prevention is the obliteration of dead space between tissues, which can be achieved by external compression. To assess whether the use of a neuromuscular bandage employing the compressive technique during the first postoperative week is effective in preventing seroma. **Methods:** This study comprises a two-arm randomized superiority clinical trial to evaluate the following as primary outcomes: seroma incidence, volume and duration using a suction drain and bandage safety and satisfaction as secondary outcomes. Women aged ≥18 years submitted to a mastectomy as breast cancer treatment will be included, while women submitted to bilateral mastectomies, immediate breast reconstruction or surgical flap rotation closure, who present hematomas or surgical wound infections at the time of recruitment or autoimmune diseases that lead to skin lesions and/or allergy to tape, as well as those exhibit difficulties in understanding the study will be excluded. Randomization will be performed by lots at study enrollment. Coded envelopes will be available for intervention or control group allocations. Patients allocated in the intervention group will be submitted to the bandage application for seven days. All patients will use a suction drain according to the institution's routine. **Ethics and disclosure:** This study was approved by the Brazilian National Cancer Institute, Research Ethics Committee under no. 2,774,824 and it is registered in the ClinicalTrials.gov (NCT04471142).

KEYWORDS: breast neoplasm; seroma; prevention; physiotherapy; taping.

INTRODUCTION

Seroma is the most common early complication following surgical breast cancer treatment[1,2]. Incidence rates range from 2.5% to 85%[1-3] and the condition is directly associated to extensive surgical dissection procedures, such as mastectomies and axillary lymphadenectomies, due to the generation of more dead space between tissues[4].

There are some known risk factors for the development of seroma in women undergoing surgical treatment for breast cancer, such as older age, higher body mass index (BMI), high blood pressure, large breast volume, breast biopsy prior to surgical treatment, neoadjuvant chemotherapy, thromboprophylaxis, presence of lymph node metastasis, greater number of removed lymph nodes, longer surgery times, electrocautery, type of drainage and longer suction drain durations[5-9].

Although seroma formation is not life threatening, it may comprise a risk factor for the development of necrosis and dehiscence, predisposition to sepsis, upper limb movement restriction, lymphedema and a prolonged recovery period and, consequently, delays in beginning adjuvant therapy[10,11].

The obliteration of the dead space between the tissues left by the breast and axillary content removal is discussed among approaches applied to seroma prevention, mainly by two methods, namely surgical flap fixation or external compression[3].

Neuromuscular taping and the Kinesio® Taping method have been recently introduced into the clinical practice to reduce pain and swelling, also ensuring muscle activity stability[12,13].

The purpose of neuromuscular bandage treatment during the postoperative period is to facilitate the body's natural healing process by relieving tension in the muscles involved in the

[1]National Cancer Institute, Physiotherapy Service – Rio de Janeiro (RJ), Brazil.
[2]National Cancer Institute, Clinical Epidemiology Program – Rio de Janeiro (RJ), Brazil.
***Corresponding author:** ericanfabro@gmail.com
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surgical trauma, increasing proprioception through mechanoreceptor excitation, improving blood circulation and lymphatic drainage and decreasing inflammation and pain[12,14].

Neuromuscular bandages are composed of 100% cotton fibers and heat-sensitive acrylic glue. They do not contain any chemical substances, are hypoallergenic, and their length reaches up to 140% of their original size. They must always be expanded longitudinally, and their weight and thickness are very similar to skin, both porous and resistant to water, thus allowing for gas exchanges. These bandages are manufactured with digital printing technology, so that, once applied, they present better skin adherence[13,15].

This type of bandage application in women with breast cancer has been shown to be safe and effective. Martins et al.[16], for example, evaluated the safety and tolerability of the Kinesio® Taping bandage in the control of upper limb lymphedema secondary to breast cancer, and found that no patient developed skin lesions, blisters, hyperthermia, or skin scaling and/or redness at the application site. A meta-analysis of randomized clinical trials also concluded that kinesio taping was effective and safe in the control of lymphedema secondary to breast cancer[17].

