

# Quality of Life After Sentinel Lymph Node Biopsy or Axillary Lymph Node Dissection in Stage I/II Breast Cancer Patients: A Prospective Longitudinal Study

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**Background:** Breast cancer patients' quality of life (QoL) after surgery has been reported to improve significantly over time. Little is known about QoL recovery after sentinel lymph node biopsy (SLNB) in comparison to axillary lymph node dissection (ALND).

**Methods:** 175 of 195 stage I/II breast cancer patients completed the EORTC QLQ-C30: one day before surgery (T0) and after 6 (T1), 26 (T2), 52 (T3) and 104 (T4) weeks. Of these, 54 patients underwent SLNB, 56 SLNB+ALND and 65 ALND. General linear models and paired *T*-tests between T0–T4 and T1–T4 were computed. Complications, radiotherapy and systemic therapy were added to the model.

**Results:** Significant time effects were found on physical, role and emotional functioning. Physical and role functioning decreased between T0 and T1. At T4, SLNB patients' functioning had increased to their T0 level; ALND (+/- SLNB) patients' functioning had increased, but had not improved to T0 level. Emotional functioning increased linearly between T0 and T4. At T4, emotional functioning was significantly higher in all groups as compared with T0. No significant group or interaction (time × group) effects were found. Complications and chemotherapy had a significant negative effect on role, emotional and cognitive functioning. Complications had a significant effect on social functioning also. Effect sizes varied between 0.00 and 0.06.

**Conclusion:** Two years post surgery, breast cancer patients' QoL is comparable to that shortly before surgery. Women rated their emotional functioning as even better. SLNB is not associated with a better QoL than ALND. However, undergoing systemic therapy and/or experiencing complications affects QoL negatively.

**Key Words:** Breast—Cancer—Quality of life—SLNB—ALND—Stage I–II.

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One in eight women will be confronted with breast cancer during their life.<sup>1</sup> Breast cancer is the most common malignancy in women in Western countries. At present, the incidence of breast cancer in Europe is

94.3 per 100,000. With a mortality of 26.0 per 100,000, breast cancer is the most frequent cause of death in women.<sup>2</sup> However, due to breast cancer screening and new adjuvant systemic and/or hormone therapies survival after breast cancer has improved by 7–11% over the past few years.<sup>3–5</sup> Consequently, the group of breast cancer survivors is gradually increasing, making it increasingly important to gain insight into their quality of life.

In general, the quality of life of breast cancer survivors is reported to be good and comparable with that of the normal population.<sup>6–15</sup> However, 20–30% of breast cancer survivors continue to have problems adjusting or experience a decreased quality of life.<sup>16</sup> It is therefore essential to identify risk factors for poorer functioning.

As far as treatment characteristics are concerned, it has been reported that women who underwent a mastectomy<sup>17</sup> and/or (adjuvant) systemic therapy had a lower quality of life than women who did not receive these therapies.<sup>6,18–21</sup> However, other research groups did not find any difference in quality of life between these groups.<sup>13,22</sup> In addition, adjuvant radiotherapy, particularly to the axilla, was found to be related to functional problems in the arm and shoulder.<sup>23</sup>

In the 1990s, axillary lymph node dissection (ALND) was replaced by sentinel lymph node biopsy (SLNB) in breast cancer patients with a clinically and ultrasound-negative axilla.<sup>24,25</sup> With the aid of SLNB, it is possible to identify positive axillary lymph nodes in a minimally invasive manner. Nowadays, SLNB is a proven safe surgical method that causes less morbidity than ALND.<sup>26–29</sup> In about one-third to three-quarters of breast cancer patients, SLNB prevents unnecessary staging dissection of the axillary lymph nodes.<sup>30–36</sup>

