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Randomized Comparative Study of the Utility of a Controlled Compression Garment Compared with a Compressive Dressing in the Immediate Postoperative of Conserving Breast Cancer Surgery

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Abstract

Objectives: To compare the overall and individual incidence of postoperative complications, comfort and quality of life resulting from the use of compressive bandaging versus a specific controlled compression garment.

Patients and method: A randomized controlled trial was conducted in 198 patients distributed in 2 groups: bandaging (n = 88) and compression garment (n = 99). Variables related to immediate postoperative complications and satisfaction with quality of life were collected. Changes in the variables were compared in the 2 groups during the first postoperative month.

Results: The incidence of total complications was significantly lower with the compression arment: 7 days (P = .032) and 15 days (P = .009). Pain was significantly reduced with the compression garment: 7 days (P = .002) and 15 days (P = .012). The incidence of skin injury was also significantly reduced: 0%-2% with the compression garment versus 35% with bandaging (P < 0.0005). Significant differences were also found in quality of life in favor of the use of the compression garment (P < 0.0005).

Conclusion: The use of a specific controlled compression garment in the immediate postoperative period after breast cancer-conserving surgery reduces the likelihood of postoperative complications from 32% to 15% and enhanced efficacy, safety, and patient comfort compared with the usual compressive dressing.

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Keywords: Breast cancer; Breast-conserving therapy; Postoperative complications; Occlusive bandage; Compressive garment

Abbreviations: BMI: Body Mass Index; SPSS: Statistical Package for Social Sciences

Introduction

Breast cancer is the most common malignant tumor in women, with the exception of non-melanoma skin cancer, with an incidence of 29%, a population rate of 65.3 × 100,000 women, a mortality of 15.5% and a diagnosis that is more prevalent between 45 and 70 years of age [1,2]. In accordance with the principle of applying the mínimum effective treatment both at mammary and axillary level, conserving surgery has become the «gold standard» of breast cancer surgical treatment, representing at the present time 60%-80% of the operations performed, with a substantial increase in oncoplastic surgery, [3-9] and in axillary, staging selective biopsy of the sentinel node now replaces axillary lymphadenectomy [10]. Classically, after surgery the patient had a dressing or compressive bandage applied to the breast and extending to the armpit, with immobilization even of the arm in some cases. Besides covering the wound for aseptic purposes, this compressive bandaging sets out to prevent certain postoperative complications (hematomas, serum as, edema and cutaneous complications) and reduce the pain. The use of compression dressings, however, is not without its own complications associated with the appearance of painful cutaneous phlyctenae, restriction of thoracic and finally respiratory mobility, tendency to immobility of the arm and establishment of movement-limiting disease in the shoulder [11].

At present, there are compressive garments for postsurgical use which, in theory at least, successfully fix, mould and compress the operated breast and have the potential action of relieving pain, preventing hematomas, reducing postoperative oedema through improving lymphatic return and the appearance and anatomic form of the breast, which along with the curative objective represents the prime aim of breast cancer conserving surgery [12,13]. Its advantages are that it stabilizes and splints the breast appropriately after the conserving surgical treatment and the oncoplastic surgery, while assisting the curative process, since it applies moderate compression to the wound area and does not oppress or irritate the skin thanks to the use of hypoallergenic fabrics and its individual adaptation capability. Furthermore, it is easy to handle both by the patient herself and healthcare staff [14]. An observational survey promoted by the Senological Studies Group of the Spanish Society of Senology and Mammary Pathology, conducted in 2012 at the breast units of 35 Spanish hospitals on the use of a compressive dressing vs. a compression garment in the immediate postoperative period after breast cancer conserving treatment, shows that in 53% of the breast units a dressing is used compared with a 45% that uses a brassiere/compression garment. There is wide variability in the kind of brassiere used, ranging from the supportive, sports, elastic, and seam-free and moulded cup brassiere to the specific postoperative compression brassieres. The aim of this study is to compare 2 post-surgical guidelines for the management of the operated patient by means of conserving surgery for malignant mammary disease the use of a compression garment versus a classic compressive dressing, and analyze the impact on immediate postoperative complications and the quality of life of the women.