The use of neuromuscular banding for seroma treatment, although with still little scientific evidence available, may be an option for seroma prevention and treatment following breast surgery. In this regard, Bosman and Piller[18] conducted a pilot study demonstrating the use of bandaging employing the lymphatic taping technique as a non-invasive approach for seroma treatment.

Furthermore, a Phase I study, in which the safety of a compressive bandage was evaluated in patients presenting seroma secondary to surgical breast cancer treatment reported this approach as a safe method, in which only 8.8% of patients developed a skin reaction and the bandage had to be removed, while 85.7% of women felt satisfied and 68.5% reported safe use[19].

In this context, the aim of this clinical trial is to evaluate the effectiveness of a neuromuscular compressive bandaging in seroma prevention following mastectomy.

METHODS

Hypotheses

This study protocol describes a randomized clinical trial in which the application of a neuromuscular compressive bandage in women with breast cancer submitted to a mastectomy was compared to routine therapy. The hypothesis is that the use of a compressive bandage during the first postoperative week associated to a drain is effective in preventing seroma. The second hypothesis is that the compressive bandage influences the length of suction drain use, the number of aspiration punctures (when indicated), and the volume of the punctured seroma.

Study design

This is a randomized controlled clinical trial of superiority with two arms, a control group and intervention group, carried out in a single reference center for breast cancer treatment.

Patients and study site

This study was carried out in the city of Rio de Janeiro, at the Cancer Hospital III of the National Cancer Institute (HCIII/INCA), concerning women diagnosed with breast cancer submitted to mastectomy.

Eligibility criteria

Women aged 18 years or older submitted to mastectomy as surgical breast cancer treatment will be included in the study.

The exclusion criteria are: patients submitted to bilateral mastectomies as well as those submitted to immediate breast reconstruction or surgical closure with skin flap rotation, presenting hematoma or surgical wound infections at the time of recruitment, presenting autoimmune diseases that generate skin lesions and/or allergy to tape, as well as patients with difficulties in understanding the study.

Sample size

The sample size was calculated by considering the occurrence of the outcome (seroma) in 60% of the control group patients[1] and in 45% of the intervention group, at a 5% significance level and 80% test power through a one-tailed hypothesis test. This calculation indicated the inclusion of 270 patients, 135 in each group.

Randomization

Randomization will be performed by drawing lots at the moment the patient enters the study (Figure 1). A total of 27 blocks containing 10 envelopes will be made available, 5 of which will contain a code that allocates patients in group A and 5 in group B. This was established to avoid therapist or patient preferences concerning the intervention. The patients will be guided concerning their group and the follow-up will be carried out while the patient is under dressing care. All assessments, intervention and data collection will be carried out by professionals trained and qualified for this purpose.

Treatment protocols

According to the HCIII/INCA routine, a closed system used for postoperative (PO) drainage will be inserted intraoperatively in patients undergoing mastectomies or axillary dissections for seroma prevention. This system remains between seven and fourteen days, depending on the drainage volume. On the first postoperative day, all patients will be submitted to dressing at the scarring points, with the suction drain being pointed and oriented by the nursing team to clean the drain ostium only with filtered, boiled and cold water, and to apply the dressing daily,

in addition to emptying the closed drainage system and counting the drained volume twice a day.

All patients will be scheduled to return in seven days to the physiotherapy outpatient clinic for kinetic-functional, skin and healing reassessments. The drain volumes noted at home and the drain conditions will be evaluated at the nursing outpatient clinic, which assesses and cares for the dressing, in order to proceed with drain removal. The suction drain will be removed on the 7th PO day if the total volume drained on the previous day according to the patient's notes is ≤50 mL or, at the most, on the 14th PO day, regardless of the drained volume, or in the emergency cases (infection and drain externalization).

