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The Effect of Prospective Monitoring and Early Physiotherapy Intervention on Arm Morbidity Following Surgery for Breast Cancer: A Pilot Study

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ABSTRACT

Purpose: Significant arm morbidity is reported following surgery for breast cancer, yet physiotherapy is not commonly part of usual care. This study compared the effect on arm morbidity after surgery for breast cancer of a clinical care pathway including preoperative education, prospective monitoring, and early physiotherapy (experimental group) to that of preoperative education alone (comparison group). ***Methods:*** A prospective quasi-experimental pretest–posttest, non-equivalent group design compared two clinical sites; Site A ($n = 41$) received the experimental intervention, and Site B ($n = 31$) received the comparison intervention. At baseline (preoperative) and 7 months postoperative, shoulder range of motion (ROM), upper-extremity (UE) strength, UE circumference, pain, UE function, and quality of life were assessed. ***Results:*** The experimental group maintained shoulder flexion ROM at 7 months, whereas the comparison group saw a decrease (mean 1° [SD 9°] vs. −6° [SD 15°], $p = 0.03$). A lower incidence of arm morbidity and better quality of life were observed in the experimental group, but these findings were not statistically significant. Baseline characteristics and surgical approaches differed between the two sites, which may have had an impact on the findings. ***Conclusion:*** Initial results are promising and support the feasibility of integrating a surveillance approach into follow-up care. This pilot study provides the foundation for a larger, more definitive trial.

Key Words: breast neoplasms; lymphedema; muscle strength; range of motion; upper extremity.

RÉSUMÉ

Objectif : Un taux de morbidité considérable est constaté à la suite de chirurgie pour le cancer du sein, et malgré cela, la physiothérapie ne constitue pas un aspect habituel des soins. Cette étude vise à comparer l'effet d'une ligne de soins cliniques qui comprend une éducation préopératoire, un suivi prospectif et de la physiothérapie précoce (à titre expérimental) à l'éducation préopératoire seule (comparaison) sur la morbidité du bras après une chirurgie de cancer du sein. ***Méthodologie :*** Une étude prospective quasi expérimentale prétest, post-test, avec groupe témoin non équivalent a été utilisée pour comparer deux sites cliniques, dont le site A a reçu l'intervention ($n = 41$) et le site B, l'intervention de contrôle ($n = 31$). Initialement (en phase préopératoire) et en phase postopératoire après 7 mois, l'amplitude articulaire (ADM) de l'épaule, la force du membre supérieur, la circonférence du membre supérieur, la douleur et la fonction du membre supérieur ainsi que la qualité de vie ont été évaluées. ***Résultats :*** Le groupe expérimental a pu maintenir une ADM de l'épaule en flexion à 7 mois, alors que l'amplitude articulaire avait diminué dans le groupe de comparaison (moyen [écart-type] 1° [9°] comparativement à −6° [15°], $p = 0{,}03$). Une plus faible incidence de morbidité du bras et une meilleure qualité de vie ont été observées dans le groupe expérimental comparativement au groupe de comparaison; toutefois, les conclusions obtenues ne sont pas significatives sur le plan statistique. Les caractéristiques initiales et les approches chirurgicales différaient dans les deux sites, ce qui pourrait avoir influé sur les résultats obtenus. ***Conclusion :*** Les résultats initiaux sont prometteurs et appuient la faisabilité de l'intégration d'une approche de surveillance aux soins de suivi. Cette étude pilote pourrait fournir les bases d'un essai plus important et plus concluant.

Advances in early detection and adjuvant treatment have led to a 5-year survival rate of 88% for women diagnosed with breast cancer in Canada. Preventing or minimizing the complications of breast-cancer treatment are important to maximize function and quality of life (QOL) after breast cancer treatment.[1,2] Arm morbidity—defined as decreased shoulder range of motion (ROM), arm strength, and arm function; increased arm pain; or the development of breast-cancer-related lymphedema—is a complication commonly experienced following surgery

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for breast cancer. In a 2008 Canadian study that looked at ROM, pain, and lymphedema 6 to 12 months after breast-cancer surgery, 50% of women had ROM restrictions, 39% reported pain, and 12% had lymphedema (based on three different measures).[3] These findings are consistent with those of a prospective cohort study in Australia.[4–6] Despite this evidence of a high incidence of arm morbidity following surgery for breast cancer, there has been minimal research on early detection via surveillance or examining interventions to prevent arm morbidity.[7–9] Despite advances in cancer-treatment techniques such as the sentinel lymph node biopsy approach,[7,10–12] arm morbidity continues to have a substantial impact on women's lives.[3,5,13] In addition, women have reported that ''returning to normal activities'' following surgery took longer than they or their physicians expected.[14]

