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Research Article

Compression Orthosis as Factor that Reduces Complications in Conservative Breast Cancer Surgery with Respect to the Use of a Compressive Dressing

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Abstract

Objectives: To demonstrate that the use of controlled compression orthosis versus classic compressive dressing reduces postoperative complications in conservative breast cancer surgery. Patients and Method: The 186 patients who were randomised to use an orthosis or a compressive dressing after conservative breast cancer surgery were included. Clinical-pathological variables were recorded and their relationship with the development of postoperative complications in the two weeks following surgery was studied, and a multivariate analysis was carried out with significant variables or with a tendency towards such a relationship. Results: As variables related to the appearance of postoperative complications in the two weeks following surgery we measured: medium or large size (P=.023), the use of a compressive dressing vs. an orthosis (P =.009), the intrinsic Her2neu subtype (P =.004), the use of breast drainage (P =.010) or axillary drainage (P =.017) and the extensive lymphadenectomy (P=.010). The use of a compressive dressing, the intrinsic Her2neu subtype and the use of breast drainage, persist as independent factors after the multivariate analysis. Conclusion: The compression orthosis versus the compressive dressing is an independent protective factor for early postoperative complications in breast cancer.

Keywords: breast cancer; breast-conserving therapy; postoperative complications; occlusive bandage; compressive garment

Introduction

Conservative breast and axillary surgery is the reference standard [1-6] in the surgical treatment of breast cancer, in line with the principle of applying the minimum effective treatment at both the breast and axillary levels. The evolution and surge in oncoplastic breast surgery [7] and selective sentinel lymph node biopsy for ganglionic staging8 currently include both surgical procedures in 80% and 95% of the surgical procedures indicated to achieve the

best oncological, cosmetic and quality of life results, respectively.

Traditionally, once the patient has been operated on, a compressive dressing or bandage is placed over the scar on the breast, and it usually extends to the armpit in order to avoid local complications, such as bruises, serous-lymphatic collections or breast oedema, and also to reduce postoperative pain. The use of compressive dressings is not free from local complications, such as skin lesions, limitation of thoracic mobility with restrictive respiratory trouble and functional limitation of arm mobility [8,10,11].

Wearing a suitable bra that promotes good blood and lymphatic circulation of the breasts, at baseline conditions, and that, in cases of larger breasts supports their weight better, keeping the shoulders and back relaxed, has been shown to prevent the development of certain conditions such as osteomuscular pain, costoclavicular syndrome, respiratory failure, circadian rhythm disorders, and breast pain or oedema [12-17]. There are currently "well-fitted" orthoses with controlled compression that are personalised in size and cup designed to fix, mould and collect the breast from the armpit; these details are recognised as very important for postoperative care of the breast and the armpit that have undergone conservative oncological surgery, which is a surgical technique, moreover, that is not free of complications and undesirable effects, such as breast oedema, hematomas, seromas, skin lesions, pain, infection and an impact on quality of life [18-21].

An observational survey promoted by the Senological Studies Group of the Spanish Society of Senology and Breast Disease (SESPM), carried out in 2012 in the breast units of 35 Spanish hospitals, on the use of a compressive dressing versus orthosis immediately after operation in the conservative treatment of breast cancer, shows that in 53% of breast units a dressing is used versus 45%, where a bra/orthosis is used, with there being a high variability in the type of bras used, from sports, elastic, seamless bras and those with preformed cups to specific postoperative compression bras [22].

Given all of the above, in 2016 a randomised prospective multicentre study was carried out, [22 in which the use of an orthosis was compared with that of a classic compressive dressing, with the combined incidence of complications, comfort, ease of use, aesthetic satisfaction and quality of life [23] being analysed, and the significant reduction of complications with the use of an orthosis versus a dressing two weeks after surgery being identified.

The objective of this retrospective study is to demonstrate and quantify the efficacy of orthoses versus dressings in the reduction of postoperative complications, adjusting the compression procedure for other complication predictive factors.

