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Long-term morbidity after a negative sentinel node in breast cancer patients

Reference:

Verbelen Hanne, Tjalma Wiebren, Meirte Jill, Gebruers Nick.- Long-term morbidity after a negative sentinel node in breast cancer patients
European journal of cancer care - ISSN 0961-5423 - 28:5(2019), e13077
Full text (Publisher's DOI): <https://doi.org/10.1111/ECC.13077>
To cite this reference: <https://hdl.handle.net/10067/1596550151162165141>

Abstract

Morbidity after sentinel lymph node biopsy is often underestimated. The aim of this study is to inventory arm and shoulder complaints in sentinel node negative breast cancer patients post-surgery after long-term follow-up. Sentinel-node-negative breast cancer patients with at least 2 years of follow-up after surgery were included in this study. Self-reported arm and shoulder morbidities were assessed using a survey. Patients (n=126) were asked if they ever developed complaints, if these complaints were still present and whether they were ever treated for these complaints. After a mean follow-up of 55.5 months (range 25-86 months) the prevalence of the self-reported arm and shoulder complaints was 25.8% for pain, 12.0% for numbness, 6.4% for paresthesias, 7.1% for lymphedema, 8.0% for axillary web syndrome, 26.2% for loss of strength and 19.5% for limitations in range of motion. 38.1% of the patients were treated by a physical therapist concerning the experienced complaints after SLNB. Up to 7 years post-surgery a considerable amount of sentinel negative patients still suffer from arm and shoulder complaints. These complaints affect the activities of daily living. Therefore, more research is needed regarding the value of early detection and treatment of these complaints.

Key words: Breast Neoplasms, Sentinel lymph node biopsy, Morbidity, Survey

Introduction

In scientific literature a distinction is made between an axillary lymph node dissection (ALND) and a sentinel lymph node biopsy (SLNB) in the treatment of breast cancer. The less invasive SLNB results in considerably less arm and shoulder morbidity (Liu, Guo, Shi, & Sheng, 2009). However, the negative aspects of the SLNB should not be underestimated. Our systematic review in sentinel node negative patients demonstrated that a large group of patients developed arm and shoulder complaints post-treatment like pain, numbness, paresthesias, lymphedema, axillary web syndrome, loss of strength and loss of mobility (Verbelen, Gebruers, Eeckhout, Verlinden, & Tjalma, 2014). Due to the evolution in breast cancer treatment, survival has increased significantly (Allemani & Coleman, 2015). As a result, treatment-related health problems and post-cancer functioning are becoming more important (Belmonte et al., 2012). To cover all health-related aspects, one should look at the bio-psychosocial framework. The International Classification of Functioning Disability and Health (ICF) is an extensively used framework to describe the health condition of a patient within this bio-psychosocial context (www.who.int/classifications/icf/en). The ICF covers all domains of disability. Disability involves dysfunctioning at one or more levels: impairments in body functions or structures, activity limitations and participation restrictions. The self-reported measures in this study focus on all the domains of the ICF. The majority of studies on the morbidities after SLNB have only a short follow-up (1 to 3 years) (Aerts, De Vries, Van der Steeg, & Roukema, 2011; Arnaud et al., 2004; Ashikaga et al., 2010; Barranger et al., 2005; Belmonte et al., 2012; Burak et al., 2002; Helms, Kühn, Moser, Rimmel, & Kreienberg, 2009; Husen, Paaschburg, & Flyger, 2006; Kootstra et al., 2010; Land et al., 2010; Langer et al., 2007; Mansel et al., 2006; Peintinger, Reitsamer, Stranzl, & Ralph, 2003; Purushotham et al., 2005; J S Rietman et al., 2004, 2006; Johan S Rietman et al., 2003; Rönkä, von Smitten, Tasmuth, & Leidenius, 2005; Schulze,

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3 Mucke, Markwardt, Schlag, & Bembenek, 2006; Swenson, 2002). Although an abundance of
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5 previous research is available on morbidity after SLNB, the follow-up period is often short and
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7 self-reported measures focus on a specific domain of dysfunctioning. Understanding morbidity
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9 and its timeline is essential to organize adequate health care. Therefore, the aim of this study is
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11 to inventory impairments involving arm and shoulder complaints in sentinel node negative
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13 breast cancer patients and to identify activity limitations and participation restrictions. The
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15 secondary aims are to investigate which arm and shoulder complaints are still present in those
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17 patients after long term follow-up and to investigate if patients with these complaints were
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19 treated and what treatment they received.
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26 **Materials and methods**

27 *Study population*

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35 In this cross-sectional study, breast cancer patients who have had breast cancer treatment
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37 between January 2007 and January 2012 in the Multidisciplinary Breast Clinic of the Antwerp
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39 University Hospital were identified in the Clinic's database (MOCA, Medical Oncology Center
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41 Antwerp). Primary surgery consisted of breast-conserving surgery or mastectomy. Patients
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43 were eligible if they were surgically treated using the sentinel-procedure only and if the sentinel
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45 node was negative. If indicated, post-operative adjuvant treatment consisted of radiation
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47 therapy, chemotherapy, herceptin and/or hormonal therapy. Patients who have had a sentinel
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49 lymph node biopsy followed by an axillary lymph node dissection and patients who were unable
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51 to fill out a Dutch survey were excluded. Eligible participants were contacted by phone between
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53 February and April 2014. Patients who gave written consent were surveyed by mail. Patients
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55 were asked to reply within 14 days. If after three weeks no survey was received, a reminder was
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3 sent to these patients. The survey was approved by the Ethical Committee of the Antwerp
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5 University Hospital (registration: B300201317503).
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10 *Data collection*

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14 Self-reported arm and shoulder morbidities were assessed by means of a survey. The survey
15 was developed, based upon the results of our systematic review, to collect information on the
16 following morbidities: loss of strength, loss of mobility, numbness, paresthesias, lymphedema,
17 axillary web syndrome and pain (Verbelen et al., 2014). Patients were 1) asked if they ever
18 developed these complaints, 2) if these complaints are still present and 3) whether they were
19 ever treated for one of these complaints. Data was collected retrospectively, however data
20 concerning long-term morbidities were collected at the time patients filled out the survey.
21 Several activity limitations and participation restrictions were scored on a 11-point Likert scale.
22 A score of 0 was given when an activity was not limited at all, a score of 10 was given when
23 an activity was impossible to execute. Current personal data like age, menopausal status,
24 preoperative bra cup size and body mass index were also collected by the survey. In addition,
25 medical information e.g. type of surgery, the date of surgery and the adjuvant therapies was
26 extracted from the electronic medical file of the patients.
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46 *Data analysis*