Several studies compared quality of life between patients who underwent ALND and women who underwent SLNB.<sup>37–43</sup> These studies showed that the SLNB women experienced a comparable or better quality of life than the ALND patients. However, these studies had limitations, such as the use of nonvalidated questionnaires, only one postoperative measurement was performed, lack of clarity about the stage of breast cancer in the study population, or obscure information about the level of axillary lymph node dissection. Four of these studies obtained longitudinal data on quality of life and had a prospective design.<sup>39,41–43</sup> The limitations in these studies were small population size,<sup>41</sup> or 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 radiotherapy to the axilla.<sup>39,42</sup>

The aim of the present study was to measure the course of quality of life over a period of 2 years in women with stage I or II breast cancer who underwent SLNB, or SLNB followed by ALND (SLNB + ALND), or ALND. It was assumed that (1) quality of life after treatment for breast cancer would improve over the course of time and (2) that there would be fewer limitations in quality of life postoperatively after SLNB than after SLNB + ALND or ALND. This study forms part of a larger study on functional shoulder complaints after breast cancer treatment.<sup>44</sup>

## METHODS

### Patients

Over a 2-year period, all the women suspected of having stage I or II breast cancer at the University Medical Centre Groningen (UMCG) and the Martini Hospital Groningen (MZ) were informed by the nurse practitioner about and invited to participate in a prospective study on quality of life following breast cancer treatment. Exclusion criteria were distant metastases and pre-existing shoulder complaints that had been treated surgically, with medication or physiotherapy. All the participants gave written informed consent.

The patients filled in the first questionnaire at the hospital on the day before surgery (T0). Postoperative questionnaires were sent to the patients 2 weeks before each follow-up appointment, at 6 weeks (T1), 6 months (T2), 1 year (T3) and 2 years (T4). Questionnaires were filled in at home and returned to us in a stamped addressed envelope, or brought along to the outpatient check-up. The study was approved by the Medical Ethics Committees (METCs) at the two hospitals.

### Treatment

The breast cancer patients underwent SLNB, SLNB + ALND, or ALND. SLNB was conducted as described previously.<sup>45</sup> When lymph node metastases were found in the SLNB, level I–II ALND was performed within 2 weeks. Surgical treatment consisted of breast-conserving treatment or mastectomy. All the women who underwent breast-conserving treatment received postoperative radiotherapy to the breast. Adjuvant systemic chemotherapy, hormonal

treatment and/or locoregional radiotherapy was given according to the national guidelines.<sup>46</sup>

**Questionnaires**

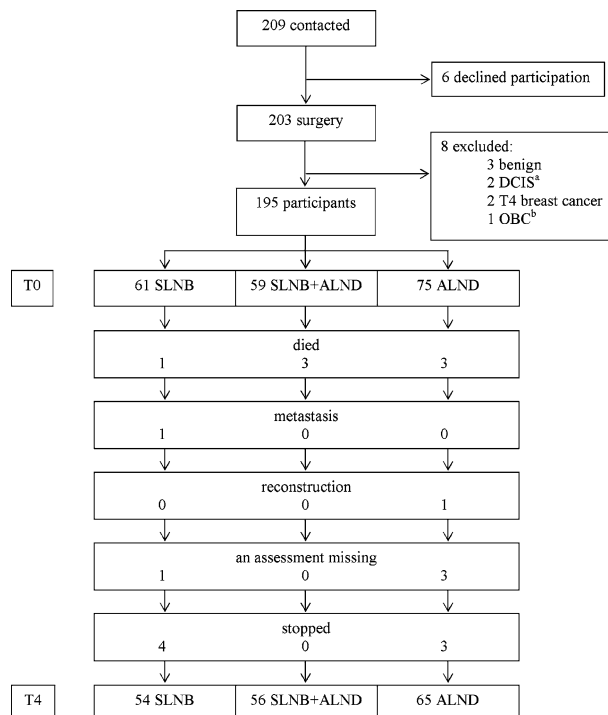
Quality of life was measured using the EORTC-QLQ C-30, developed by the European Organisation in Research and Treatment of Cancer (EORTC) study group. It is a frequently used (nationally and internationally), validated, 30-question cancer-specific health-related questionnaire.<sup>47</sup> In this study, we analysed the global quality of life score and the five functional scales (physical, role, cognitive, emotional and social). Each item has four answer categories: 1 = not at all, 2 = a little, 3 = rather a lot, 4 = very much. Scores were transformed into a scale from 0 to 100 according to the manual, on which a higher global quality-of-life score and higher functional scores corresponded with better quality of life.<sup>48</sup>