Patients and Method

A comparative, prospective, randomized, open study was conducted from October 2013 to June 2015, at 5 Spanish hospitals: Hospital Universitario Virgen del Rocío (Sevilla), Hospital Universitario Virgen de Valme (Sevilla), Complejo Hospitalario Universitario de Vigo, Hospital Clínic (Barcelona) and Hospital Universitario Reina Sofía (Córdoba), promoted by the Senological Studies Group of the Spanish Society of Senology and Mammary Pathology. The protocol was approved by the respective clinical research ethics committees of the participating hospitals, with that of Hospital Universitario Virgen del Rocío, Sevilla, code CEI 2013PI/309, acting as the reference committee. Cases of women of full age with an indication of unilateral breast-conserving surgery who gave their consent to take part in the study were included. Cases with primary systemic therapy, contraindications for the conserving surgical treatment, those with anticoagulant therapy or those who did not accept participation in the study were all excluded. A sample size was calculated so as to permit demonstration of a reduction in the joint ¡ncidence of post-surgical complications of 32% in the dressing group and of 15% in the compression garment group. A power of 80% and a type 1 error of 5%, assuming non-evaluable losses of cases of 5%, called for a sample of at least 86 cases per group. The patients were selected for the study on the day of first consultation, when they were informed both orally and in writing and accepted by signing the specific informed consent. Randomization was done by SPSS 2.67 program for Windows®. All the patients complied with the normal

protocol in clinical practice, the prophylactic medication, the conserving surgery and the postoperative checks. After undergoing the conserving and nodal staging surgery, in the operating theatre they were fitted with the appropriate compression system depending on their randomization.

Compression garment group

Use was made of the Anita Care® brassiere reference 1194, characterized by moulded two-layer seamless cups, made with high percentage cotton fabric (60%); it has wide straps individually adjustable by means of a velcro strip and a side band between the 2 layers exerting a compression regulated from the lateral area of the lower chest to the start of the strap. A front zip with a clasp closure system assists its fitting and shortens the healing time. Broad, elastic under-bust band with cotton in contact with the skin, which prevents movement of the brassiere and local irritation. High back Personalized good fit sizing (adjusted to the patient's specific bra and cup size), which permits controlled compression.

Classic dressing group

Prior skin protection with Nobecutan®, over the surgical wound a cushioning dressing is made with gauze or compresses which is secured with adhesives bands or plaster encompassing both the breast and the armpit, with peripheral support on the chest Wall and in the supraclavicular space. Subsequently, the monitoring visits were made at 24 h, upon discharge and after [7,15] and 30 days. The compressive dressing is maintained for 48 h at the most and is replaced with a simple dressing and the regular brassiere, which is maintained, as in the compression garment group, for up to 30 days. The variables collected for their analysis were: local complications (hematoma, breast oedema, seroma, cutaneous alterations), pain assessment by means of the visual analogue scale at the different check-up times, mobility of the ipsilateral upper limb, particularly functional limitation of the shoulder or of thoracic mobility, by means of physical examination and the patient's subjective evaluation with the Constant-Murley scale;15 as a measure of effectiveness, assessment is made of the facility of use, the level of comfort and aesthetic satisfaction by means of the Likert type Usability Scale (score of 0-5: completely dissatisfied, dissatisfied, undecided, satisfied and fully satisfied), whilst quality of life is measured with the SF-12 health questionnaire [16].