Patients and Method

For this, a sample was taken consisting of the 198 patients who were included in the CIR-ORT 2013 trial, [22,23] who received conservative surgery due to breast cancer, and who were followed up from 24 hours to 30 days after surgery.

In all cases, quality of life and the incidence of complications were recorded on five occasions during this time period.

The sample included cases from 5 Spanish hospitals: Virgen del Rocío University Hospital (Seville), Virgen de Valme University Hospital (Seville), Vigo University Hospital Complex, Clínic Hospital (Barcelona) and Reina Sofía University Hospital (Cordoba), and the study was promoted by the Senological Studies Group of the Spanish Society of Senology and Breast Disease. The protocol was approved by the corresponding Clinical Research Ethics Committees in all participating centres.

We included cases of women of legal age with an indication for conservative surgery for unilateral breast cancer, who granted their consent to participate in the study. We excluded patients with primary systemic therapy, with contraindications for conservative surgical treatment, those on anticoagulant treatment or those who did not accept participation.

The patients followed the normal care protocol in clinical practice and after undergoing conservative surgery and ganglionic staging, in the operating room they received the compression system with an orthosis or a compressive dressing depending on their randomisation, carried out through the at the time when the surgery was authorised. As an orthosis, the bra with reference 1194 by Anita Care® was used, characterised by seamless double layer preformed cups, made from cotton fabric (60%), with adjustable wide straps and side waistbands that exert regulated compression. This orthosis has a front zipper with a hook and eye fastening, which facilitates its wearing and decreases the healing time, as well as with a wide elastic band under the breast, which has cotton on the skin side, allowing controlled compression.

The classic dressing was prepared with gauzes or compresses and was applied on the injury, following protection of the skin with Nobecutan®, and was put in place with adhesive strips or surgical tape and covered the breast and the armpit, with peripheral support on the thoracic wall and the supraclavicular space. The compressive dressing was held in place for a maximum period of 48 hours and afterwards, it was replaced by a simple dressing in addition to a normal bra, which was maintained, as in the orthosis group, for 30 days. Subsequently, check-ups were carried out after 24 hours, upon discharge, and on follow-up days 7, 15 and 30.

The variables recorded were those considered to be potentially influential on the appearance of complica-

tions: age, BMI, bra size, tumour size, grade and phenotype, procedure on the breast and armpit, number of lymph nodes removed and breast and/or axillary drainage.

Local complications were considered (hematoma, breast oedema, seroma, skin complications) [24], assessment of pain through the visual analogue scale in the different check-ups, mobility of the ipsilateral upper limb, particularly the functional limitation of the shoulder or of thoracic mobility, through a physical examination and subjective assessment of the patient with the Constant-Murley scale [25]; as an efficacy measurement, we assessed the ease of use, the degree of comfort and aesthetic satisfaction through the Likert-type Usability Scale (rating from 0-5: completely dissatisfied, dissatisfied, undecided, satisfied and completely satisfied), and the quality of life was measured with the health questionnaire SF-12 [26].

The complications observed in the first two weeks after surgery were recorded with the aim of carrying out a comparative study between the groups with an orthosis and those with a compressive dressing, as well as a multivariate analysis for the complications two weeks after surgery, with the aim of identifying and confirming treatment with compressive dressings as a predictive factor for these complications, as well as quantifying their impact.

Sample size

Considering expected complication percentages of between 20% and 40% with an α error of 5%, a bilateral test power of 80% and an estimated loss of study participants of 5%, it was necessary to analyse at least 86 patients per group, 172 in total. The calculation was performed with the n Query Advisor 7.0 software for Windows.

