Preventing lymphoedema after breast cancer surgery by elastic restraint orthosis and manual lymphatic drainage: a randomised clinical trial

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ABSTRACT

Background and objective: Secondary lymphoedema is considered one of the most common complications after breast cancer surgery. The aim of the present study was to analyze the effectiveness of containment elastic orthosis and manual lymphatic drainage in the prevention of lymphoedema secondary to mastectomy.

Patients and method: An experimental study was performed with a control group. Forty-eight patients were randomly assigned to experimental (containment elastic orthosis and manual lymphatic drainage) and control (postural measures) groups. Outcomes measures were quality of life, body composition, temperature, functional assessment of the shoulder, pain and limb volume. Measures were performed at baseline and after 8-months intervention.

Results: After the intervention period, the experimental group showed significant differences (P < 0.05) in the quality of life, extracellular water, and functional assessment of the volume of the limb of the mastectomized side.

Conclusions: The application of containment elastic orthosis and manual lymphatic drainage contribute to prevent secondary lymphoedema after breast cancer surgery, improving the quality of life in these patients.

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Palabras clave: Linfoedema, Cancer de mama, Prevención, Ortesis, Ensayo clinico aleatorizado

RESUMEN

Fundamento y objetivo: El linfoedema secundario es una de las complicaciones más comunes tras cirugía de cáncer de mama. El objetivo del presente trabajo fue analizar la eficacia de la ortesis elástica de contención y drenaje linfático manual en la prevención del linfoedema de miembro superior secundario a mastectomía.

Patients y método: Se realizó un estudio experimental con grupo control. Se asignaron de forma aleatoria 48 pacientes a grupo experimental (ortesis elástica de contención y drenaje linfático manual) y grupo control (medidas posturales). Las dimensiones de estudio fueron la calidad de vida, composición corporal, temperatura, valoración funcional de hombro, dolor y volumen del miembro. Las evaluaciones se realizaron en el momento basal y al finalizar los 8 meses de intervención.

Resultados: Finalizado el período de intervención, en el grupo experimental se encontraron diferencias significativas (p < 0.05) en la calidad de vida, agua extracelular, valoración funcional y volumen del miembro del lado mastectomizado.

Conclusiones: La aplicación de la ortesis elástica de contención y el drenaje linfático manual contribuye a prevenir el linfoedema secundario tras cirugía de cáncer de mama, mejorando la calidad de vida de estas pacientes.

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Introduction

Lymphoedema is a hard and asymmetric oedema, with positive Stemmer sign. Postmastectomy lymphoedema is one of the most common complications of breast cancer treatment. It is considered a nosological entity in itself, not only due to its clear relationship to the therapeutic action of breast cancer but also for its incidence, as it is the second most common of all primary and secondary cases of lymphoedema (affecting approximately 20% to 25% of patients).

Lymphoedema can be considered not only as a complication of mastectomy, but of the entire intervention and subsequent treatment, especially radiotherapy. This complication has a considerable impact, with negative effects on the quality of life and psychosocial well-being of those affected. These complications include a more or less notable increase in upper limb volume, pain, feeling of tightness or heaviness and, often, recurrent skin infections which can seriously affect limb functionality. The time of onset of lymphoedema is very variable and can range from an immediate presentation to 2 years postmastectomy. In cases of immediate appearance, the cause-effect relationship between tumour treatment and the onset of lymphoedema seems evident. Lymph return is severely affected in 100% of women undergoing mastectomy because the anatomical transport capacity decreases dramatically due to axillary nodal excision. Nevertheless, this decrease in transport capacity is accompanied by a highly variable functional compensation. Functional capacity is influenced by the opening of a series of compensatory pathways through collateral or subcutaneous, networks, spontaneous opening of lymphovenous anastomosis and satellite lymph pathways of the cephalic vein, reaching the deltoid lymph nodes and the supraclavicular region.