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51 Data from the survey and the electronic medical file of the study participants were processed
52 using ‘Open Clinica’, an open source clinical trial software for electronic data capture and
53 clinical data management. The Statistical Package for the Social Sciences (SPSS) version 22
54 was used to analyze results. Socio-demographic and clinical variables were analyzed using
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3 descriptive statistics as frequencies, means, standard deviations and percentages. Additionally,
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5 Chi-square and t-test statistics were performed to analyze the relationship between arm &
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7 shoulder complaints to the type of surgery and adjuvant therapy
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10 11 12 **Results**

13 14 15 16 17 *Respondents and their characteristics*

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21 A total of 126 sentinel negative breast cancer patients were enrolled in this descriptive cross-
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23 sectional study. A response rate of 83% was accomplished. For a detailed overview of the
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25 participant selection process, see Figure 1. In all patients a radioactive isotope was the only
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27 method used to detect the sentinel node. Between 1 and 3 lymph nodes were removed, with a
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29 median of 2 lymph nodes. The characteristics of the study population are shown in Table 1.
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38 *Impairments; Arm and shoulder complaints*

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42 Many sentinel negative patients have reported post-surgery complaints (see Figure 2a). The
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44 results are presented in 2 categories. First, “Prevalence post-surgery” applies to the percentage
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46 of patients who have ever experienced complaints following surgery. For pain, 43.5% of
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48 patients developed this complaint, 22.4% for numbness, 12.3% for paresthesias, 7.1% for
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50 lymphedema, 14.6% for axillary web syndrome, 43.2% for loss of strength and 53.7% for
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52 limitations in range of motion. Second, “Prevalence 2 to 7 years post-surgery” applies to the
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54 percentage of patients who indicated that they still had complaints at the moment they filled out
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56 the survey. In this study women were on average 55.5 months post-surgery. Exploring the
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3 impairments; 25.8% reported pain, 12.0% numbness, 6.4% paresthesias, 5.6% lymphedema,
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5 8.0% axillary web syndrome, 26.2% loss of strength and 19.5% limitations in range of motion.
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7 Figure 2b gives an overview of the prevalence of the arm and shoulder complaints according to
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9 the type of surgery using Chi-squared tests. Post-surgery, numbness ($p=0.001$), lymphedema
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11 ($p=0.005$) and loss of mobility ($p=0.016$) are shown to be significantly more present after
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13 mastectomy. Two to 7 years post-surgery, only numbness ($p=0.005$) and lymphedema
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15 ($p=0.037$) are significantly more present after mastectomy. Nevertheless, these results have to
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17 be interpreted with caution because patients who underwent breast-conserving surgery received
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19 significantly more radiation therapy compared to the patients who underwent a mastectomy
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21 ($p<0.001$) using an independent sample t-test. Of the patients who received breast-conserving
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23 surgery, 92.7% received radiation therapy versus 29.5% for the mastectomy-patients. From this
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25 point of view, the prevalence of arm and shoulder complaints were analyzed related to the
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27 adjuvant treatment using Chi-squared tests. Our analyses showed that patients who received
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29 radiation therapy had significantly more numbness compared to patients who did not receive
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31 radiation therapy ($p=0.027$). For the other complaints, no significant differences were found.
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42 *Activity limitations and participation restrictions*

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46 The activity limitations with the highest prevalence are putting on a bra (58.7%), getting dressed
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48 (57.9%), wearing a bra (50.8%), sleeping (50.0%), sports (48.4%) and driving (35.7%). For an
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50 overview of the prevalence of all the activity limitations, see Table 2. Other activity limitations
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52 reported by the participants were combing hair, lifting heavy objects and hugging. The
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54 prevalence of the participation restrictions was 55.5% for household and 39.7% for work.
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Treatment of arm and shoulder complaints

38.1% of all participants reported that they were treated by a physical therapist concerning their arm and shoulder complaints. Several physical therapy modalities were reported: passive mobilization, massage, exercise therapy, myofascial therapy, trigger point therapy, bandaging, manual lymph drainage, fango therapy and scar tissue treatment. 72.2% of patients who were treated, indicated that their complaints improved after treatment, 11.1% noticed no difference after physical therapy and 16.7% indicated that their complaints completely resolved.

Discussion

This retrospective study revealed that a large proportion of sentinel negative patients reported arm and shoulder complaints post-surgery with a severe impact on activities of daily living. Loss of mobility, loss of strength and pain were the most common morbidities. In the literature SLNB is often compared with ALND with beneficial results in favor SLNB concerning arm and shoulder morbidity (Verbelen et al., 2014). However, in a systematic review it was demonstrated that arm and shoulder complaints after SLNB should not be underestimated (Verbelen et al., 2014). The data of the current study are well within the range of the prevalences found in the literature (see Table 3) (Gebruers, Truijen, Engelborghs, & De Deyn, 2007; Verbelen et al., 2014). However, the prevalence of paresthesia and loss of strength are higher in the present study. In the literature many different assessment methods are used, which makes comparison of data among studies difficult. Studies use different criteria to define a morbidity, which partially explains the wide variation in prevalence. The literature showed that mainly abduction and forward flexion were limited (Aerts et al., 2011; Belmonte et al., 2012; De Groef et al., 2016; Kootstra et al., 2010; Leidenius, Leppänen, Krogerus, & Von Smitten, 2003;