Statistical analysis

Initially, the comparison of the potentially confusing variables of the relationship between the compression procedure and the general complications two weeks after surgery was carried out. Subsequently, the prediction of complications was studied univariately from their predictive potential variables. For this, Student's t test was applied for independent samples and the nonparametric Mann-Whitney U test was applied in the case of quantitative variables. To analyse the associations between the qualitative variables and complications, contingency tables were created and the Chi-square test or the non-asymptotic methods of the Monte Carlo test and the Exacta test were applied. Lastly, a multivariate binary logistic regression model was generated for the complications event, with all the variables related to it below 25%, to try to identify the compression treatment as an independent predictor of the presence of complications.

Results

A total of 99 patients were studied in the group with orthoses and 87 with compressive dressings, whose general characteristics can be seen in Table 1. It can be seen that both groups are comparable for all the characteristics considered; however, the lymphadenectomy, the total number of lymph nodes removed, a tumour size of less than 2 cm and the result of selective sentinel node biopsy (SLNB) differed slightly by treatment, so they were considered subsequently in the final analysis for the adjustment of the compression treatment factor as a potential predictor of postoperative complications.

After the multivariate analysis, the possible variables associated with general complications two weeks after breast surgery were the size (P=.023) the phenotype of the tumour (P =.004); breast and axillary drainages (P =.010 and .017, respectively); the total number of lymph nodes removed (P =.010); and the breast compressor procedure, a factor in the study that showed a reduction of more than half in the number of complications when the orthosis was used than when the compressive dressing was used (P =0.009). We also observed the tendency for a relationship with a greater risk of complications, although without achieving statistical significance, in the type of surgery on the breast, the performing of a lymphadenectomy, the size of the tumour <2cm and the existence of lymphovascular invasion (Table 2).

After the multivariate analysis of the variables that could affect this association or were univariately significant for complications, independent predictive factors were identified for the presence of postoperative complications at two weeks: the compression procedure, resulting in the orthosis protecting by a factor of 3 versus the dressing; the tumour phenotype, such that a Luminal B or Her-2 tumour would be linked two or five times more to complications, respectively, than a Luminal A; and to the use of drainage in the breast, multiplying by four the risk of the appearance of complications (Tables 3 and 4).

Discussion

The brassiere or bra is an item of feminine lingerie with a predominantly aesthetic function. The invention of the modern bra is attributed to Pierre Poiret who, in 1907, joined two handkerchiefs with a silk ribbon and created one of the underwear items most used by women: the brassiere: But it was the American Mary Phelps Jacobs who in 1914 patented the brand with the name “backless brassiere” [27]. Since then, the bra has been an item of femininity that has been determining the specific and individual needs of women: comfort, function, need, fashion, seduction and price. Subsequently, the industry adapted the characteristics of the bra to the needs of each woman beyond fashion, innovating different types of bras for each type of chest and specifically for each situation:

Table 1. General characteristics of the study groups.

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 (%)			0.644
Lumpectomy	41 (47.1)	41 (42.3)	
Wedge resection	34 (39.1)	38 (39.2)	
Quadrant/Expansion of margins	12 (13.8)	18 (18.6)	
Breast operation n (%):			0.644
Lumpectomy	41 (47.1)	41 (42.3)	
Wedge resection	34 (39.1)	38 (39.2)	
Quadrant/Expansion of margins	12 (13.8)	18 (18.6)	
Lymphadenectomy n (%):			0.241
No	75 (86.2)	91 (91.9)	
Yes	12 (13.8)	8 (8.1)	
Tumour pathological type n (%):			0.445
In situ	(6.9)	10 (10.3)	
infiltrating	81 (93.1)	87 (89.7)	
SLNB n (%)			0.195
No	7 (8.0)	3 (3.1)	
Yes	80 (92. 0)	94 (96.9)	
Tumour size n (%)			0.259
T1	67 (77.0)	82 (84.5)	
T2	20 (23.0)	15 (15.5)	
Tumour grade n (%):			0.577
I	19 (22.1)	19 (20.2)	
II	49 (57.0)	49 (52.1)	
III	18 (20.9)	26 (27.7)	
Lymphovascular infiltration n (%):			1
No	77 (88.5)	87 (87.9)	
Yes	10 (11.5)	12 (12.1)	

