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Patient-Reported Outcomes

Quality-of-Life Impact of Sentinel Lymph Node Biopsy Versus Axillary Lymph Node Dissection in Breast Cancer Patients

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A B S T R A C T

Objectives: Controversy about quality-of-life (QOL) benefits of sentinel lymph node biopsy (SLNB) versus axillary lymph node dissection (ALND) in patients with breast cancer remains. Our aim was to compare the impact of SLNB and ALND on QOL and arm symptoms of patients with early breast cancer, using generic (short form 36 health survey) and tumor site–specific (FACT-B+4) instruments. **Methods:** This was a prospective longitudinal observational study of 93 patients (64 SLNB, 29 ALND). Patients were evaluated presurgery and 1, 6, and 12 months postsurgery. Generalized estimation equation models were constructed to assess the effect of treatment on QOL. The relative risks of edema, dysesthesia, and heaviness were calculated comparing ALND to SLND. **Results:** Most patients presented T1 (67.7%) and underwent breast-conserving surgery (92.5%). At 12 months, the SLNB group presented deterioration on the FACT-B+4 Arm Scale (beta coefficient estimated a change of −1.6 score points; $P < 0.01$) while, compared with SLNB, the deterioration in the ALND group was almost 2 additional score points higher ($P = 0.009$). FACT-B+4 global summary and short form 36 health survey did not show statistically significant differences between groups. Relative risk of dysesthesia and subjective edema was higher for the ALND group than for the SLNB group (1.97 and 2.11 at month 12; $P < 0.01$). **Conclusion:** These results confirm the benefit of SLNB due to its lower arm morbidity impact on QOL, compared with ALND. There are clinically relevant between-treatment differences in the Arm Scale of FACT-B+4, while there were no relevant differences in general well-being, measured with the disease-specific FACT-B+4 and the generic short form 36 health survey.

Keywords: breast cancer, health-related quality of life.

Introduction

Breast cancer is the most prevalent cancer among women in developed countries. In Spain, the incidence is 81.1 new cases a year per 100,000 women, the 5-year survival is 82%, and consequently the prevalence of women who have undergone breast cancer is very high [1,2]. This means that minimizing the morbidity associated with breast cancer treatments and maintaining quality of life (QOL) are priority goals.

The clinical stage plays a central role in the breast cancer surgical approach. Breast-conserving surgery is considered the standard option in early stages [3], and full dose of radiotherapy must be delivered usually after. Breast-conserving surgery provides a better body image than mastectomy initially after surgery [4]. The mastectomy approach must be chosen when there is a high risk of local recurrence. Large tumors in a small breast, persistent positive margins after resection, diffuse calcifications, predictable poor cosmetic outcome, and contraindications to radiation therapy are breast-conserving contraindications. Finally, women with early stage breast cancer may opt for mastectomy because of personal preference.

Lymph node spread is an important prognostic factor in breast cancer. In early stage tumors, with clinically and ultrasound negative involvement of the axilla, node spread can be determined by the technique of selective sentinel lymph node biopsy (SLNB). The American Society of Clinical Oncology in 2005 [5], and more recently the British Association of Surgical Oncology [6], endorsed SLNB as the recommended method of staging early breast cancer in clinically node negative patients because of its benefits compared with axillary dissection on arm morbidity. When sentinel nodes are tumor free, axillary lymph node dissection (ALND) is considered unnecessary [7], and so SLNB enables a large number of patients to save their axillary nodes and, consequently, avoid the potential side effects of axillary clearance [8–12]. Despite the extension of this conservative method, ALND remains a necessary technique in node-pos-

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Table 1 – Patient characteristics.