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3 Mansel et al., 2006; Peintinger et al., 2003; J S Rietman et al., 2004, 2006; Johan S Rietman et
4 al., 2003; Rönkä et al., 2005). Our survey did not make a subdivision based on the movement
5 direction. We assessed loss of mobility by asking whether the patients were able to raise the
6 arm above the shoulder. The same can be applied for loss of strength where in the literature a
7 subdivision is often made between shoulder abductors, elbow flexors and grip strength (De
8 Groef et al., 2016; Kootstra et al., 2010; J S Rietman et al., 2004, 2006; Johan S Rietman et al.,
9 2003). Our survey evaluated loss of strength by evaluating the ability to lift heavy objects.
10 Therefore, the results should be interpreted with caution.
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24 The long-term follow-up of patients who underwent SLNB showed that arm and shoulder
25 complaints can persist for many years after initial treatment. Literature concerning long-term
26 consequences of SLNB on shoulder and arm function is scarce. Kootstra et al. investigated arm
27 and shoulder complaints in breast cancer survivors 7 years after diagnosis. Seven years after a
28 SLNB 18% of patients had limited abduction measured using a goniometer (Kootstra et al.,
29 2013). These results are similar to the percentages found in our study (19.8%), although the
30 follow-up in our study is between 2 and 7 years. Regarding loss of strength, the long-term
31 prevalence in our study (27.1%) is slightly higher than in the study of Kootstra et al. (18%).
32 Strength of the shoulder abductors was measured using a hand-held dynamometer (Kootstra et
33 al., 2013). None of the patients had lymphedema measured using circumference measurements,
34 compared to 7.1% in the current study (Kootstra et al., 2013). A possible explanation is that in
35 the study of Kootstra lymphedema is defined as a difference of ≥ 200 ml in arm volume, whereas
36 in the present study the presence of lymphedema is self-reported.
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56 This study reported on the prevalence of arm and shoulder complaints in patients who
57 underwent SLNB in addition to breast surgery. It is possible that the reported outcomes are
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3 related to the SLNB or to other potential factors such as the breast surgery itself; whether the
4 patients underwent breast-conserving surgery or mastectomy. As depicted in figure 2b; post-
5 surgery numbness ($p=0.001$), lymphedema ($p=0.005$) and loss of mobility ($p=0.016$) are
6 significantly more present after mastectomy. Two to 7 years post-surgery, only numbness
7 ($p=0.005$) and lymphedema ($p=0.037$) are significantly more present after mastectomy.
8 Nevertheless, these results have to be interpreted with caution because patients who underwent
9 breast-conserving surgery received significantly more radiation therapy compared to the
10 patients who underwent a mastectomy. Of the patients who received breast-conserving surgery,
11 92.7% received radiation therapy versus 29.5% for the mastectomy-patients. From this point of
12 view, patients who received radiation therapy had significantly more numbness compared to
13 patients who did not receive radiation therapy ($p=0.027$). For the other complaints, no
14 significant differences were found. However, we did expect that radiation therapy would
15 provoke lymphedema as well. According to a systematic review of Disipio et al. radiation
16 therapy is a risk factor for lymphedema that is lent support by a moderate level of evidence
17 (DiSipio, Rye, Newman, & Hayes, 2013). However, this is not the case in our study.
18 Furthermore in the current study, none of the complaints were related to chemotherapy and
19 hormonal therapy.
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46 Although the prevalence of arm and shoulder complaints are relatively high, only 38.1% of
47 patients were treated for their complaints. Oddly, only 7.1% of the patients developed
48 lymphedema but more than double (15.1 %) of the patients received manual lymphatic
49 drainage. It is well known that manual lymphatic drainage in addition to information and
50 exercise therapy is unlikely to reduce the prevalence of arm lymphedema (Devoogdt et al.,
51 2011). It appears that patients often receive manual lymphatic drainage as a prevention therapy
52 and not as a treatment for lymphedema. Despite the fact that impairments in body functions and
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3 activity limitations are very common, few patients received adequate therapy. What is the main
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5 reason behind this? Was it because they didn't seek for help, or because they were not referred
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7 properly by the health care workers. Health care providers should be aware of the possible
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9 complaints and their treatments; and therefore refer patients to a specialized physical therapist
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11 for tailored therapy more quickly.
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17 This study demonstrates that many patients still suffer from arm or shoulder complaints months
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19 and even years after their cancer treatment. The arm and shoulder complaints influence the
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21 activities of daily living and quality of life (Aerts et al., 2011; Belmonte et al., 2012; Dubernard
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23 et al., 2004; Fleissig et al., 2006; Peintinger et al., 2003). From this point of view it is important
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25 to include early detection of morbidities and referral for an appropriate treatment. According to
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27 the literature; passive mobilization, exercises, and the combination of manual stretching and
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29 general exercises are effective for the improvement of shoulder range of motion after breast
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31 cancer surgery (Beurskens, van Uden, Strobbe, Oostendorp, & Wobbes, 2007; Box, Reul-
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33 Hirche, Bullock-Saxton, & Furnival, 2002; Cinar et al., 2008; De Groef et al., 2015; De Rezende
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35 et al., 2006; Kilbreath et al., 2012; Le Vu, Dumortier, Guillaume, Mouriessse, & Barreau-
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37 Pouhaer, 1997). Exercise is also effective for treatment of postoperative pain of the upper limb
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39 (Beurskens et al., 2007; De Groef et al., 2015). However, high-quality studies are necessary to
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41 prove the effectiveness of passive mobilization, stretching, and myofascial therapy as part of
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43 the multifactorial treatment (De Groef et al., 2015). In addition, the appropriate timing and
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45 content of the exercise programs need to be further investigated. Self-assessment using a
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47 checklist or annual evaluation during follow-up are both feasible approaches.
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Study limitations

Data were collected via a self-administrated survey. Some items from the survey remained blank. It is possible that patients did not fill in all questions because the complaint was not present, the question was not clear or the question was not applicable (e.g. bra cup size or menopause in male patients). If we collected our data via a face-to-face interview, we could clarify items who were not clear for some patients. Study participants were treated between 2 and 7 years ago. The researchers are aware of the risk of recall bias due to the retrospective character of the data collection. However, we strongly believe that the current study has provided useful information about long-term morbidity that has been collected prospectively. Long-term arm and shoulder complaints of sentinel negative patients were not collected retrospectively, but at the time the patients filled out the survey. Patients were asked if the arm and shoulder complaints were currently present. Furthermore, the results of this study are within the range of the prevalence found in the literature (see Table 3). Another limitation of this study is that arm and shoulder complaints are self-reported. The researchers are aware of the limitations of this type of data gathering, however, it is an efficient way to collect information about the history of a large sample. The response rate is often a difficult aspect when using a survey. We have anticipated this difficulty by contacting the participants by phone before sending the survey. Using this methodology, we managed to achieve an excellent response rate of 83%.