On the first postoperative day, patients may be randomized to the following groups:

- Group A (Intervention with neuromuscular banding): Patients allocated in this group will undergo neuromuscular compressive bandage on the hospital discharge day. The bandage will be removed on the 7th day, when the patient will be scheduled to return to the nursing clinic. The patients will be instructed to remove the material at home in case of any symptom such as itching, redness, discomfort and/or any other occurrence due to bandage use.
  - For bandage application:
    1. Assessment and scarring care by the nursing team.
    2. Placement of the sterile microporous tape over the scarring region to avoid contact with the bandage glue, and protect the scar points if the patient needs to remove the bandage at home. This adhesive tape is a sterile material used to protect the scarring points.
    3. Application of the 7.5 cm wide Vitaltape® neuromuscular bandage, through maximum stretching on the plastron, armpit, and lateral thorax portion regions. The bandage will be placed without stretching at both ends, using between two and three centimeters. The necessary number of bandage bundles will be applied according to the trunk height and width of each patient.

All applications will be performed by trained physiotherapists for proper neuromuscular bandage placement employing the

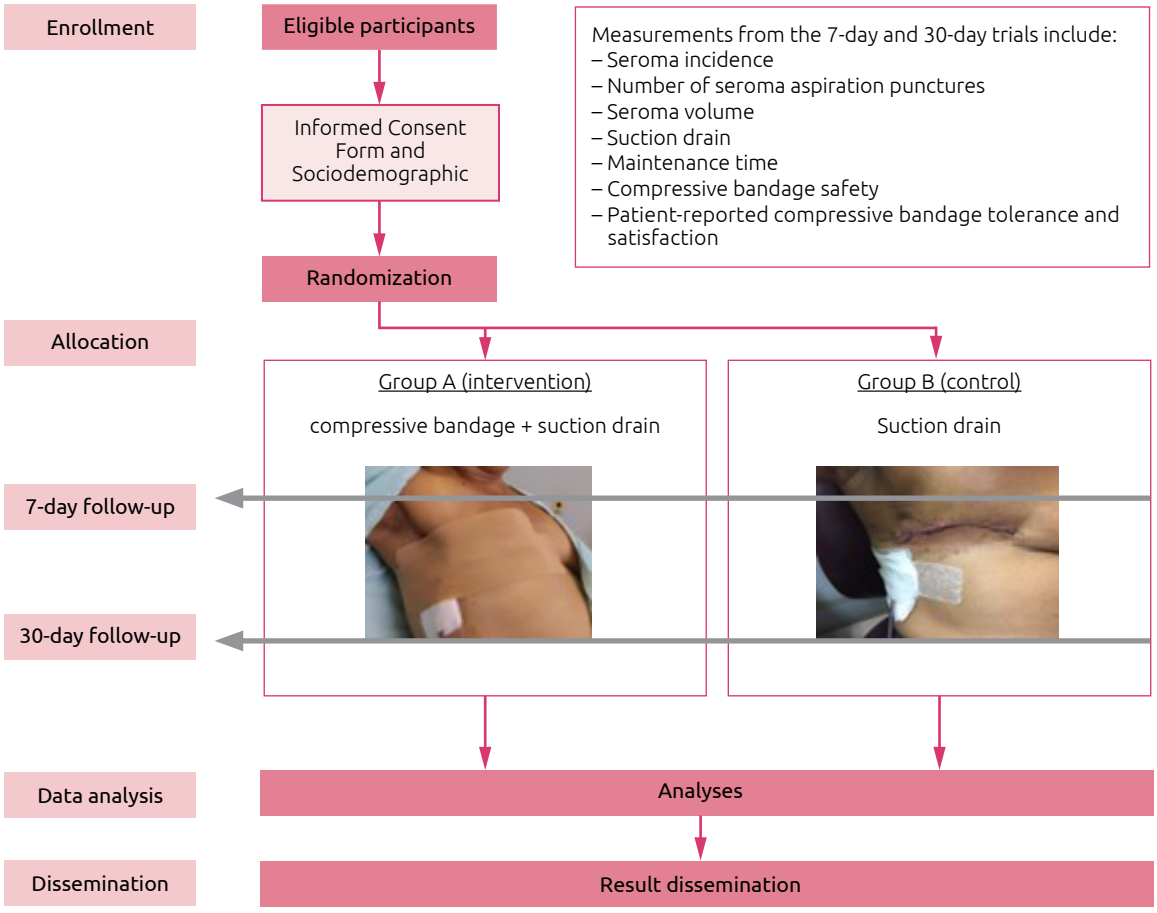

Figure 1. Study randomization protocol.

compressive technique. Research participants will receive a home guidance manual with instructions on bandage use and a home checklist that must be completed with daily observations and collected at the end of seven days (the Complementary document).