Table 2. Complication prediction factors two weeks after surgery

Variables	n total	n (%) complications	P univariate
Size of the bra:			
Small	59	10 (16.9)	
Medium/Large	125	43 (34.4)	0.023
Compression procedure:			
Dressing	86	33 (38.4)	0.009
Orthosis	98	20 (20.4)	
Tumour intrinsic subtype:			
Luminal A (ref.)	90	19 (21.1)	
Luminal B	61	22 (36.1)	0.004
Her-2	10	7 (70.0)	
Basal	8	1(12.5)	
Breast procedure:	81	27 (33.3)	
Lumpectomy (ref.)	72	22 (30.6)	0.111
Wedge resection			
Quadrant/Expansion of margins	30	4 (13.3)	

Lymphadenectomy: no yes	 164 20	 44 (26.8) 9 (45.0)	0.116
Breast drainage: no yes	 163 20	 42 (25.8) 11 (55.0)	0.010
Axillary drainage: no yes	 159 24	 41 (25.8) 12 (50.0)	0.017
Bra cup: A or B C or D	 92 92	 27 (29.3) 26 (28.3)	1
Tumour pathological type: In situ Infiltrating	 16 167	 4 (25.0) 49 (29.3)	0.783
SLNB: no yes	 10 173	 4 (40.0) 49 (28.3)	0.479
Tumour size: T1 T2	 148 35	 41 (27.7) 12 (34.3)	0.534
Tumour grade: I II III	 38 97 44	 10 (26.3) 27 (27.8) 15 (34.1)	0.687
Lymphovascular Infiltration: no yes	 162 22	 45 (27.8) 8 (36.4)	0.454
Age (mean ± standard deviation) Without complications With complications	 131 53	 55.5±9.1 52.6±9.7	0.060
BMI * Without complications With complications	 131 53	 27.1 (23.8; 30.2) 25.6 (23.0; 29.9)	0.212
Total no. lymph nodes removed * Without complications With complications	 130 53	 2 (1; 2) 2 (1.5; 3)	0.010
No. Comorbidities * Without complications With complications	 131 53	 1 (0; 2) 2 (0; 2)	0.426

* Median (P25; P75), asymmetrical distribution

Table 3. Variables initially considered in the multivariate model

	Wald	gl	Sig.	OR	C.I. 95% for OR	
					Inferior	Superior
Age	2.275	1	.131	.968	.927	1.010
BMI	1.363	1	.243	.961	.899	1.027
No. lymph nodes removed	.644	1	.422	1.108	.863	1.423
Compression procedure	3.735	1	.053	.457	.207	1.011
Bra size	3.816	1	.051	2.615	.997	6.862
Breast procedure	2.017	1	.156	.669	.384	1.165
Lymphadenectomy	258	1	.612	.499	.034	7.319
Breast drainage	3.716	1	.054	2.817	.983	8.072
Axillary drainage	2.400	1	.121	2.665	.771	9.211
Tumour phenotype	.670	1	.413	1.212	.765	1.920
Constant	.102	1	.749	1.693		

Table 4. Variables in the final multivariate model

	Wald	gl	Sig	Adjusted OR	C.I. 95% for Adjusted OR	
					Inferior	Superior
Compression procedure (orthosis)	6.827	1	.009	.373	.178	.782
Breast drainage (yes)	5.300	1	.021	3.642	1.212	10.943
Tumour phenotype	8.506	3	.037			
Luminal B	4.397	1	.036	2.255	1.054	4.821
Her-2	4.664	1	.031	5.390	1.168	24.868
Basal	.319	1	.572	.528	.057	4.851
Constant	10.845	1	.001	.362		

daily use, pregnancy, lactation, sport, parties, premenstrual state and therapeutic use per se. The ultimate goal is comfort and the avoidance of the emergence of diseases in the breast [28].