Conclusion

Long-term health problems related to breast cancer treatment and the quality of life are becoming more important as the life expectancy is increasing. Up to 7 years post-surgery a

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3 considerable percentage of sentinel negative patients still suffer from arm and shoulder
4 complaints. These complaints affect the activities of daily living. Therefore, more attention for
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6 early detection and treatment of these complaints is warranted.
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10 11 12 **Acknowledgments** 13

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17 The authors like to thank Paul vanden Broucke and Kin Jip Cheung for their support concerning
18 the implementation of 'Open Clinica'.
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22 This research was approved by the Ethical Committee of the Antwerp University Hospital
23 (registration: B300201317503).
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30 31 **Conflict of interest** 32

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34 The authors declare that they have no conflict of interest.
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For Peer Review

Abstract

Morbidity after sentinel lymph node biopsy is often underestimated. The aim of this study is to inventory arm and shoulder complaints in sentinel node negative breast cancer patients post-surgery after long-term follow-up. Sentinel-node-negative breast cancer patients with at least 2 years of follow-up after surgery were included in this study. Self-reported arm and shoulder morbidities were assessed using a survey. Patients (n=126) were asked if they ever developed complaints, if these complaints were still present and whether they were ever treated for these complaints. After a mean follow-up of 55.5 months (range 25-86 months) the prevalence of the self-reported arm and shoulder complaints was 25.8% for pain, 12.0% for numbness, 6.4% for paresthesias, 7.1% for lymphedema, 8.0% for axillary web syndrome, 26.2% for loss of strength and 19.5% for limitations in range of motion. 38.1% of the patients were treated by a physical therapist concerning the experienced complaints after SLNB. Up to 7 years post-surgery a considerable amount of sentinel negative patients still suffer from arm and shoulder complaints. These complaints affect the activities of daily living. Therefore, more research is needed regarding the value of early detection and treatment of these complaints.

Key words: Breast Neoplasms, Sentinel lymph node biopsy, Morbidity, Survey

Introduction

In scientific literature a distinction is made between an axillary lymph node dissection (ALND) and a sentinel lymph node biopsy (SLNB) in the treatment of breast cancer. The less invasive SLNB results in considerably less arm and shoulder morbidity (Liu, Guo, Shi, & Sheng, 2009). However, the negative aspects of the SLNB should not be underestimated. Our systematic review in sentinel node negative patients demonstrated that a large group of patients developed arm and shoulder complaints post-treatment like pain, numbness, paresthesias, lymphedema, axillary web syndrome, loss of strength and loss of mobility (Verbelen, Gebruers, Eeckhout, Verlinden, & Tjalma, 2014). Due to the evolution in breast cancer treatment, survival has increased significantly (Allemani & Coleman, 2015). As a result, treatment-related health problems and post-cancer functioning are becoming more important (Belmonte et al., 2012). To cover all health-related aspects, one should look at the bio-psychosocial framework. The International Classification of Functioning Disability and Health (ICF) is an extensively used framework to describe the health condition of a patient within this bio-psychosocial context (www.who.int/classifications/icf/en). The ICF covers all domains of disability. Disability involves dysfunctioning at one or more levels: impairments in body functions or structures, activity limitations and participation restrictions. The self-reported measures in this study focus on all the domains of the ICF. The majority of studies on the morbidities after SLNB have only a short follow-up (1 to 3 years) (Aerts, De Vries, Van der Steeg, & Roukema, 2011; Arnaud et al., 2004; Ashikaga et al., 2010; Barranger et al., 2005; Belmonte et al., 2012; Burak et al., 2002; Helms, Kühn, Moser, Rimmel, & Kreienberg, 2009; Husen, Paaschburg, & Flyger, 2006; Kootstra et al., 2010; Land et al., 2010; Langer et al., 2007; Mansel et al., 2006; Peintinger, Reitsamer, Stranzl, & Ralph, 2003; Purushotham et al., 2005; J S Rietman et al., 2004, 2006; Johan S Rietman et al., 2003; Rönkä, von Smitten, Tasmuth, & Leidenius, 2005; Schulze,

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3 Mucke, Markwardt, Schlag, & Bembenek, 2006; Swenson, 2002). Although an abundance of
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5 previous research is available on morbidity after SLNB, the follow-up period is often short and
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7 self-reported measures focus on a specific domain of dysfunctioning. Understanding morbidity
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9 and its timeline is essential to organize adequate health care. Therefore, the aim of this study is
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11 to inventory impairments involving arm and shoulder complaints in sentinel node negative
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13 breast cancer patients and to identify activity limitations and participation restrictions. The
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15 secondary aims are to investigate which arm and shoulder complaints are still present in those
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17 patients after long term follow-up and to investigate if patients with these complaints were
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19 treated and what treatment they received.
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26 **Materials and methods**

27 *Study population*

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35 In this cross-sectional study, breast cancer patients who have had breast cancer treatment
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37 between January 2007 and January 2012 in the Multidisciplinary Breast Clinic of the Antwerp
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39 University Hospital were identified in the Clinic's database (MOCA, Medical Oncology Center
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41 Antwerp). Primary surgery consisted of breast-conserving surgery or mastectomy. Patients
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43 were eligible if they were surgically treated using the sentinel-procedure only and if the sentinel
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45 node was negative. If indicated, post-operative adjuvant treatment consisted of radiation
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47 therapy, chemotherapy, herceptin and/or hormonal therapy. Patients who have had a sentinel
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49 lymph node biopsy followed by an axillary lymph node dissection and patients who were unable
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51 to fill out a Dutch survey were excluded. Eligible participants were contacted by phone between
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53 February and April 2014. Patients who gave written consent were surveyed by mail. Patients
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55 were asked to reply within 14 days. If after three weeks no survey was received, a reminder was
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3 sent to these patients. The survey was approved by the Ethical Committee of the Antwerp
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5 University Hospital (registration: B300201317503).
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10 *Data collection*

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14 Self-reported arm and shoulder morbidities were assessed by means of a survey. The survey
15 was developed, based upon the results of our systematic review, to collect information on the
16 following morbidities: loss of strength, loss of mobility, numbness, paresthesias, lymphedema,
17 axillary web syndrome and pain (Verbelen et al., 2014). Patients were 1) asked if they ever
18 developed these complaints, 2) if these complaints are still present and 3) whether they were
19 ever treated for one of these complaints. Data was collected retrospectively, however data
20 concerning long-term morbidities were collected at the time patients filled out the survey.
21 Several activity limitations and participation restrictions were scored on a 11-point Likert scale.
22 A score of 0 was given when an activity was not limited at all, a score of 10 was given when
23 an activity was impossible to execute. Current personal data like age, menopausal status,
24 preoperative bra cup size and body mass index were also collected by the survey. In addition,
25 medical information e.g. type of surgery, the date of surgery and the adjuvant therapies was
26 extracted from the electronic medical file of the patients.
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46 *Data analysis*