- Grupo B (control):
  The patients allocated in this group will follow the institutional routine using only the suction drain, and will be instructed by the nursing team to maintain the scarring points uncovered and wash them daily with filtered, boiled, and cold water, returning to the nursing clinic in 7 days for reassessment.

Blinding

As this survey aims to assess the use of a medical device, blinding is not possible due to the intervention characteristics. Thus, neither participants nor researchers who will assess the outcomes and collect the data will be blinded.

Data collection

Data will be collected through interviews and physical examinations, and complemented by an active search using both electronic and physical medical records. Information regarding type of oncological treatment, histopathological reports and clinical data on dressing care will be obtained from hospital records.

Patient follow-ups

Interviews and physical examinations will be performed during the study enrollment moment, and after 7 and 30 days of surgery. Data on sociodemographic characteristics and life habits will be obtained during the initial interview. After 7 days, patients in the intervention group (Group A) will be asked about local symptoms due to bandage use (concerning compressive bandage safety), as well as bandage use tolerance and satisfaction.

Outcomes parameters and statistical analysis

Primary outcome

The primary outcomes of this study will be assessed considering physical and/or electronic medical records obtained by the nursing team responsible for dressing care.

- Seroma incidence: seroma will be considered as the presence of local fluctuations with aspiration puncture indication condition for resolution, regardless of drained volume.
- Number of punctures: considered as the number of times the patient returned to the Institution to perform seroma puncture aspiration until complete resolution.
- Seroma volume: considered as the sum of all punctured volumes at each patient visit.
- Suction drain maintenance time: the time the suction drain must be maintained, in days.

Secondary outcomes

Secondary outcomes will only be evaluated in the intervention group (Group A) on the 7th postoperative day, as they are directly associated to compressive bandage use (Figure 2).

- Compressive bandage safety: any dermal alterations caused by the bandage will be evaluated.
- Compressive bandage tolerance: reports on the sensations of patient using the compressive bandage.

Descriptive and control variables

The following variables will be employed: patient characteristics (age, marital status, education, skin color, body mass index, arterial hypertension, Diabetes Mellitus status, smoking and alcohol consumption), as well as tumor characteristics, oncological treatment (clinical staging, molecular subtype, type of breast biopsy, neoadjuvant treatment (chemotherapy, targeted therapy, hormone therapy), type of breast surgery, number of removed lymph nodes, number of involved lymph nodes, use of an electric intraoperative scalpel, surgical laterality and breast weight, and postoperative complications characteristics (spontaneous dehiscence of the surgical stitches, epidermolysis, necrosis, instrumental debridement, surgical wound infection and hematoma, delayed healing, paresthesia along the course of the intercostobrachial nerve, paresthesia in the plastron, intercostobrachialgia, plastron pain, axillary net and early edema in the upper limb ipsilateral to the surgical treatment)).

Data analyses

Descriptive analysis will be performed concerning the selected variables and the main outcomes. Numerical variables will be presented using central tendency and dispersion measures, and categorical variables will be presented as frequency distributions.

The Shapiro-Wilk test will be applied to assess data distribution normality, considering a significance level of 5%. The comparison of continuous variables between the intervention groups will be performed using the Student's t test, while for categorical variables the chi-square test or Fisher's exact test will be performed. Outcome assessments for dichotomous variables will be carried out using odds ratios at a 95% confidence interval.

Multiple logistic regressions and multiple linear regressions will be performed to control confounding variables. The variables to be included in the model will be selected by the Stepwise Forward method (progressive variable inclusion), maintaining those presenting $p<0.05$

The SPSS version 24.0 will be used for the data analysis.