In this context, a controlled compression orthosis must meet the following conditions: 1) it must be moulded as if it were a second skin; 2) the compression must be uniform throughout the breast; 3) it must be very well adapted to the body, and not leave space or friction points; 4) it must be made with breathable and hypoallergenic fabric; and lastly, 5) it must be easy to put on and take off [22].

Therefore, its advantages are that it stabilises and immobilises the breast after any breast-conserving surgical operation and after plastic surgery; it favours the healing process, since it moderately compresses the area of the scar and benefits the lymphatic flow; it does not oppress or irritate the skin, thanks to the use of soft and hypoallergenic materials and its capacity for individual adaptation; and, in addition, it is easy to use for both the patient and the healthcare staff. All of the above give it therapeutic value per se and usefulness for reducing the functional limitation secondary to the surgical treatment of breast cancer [22-23].

Currently, there are several types of compression orthoses that meet the therapeutic expectations mentioned above. A comprehensive literature review in several repertoires (Medline, PubMed, Embase, Cochrane) has not allowed the authors to find studies that provide information on the relationship between the use of orthoses and the appearance of postoperative complications, and, as such, this would be a pioneering study in this field. In this context, as one of the few existing studies on bras and orthoses, in 2004 Sharon et al. [26] published that postsurgical discomfort is reduced more when an adequate well-fitting bra is used instead of a tubular bandage, as a conclusion of their comparative study

between both postoperative compression techniques, although without analysing the effects of the bra on postoperative complications.

The already published results of the CIR-ORT 201322-23 clinical trial showed significant differences in the appearance of total and individual general complications (hematoma, seroma, breast oedema, pain intensity, skin lesions and functional limitation of the arm) depending on the use of orthoses or compressive dressings, with greater aesthetic satisfaction and quality of life being found with the use of the former. Thus, after 15 days, these differences become significant (P= .035), being 33% in favour of the orthosis in patients with lymphadenectomy and 15% in favour of the orthosis in patients without this intervention.

With the present study, we have tried to analyse this relationship and get to know better which factors are dependent on the management of these patients that are more related to the appearance of complications depending on the use of orthotics or a standard compressive dressing. Among the data provided by this study, we can highlight the relationships between certain factors and the appearance of complications that can be reduced or modulated, at least theoretically, by the use of orthoses instead of the traditional compressive dressing. Thus the size and the cup of the bra, with three times the complications when using C/D/E cups versus A/B, a more exhaustive axillary dissection when necessary, with the risk of complications doubling for every 7 nodes removed, or the use of breast and axillary drainage, which would multiply by three the appearance of these complications, are management issues that should be considered when indicating the use of the dressing or orthosis in the period immediately following surgery.

More curious, although with fewer practical implications, would be finding a relationship between the intrinsic molecular subtype of the tumours and the emergence of complications. In fact, while the luminal profile A is associated with fewer complications, the HER2 neu profile duplicates them. In addition, this relationship persists after performing the multivariate analysis.

With a more general perspective, and from a practical point of view, it is very important that every woman recently operated on for breast cancer with conservative surgery, is able to participate in their social life and feel healthy, improve their quality of life and not be limited by the use of traditional compressive dressing. In this regard, the results coincide with those of Sharon et al. [29] and Gho et al. [30] and O'Hea et al. [31] on the importance of using tools that improve the quality of life of patients to reduce pain, seroma formation and in general the discomfort after conservative breast cancer surgery. It should be emphasised how the use of controlled compression orthoses that minimises the formation of blisters, a frequent adverse effect with the use of dressings that can be categorised as banal, is one of the most negatively assessed impacts by patients [22-23].

The interpretation of the statistical model has to be carried out from the perspective of the identification of postoperative complication predictive factors after breast cancer conservative surgery, since it would be necessary to have a larger sample size to replicate the model and adjust their confidence intervals for the odds ratios.

In conclusion, orthosis versus the traditional dressing in the compression procedure after conservative breast surgery is a protective predictor, and it therefore reduces general complications two weeks after the aforementioned surgery.

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