**Statistical Analysis**

Descriptive analyses were used to evaluate the study groups.  $\chi^2$  and *T*-tests were used to compare the women who underwent SLNB to the other two groups (SLNB + ALND and ALND) at T0. A general linear model (GLM) procedure analysed longitudinal time, group (SLNB, SLNB + ALND and ALND) and interaction (time × group) effects on the EORTC-QLQ-C30 subscales. The level of clinical relevance was calculated using the effect size, in which an effect size of 0.20–0.49 reflected a small clinically relevant difference, an effect size of between 0.50–0.80 reflected a moderate clinically relevant difference and >0.80 reflected a large clinically relevant difference.<sup>49</sup> To evaluate whether recovery occurred and/or returned to the preoperative level (T0–T4) and whether postoperative recovery was significant (T1–T4), paired *T*-tests were used. A difference of 5–10 points on the quality-of-life subscale of the EORTC-QLQ-C30 meant a small clinically relevant difference, a difference of 10–20 points meant a moderate clinically relevant difference and a difference of >20 points meant a large clinically relevant difference.<sup>50</sup> All the statistical procedures were carried out with SPSS 14. Differences were significant at a *p* value of 0.05 or smaller.

**RESULTS**

Only six patients decided not to participate in the study before their operation. A total of 203 patients filled in the preoperative assessment. The surgical



**FIG. 1.** Flow chart of patients.

findings in eight patients showed that they did not meet the inclusion criteria: three patients had a benign tumour, two patients had ductal carcinoma in situ (DCIS), two patients had a stage 4 tumour and in one patient the primary tumour could not be identified. Consequently, 195 out of 201 eligible patients (response rate 97%) were included in the study. It was found that three patients had not fully completed the preoperative questionnaire. At T1, 6 weeks after surgery, 190 (97%) patients returned the questionnaire; at T2, 6 months after surgery, 186 patients returned the questionnaire; at T3, 1 year after surgery, 181 (93%) returned the questionnaire; at T4, 2 years after surgery, 175 (90%) returned the questionnaire. Reasons why the 20 patients (7 SLNB, 3 SLNB + ALND, 10 ALND) dropped out were: seven had died from the disease (1 SLNB, 3 SLNB + ALND, 3 ALND), one SLNB patient was found to have distant metastases at T4, one ALND patient was excluded because of breast reconstruction, four patients had missing values (1 SLNB, 3 ALND) and seven patients dropped out because of lack of interest (4 SLNB, 3 ALND) (Fig. 1).

In the remaining group of 175 patients, 110 had undergone SLNB (63%). The biopsy had been positive in 56 patients (51%) and followed by ALND (Fig. 1). Therefore, the SLNB group was comprised

TABLE 1. Patient characteristics

Variable	SLNB(N = 54)	SLNB+ALND (N = 56)	ALND(N = 65)	Test value	P
Age, years					
Mean (SD)	58.1 (11.8)	53.75 (9.9)	56.5 (11.1)	F = 2.19 <sup>d</sup>	0.124
TNM classification <sup>a</sup>	N (%)	N (%)	N (%)	$\chi^2 = 49.24$	<0.001 <sup>e</sup>
Stage I	41 (76)	8 (14)	28 (43)		
Stage II A	12 (22)	42 (75)	25 (38)		
Stage II B	1 (2)	6 (11)	12 (19)		
Breast surgery				$\chi^2 = 15.28$	<0.001
BCT <sup>b</sup>	37 (69)	40 (71)	26 (40)		
Mastectomy	17 (31)	16 (29)	39 (60)		
Complications				$\chi^2 = 9.07$	0.011 <sup>f</sup>
No	49 (90)	38 (68)	47 (72)		
Yes					
> 4 weeks seroma	2 (4)	6 (11)	10 (16)		
Inflammation <sup>c</sup>	3 (6)	12 (21)	8 (12)		
Radiotherapy				$\chi^2 = 10.63$	0.005 <sup>g</sup>
No	17 (31)	12 (21)	32 (49)		
Yes					
Breast	37 (69)	39 (70)	26 (40)		
Breast and axilla	0 (0)	5 (9)	7 (11)		
Systemic therapy				$\chi^2 = 39.89$	<0.001 <sup>h</sup>
No	40 (74)	8 (14)	29 (45)		
Yes					
Chemo + tamoxifen –	4 (8)	8 (14)	13 (20)		
Chemo + tamoxifen +	5 (9)	21 (38)	8 (12)		
Chemo – tamoxifen +	5 (9)	19 (34)	15 (23)		

