

Quality of Life After Sentinel Lymph Node Biopsy Versus Complete Axillary Lymph Node Dissection in Early Breast Cancer: A 3-Year Follow-up Study

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Key Words: breast cancer; sentinel lymph node biopsy; axillary lymph node dissection; quality of life.

Abstract. *Background and Objectives.* The rating of life quality may belong to the method of surgical treatment: after the axillary lymph node dissection patients may suffer from arm symptoms; after sentinel lymph node biopsy women may highlight the anxiety about the success of radical treatment. The aim was to assess the influence of sentinel lymph node biopsy on the quality of life of the patients with early stage breast cancer compared with total axillary lymph node dissection.

Material and Methods. In a prospective case-control study, 48 patients with early invasive breast cancer and no evidence of lymph nodes involvement underwent breast conserving surgery with sentinel lymph node biopsy. They were grouped as matched pairs with the patients who underwent axillary lymph node dissection, according to the age, TNM stage, localization, hormonal receptor status, and surgical characteristics. Quality of life was evaluated using the QLQ-C30 and QLQ-BR-23 questionnaires before surgery and after 1, 3, 6, 12, and 36 months.

Results. The patients who underwent sentinel lymph node biopsy scored better on the emotional functioning, pain, sexual functioning, and future perspective scales in comparison with those who underwent axillary lymph node dissection. The score on the arm symptom scale remained significantly better in the sentinel lymph node biopsy group than the axillary lymph node dissection group within the overall follow-up period.

Conclusions. The women who underwent sentinel lymph node biopsy experienced better quality of life than the patients who underwent axillary lymph node dissection.

Introduction

Breast cancer is the most common cancer among women across the world, especially in economically developed countries. The standard local treatment of early breast cancer is oncoplastic breast-conserving surgery with sentinel lymph node biopsy. Due to breast cancer screening and new adjuvant treatment with new biological agents, survival after breast cancer has improved, and the number of breast cancer survivors is constantly increasing (1). During 2002–2007, breast cancer mortality rates declined by 6.9% in the European Union and by 6.3% in Lithuania (2). Nearly 70%–80% of patients with breast cancer remain alive, and quality of life (QoL) plays a significant role in women's well-being.

Numerous nonrandomized studies comparing sentinel lymph node biopsy (SLNB) with axillary lymph node dissection (ALND) have been carried out (3–5). However, the patients undergoing dissec-

tion were predominately those with nodal involvement, making difficult to separate out the effects on QoL due to differences in axillary surgery from those to the differences in adjuvant treatment and prognosis (6). Other studies comparing QoL after SLNB and ALND had limitations, such as the use of nonvalidated questionnaires, only one postoperative measurement, lack of clarity about the stage of breast cancer in the study population, obscure information about the extent of ALND, or small sample size, as well that groups were treated according to the intention-to-treat principle, which implies that the SLNB group also contained SLNB-positive patients who underwent secondary ALND, or extended radiotherapy to the axilla (6–8). Some of the patients underwent breast conserving surgery, others mastectomy.

The aim of our study was to assess the impact of SLNB on the quality of life of patients with early stage breast cancer compared with total ALND patients. The “pure” investigative groups with only one difference of lymph node quantity removed was distinguished. The prospective observation period was designed to be 3 years, compared with 2 years in other trials.

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Material and Methods

This prospective, single-institution, case-control study of early breast cancer enrolled 48 consecutive patients with unilateral invasive breast cancer with no clinical and ultrasound evidence of regional lymph node involvement, who underwent oncoplastic breast-conserving surgery with SLNB. All patients were grouped as matched pairs with patients who underwent axillary I–II level lymph node dissection according to the age, TNM stage, localization, hormonal receptor (ER, PR, and HER2) status and surgical characteristics (48 in each group). All the patients underwent type I and II oncoplastic surgery. The mean patients' age was 55 years. The medium tumor size was 17.2 mm, and no lymph node involvement at pathology in any patient was documented. The patients scheduled for mastectomy were not included into the study. The adjuvant systemic treatment (chemotherapy and hormonal therapy) was based on the national protocol, and it was administered in both groups. All patients received radiation therapy at a cumulative dose of 50 Gy, except 1 patient in the ALND group (treatment was not completed due to an allergic reaction).