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51 Data from the survey and the electronic medical file of the study participants were processed
52 using ‘Open Clinica’, an open source clinical trial software for electronic data capture and
53 clinical data management. The Statistical Package for the Social Sciences (SPSS) version 22
54 was used to analyze results. Socio-demographic and clinical variables were analyzed using
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3 descriptive statistics as frequencies, means, standard deviations and percentages. Additionally,
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5 Chi-square and t-test statistics were performed to analyze the relationship between arm &
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shoulder complaints to the type of surgery and adjuvant therapy

Results

Respondents and their characteristics

A total of 126 sentinel negative breast cancer patients were enrolled in this descriptive cross-sectional study. A response rate of 83% was accomplished. For a detailed overview of the participant selection process, see Figure 1. In all patients a radioactive isotope was the only method used to detect the sentinel node. Between 1 and 3 lymph nodes were removed, with a median of 2 lymph nodes. The characteristics of the study population are shown in Table 1.

Impairments; Arm and shoulder complaints

Many sentinel negative patients have reported post-surgery complaints (see Figure 2a). The results are presented in 2 categories. First, “Prevalence post-surgery” applies to the percentage of patients who have ever experienced complaints following surgery. For pain, 43.5% of patients developed this complaint, 22.4% for numbness, 12.3% for paresthesias, 7.1% for lymphedema, 14.6% for axillary web syndrome, 43.2% for loss of strength and 53.7% for limitations in range of motion. Second, “Prevalence 2 to 7 years post-surgery” applies to the percentage of patients who indicated that they still had complaints at the moment they filled out the survey. In this study women were on average 55.5 months post-surgery. Exploring the

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3 impairments; 25.8% reported pain, 12.0% numbness, 6.4% paresthesias, 5.6% lymphedema,
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5 8.0% axillary web syndrome, 26.2% loss of strength and 19.5% limitations in range of motion.
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8 Figure 2b gives an overview of the prevalence of the arm and shoulder complaints according to
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10 the type of surgery using Chi-squared tests. Post-surgery, numbness ($p=0.001$), lymphedema
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12 ($p=0.005$) and loss of mobility ($p=0.016$) are shown to be significantly more present after
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14 mastectomy. Two to 7 years post-surgery, only numbness ($p=0.005$) and lymphedema
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16 ($p=0.037$) are significantly more present after mastectomy. Nevertheless, these results have to
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18 be interpreted with caution because patients who underwent breast-conserving surgery received
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20 significantly more radiation therapy compared to the patients who underwent a mastectomy
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22 ($p<0.001$) using an independent sample t-test. Of the patients who received breast-conserving
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24 surgery, 92.7% received radiation therapy versus 29.5% for the mastectomy-patients. From this
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26 point of view, the prevalence of arm and shoulder complaints were analyzed related to the
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28 adjuvant treatment using Chi-squared tests. Our analyses showed that patients who received
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30 radiation therapy had significantly more numbness compared to patients who did not receive
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32 radiation therapy ($p=0.027$). For the other complaints, no significant differences were found.
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43 *Activity limitations and participation restrictions*

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46 The activity limitations with the highest prevalence are putting on a bra (58.7%), getting dressed
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48 (57.9%), wearing a bra (50.8%), sleeping (50.0%), sports (48.4%) and driving (35.7%). For an
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50 overview of the prevalence of all the activity limitations, see Table 2. Other activity limitations
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52 reported by the participants were combing hair, lifting heavy objects and hugging. The
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54 prevalence of the participation restrictions was 55.5% for household and 39.7% for work.
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Treatment of arm and shoulder complaints

38.1% of all participants reported that they were treated by a physical therapist concerning their arm and shoulder complaints. Several physical therapy modalities were reported: passive mobilization, massage, exercise therapy, myofascial therapy, trigger point therapy, bandaging, manual lymph drainage, fango therapy and scar tissue treatment. 72.2% of patients who were treated, indicated that their complaints improved after treatment, 11.1% noticed no difference after physical therapy and 16.7% indicated that their complaints completely resolved.

Discussion

This retrospective study revealed that a large proportion of sentinel negative patients reported arm and shoulder complaints post-surgery with a severe impact on activities of daily living. Loss of mobility, loss of strength and pain were the most common morbidities. In the literature SLNB is often compared with ALND with beneficial results in favor SLNB concerning arm and shoulder morbidity (Verbelen et al., 2014). However, in a systematic review it was demonstrated that arm and shoulder complaints after SLNB should not be underestimated (Verbelen et al., 2014). The data of the current study are well within the range of the prevalences found in the literature (see Table 3) (Gebruers, Truijen, Engelborghs, & De Deyn, 2007; Verbelen et al., 2014). However, the prevalence of paresthesia and loss of strength are higher in the present study. In the literature many different assessment methods are used, which makes comparison of data among studies difficult. Studies use different criteria to define a morbidity, which partially explains the wide variation in prevalence. The literature showed that mainly abduction and forward flexion were limited (Aerts et al., 2011; Belmonte et al., 2012; De Groef et al., 2016; Kootstra et al., 2010; Leidenius, Leppänen, Krogerus, & Von Smitten, 2003;