<sup>a</sup> TNM, tumour node metastasis; <sup>b</sup> BCT, breast-conserving therapy; <sup>c</sup> inflammation treated with antibiotics; <sup>d</sup> one-way analysis of variance (ANOVA); <sup>e</sup> patients diagnosed with breast cancer stage I versus IIa and IIb; <sup>f</sup> no complications versus complications; <sup>g</sup> no radiotherapy versus radiotherapy; <sup>h</sup> no systemic therapy versus systemic therapy.

of 54 patients (31%), the SLNB+ALND group was comprised of 56 patients (32%) and the ALND group was comprised of 65 patients (37%). Patient characteristics of these 175 women are shown in Table 1. Average age at inclusion was 56 years (standard deviation [SD] 11 years); there was no significant difference in age between the three groups. All lumpectomy patients and 11 mastectomy patients received radiotherapy. Tumour–node–metastasis (TNM) classification, breast surgery, complications, radiotherapy and systemic therapy differed between the groups (*p* varied between <0.001 to 0.011). Therefore, the variables complications (yes/no), systemic therapy (yes/no) and radiotherapy (yes/no) were included in the analyses. A second series of analyses was performed in which radiotherapy was replaced by type of surgery because of overlap between the variables radiotherapy and type of surgery. TNM classification determines the adjuvant treatment protocol (radiotherapy and/or chemotherapy) and was therefore not included.

### Quality of Life

At T0, there were no significant differences in the scores on the EORTC-QLQ-C30 subscales between the three groups.

Significant time effects were found for physical, role and emotional functioning (Table 2 and Fig. 2). Emotional functioning improved linearly over the course of time; physical and role functioning decreased between T0 and T1, increased between T1 and T2 and then stabilised. No significant group or time × group interaction effects were found. The effect sizes of time, group and interaction effects varied from 0.000 for the group effect in global quality of life to 0.060 for the time effect in emotional functioning (Table 2).

Complications and systemic therapy had significant effects on role, emotional and cognitive functioning; complications also had a significant effect on social functioning. The women who had complications and/or systemic therapy reported poorer functioning than the women without complications and/or systemic therapy. Radiotherapy did not have any significant effect on the EORTC subscales (Table 2), nor did type of breast surgery (data not shown). The effect sizes of these factors varied between 0.000 and 0.061.

At T4, physical and role functioning were significantly poorer (decrease of between 5–10 points) in the SLNB+ALND and ALND groups than at T0. Emotional functioning at T4 was significantly better in all three groups (increase of between 10–20 points) than at T0. Cognitive functioning was significantly

TABLE 2. General linear model (GLM)