Statistical Analysis

After statistical examination of the data, these are described according to the 2 procedures under study: compression garment and dressing. The quantitative variables are expressed with means and standard deviations, or medians and quartiles in the case of asymmetric distributions, and the qualitative variables are percentages. Immediately afterwards, an initial comparability analysis is made between the 2 groups according to age, BMI, brassiere cup and demographic or tumor-related variables and their type. To analyze the associations of qualitative variables with the procedures, contingency tables and the Chi-square test is applied. The differences in quantitative variables between the 2 guidelines were studied with the Student-t test for separate samples and the Mann-Whitney U test in the case of non-normality. Significant mean or median differences are quantified with 95% confidence intervals. To analyze the time evolution of a numerical parameter according to the post-surgical guideline, Friedman's non-parametric test is applied, or else Wilcoxon's for only 2 points of time. In addition, in order to detect changes over time in a dichotomous qualitative variable, either Cochran's non-parametric Q test is applied, or else McNemar's test for 2 points of time. Data are analyzed with the IBM® SPSS® 23.0 statistical program for Windows®.

Results

Out of a total of 198 patients, only 187 fulfilled valid criteria: 99 in the compression garment group and 88 in the dressing group. In both groups the homogeneity of the series was confirmed, with specification of the data in Table 1.

Variables	Dressing (n=87)	Orthosis (n=99)	*P* Comparison
Age (Mean ± SD)	54.1±9.4	55.1±9.3	0.614
BMI*	26.8 (23.8; 30.8)	26.5 (23.3; 29.9)	0.380
No. Comorbidities *	1 (0; 2)	1 (0; 2)	0.345
Total No. Lymph Nodes Removed *	2 (1; 3)	2 (1; 2)	0.107
Breast Operation n (%): Lumpectomy Wedge Resection Quadrant/Expansion of Margins	 41 (47.1) 34 (39.1) 12 (13.8)	 41 (42.3) 38 (39.2) 18 (18.6)	0.644

Lymphadenectomy n (%): No Yes	 75 (86.2) 12 (13.8)	 91 (91.9) 8 (8.1)	0.241
Tumour Pathological Type n (%): In Situ Infiltrating	 6 (6.9) 81 (93.1)	 10 (10.3) 87 (89.7)	0.445
SLNB N (%): No Yes	 7 (8.0) 80 (92.0)	 3 (3.1) 94 (96.9)	0.195
Tumour Size n (%): T1 T2	 67 (77.0) 20 (23.0)	 82 (84.5) 15 (15.5)	0.259
Tumour Grade n (%): I II III	 19 (22.1) 49 (57.0) 18 (20.9)	 19 (20.2) 49 (52.1) 26 (27.7)	0.577
Lymphovascular Infiltration n (%): No Yes	 77 (88.5) 10 (11.5)	 87 (87.9) 12 (12.1)	1

Table 1: General characteristics of the study groups.

The incidence of total general complications in each of the groups is shown in Figure 1.

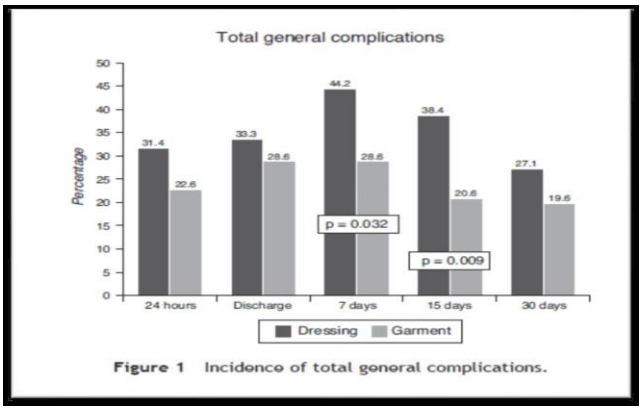

Figure 1: Incidence of total general complications.