The primary exclusion criteria were pre-existing shoulder complaints that had been treated surgically, with medication or physiotherapy. The secondary exclusion criteria of the study were applied for 2 patients from the SLNB group and their matched pairs, because of the systemic dissemination of the disease.

The Local Bioethics Committee approved the study protocol and the informed consent form. All patients were given to sign written informed consent for the participation in this study.

QoL was evaluated using the Quality of Life Questionnaire Core 30 of the European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) and the breast module, the EORTC QLQ-BR-23, to assess the global health status and the arm and breast symptom scales. The QLQ-C30 and its breast module BR-23 are validated tools to assess QoL in cancer patients and more specifically in breast cancer patients.

The QLQ-C30 is composed of 30 items which allow generating 15 scores: general health score, 5 scores of functional parameters, 1 score of financial difficulties, and 8 scores of symptoms. The breast cancer module comprises 23 questions assessing disease symptoms and side-effects of treatment.

One day before surgery, the patients filled in the first questionnaire at the hospital. Postoperative questionnaires were filled in the outpatient department at 1, 3, 6, 12, and 36 months after surgery. All patients completed participation in the study.

Continuous and quantitative variables were described by means, standard deviation, medians and percentages. Patients' clinical characteristics were

compared according to the extent of lymph node dissection. The Kruskal-Wallis test was used to test the homogeneity of the compared groups for quantitative variables, and the Pearson chi-square test and the Fisher exact test for qualitative variables were used.

QoL scores were described for each surgical procedure at each follow-up by means, standard deviations, medians and percentages. The Kruskal-Wallis test was used to compare scores of surgical procedure performed for the study patients. The Wilcoxon statistical analysis for matched pairs was used.

Statistical analysis was performed using SPSS version 15. Average values, using Student *t* test with one-tailed confidence level of *P* value less than 0.05 considered statistically significant.

The initial QoL score before surgery was equated to 0 and evaluated as baseline, and the subsequent scores were shown as differences from the baseline.

Results

There were no significant differences in any characteristic of patients or tumor comparing the groups (Table 1), except for the number of removed axillary lymph nodes. The mean number of the lymph nodes removed in the SLNB and ALND groups was 1.95 (SD, 1.4; range, 1–5) and 12.7 (SD, 5.3; range, 7–32), respectively.

The postoperative morbidity rate was 4.1%: 2 patients in the ALND group and 1 patient in the SLNB group developed a donor site infection, and 1 patient in the ALND group had partial flap necrosis ($P=0.36$). The latter patient underwent repeated operation.

Before the surgery, the score of general health was greater in the ALND group, but after the surgery, this score became greater in the SLNB groups at 1-, 3-, 6-, 12-, and 36-month follow-ups ($P>0.05$) (Table 2). Emotional functioning and cognitive functioning were significantly better in the SLNB group than ALND group at the 12-month follow-up ($P<0.05$). The comparison of scale scores after the surgery within the groups showed that women who underwent SLNB rated their emotional functioning significantly better at 1-, 6-, 12, and 36-month follow-ups than before the surgery ($P<0.05$). In the ALND group, pain was scored worse on the pain scale at 1-, 3-, and 6-month follow-ups as compared with the score before the surgery. Fig. 1 depicts the differences in the QLQ-C30 scores on 5 functional scales, 3 symptoms scales, and 5 single-item scales (except for diarrhea) in both the groups within the whole 3-year period.