Preventive measures for lymphoedema are designed to avoid its worsening and complications. These measures (respiratory exercises, shoulder exercises, postural measures, etc.) have not included studies on the preventive effect of elastic restraint braces (orthosis). Therefore, the objective of this work is to analyse the effectiveness of an elastic restraint brace and manual lymphatic drainage in the prevention of upper limb lymphoedema secondary to mastectomy.

Patients and Method

This was a prospective, analytical, experimental study, designed as a simple-blind, clinical trial with experimental and control groups. We established intra-group and inter-group comparisons. The study period was between October 2008 and November 2009. The study subjects were women who had undergone surgical treatment for breast cancer. The sample consisted of 48 women who met the inclusion criteria: having undergone mastectomy with partial emptying of axillary node chains and subsequently receiving at least 30 sessions of radiotherapy, with an age range between 30 and 60 years. In addition, the exclusion criteria were: having developed oedema prior to the study, presenting a diagnosed arterial or venous pathology which could influence the development of oedema, suffering systemic processes or any other affecting the liver and kidneys, presenting psychological or psychiatric abnormalities, having undergone prior surgical interventions related to ipsilateral breast cancer, having received prophylaxis or treatment, either chemical (e.g. diuretics) or physical (e.g. manual lymphatic drainage, preventive kinesitherapy) for oedema, as well as presenting cutaneous abnormalities interfering with the use of the elastic brace. The accessible sample was obtained by accidental non-probability sampling, and consisted of 72 patients from the Radiotherapy Service at “San Cecilio” and “Virgen de las Nieves” University Hospitals, in Granada, Spain. Those patients who fit the criteria and volunteered to participate in the study were distributed into an experimental group (elastic restraint brace + manual lymphatic drainage opening lymph anastomosis) and a control group (health education on hygiene measures) via simple randomisation using opaque, sealed envelopes. The randomisation sequence was generated by the author responsible for the design of the study and its final approval. Simple binding was established by the researcher who conducted the determination of dependent variables.

Informed consent was obtained from patients according to the ethical criteria established in the Declaration of Helsinki. Furthermore, the project was approved by the Ethics Committees of “Virgen de las Nieves” Hospital Complex and “San Cecilio” University Hospital, in Granada, Spain.

Before and after the intervention phase we collected data on the primary measurement variable in the limb of the mastectomised side [upper limb volume, using the formula: $H \times (C_2 + C_0 + C_1) = H \times (C_2 + C_0 + C_1)$, where $H = height$, $C = circumference$ at the root of the limb, $c = circumference$ at the base of the limb]. Subsequently, we registered secondary variables in the following order: pain (visual analogue scale), body composition (bioelectrical impedance analysis device, Interstitial System-Medical Ibérica), temperature (thermal imaging infrared scanner, Dermatemp 1001-Exergen) and quality of life (EORTC-QLQ-C30 quality of life questionnaire for cancer patients).

The intervention period was 8 months. The onset of lymphoedema after the intervention period was determined by the difference between limb volume on the mastectomised side and limb volume on the unaffected side. Patients in the experimental group (n=24) underwent manual lymphatic drainage manoeuvres, following the Leduc method, to facilitate anastomosis (transhilar thoracoabdominal) through lymphatic drainage towards supplementary chains (dorsal cell and reabsorption manoeuvres, drainage towards the Kaplan posterior derivative and Mascagni anterior derivative lymph pathways; reabsorption manoeuvres in the arm, forearm, hand and fingers; and pressure manoeuvres on the elbow). Lymphatic drainage was administered 5 days a week. Once the drainage was completed, patients used the elastic restraint brace (Model Mediven 95) on the limb of the mastectomised side. Patients in the control group (n=24) were given instructions on hygienic and postural preventive measures for the upper limb of the mastectomised side.