Variable	Effect	F	P	Effect size
gQoL	Time	0.21	0.935	0.001
	Group <sup>a</sup>	0.01	0.993	0.000
	Interaction <sup>b</sup>	1.14	0.331	0.013
	Complications	2.81	0.095	0.016
	Radiotherapy	0.10	0.754	0.001
Physical	Systemic therapy	1.16	0.203	0.010
	Time	3.98	<b>0.003</b>	0.023
	Group	0.20	0.823	0.002
	Interaction	1.57	0.129	0.019
	Complications	0.84	0.361	0.005
Role	Radiotherapy	0.24	0.625	0.001
	Systemic therapy	0.57	0.435	0.003
	Time	4.26	<b>0.002</b>	0.025
	Group	0.53	0.588	0.006
	Interaction	1.04	0.408	0.012
Emotional	Complications	5.85	<b>0.017</b>	0.033
	Radiotherapy	0.09	0.762	0.001
	Systemic therapy	5.45	<b>0.021</b>	0.031
	Time	10.66	<b>&lt;0.001</b>	0.060
	Group	0.16	0.849	0.002
Cognitive	Interaction	0.50	0.857	0.006
	Complications	10.87	<b>0.001</b>	0.061
	Radiotherapy	0.77	0.383	0.005
	Systemic therapy	5.00	<b>0.027</b>	0.029
	Time	1.35	0.284	0.008
Social	Group	0.46	0.633	0.005
	Interaction	1.29	0.245	0.015
	Complications	7.38	<b>0.007</b>	0.042
	Radiotherapy	0.04	0.850	0.000
	Systemic therapy	4.97	<b>0.027</b>	0.029
	Time	1.42	0.225	0.008
	Group	0.30	0.741	0.004
	Interaction	0.44	0.899	0.005
	Complications	6.68	<b>0.011</b>	0.038
	Radiotherapy	2.94	0.089	0.017
	Systemic therapy	3.31	0.071	0.019

gQoL, global quality of life; <sup>a</sup> group = SLNB, ALND, or SLNB + ALND; <sup>b</sup> interaction = effect of time × group.

The values are in bold since they are significant and facilitate reading.

better (increase of less than 5 points) in the SLNB group than at T0 (Table 3).

In the ALND group, global quality of life (increase of between 10–20 points), emotional and cognitive functioning (increases of between 5–10 points) were significantly higher at T4 than at T1. In the SLNB and ALND groups, physical functioning was significantly better (increase of between 5–10 points) at T4 than at T1. Role functioning (increase of between 10–20 points) and social functioning (increase of less than 5 points in the SLNB group, 5–10 points in the SLNB + ALND group and ALND group) were significantly better at T4 than at T1 (Table 3).

## DISCUSSION

This longitudinal study evaluated the quality of life of women with stage I or II breast cancer who were

disease free 24 months after surgery. Comparisons were made between three groups of women who were classified according to the treatment received: SLNB, SLNB + ALND or ALND. It was assumed that quality of life would improve over the course of time and that the women who had undergone SLNB would experience better quality of life than the women who had undergone SLNB + ALND or ALND.

Significant changes over time were found on three subscales of the EORTC. Patterns of change differed between the three subscales. Directly after the operation, women reported their physical and role functioning to be poorer than preoperatively. These improved over the course of time. Changes over time were significant, but the clinical relevance was negligible. At 24 months after the operation, functioning in the women who had undergone ALND (+/- SLNB) was poorer than preoperatively (small clinical difference). This contradicts an earlier study that demonstrated that, after 18 months, the functioning of women who had been treated with SLNB or ALND was comparable to the preoperative level.<sup>39</sup> However, and in line with that study, we found that, in the women who had undergone SLNB, functioning at 24 months after the operation was comparable with the preoperative situation.

Emotional functioning was at the lowest level preoperatively in all three groups of women, but gradually improved with time. It is not surprising that the women experienced high levels of psychological stress after hearing the diagnosis of breast cancer, in view of the life-threatening nature of the disease. All the women who participated in this study were disease free at 24 months after surgery, which suggests that treatment was successful. This seems to be reflected in their improved emotional functioning. The greatest improvement in emotional functioning was seen at the first check-up, 6 weeks after the operation. The improvement in emotional functioning over the 24 months after surgery was moderate in clinical terms in all three groups. An earlier study did not find any significant improvement in emotional functioning over time.<sup>41</sup>