The comparison of QLQ-BR-23 scores between the SLNB and ALND groups showed that women who underwent SLNB scored their sexual functioning significantly better at 3-, 12-, and 36-month

Table 1. Patient and Tumor Characteristics

Variable	Group		P value
	SLNB N=48	ALND N=48	
Tumor			
T1	27 (28.1)	24 (25)	0.539
T2	21 (21.9)	24 (25)	
Node			
N0	48 (50)	48 (50)	
Localization			
C50.1	2 (2.1)	4 (4.2)	0.616
C50.2	8 (8.3)	5 (5.2)	
C50.3	6 (6.3)	3 (3.1)	
C50.4	24 (25)	26 (27.1)	
C50.5	8 (8.3)	10 (10.4)	
Histology			
ductal	37 (38.5)	34 (35.4)	0.710
lobular	8 (8.3)	9 (9.4)	
other	3 (3.1)	5 (5.2)	
Grade			
G1	9 (9.4)	5 (5.2)	0.090
G2	31 (32.3)	26 (27.1)	
G3	8 (8.3)	17 (17.7)	
Perivascular invasion			
L0	31 (32.3)	34 (35.4)	0.513
L1	17 (17.7)	14 (14.6)	
V0	33 (34.4)	32 (33.3)	0.827
V1	15 (15.6)	16 (16.7)	
Hormone receptor status			
Estrogen (ER)			
–	16 (16.7)	19 (19.8)	0.921
+	5 (5.2)	5 (5.2)	
++	4 (4.2)	3 (3.1)	
+++	23 (24)	21 (21.9)	
Progesterone (PR)			
–	24 (25)	20 (20.8)	0.574
+	5 (5.2)	9 (9.4)	
++	7 (7.3)	5 (5.2)	
+++	12 (12.5)	14 (14.6)	
Her-2-neu			
–	41 (42.7)	39 (40.6)	0.584
+++	7 (7.3)	9 (9.4)	
Oncoplastic operation type			
I	33 (34.4)	26 (27.1)	0.142
II	15 (15.6)	22 (22.9)	
Chemotherapy			
Yes	35 (36.5)	37 (38.5)	0.637
No	13 (13.5)	11 (11.5)	
Radiotherapy			
Yes	48 (50)	47 (1)	0.315
No	0	1 (1)	
Hormonal therapy			
Yes	28 (29.2)	25 (26)	0.538
No	20 (20.8)	23 (24)	

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

follow-ups than their counterparts in the ALND group ($P<0.05$). Moreover, the score on the arm symptom subscale was significantly worse at 1-, 6-, and 36-month follow-ups in the ALND than SLNB group ($P<0.05$).

The comparison of subscale scores after the surgery within the groups showed that women who underwent SLNB rated their future perspective sig-

nificantly better at 6-, 12, and 36-month follow-ups than before the surgery ($P<0.05$). Both the groups reported significantly worse scores on the breast symptom subscale at 1- and 6-month follow-ups as compared with the baseline scores ($P<0.05$). Only women in the ALND group gave worse scores on the arm symptom subscale ($P<0.05$).

Fig. 2 shows the differences in the QLQ-BR-23 scores on all subscales in both the groups within the whole 3-year period.

Discussion

There are numerous studies that compared the quality of life of patients who underwent ALND or SLNB (1, 3–10). However, in these studies, the patients who underwent breast-conserving surgery or mastectomy were included in the same group. In order to disclose the advantages of SLNB over axillary dissection, patients should be treated similarly, i.e., either mastectomy or breast-conserving surgery should be performed (4), but morbidity after mastectomy may mask any benefit of sentinel lymph node biopsy (11–13). The NSABP B-32 trial compared the mastectomy and breast-conserving groups separately. Among patients who were scheduled for mastectomy, longitudinal analysis revealed that ALND patients reported significantly greater arm use avoidance, arm swelling, arm and breast numbness, arm skin sensitivity, arm tightness, and social limitations than SLNB patients (13). The treatment difference in arm swelling diminished over time, but other differences persisted (13).