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3 Mansel et al., 2006; Peintinger et al., 2003; J S Rietman et al., 2004, 2006; Johan S Rietman et
4 al., 2003; Rönkä et al., 2005). Our survey did not make a subdivision based on the movement
5 direction. We assessed loss of mobility by asking whether the patients were able to raise the
6 arm above the shoulder. The same can be applied for loss of strength where in the literature a
7 subdivision is often made between shoulder abductors, elbow flexors and grip strength (De
8 Groef et al., 2016; Kootstra et al., 2010; J S Rietman et al., 2004, 2006; Johan S Rietman et al.,
9 2003). Our survey evaluated loss of strength by evaluating the ability to lift heavy objects.
10 Therefore, the results should be interpreted with caution.
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24 The long-term follow-up of patients who underwent SLNB showed that arm and shoulder
25 complaints can persist for many years after initial treatment. Literature concerning long-term
26 consequences of SLNB on shoulder and arm function is scarce. Kootstra et al. investigated arm
27 and shoulder complaints in breast cancer survivors 7 years after diagnosis. Seven years after a
28 SLNB 18% of patients had limited abduction measured using a goniometer (Kootstra et al.,
29 2013). These results are similar to the percentages found in our study (19.8%), although the
30 follow-up in our study is between 2 and 7 years. Regarding loss of strength, the long-term
31 prevalence in our study (27.1%) is slightly higher than in the study of Kootstra et al. (18%).
32 Strength of the shoulder abductors was measured using a hand-held dynamometer (Kootstra et
33 al., 2013). None of the patients had lymphedema measured using circumference measurements,
34 compared to 7.1% in the current study (Kootstra et al., 2013). A possible explanation is that in
35 the study of Kootstra lymphedema is defined as a difference of ≥ 200 ml in arm volume, whereas
36 in the present study the presence of lymphedema is self-reported.
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56 This study reported on the prevalence of arm and shoulder complaints in patients who
57 underwent SLNB in addition to breast surgery. It is possible that the reported outcomes are
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3 related to the SLNB or to other potential factors such as the breast surgery itself; whether the
4 patients underwent breast-conserving surgery or mastectomy. As depicted in figure 2b; post-
5 surgery numbness ($p=0.001$), lymphedema ($p=0.005$) and loss of mobility ($p=0.016$) are
6 significantly more present after mastectomy. Two to 7 years post-surgery, only numbness
7 ($p=0.005$) and lymphedema ($p=0.037$) are significantly more present after mastectomy.
8 Nevertheless, these results have to be interpreted with caution because patients who underwent
9 breast-conserving surgery received significantly more radiation therapy compared to the
10 patients who underwent a mastectomy. Of the patients who received breast-conserving surgery,
11 92.7% received radiation therapy versus 29.5% for the mastectomy-patients. From this point of
12 view, patients who received radiation therapy had significantly more numbness compared to
13 patients who did not receive radiation therapy ($p=0.027$). For the other complaints, no
14 significant differences were found. However, we did expect that radiation therapy would
15 provoke lymphedema as well. According to a systematic review of DiSipio et al. radiation
16 therapy is a risk factor for lymphedema that is lent support by a moderate level of evidence
17 (DiSipio, Rye, Newman, & Hayes, 2013). However, this is not the case in our study.
18 Furthermore in the current study, none of the complaints were related to chemotherapy and
19 hormonal therapy.

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46 Although the prevalence of arm and shoulder complaints are relatively high, only 38.1% of
47 patients were treated for their complaints. Oddly, only 7.1% of the patients developed
48 lymphedema but more than double (15.1 %) of the patients received manual lymphatic
49 drainage. It is well known that manual lymphatic drainage in addition to information and
50 exercise therapy is unlikely to reduce the prevalence of arm lymphedema (Devoogdt et al.,
51 2011). It appears that patients often receive manual lymphatic drainage as a prevention therapy
52 and not as a treatment for lymphedema. Despite the fact that impairments in body functions and

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3 activity limitations are very common, few patients received adequate therapy. What is the main
4 reason behind this? Was it because they didn't seek for help, or because they were not referred
5 properly by the health care workers. Health care providers should be aware of the possible
6 complaints and their treatments; and therefore refer patients to a specialized physical therapist
7 for tailored therapy more quickly.
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17 This study demonstrates that many patients still suffer from arm or shoulder complaints months
18 and even years after their cancer treatment. The arm and shoulder complaints influence the
19 activities of daily living and quality of life (Aerts et al., 2011; Belmonte et al., 2012; Dubernard
20 et al., 2004; Fleissig et al., 2006; Peintinger et al., 2003). From this point of view it is important
21 to include early detection of morbidities and referral for an appropriate treatment. According to
22 the literature; passive mobilization, exercises, and the combination of manual stretching and
23 general exercises are effective for the improvement of shoulder range of motion after breast
24 cancer surgery (Beurskens, van Uden, Strobbe, Oostendorp, & Wobbes, 2007; Box, Reul-
25 Hirche, Bullock-Saxton, & Furnival, 2002; Cinar et al., 2008; De Groef et al., 2015; De Rezende
26 et al., 2006; Kilbreath et al., 2012; Le Vu, Dumortier, Guillaume, Mouriessse, & Barreau-
27 Pouhaer, 1997). Exercise is also effective for treatment of postoperative pain of the upper limb
28 (Beurskens et al., 2007; De Groef et al., 2015). However, high-quality studies are necessary to
29 prove the effectiveness of passive mobilization, stretching, and myofascial therapy as part of
30 the multifactorial treatment (De Groef et al., 2015). In addition, the appropriate timing and
31 content of the exercise programs need to be further investigated. Self-assessment using a
32 checklist or annual evaluation during follow-up are both feasible approaches.
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Study limitations

Data were collected via a self-administrated survey. Some items from the survey remained blank. It is possible that patients did not fill in all questions because the complaint was not present, the question was not clear or the question was not applicable (e.g. bra cup size or menopause in male patients). If we collected our data via a face-to-face interview, we could clarify items who were not clear for some patients. Study participants were treated between 2 and 7 years ago. The researchers are aware of the risk of recall bias due to the retrospective character of the data collection. However, we strongly believe that the current study has provided useful information about long-term morbidity that has been collected prospectively. Long-term arm and shoulder complaints of sentinel negative patients were not collected retrospectively, but at the time the patients filled out the survey. Patients were asked if the arm and shoulder complaints were currently present. Furthermore, the results of this study are within the range of the prevalence found in the literature (see Table 3). Another limitation of this study is that arm and shoulder complaints are self-reported. The researchers are aware of the limitations of this type of data gathering, however, it is an efficient way to collect information about the history of a large sample. The response rate is often a difficult aspect when using a survey. We have anticipated this difficulty by contacting the participants by phone before sending the survey. Using this methodology, we managed to achieve an excellent response rate of 83%.