Ethics and dissemination

Data collection and confidentiality

Patients who meet the inclusion criteria will be informed about the purpose of the study, its duration, possible side effects and

Dermal alterations:

- Color alterations (redness): defined according to the presence of hyperemia at the bandage application site.
- Local temperature increases: defined according to the presence of hyperthemia at the bandage application site.
- Peeling: the presence of dry or wet desquamation at the bandage application site will be assessed, graded as mild, moderate or intense.
- Wounds: the presence of continuity solution (wounds) at the bandage application site will be assessed, being graded as mild, moderate or intense.
- Bullous lesions: the presence of blisters at the bandage application site will be assessed, graded as mild, moderate or intense.

Patient sensations:

- Pain at the application site: considered by patient reports and graded according to a Numerical Visual Scale (0-10).
- Pruritus: reports on itching or irritation at the bandage application site will be assessed, graded according to the Numeric Visual Scale (0-10).
- Burning: report on burning at the bandage application site will be assessed, graded according to a Numerical Visual Scale (0-10).
- Discomfort: discomfort at the application site will be assessed, graded according to a Numerical Visual Scale (0-10).
- Feeling of tightness: uncomfortable tightness will be assessed, graded according to a Numeric Visual Scale (0-10).

Figure 2. Dermal alterations and sensations referred to during the intervention period.

non-mandatory participation. Upon participation acceptance, confidentiality will be guaranteed through the confidential filing of information concerning patient health and personal data, and an informed consent form will be provided.

Patients participating in the intervention group may report discomfort at the bandage application site (itching, local heat, burning, redness, swelling, pain). Upon any complication, the intervention will be suspended. Possible discomfort monitoring and follow-up will be carried out until full patient recovery by the physiotherapy and nursing services, and by the Emergency Care Service assistance team, as this service may comprise the main gateway in case of any local discomfort due to bandage use.

Ethics

This study was approved by the National Cancer Institute Research Ethics Committee (CEP-INCA), Rio de Janeiro, Brazil, under No. 2,774,824, in accordance with attributions defined in CNS Resolution No. 466/2012 and CNS Operational Standard No. 001/2013.

This clinical trial is registered at Clinical Trials.gov under identifier No. NCT04471142.

Withdrawal

All participants are free to withdraw from the study at any time and for any reason.

Dissemination plan

This study protocol intends to answer whether the use of a compressive bandage during the first postoperative week associated with the use of a drain is effective in preventing seroma. The results of this research will be published in scientific publications, national and international scientific events, and other media portals. The study protocol will be presented to healthcare professionals and shared with patient groups through workshops and webinars.

DISCUSSION

Seroma stands out as the most common complication arising from breast cancer treatment. Its presence can increase the likelihood of developing infections, edema, and limitations in joint amplitude. This can result in setbacks for adjuvant treatment, as well as causing discomfort when engaging in daily tasks, leisure, and work.

The utilization of a compressive bandage was deemed a secure approach for patients experiencing seroma after undergoing surgical treatment for breast cancer, necessitating aspiration to alleviate discomfort.

A clinical trial was designed to explore the potential effectiveness of utilizing a compressive bandage during the initial week following mastectomy surgery, as part of the surgical treatment for breast cancer. This approach aims to offer a cost-effective strategy for preventing seroma formation.

CONCLUSIONS

The application of compressive bandage can be an effective and non-invasive strategy to prevent seroma in patients after mastectomy surgery.

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AUTHORS' CONTRIBUTIONS

EANF: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Writing – original draft. RMC: Data curation, Investigation, Methodology, Project administration, Writing – original draft. FOM: Investigation, Methodology, Writing – original draft. DMT: Investigation, Methodology, Writing – original draft. SSA: Formal analysis, Writing – review & editing. LCST: Supervision, Writing – review & editing. AB: Conceptualization, Data curation, Formal analysis, Supervision, Writing – review & editing.

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