It may be seen that it is lower at all moments of time in the compression garment group as compared with the dressing group, with statistically significant differences at 7 ($p = 0.032$) and at 15 days ($p = 0.009$). The incidence of breast hematoma differs significantly ($p = 0.043$) in favor of the garment group (9.2%) at 7 days versus the dressing group, where it increases in one week from 4.3% to 21%. Reduction in mobility shows significant differences in favor of the compression garment ($p = 0.001$) at 7 days, with an incidence of 28% in the dressing versus 16% the garment group, and a considerable reduction in the garment group down to 8% at 15 days. At 24 h or at discharge no complication differs between the 2 groups, although it should be mentioned that the decrease in mobility is 21% in the dressing versus 14% in the garment group. Likewise, there is a 7% of breast oedema versus only 3.6%, respectively, in addition to there being no breast oedema at discharge with the compression garment. At 15 days, the only significant difference between groups is breast oedema ($p = 0.048$), present in 9% in the dressing versus only 3% in the garment group, with a risk for dressing of 4.9 and a 95% CI of 1-24. At 30 days, special mention should be made of the difference in the decrease in mobility, which is reduced to only 4% in the garment versus the 10.7% observed in the dressing group, as well as the fact that axillary insensitivity is lower in the garment than in the dressing group at all points of time. In the variables related to morbidity (breast or axillary seroma, breast or axillary hematoma), at 24 h we observe a discreet, non-significant difference favorable to the dressing group. In the dressing group too pain intensity does not drop noticeably until 15 days after surgery, with no significant decrease, of one and a half points on the visual analogue scale, occurring until one month after ($p < 0.0005$). In the garment group, however, pain decreases significantly after 7 days ($p < 0.0005$), with a drop of one and a half points taking place. When pain intensity all the time is compared between the 2 groups, there are significant differences at 7 ($p = 0.002$) and at 15 days ($p = 0,012$), although pain becomes the same at 30 days (Figure 2).

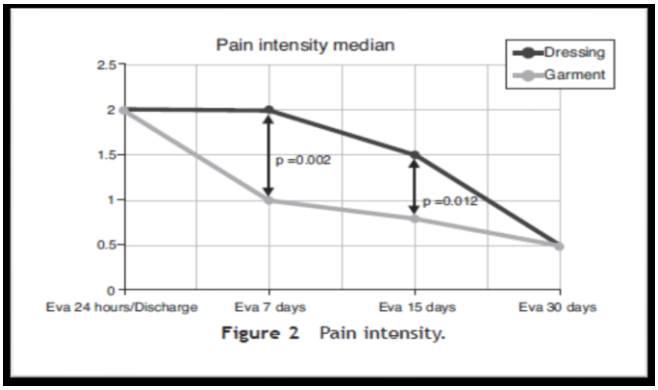

Figure 2: Pain intensity.

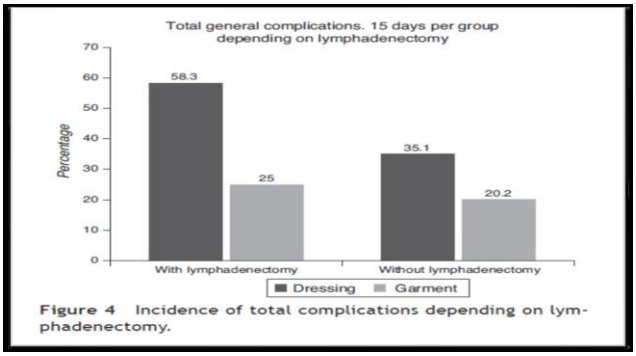

Figure 4: Incidence of total complications depending on lym-phadenectomy.

As shown in Figure 3,

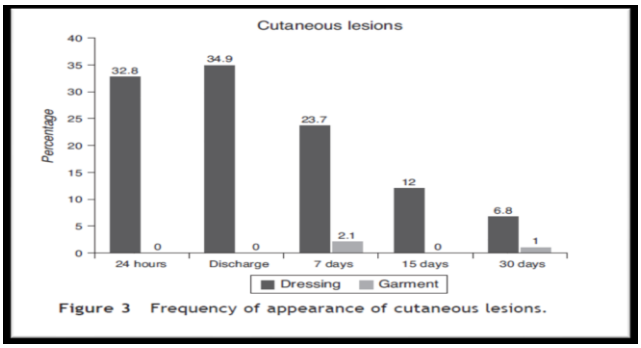

Figure 3: Frequency of appearance of cutaneous lesions.