Statistical Analysis

We performed a descriptive study of variables. In the intention to treat (ITT) analysis, comparisons between data at baseline and after 8 months were performed using a paired t-test for related samples within each of the groups. In comparisons between the study groups we carried out a t-test for independent samples. In all cases we applied a significance level of $P<.05$ (95% confidence interval [95% CI]). Statistical analysis was conducted using the statistical package SPSS, version 18.0.

Results

The mean age of the study population ranged between 34 and 60 years (the mean [SD] age in the experimental group was 42.23 [9.42] years and in the control group 49.28 [10.13] years), with 64% of patients undergoing left mastectomy and 36% right mastectomy. There were no dropouts in either study group. We found no significant differences in the descriptive variables. We observed significant differences between the study groups at baseline in the values of overall quality of life ($P<.034$), constipation ($P<.043$), diarrhoea ($P<.048$) and financial difficulties ($P<.037$) (Table 1). After the application of both types of intervention, the intervention group...
results are consistent with those reported in previous studies.6,7 The
control group versus 1 patient in the experimental group. These
Discussion
in Table 2.

![Table 2]

Differences in quality of life values between the study groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean at baseline (95% CI)</th>
<th>P</th>
<th>Mean at 8 months (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EG (n=24)</td>
<td>CG (n=24)</td>
<td></td>
<td>EG (n=24)</td>
</tr>
<tr>
<td>Physical function</td>
<td>114.02 (107.57-120.47)</td>
<td>.078</td>
<td>144.15 (131.69-156.61)</td>
</tr>
<tr>
<td>Emotional function</td>
<td>94.91 (86.57-103.25)</td>
<td>.246</td>
<td>98.26 (87.01-105.51)</td>
</tr>
<tr>
<td>Role function</td>
<td>88.34 (81.37-95.31)</td>
<td>.601</td>
<td>92.35 (87.08-106.62)</td>
</tr>
<tr>
<td>Cognitive function</td>
<td>117.35 (108.09-126.61)</td>
<td>.489</td>
<td>119.92 (105.63-134.21)</td>
</tr>
<tr>
<td>Social function</td>
<td>119.67 (111.13-128.21)</td>
<td>.112</td>
<td>144.25 (133.43-158.07)</td>
</tr>
<tr>
<td>Overall scale</td>
<td>73.21 (65.03-81.39)</td>
<td>.034*</td>
<td>88.24 (78.73-97.75)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>55.57 (48.01-62.23)</td>
<td>.743</td>
<td>46.71 (38.79-64.63)</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>55.82 (41.88-69.76)</td>
<td>.089</td>
<td>34.56 (27.15-56.37)</td>
</tr>
<tr>
<td>Pain</td>
<td>52.54 (37.67-67.41)</td>
<td>.093</td>
<td>21.34 (15.51-62.77)</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>35.05 (25.68-45.62)</td>
<td>.106</td>
<td>16.36 (11.42-30.29)</td>
</tr>
<tr>
<td>Sleep problems</td>
<td>42.65 (26.08-65.16)</td>
<td>.125</td>
<td>32.92 (21.67-54.17)</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>23.63 (13.29-33.97)</td>
<td>.056</td>
<td>12.36 (2.91-21.81)</td>
</tr>
<tr>
<td>Constipation</td>
<td>3.46 (0.68-6.24)</td>
<td>.043*</td>
<td>4.87 (0.96-8.78)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>44.23 (23.51-64.97)</td>
<td>.048*</td>
<td>3.14 (2.05-4.23)</td>
</tr>
<tr>
<td>Financial difficulties</td>
<td>5.23 (1.32-9.14)</td>
<td>.037*</td>
<td>13.93 (6.74-21.12)</td>
</tr>
</tbody>
</table>

95% CI: 95% confidence interval; CG: control group; EG: experimental group.