Conclusion

Long-term health problems related to breast cancer treatment and the quality of life are becoming more important as the life expectancy is increasing. Up to 7 years post-surgery a

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2
3 considerable percentage of sentinel negative patients still suffer from arm and shoulder
4 complaints. These complaints affect the activities of daily living. Therefore, more attention for
5
6 early detection and treatment of these complaints is warranted.
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10 11 12 **Acknowledgments** 13

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17 The authors like to thank Paul vanden Broucke and Kin Jip Cheung for their support concerning
18 the implementation of 'Open Clinica'.
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22 This research was approved by the Ethical Committee of the Antwerp University Hospital
23 (registration: B300201317503).
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28 29 30 **Conflict of interest** 31

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34 The authors declare that they have no conflict of interest.
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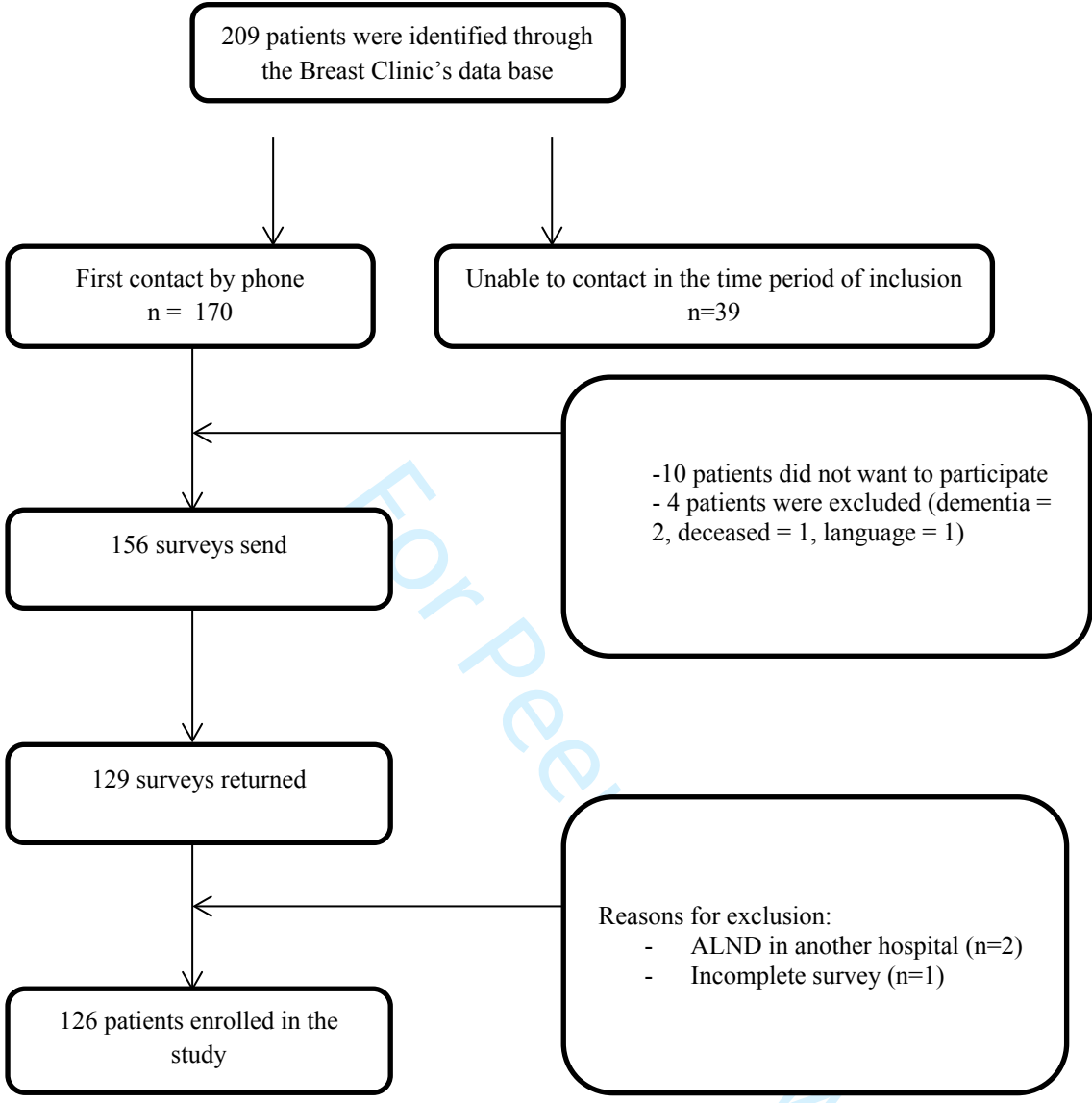