Our patients were examined as separate groups: those who underwent SLNB or ALND. Therefore, we had the chance to obtain “pure” groups with no difference in treatment options, except the extent of axillary lymph node dissection, and compare the results during the 3-year follow-up period. The most widely used QLQ-C30 and breast cancer module BR-23 questionnaires, which are validated tools to assess QoL in patients with cancer, specifically with breast cancer, were applied in this study. Four of the studies reporting longitudinal data on quality of life had a prospective design (3, 6–8). These studies demonstrated that overall QoL was significantly better in patients who underwent SLNB during the postoperative period. This confirms that the symptoms after axillary dissection are important for women’s overall perception of QoL. However, there was a slight difference in the treatment results at 6 months, but there was no difference at 36 months.

Similarly, 2 trials – GIVOM and ALMANAC – showed no negative effect of SLNB on mental or emotional function. The authors of these studies concluded that SLNB was associated with reduced arm morbidity and better QoL, with no increase in anxiety (3, 6). In our study, the greatest differenc-

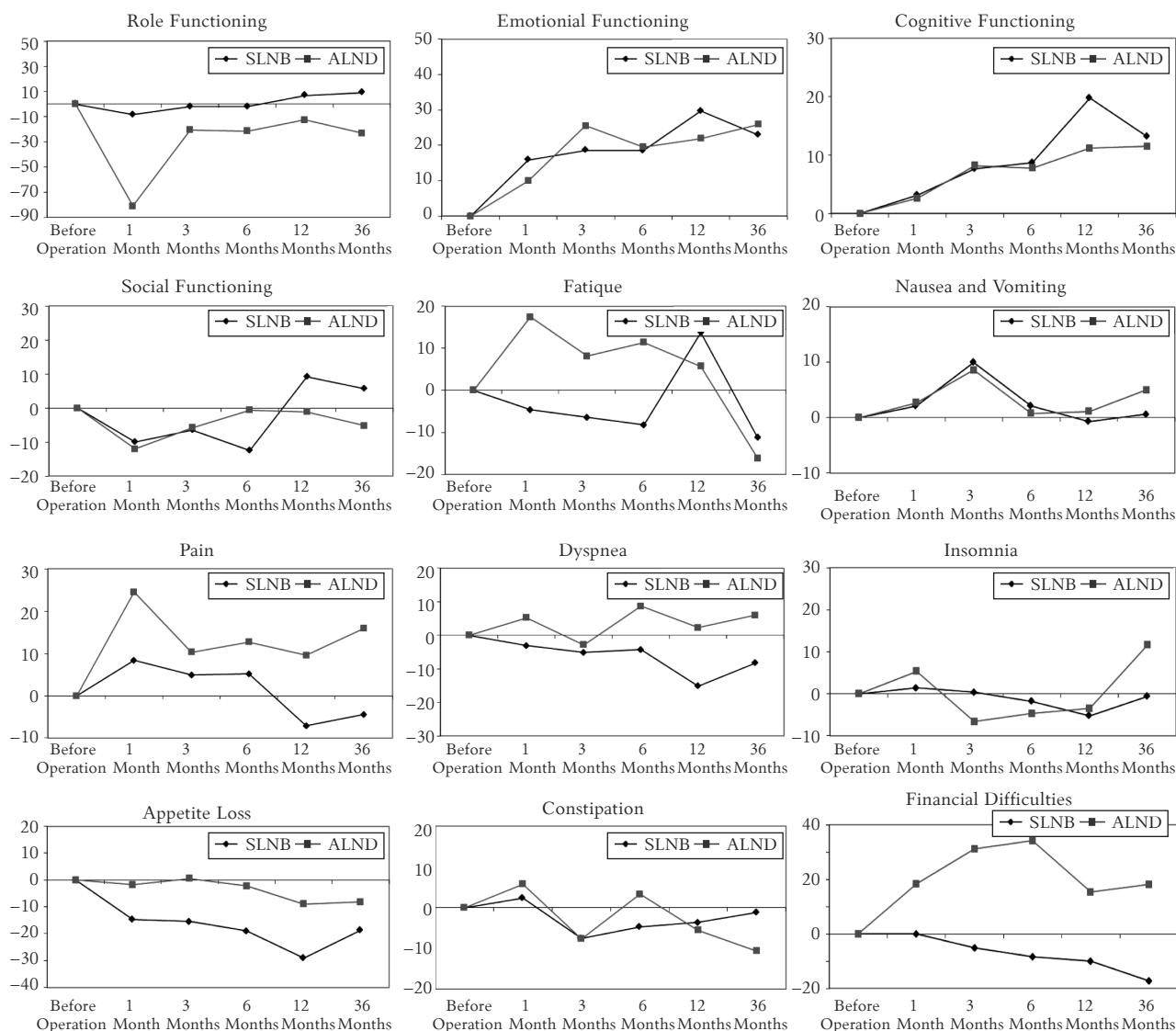


Fig. 1. The differences of QoL from baseline level in QLQ-C30 scores comparing SLNB and ALND groups in 3 years follow-up