P<.05 (95% confidence interval).

obtained a significant reduction in extracellular water (P<.047). In
addition, we found significant improvements in the dimensions of
functional shoulder scale (P<.042), number of patients with
lymphoedema (P<.041), physical function (P<.023), social function
(P<.025) and fatigue (P<.049). In the placebo control group, we found
significant differences in limb volume (P<.049), numbers of patients
with lymphoedema (P<.037), physical function (P<.047) and fatigue
(P<.042). The differences between the study groups are represented in
Table 2.

Discussion
In our study, the presence of lymphoedema was determined,
between 6 and 8 months after breast surgery, in 6 patients in the
control group versus 1 patient in the experimental group. These
results are consistent with those reported in previous studies.6,7 The
presence of secondary lymphoedema could be caused by the sum of
several risk factors such as excess weight, axillary lymph node
dissection, postoperative complications and others. Previous studies
have examined the beneficial effects of exercise, health education and
early rehabilitation in preventing secondary lymphoedema after breast cancer surgery.8,9 Furthermore, massage has shown good results on stress management and mood in these patients. However, since it was not administered in conjunction with manual lymphatic drainage procedures or an exercise program it did not show a preventive effect on the development of secondary lymphoedema after surgery.10 Consequently, manual lymphatic drainage together with the application of an elastic restraint brace helps to prevent secondary lymphoedema, as well as to improve functional capacity of the shoulder and quality of life of patients.

One limitation of our study was not carrying out multiple analysis
tests during the statistical study. These tests were not performed
because there were only 2 study groups, with 2 determinations of the
study variables (baseline and after intervention). Another limitation of the study was the failure to conduct monitoring in order to verify the progression of results regarding the duration of the intervention in preventing the presence of lymphoedema.

Conflict of Interests
The authors have no conflict of interests to declare.

Table 2
Differences in the values of body composition, temperature, functional assessment of shoulder, pain and number of patients with lymphoedema between the study groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean at baseline (95% CI)</th>
<th>P</th>
<th>Mean at 8 months (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EG (n=24)</td>
<td>CG (n=24)</td>
<td></td>
<td>EG (n=24)</td>
</tr>
<tr>
<td>Body composition</td>
<td>Protein mass (g/kg/d)</td>
<td>43.47 (38.69-48.25)</td>
<td>.206</td>
</tr>
<tr>
<td>Fat mass (kg)</td>
<td>55.50 (49.27-61.73)</td>
<td>.953</td>
<td>53.70 (41.05-66.35)</td>
</tr>
<tr>
<td>Extracellular water (l)</td>
<td>8.27 (6.2-13.92)</td>
<td>.365</td>
<td>3.75 (0.05-7)</td>
</tr>
<tr>
<td>Temperature (ºC)</td>
<td>Back of hand</td>
<td>35.51 (35.28-35.74)</td>
<td>.933</td>
</tr>
<tr>
<td>Anterior part of forearm</td>
<td>36.08 (35.63-36.98)</td>
<td>.621</td>
<td>36.19 (34.56-39.62)</td>
</tr>
<tr>
<td>Elbow flexion</td>
<td>36.69 (36.06-37.32)</td>
<td>.803</td>
<td>36.42 (35.54-37.33)</td>
</tr>
<tr>
<td>Functional assessment (UCLA)</td>
<td>22.89 (22.06-23.72)</td>
<td>.578</td>
<td>24.23 (23.66-24.68)</td>
</tr>
<tr>
<td>Pain (VAS)</td>
<td>6.81 (5.14-8.48)</td>
<td>.744</td>
<td>4.51 (2.68-6.34)</td>
</tr>
<tr>
<td>Volume of limb (ml)</td>
<td>307.45 (173.22-441.68)</td>
<td>.067</td>
<td>312.72 (206.55-417.99)</td>
</tr>
<tr>
<td>Number of patients with lymphoedema (N)</td>
<td>–</td>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

95% CI: 95% confidence interval; CG: control group; EG: experimental group; VAS: Visual analogue scale.

P<.05 (95% confidence interval).
Bibliografía