Figure 1. Selection process of the participating patients

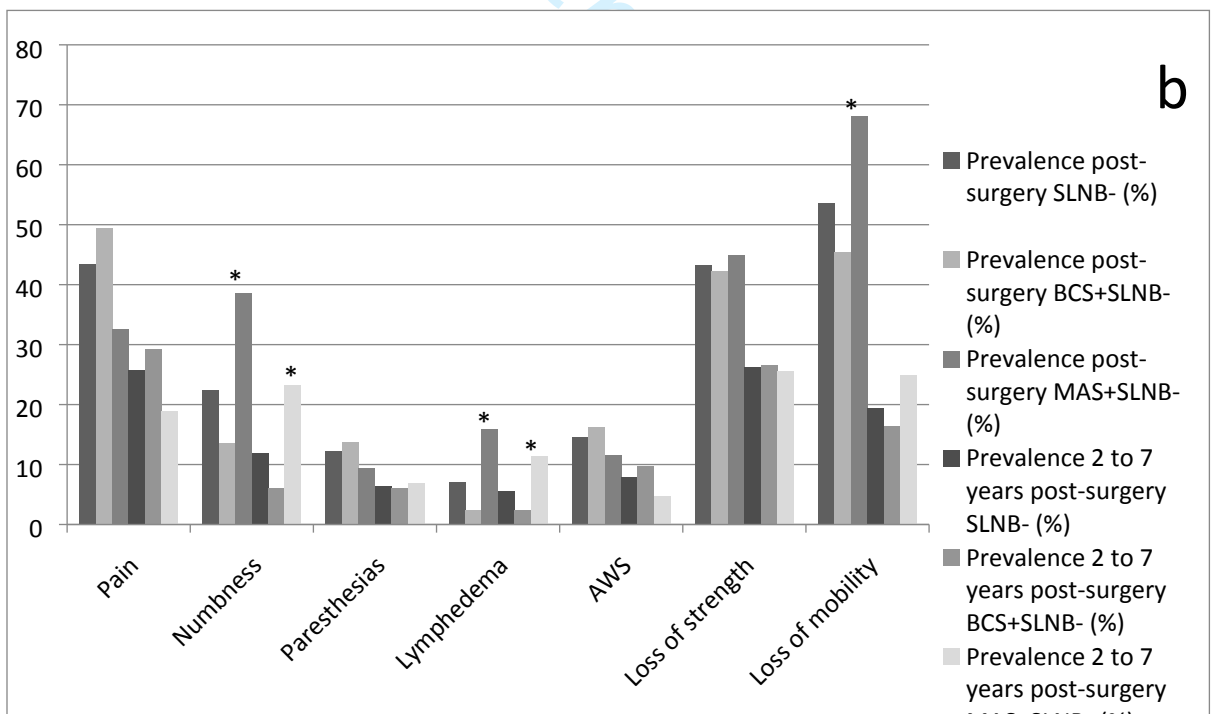
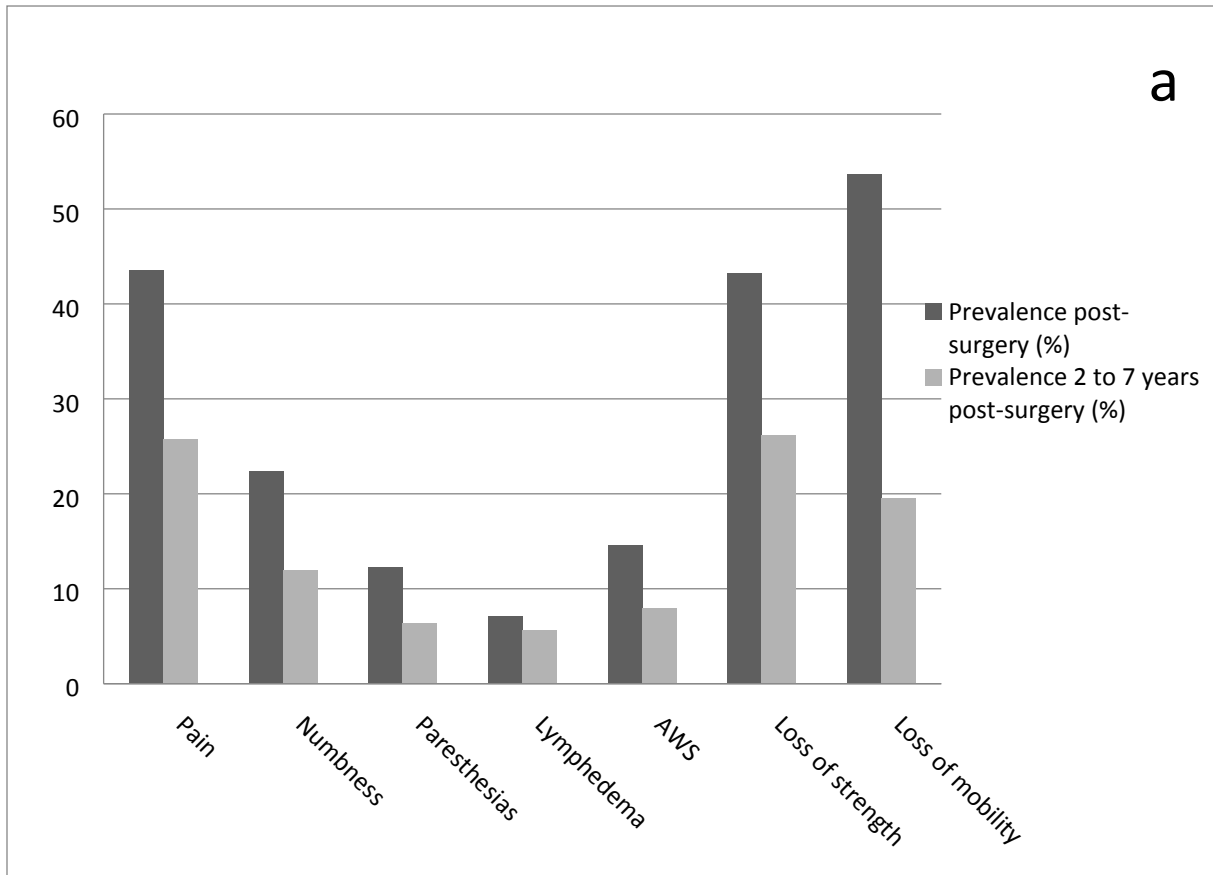


Figure 2. The prevalence of arm and shoulder complaints in sentinel negative patients. **a:** Prevalence in all sentinel node negative patients. **b:** Prevalence according to type of surgery. Abbreviations: AWS axillary web syndrome, SLNB- sentinel node negative patients, MAS mastectomy, BCS breast-conserving surgery, *significant difference ($p < .005$)

Table 1

Characteristics of the surveyed sentinel node negative breast cancer patients

(n=126)

Age (years) mean (SD)	64.3 (SD±9.5)
Time between SLNB and data collection (months) mean (SD)	55.5 (SD±17.0)
BMI mean (SD)	25.7 (SD±4.1)
	n (%)
Sex	
Male	2 (1.6%)
Female	124 (98.4%)
Breast surgery	
BCS	82 (65.1%)
Mastectomy	44 (34.9%)
Surgery on dominant side	53 (42.1%)
Preoperative bra cup size	
A	11 (8.7%)
B	31 (24.6%)
C	44 (34.9%)

D	13 (10.3%)
E	6 (4.8%)
F	0 (0%)
G	1 (0.8%)
H	1 (0.8)
Unknown	19 (15.1%)
Radiation therapy	89 (70.6%)
Chemotherapy	23 (18.3%)
Hormonal therapy	101 (80.2%)
Post-menopausal	79 (62.7%)

SD standard deviation, *SLNB* sentinel lymph node biopsy, *BMI* body mass index, *BCS* breast-conserving surgery

Table 2 Percentages of activity limitations and participation restrictions in sentinel negative patients

Activity limitations	
Putting on a bra	58.7%
Getting dressed	57.9%
Wearing a bra	50.8%
Sleeping	50.0%
Sports	48.4%
Driving	35.7%
Walking	27.0%
Reading/craft work/TV	26.2%
Sitting	23.0%
Participation restrictions	
Household	55.5%
Work	39.7%

Table 3 Prevalence of arm and shoulder complaints in the present study compared to the prevalence found in the literature

	Prevalence in present study (%)	Prevalence in literature* (%)
Pain	43.5	3.3-56.6
Numbness	22.4	2.7-64.0
Paresthesias	12.3	8.6-10.4
Lymphedema	7.1	0-15.8
AWS	14.6	11.7-20.0
Loss of strength	43.2	5.0-28.0
Loss of mobility	53.7	0-100

AWS Axillary web syndrome; * based upon the systematic review of Verbelen et al, 2014 BCRT