es between the groups were observed on the arm symptom subscale with the better scores being in the SLNB group, and the differences remained significant at 1-, 6-, and 36-month follow-ups. The arm symptoms may affect physical, emotional, and even sexual functioning that finally results in the reduced perception of QoL and even future perspective. The score of arm symptoms in ALND group remained higher in comparison to baseline during the all 3 year observation period, ipso facto it differed from the results obtained in other studies.

A meta-analysis by Wang et al. showed that the pooled OR for lymphedema was 0.24 (95% CI, 0.11–0.53), with the rate of postoperative lymph edema being higher in the ALND group (14). All the included studies reported a significantly greater impairment of arm movement in patients allocated to ALND than those allocated to SLNB (14).

The follow-up period differs across the trials. In our study as well as in the NSABP B-32 trial, the patients were followed up for 3 years, but the authors of NSABP B-32 study mentioned that there were no available, well-validated, widely used instruments to measure arm and breast morbidity for their study (13). Most frequently, the observation lasted for 2 years (13).

The data of longer term follow-up are available from small observational studies (15–22). In one study with a mean follow-up of 6.6 years after ALND and of 4.9 years after SLNB, ALND was associated with a significantly greater likelihood of subjective arm numbness, chest or axillar numbness, and arm or hand swelling (23). In other study, symptoms were moderately expressed but were worse among patients who received ALND, even after 2 years (11). Therefore, these results did not

Table 2. The Mean QLQ-30 Scores in the Sentinel Lymph Node Biopsy (SLNB) and Axillary Lymph Node Dissection (ALND) Groups During the 3-Year Follow-up