There are significant differences (p< 0.0005) between the Frequencies of cutaneous lesions of the 2 groups in favor of the garment, where the incidence of lesions is extremely low at any point of time, between 0%-2%, whereas in the dressing group cutaneous lesions vary between 35% at discharge and 12% at 15 days. Although there are no differences in the limitation of thoracic mobility and respiratory problems, significant differences were found in functional limitation of the arm between the 2 groups in favor of using the garment (p = 0.032 and p = 0.046 at 24 h and at discharge, respectively). The incidence of complications is lower in the garment than in the dressing group at any point of time, whether there has been lymphadenectomy or not. At 15 days, these differences become significant (p = 0.035), reaching 33% in favor of the garment in patients with lymphadenectomy and 15% in favor of the garment in patients without this operation (Figure 4).

As regards the quality rating appreciated by the patient and in relation to facility of use, comfort and aesthetic satisfaction, as may be seen in Figure 5, there are significant differences (p < 0.0005) between the groups and at each of the points of time of the postoperative period. Notable for the 3 characteristics and at all points of times is the "fully satisfied" response, both because it shows a difference of more than 50% in favor of the garment throughout the whole postoperative period and for the high frequency observed with this treatment.

No significant differences are shown between the 2 groups when we evaluate the time required for fitting the garment or the dressing, except at discharge (p = 0.048), where there is a difference of 12% less incidence with the garment in fitting time (5-10 min.) compared with the dressing, due to the fact that with the former 10% of the patients who took that period of time to fit the product go on to do so in less than 5 min.

Discussion

After carrying out a thorough bibliographic review (Medline, pubMed, Embase, Cochrane), it may be emphasized that the only study found on the matter is one published in 2004 by [17] who compare the use of a tubular elastic bandage with a brassiere in a breast cancer postoperative and conclude that postsurgical discomfort is reduced more by using a suitable/well-fitting brassiere than tubular bandaging. Since it does not study the effects of the brassiere on postoperative complications, we consider that this clinical trial may be pioneering as it analyses how to reduce the adverse effects of breast-conserving surgery and axillary staging in terms of applying the best postoperative compression treatment, namely by using personalized staging and the best well-fitting garment in terms of size and cup. This study has allowed us to assess how the use of a suitable garment

instead of the traditional dressing has a favorable influence and what benefits it brings. One of the adverse effects of the use of a compressive dressing, which could be classed as banal but is rated most negatively by patients, is the formation of phlyctenae. In addition [18] report that the use of a dressing is not effective in reducing the drainage debit and may increase the formation of postoperative seromas after a lymphadenectomy. We consider it important that every woman, recently operated for breast cancer with conserving surgery, may be able to play a full part in her social life and feel healthy, improve her quality of life and not feel limited by the use of a traditional compressive dressing. In this respect, the results coincide with those of [17,19] in the importance of minimizing the discomfort of breast cancer surgery by using tools that enhance the quality of life of the patients.

The use of an unsuitable brassiere, in basal conditions, may give rise to certain involvements: alterations of the circadian rhythm, the autonomous nervous system or intestinal transit, osteomuscular pain, headaches, costoclavicular syndrome, respiratory insufficiency and mammary pain [20-31]. In this context we should underline the importance of having a brassiere/garment that may be adapted to the particular specific needs of the immediate postoperative period. In addition, its proper use is one of the most effective measures that may be implemented in women subjected to conserving surgery for breast cancer. In conclusion, this study shows that the use of a controlled compression garment in the immediate postoperative period of breast cancer conserving surgery compared with use of the classic dressing reduces the incidence of postsurgical complications and improves the quality of life of the patient in terms of comfort and handling of the device.

Ethical Responsibilities

Protection of persons and animals

The authors declare that no experiments have been done with human beings or animals for this investigation.

Confidentiality of the data

The authors declare that no details of patients appear in this article.

Right to privacy and informed consent

The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

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