Currently, the incidence of breast-cancer-related lymphedema varies in the literature from 5% to 56% within 2 years of surgery for breast cancer.[12,15–18] Among women who develop breast-cancer-related lymphedema, it most commonly presents within 12 months after surgery.[19] The development of lymphedema results in physical disability, pain, predisposition to infection, and substantial out-of-pocket treatment costs.[20–24] If not treated early, lymphedema may develop into a chronic condition; when lymphedema is detected later as opposed to earlier, treatment costs are five times as high ($3,124 vs. $636).[25]

The presence of other upper-body symptoms after breast surgery, including weakness, stiffness, numbness, tingling, pain, and poor ROM, is variably reported in the literature.[4,5] This variability could be due to differences in reporting methods, as well as to the varied length of follow-up periods after the surgery. In a study by Hayes et al., between 10% and 60% of women reported at least one upper-body symptom at any point from 6 months to 3 years after breast-cancer surgery, and it was more common to have multiple symptoms than one symptom alone.[4] Of these symptoms, pain (including breast pain, myofascial pain syndrome, and axillary web syndrome[15,16]) has been reported by 12%–51% of women.[4]

Emerging research suggests that preoperative education and postoperative physiotherapy can help women to regain their shoulder ROM after surgery and improve upper-body symptoms relative to usual care, but limited sample sizes and study methods have precluded conclusive findings.[26–28] Furthermore, a surveillance programme that included preoperative limb-volume measurement and postoperative follow-up to detect and treat subclinical lymphedema with compression was shown to be effective at returning limb volume to normal values.[9] In 2010, Spanish researchers reported on a randomized controlled trial comparing education alone to education plus early physiotherapy to prevent secondary lymphedema. Participants in the group receiving education alone were diagnosed with secondary lymphedema three times as often (risk ratio 0.28, 95% CI, 0.10–0.79) as the group receiving education and early physiotherapy.[8] In this study, the early physiotherapy intervention was three physiotherapy treatment sessions per week for 3 weeks, regardless of postoperative presentation. In contrast, prospective postoperative monitoring with targeted early physiotherapy treatment may be as efficacious and more cost effective in reducing the prevalence of persistent arm morbidity following surgery for breast cancer.

The purpose of this study was to determine the effect of a clinical care pathway including preoperative education, prospective monitoring, and early physiotherapy versus preoperative education alone in reducing arm morbidity and improving QOL at 7 months after surgery in women who received surgery for breast cancer.

METHODS

Study design

Using a prospective quasi-experimental pretest–posttest, non-equivalent group design, we recruited women undergoing surgery for breast cancer at two sites within the same health authority in British Columbia, Canada. The sites were chosen because they had similar numbers of breast-cancer surgeries and an existing difference in physiotherapy clinical practice. At Site A, a breast-cancer clinical care pathway was already in place that included physiotherapy preoperative teaching, postoperative monitoring by a physiotherapist, and early physiotherapy intervention; participants recruited from this site, therefore, constituted the experimental group. At Site B, there was no clinical care pathway for physiotherapy in place; participants recruited at this site constituted the control (comparison) group.

Participants

Potential participants were given information about the study during their initial visit to the pre-admission clinic. Eligible participants were women receiving surgery for breast cancer, including modified radical mastectomy, simple mastectomy, or breast-conserving surgery. All cancer stages were included in the study. Women were excluded if they were (1) receiving transverse rectus abdominis myocutaneous (TRAM) flap reconstructive surgery at the same time as the breast surgery; (2) unable to provide informed consent in English; or (3) physically unable to engage in a physiotherapy protocol. Ethical approval to conduct the study was obtained from the Fraser Health Research Ethics Board; all participants provided informed consent.

Study treatment

At baseline (preoperative) and 7 months after surgery, all participants attended a standard physiotherapy assessment that included measurement of shoulder active range of motion (AROM), upper-extremity (UE) strength, and UE circumference at 9 points.

Both groups received standardized preoperative education, including standard postoperative AROM exercises, information about lymphedema, and information about