Scale	Group	Before Surgery	After Surgery				
			1 Month	3 Months	6 Months	12 Months	36 Months
General health	SLNB	61.5 (22.3)	74.7 (18.2)	70.1 (24.9)	65.7 (19.4)	78.3 (20.3)	71.4 (20.4)
	ALND	68.6 (24.6)	65.7 (22.2)	62.5 (18.3)	64.7 (28.9)	68.9 (21.8)	69.4 (17.0)
Physical functioning	SLNB	77.2 (19.0)	73.9 (22.5)	78.3 (25.1)	79.3 (20.2)	81.3 (17.4)	78.5 (20.6)
	ALND	84.2 (21.6)	68.8 (21.7)	80.4 (13.7)	76.0 (22.2)	78.1 (16.8)	75.0 (18.2)
Role functioning	SLNB	75.6 (26.8)	67.3 (28.7)†	73.6 (29.9)	73.7 (29.0)	82.5 (26.2)	84.8 (21.8)
	ALND	86.1 (23.0)	65.1 (34.3)	65.6 (23.9)	64.6 (25.0)	73.7 (24.1)	69.6 (29.6)
Emotional functioning	SLNB	57.0 (28.3)	72.9 (27.9)†	75.6 (21.3)	75.5 (21.3)†	86.7 (23.2)†	79.9 (29.2)†
	ALND	50.5 (28.2)	60.5 (28.7)	76.0 (17.2)	70.0 (30.5)	72.4 (26.1)*	76.4 (23.4)
Cognitive functioning	SLNB	70.7 (26.0)	73.3 (23.6)	77.8 (20.1)	78.8 (25.4)	89.9 (12.6)	83.3 (21.8)
	ALND	66.7 (27.4)	69.3 (26.8)	74.9 (23.6)	74.5 (22.9)	77.9 (22.4)*	78.2 (23.3)
Social functioning	SLNB	80.0 (26.8)	70.1 (29.9)	73.6 (35.4)	67.6 (27.7)	89.2 (16.5)	85.7 (26.0)
	ALND	78.7 (24.8)	66.7 (22.9)	72.9 (23.5)	78.1 (23.4)	77.6 (27.0)	73.5 (29.0)
Fatigue	SLNB	41.5 (32.7)	36.9 (23.9)	35.1 (29.0)	33.3 (28.8)	27.8 (27.8)	30.3 (27.0)
	ALND	25.9 (23.5)	43.3 (31.0)	34.0 (22.4)	37.3 (28.6)	31.6 (23.5)	35.7 (30.3)
Nausea and vomiting	SLNB	3.2 (8.2)	5.3 (10.5)	13.2 (17.0)	5.3 (9.7)	2.5 (8.2)	3.8 (14.5)
	ALND	0.8 (3.8)	3.5 (7.0)	9.4 (14.9)	5.9 (13.0)	1.9 (5.4)	5.8 (15.6)
Pain	SLNB	26.3 (28.4)	34.7 (24.5)	31.2 (28.8)	31.5 (27.9)	19.2 (21.2)	21.9 (22.6)
	ALND	16.7 (19.0)	41.2 (33.0)†	27.0 (17.0)†	29.4 (24.7)†	26.3 (23.2)	32.6 (23.8)
Dyspnea	SLNB	21.8 (29.7)	18.7 (27.4)	16.7 (29.5)	17.5 (20.4)	6.7 (17.4)	13.6 (22.2)
	ALND	7.0 (21.0)*	12.2 (27.7)	4.2 (16.7)	15.7 (20.8)	9.3 (18.0)	13.0 (24.0)
Insomnia	SLNB	38.5 (38.5)	39.9 (34.7)	38.9 (32.1)	36.7 (28.4)	33.3 (37.5)	37.9 (31.4)
	ALND	42.0 (33.0)	47.4 (37.4)	35.4 (39.4)	37.3 (37.0)	38.5 (38.5)	53.6 (43.5)
Appetite loss	SLNB	30.7 (38.8)	16.0 (25.7)	15.3 (27.8)	11.7 (24.8)	1.7 (7.5)	12.1 (21.9)
	ALND	14.0 (25.6)	12.2 (22.8)	14.6 (27.1)	11.8 (20.2)	5.1 (12.3)	5.8 (19.2)
Constipation	SLNB	26.9 (36.5)	29.3 (33.8)	19.4 (29.3)	22.2 (34.3)	23.3 (34.4)	25.8 (32.4)
	ALND	22.2 (30.3)	28.0 (35.6)	14.6 (21.0)	25.5 (36.4)	16.7 (25.4)	11.6 (23.8)
Diarrhea	SLNB	8.9 (24.0)	1.3 (6.7)	2.8 (9.4)	3.7 (10.8)	1.7 (7.5)	4.5 (15.6)
	ALND	7.4 (21.6)	5.2 (16.7)	4.2 (11.4)	0 (0)	6.4 (16.4)	7.2 (20.0)
Financial difficulties	SLNB	39.9 (33.3)	39.9 (37.3)	34.7 (33.3)	31.5 (33.3)	29.9 (30.4)	22.7 (31.5)
	ALND	16.7 (30.8)*	35 (28.3)	47.9 (36.5)	50.9 (41)	32 (31.2)	34.8 (34.0)

* $P < 0.05$ comparing the groups.† $P < 0.05$ comparing with the baseline values within the groups.