Overall, there were no differences in quality of life between the women treated with SLNB, SLNB + ALND or ALND. This was in agreement with several other studies.<sup>41–43</sup> However, our results were discordant with those of the axillary lymphatic mapping against nodal axillary clearance (ALMANAC) trial, in which the women who underwent SLNB experienced better quality of life than the women who underwent ALND.<sup>39</sup> These results were striking, because the SLNB group in the ALMANAC trial was not homogeneous. Owing to the intention-to-treat

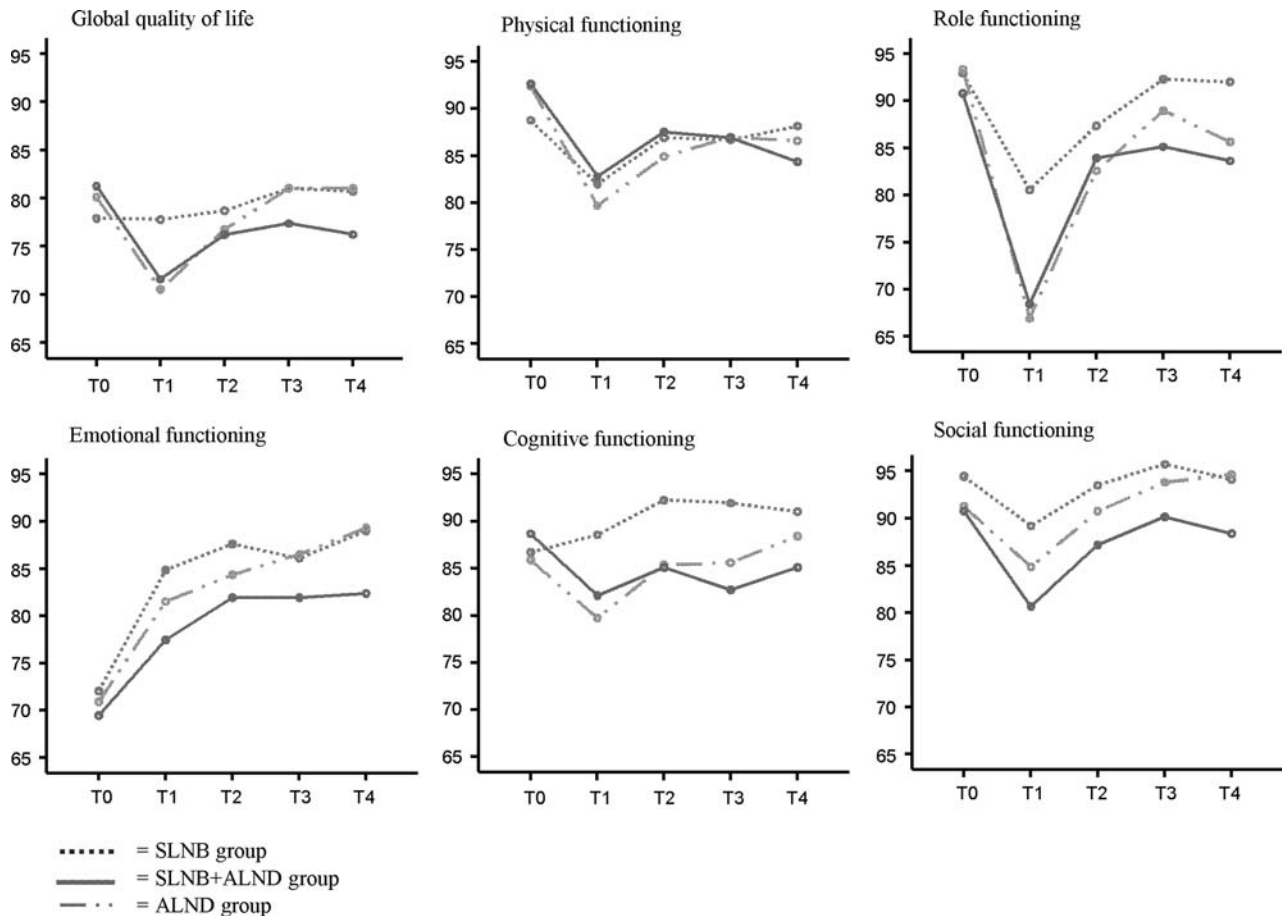


FIG. 2. EORTC-QLQ-C30 global quality of life and the five functional scales.