	All (n = 93)	SLNB (n = 64)	ALND (n = 29)	P
Age (y), mean ± SD	59.2 ± 8.6	59.8 ± 8.8	57.9 ± 8.0	0.320
Body mass index (kg/m^2)	32.1 (24.6)	32.7 (29.6)	30.7 (5.3)	0.711
Affected side				
Dominant	51 (58.0%)	34 (56.7%)	17 (60.7%)	0.720
Nondominant	37 (42.0%)	26 (43.3%)	11 (39.3%)	
Surgery technique				
Breast conserving	86 (92.5%)	64 (100.0%)	22 (75.9%)	<0.001
Mastectomy	7 (7.5%)	0 (0.0%)	7 (24.1%)	
T (tumor size category)				
IS	9 (9.7%)	9 (14.1%)	0 (0.0%)	<0.001
1	63 (67.7%)	48 (75.0%)	15 (51.7%)	
2	20 (21.5%)	7 (10.9%)	13 (44.8%)	
3	1 (1.1%)	0 (0.0%)	1 (3.4%)	
N (node involvement)				
0	68 (73.1%)	64 (100.0%)	4 (13.8%)	<0.001
1	22 (23.7%)	0 (0.0%)	22 (75.9%)	
2–3	3 (2.2%)	0 (0.0%)	3 (10.3%)	
Tumor size (mm)	13.9 (7.4)	12.6 (6.1)	18.1 (9.4)	0.009
Number of lymph nodes removed, mean ± SD	6.1 ± 7.4	1.6 ± 0.8	16.0 ± 5.1	<0.001
Histology				
Ductal carcinoma	82 (88.2%)	58 (90.6%)	24 (82.8%)	0.277
Lobular carcinoma	11 (11.8%)	6 (9.4%)	5 (17.2%)	
Multiple primary neoplasm				
No	81 (87.1%)	58 (90.6%)	23 (79.3%)	0.132
Yes	12 (12.9%)	6 (9.4%)	6 (20.7%)	
Differentiation				
I	27 (32.9%)	23 (39.7%)	4 (16.7%)	0.128
II	32 (39.0%)	20 (34.5%)	12 (50.0%)	
III	23 (28.0%)	15 (25.9%)	8 (33.3%)	
Radiotherapy	84 (90.3%)	58 (90.6%)	26 (89.7%)	0.883
Chemotherapy	47 (50.5%)	21 (32.8%)	26 (89.7%)	<0.001
Hormonotherapy	70 (75.3%)	48 (75.0%)	22 (75.9%)	0.929
Education				
Primary	61 (69.3%)	42 (71.2%)	19 (65.5%)	0.588
Secondary and university	27 (30.7%)	17 (28.8%)	10 (34.5%)	
Work				
Employed	34 (38.6%)	25 (42.4%)	9 (31.0%)	0.689
Unemployed	4 (4.5%)	3 (5.1%)	1 (3.4%)	
Housewife	31 (35.2%)	18 (30.5%)	13 (44.8%)	
Permanently incapacitated	2 (2.3%)	1 (1.7%)	1 (3.4%)	
Retired	17 (19.3%)	12 (20.3%)	5 (17.2%)	

ALND, axillary lymph node dissection; SLNB, sentinel lymph node biopsy.

itive cases or is still applied as the first option in a significant number of patients.

Several studies comparing both surgical procedures, SLNB and ALND, showed that SLNB is associated with shorter hospital stay, earlier return to normal activity, and lower rates of short- and long-term morbidities, such as infection, seroma, shoulder movement impairment [11–15], neuropathy, and upper limb lymphedema [16–18].

However, QOL benefits of SLNB are not as clearly demonstrated. Most studies presented some methodological problems, such as the absence of pretreatment assessment and reliable and validated QOL instruments. Kootstra et al. [19], focusing on published well-designed prospective studies (observational or randomized clinical trials), pointed out that there were no differences in QOL between women treated with SLNB or ALND. The Axillary Lymphatic Mapping Against Nodal Axillary Clearance (ALMANAC) trial was the only exception to this pattern, showing better QOL among women of the SNLB group [20]. This striking discrepancy has been explained by suggesting certain limitations in the questionnaires to cover all relevant aspects in this area [21,22]. All the above studies used generic QOL instruments such as short form 36 health survey (SF-36) or European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30), whereas the ALMANAC trial was the only one using the FACT-B+4, a tumor site–specific instrument.

The main objective of this study was to compare the impact of SLNB and ALND on the QOL of patients with early breast cancer during the first year after surgery using both generic (SF-36) and tumor site–specific (FACT-B+4) instruments that assess upper limb impairment.

Methods

This was a prospective longitudinal observational study of incident breast cancer patients with surgery as first treatment. Authorization was obtained from the Ethics Committee on Medical Research, and all participants gave their written informed consent.

Consecutive patients of all ages were recruited from the surgery department of a general university hospital with a commu-