Table 3. The Mean QLQ-BR-23 Scores in the Sentinel Lymph Node Biopsy (SLNB) and Axillary Lymph Node Dissection (ALND) Groups During the 3-Year Follow-up

Subscale	Group	Before Surgery	After Surgery				
			1 Month	3 Months	6 Months	12 Months	36 Months
Body image	SLNB	77.2 (18.3)	75.3 (28.1)	72.2 (31.1)	78 (27.1)	86.8 (24.4)	78.4 (34.0)
	ALND	78.7 (17.9)	69.7 (27.5)	81.3 (22.5)	78.4 (29.5)	83.3 (21.0)	82.2 (23.3)
Sexual functioning	SLNB	74.6 (31.6)	78.5 (28.9)	79.2 (24.2)	84.3 (21.0)	80.0 (27.4)	82.5 (24.4)
	ALND	52.7 (31.9)*	62.5 (31.3)	53.1 (21.3)*	68.7 (30.4)	62.9 (25.7)*	73.8 (27.2)
Sexual enjoyment	SLNB	58.8 (41.7)	61.5 (38.1)	61.5 (30.0)	51.9 (33.8)	28.6 (12.6)	80.4 (29.0)
	ALND	49.9 (32.4)	39.4 (29.1)	41.0 (24.2)	46.7 (35.8)	42.2 (29.5)	69.8 (33.2)
Future perspective	SLNB	29.3 (33.8)	39.9 (36.0)	41.7 (33.0)	43.9 (36.9)†	64.9 (26.6)†	46.9 (33.6)†
	ALND	16.6 (20.6)	31.6 (35.9)	39.2 (37.7)	41.2 (38.2)	55.6 (35.0)	53.6 (33.0)
Systemic therapy side effects	SLNB	28.2 (25.1)	22.5 (16.6)	30.6 (20.8)	22.6 (18.2)	17.0 (15.0)	21.9 (20.9)
	ALND	21.9 (19.2)	24.1 (18.9)	31.7 (16.5)	25.2 (18.9)	21.2 (15.5)	23.1 (20.6)
Breast symptoms	SLNB	15.7 (17.0)	26.0 (19.7)†	21.0 (19.8)	29.9 (15.0)†	20.0 (15.4)	19.7 (17.9)
	ALND	17.5 (17.5)	32.0 (20.8)†	24.0 (22.4)	36.5 (20.8)†	28.1 (20.2)	23.4 (19.7)
Arm symptoms	SLNB	16.4 (16.7)	19.1 (17.1)	18.8 (20.5)	13.7 (13.3)	20.5 (19.0)	13.6 (19.7)
	ALND	15.2 (22.3)	40.9 (21.6)*†	24.2 (17.2)	30.6 (20.5)*†	29.1 (23.8)†	31.7 (28.6)*
Upset by hair loss	SLNB	27.7 (40.0)	33.3 (28.4)	64.6 (33.3)	51.6 (47.5)	6.7 (21.0)	22.2 (32.8)
	ALND	38 (38.4)	33.3 (47.1)	38.9 (42.3)	33.3 (43.0)	33.3 (39.4)*	28.2 (38.1)

* $P < 0.05$ comparing the groups.† $P < 0.05$ comparing with the baseline values within the groups.