TABLE 3. Characteristics of the EORTC-QLQ-C30 scales at the different assessment times and paired T-tests

Variable		T0		T1		T2		T3		T4		Paired T-test	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	T0-T4	T1-T4
gQoL <sup>a</sup>	SLNB	77.9	20.3	77.8	17.1	78.7	19.4	81.0	19.4	80.7	19.9	0.264	0.254
	SLNB + ALND	81.2	18.4	71.5	23.6	76.1	18.1	77.3	20.8	76.2	19.5	0.086	0.132
	ALND	80.0	15.6	70.5	18.2	76.7	17.2	81.0	20.6	81.0	17.5	0.692	<0.001
Physical	SLNB	88.8	12.3	82.0	17.0	86.9	13.5	86.7	14.1	88.1	14.2	0.669	0.002
	SLNB + ALND	92.6	9.9	82.7	16.1	87.5	13.3	86.9	13.7	84.3	18.1	<0.001	0.540
	ALND	92.3	10.6	79.6	15.2	84.8	14.0	86.9	12.9	86.5	13.5	0.001	<0.001
Role	SLNB	92.9	18.2	80.6	22.6	87.3	19.4	92.3	16.1	92.0	14.0	0.766	<0.001
	SLNB + ALND	90.7	17.0	68.4	24.3	83.9	22.9	85.1	20.7	83.6	26.1	0.024	<0.001
	ALND	93.3	13.7	66.9	26.7	82.5	21.7	88.9	16.4	85.6	21.8	0.014	<0.001
Emotional	SLNB	72.1	20.0	84.9	17.4	87.7	15.3	86.1	15.3	89.0	19.5	<0.001	0.069
	SLNB + ALND	69.4	20.5	77.4	24.3	81.9	22.0	81.9	23.7	82.4	21.6	<0.001	0.067
	ALND	70.8	18.5	81.5	18.6	84.3	18.5	86.5	17.5	89.3	12.3	<0.001	0.003
Cognitive	SLNB	86.7	15.7	88.6	14.8	92.3	14.4	92.0	14.0	91.0	13.6	0.038	0.280
	SLNB + ALND	88.6	14.2	82.1	17.9	85.1	19.2	82.7	19.5	85.1	17.6	0.122	0.279
	ALND	85.8	16.7	79.7	22.1	85.3	18.9	85.6	20.8	88.4	19.5	0.297	<0.001
Social	SLNB	94.4	10.2	89.2	18.1	93.5	13.9	95.7	9.8	94.1	13.0	0.859	0.038
	SLNB + ALND	90.7	18.5	80.6	22.8	87.2	19.3	90.1	19.0	88.3	20.3	0.446	0.013
	ALND	91.2	15.0	84.8	19.2	90.7	16.1	93.8	17.3	94.6	14.4	0.129	<0.001

<sup>a</sup> Global quality of life; SD, standard deviation; T0, presurgery; T1, 6 weeks post-surgery; T2, 6 months post-surgery; T3, 12 months post-surgery; T4, 24 months post-surgery.

The values are in bold since they are significant and facilitate reading.

**TABLE 4.** Overview of results from longitudinal studies on quality of life comparing SLNB, SLNB+ ALND and ALND in breast cancer patients