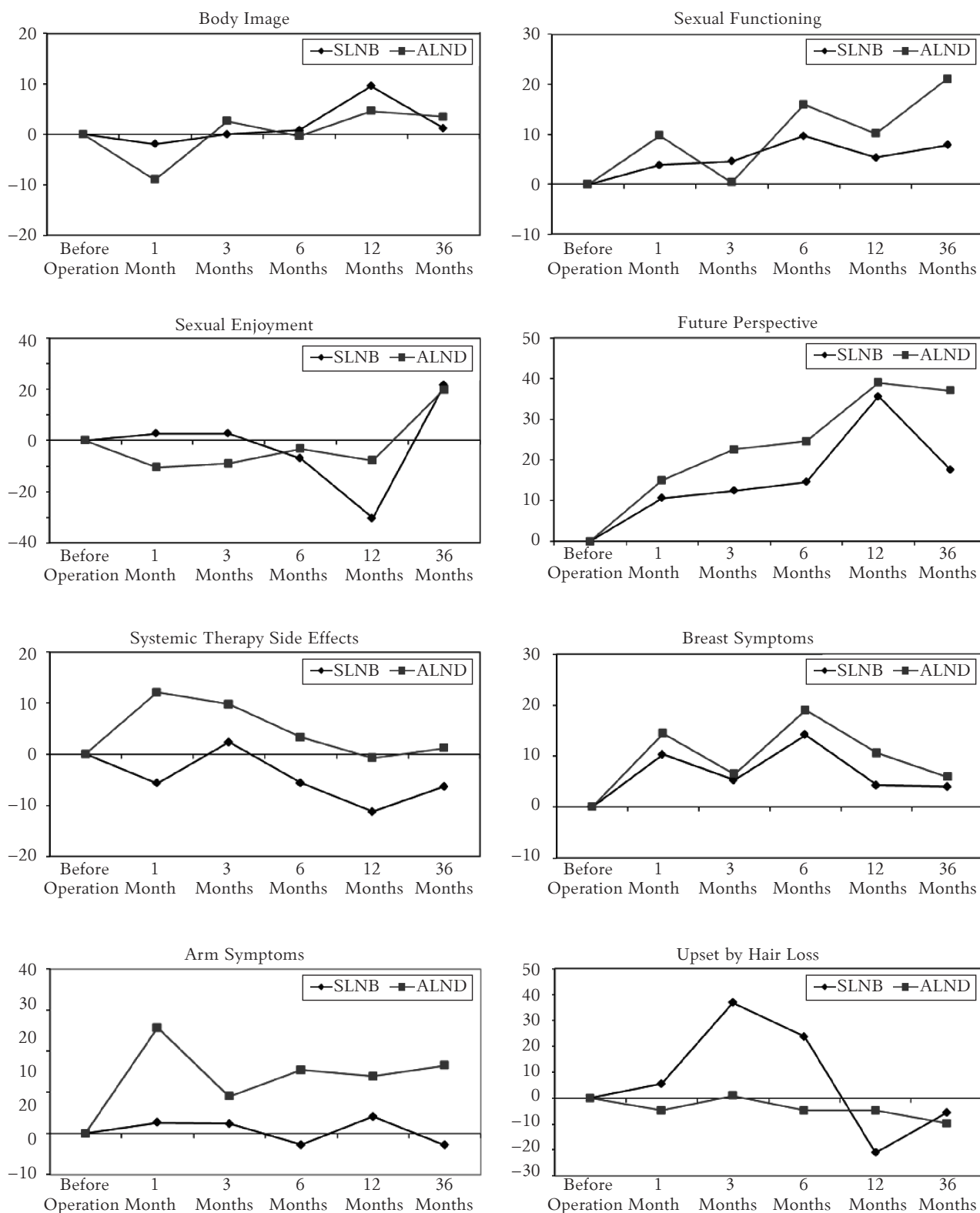


Fig. 2. The differences of QoL from baseline level in QLQ-B23 scores comparing SLNB and ALND groups in 3 years follow-up

differ from those reported in the 3-year follow-up trials. Longer follow-up seems to be meaningless.

Considering all the above studies, QoL was better in the SLNB group, except for the study by Za-

vagno et al. (24), where no significant differences in all HRQOL domains of the SF-36 were found between the groups. However, the authors reported that the mean scores of the anxiety were significant-

ly better in the SLNB group (24) and that the number of enrolled patients was not sufficient to draw definitive conclusions.

Conclusion

The patients with early stage breast cancer after oncoplastic breast operation and sentinel lymph node biopsy reported better quality of life, reporting better scores on the emotional functioning, pain,

sexual functioning, and future perspective scales in comparison with the axillary lymph node dissection group. The score on the arm symptom scale remained significantly better in the sentinel lymph node biopsy group than the axillary lymph node dissection group within the all follow-up period.

Statement of Conflict of Interest

The authors state no conflict of interest.

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