Study	Year	Design	Assessment times	Study groups			Measurement instrument	Results
				SLNB	S+A <sup>c</sup>	ALND		
Peintinger et al. <sup>41</sup>	2003	Prospective	T0: pre-surgery T1: post-surgery T2: 9–12 months	25		31	EORTC-QLQ-C30 (functional scales and global QoL)	At T1 SLNB patients reported higher global QoL than at T0. At T2, both groups reported higher global QoL than at T0. No other time differences were found. No differences between groups were found.
Purushotham et al. <sup>42</sup>	2005	RCT	T0: post-surgery T1: 3 months T2: 6 months T3: 12 months	134 <sup>a</sup>		143	SF-36 (physical summary score, physical functioning, vitality)	At T0, SLNB patients reported higher on physical summary score, physical functioning and vitality than ALND patients. No differences between groups were found at later follow-up times.
Fleissig et al. <sup>39</sup>	2006	RCT	T0: pre-surgery T1: 1 months T2: 3 months T3: 6 months T4: 12 months T5: 18 months	424 <sup>b</sup>		405	FACT-B+4 total score, TOI	SLNB patients reported better QoL at all postoperative measurement times and faster recovery to baseline levels than ALND patients. Decline in TOI was > 5 points in the ALND group at T1, T2 and T4. No clinically relevant change in TOI was found in the SLNB group.
Del Bianco et al. <sup>43</sup>	2007	Clinical trial	T0: pre-surgery T1: 6 months T2: 12 months T3: 24 months	159 <sup>a</sup>		151	SF-36 (physical and mental summary scores), PGWB (total index and anxiety)	No differences between study groups were found in the physical and mental summary scores. At T1, SLNB patients reported a higher mean PGBW score. At later measurement times, no significant differences between groups were found. At T1, T2 and T3 both groups reported a decline in physical summary score compared to T0.
Kootstra et al.	2008	Prospective	T0: pre-surgery T1: 6 weeks T2: 6 months T3: 12 months T4: 24 months	54	56	65	EORTC-QLQ-C30 (functional scales and global QoL)	Significant time effects were found in physical, role and emotional functioning. No significant effects of treatment groups were found on any of the scales. At T4, all patients reported higher emotional functioning than at T0. At T4, ALND patients (+/- SLNB) reported lower physical and role functioning than at T0.

<sup>a</sup> SLNB group included women treated with SLNB+ALND; <sup>b</sup> SLNB group included women treated with SLNB+ALND and women treated with SLNB+ axillary radiotherapy. <sup>c</sup> SLNB followed by ALND; RCT, randomised clinical trial; FACT-B+4, functional assessment cancer therapy breast version 4; TOI, trial outcome index; PGWB, psychological general well-being.

principle, it included women with a positive SLNB, adjuvant ALND or axillary radiotherapy. Furthermore, in the ALMANAC trial, ALND was performed to level III, in contrast with our level II, which may have led to more morbidity and lower quality of life.

Lastly, in our study, we included in our analyses treatment-related variables that were found to differ between the groups. The women who had systemic therapy and/or complications reported poorer quality of life on some of the subscales than those without. It appeared that adjustments in QoL were not so much

related to the surgical treatment (SLNB or ALND), but to these treatment-related variables.

Neither radiotherapy nor type of breast surgery had any significant effect on functioning according to the reports made by the women. Earlier publications showed an effect of chemotherapy and an effect of radiotherapy.<sup>51–53</sup> The literature is largely in line with our finding that there is no advantage in quality of life of lumpectomy over mastectomy.<sup>54</sup>

On the whole it should be noted that comparisons with the literature were hampered by differences in study design and measurement instruments (Table 4).

Strong points of our study were the high response rate, the use of a validated disease-specific quality-of-life questionnaire combined with a preoperative assessment, multiple postoperative measurements and a longitudinal analysis on different domains of quality of life. A limitation of the study is that no a priori power analysis was performed. Although attrition was low, the size of the groups may not have been large enough to prevent type I or II errors. However, the clinical relevance of all differences found was negligible in size. It is questionable whether analyses using larger groups would reveal clinically relevant differences.

### CONCLUSION

Physical functioning and role functioning in women with stage I or II breast cancer were lowest directly after the operation, but improved with time. Emotional functioning was lowest preoperatively, but continued to improve postoperatively. There were no differences in quality-of-life domains over the course of time between the patients treated with SLNB, SLNB + ALND or ALND. Women with complications or systemic therapy had poorer role, emotional, cognitive and social functioning than their counterparts without these factors.

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