Box 1 Standard Preoperative Education Programme Components

Intervention component	Topic	Focus
General postop exercises	Mobility	• Breathing exercises • Ankle pumping • Walking
Active-assisted ROM (10 reps every 4 h during the day)	Neck	• Rotations • Side flexion
	Wrist	• Flexion • Extension • Circumduction
	Elbow	• Flexion • Extension
	Shoulder	• Pendulum • Flexion (wall climb and self-assisted)* • Abduction (wall climb)* • Gentle pectoral stretch (seated)*
Education on lymphedema	General information	• Definition of lymphedema • Usual time course of development • Early signs and symptoms
	Risk-reduction behaviours	• Avoiding blood draws or taking blood pressure on affected arm • Avoiding extremes in temperature • Understanding the importance of good skin care (e.g., use insect repellant and sunscreen; wear gloves for protection when gardening; be careful when trimming nails) • Avoiding localized compression to the arm and chest wall region (e.g., carry your purse on the opposite side) • Maintaining a healthy body weight • Encouraging regular exercise • Understanding when to seek medical attention
	Modifiable and non-modifiable risk factors	• Number of lymph nodes removed • Radiation to axilla and regional lymph nodes • Higher body weight or BMI • Infection
Scar management	Instructions on scar massage	• When it is safe to start massage • Demonstration and practice of scar massage technique

BMI = body mass index.
*Started once the drain had been removed and at least 1 week after surgery.

scar massage along the line of the incision after healing (Box 1). The exercises included neck rotation and side flexion, wrist flexion/extension and circumduction, elbow flexion/extension, and pendular exercises for the first week after surgery. Once the drain was removed and 1 week had passed since the surgery, participants were asked to begin supine active assisted shoulder flexion and extension and wall-walking exercises for shoulder abduction and flexion, as well as a gentle seated pectoralis stretch. The information about lymphedema included a general description of the lymphatic system and lymphedema and information about preventing lymphedema and how to monitor for signs and symptoms of lymphedema. The education was carried out via a standard protocol by one of two trained physiotherapists. All participants were given the same printed educational material, which included information about postoperative exercises and activity modification, scar massage, and prevention of secondary lymphedema.

Participants in the experimental group received the standardized preoperative education and were also seen twice postoperatively, at 1 month and 6 months after surgery (monitoring visits), for reassessment using the same standardized physiotherapy assessment and progression of postoperative exercise (see Box 1). Further physiotherapy treatments were provided as indicated if, relative to baseline, there was (1) a decrease in ROM ($\geq 10^\circ$ in shoulder ROM for external rotation, shoulder

abduction, or shoulder flexion); (2) a decrease in strength (by one grade of manual muscle testing); (3) an increase in limb girth (>2 cm at any of the 9 measurement points); or poor posture (based on clinical impression). These further physiotherapy treatments focused on teaching self-management strategies and included lymphedema management (i.e., use of bandaging, self-massage and exercise, followed by compression garments as needed), scar-tissue massage, and progressive active and assisted shoulder exercises as outlined by Harris et al.[29] The duration and number of additional visits was recorded.

Outcome measures

Outcome measures were collected at baseline preoperatively and 7 months postoperatively for all participants. The primary outcome for the study was a composite measure of arm morbidity, defined as a decrease in shoulder ROM ($\geq 10^\circ$ difference from baseline) and/or the presence of lymphedema (as measured by a 2 cm increase in UE circumference between adjacent points, taking into account pre-surgical differences). The secondary outcomes were UE strength, UE function, QOL, and postoperative pain.

The physiotherapy assessment included measurement of shoulder AROM using a plastic goniometer (12″ Jamar, Lafayette Instrument Company, Lafayette, IN), UE strength (manual muscle testing), and UE circumference at 9 points,[30] using a weighted flexible tape measure (Jamar, Lafayette Instrument Company, Lafayette, IN). These measurements were carried out by one of four non-blinded physiotherapists who completed standardized education and training regarding the measurement protocol. Further assessment of measurement technique and procedures was carried out using two healthy volunteers before the study began.

Participants also completed self-report questionnaires on UE function (Disabilities of Arm, Shoulder and Hand [DASH])[31] and QOL (Functional Assessment of Cancer Therapy—Breast, which includes four questions on arm symptoms [FACT-B+4]),[32] as well as reporting the presence of pain with movement before the surgery (Y/N) and pain levels at rest and with movement after the surgery (using a visual analogue scale).

Demographic information, including age, height, and weight, was collected from the medical chart by the physiotherapists completing the measures. Medical data, including diagnosis, past medical history, current medications, type of surgery, and stage of cancer, were also abstracted from the chart. At 7 months, data on postoperative course was collected, including postoperative infection, number of lymph nodes removed, breast reconstruction, and adjuvant cancer treatment. Special attention was paid to the collection of data on risk factors for lymphedema, including body mass index (BMI), number of lymph nodes dissected, presence of a postoperative infection, and radiation to the axilla.[25]

Statistical analysis

Baseline data for participants in the experimental and comparison groups were summarized using descriptive statistics, including means and standard deviations for continuous variables and frequency counts and percentages for categorical variables. Differences between groups at baseline were assessed using independent-samples *t*-tests for continuous variables and chi-square tests for categorical variables.

To compare outcomes at 7-month follow-up, we calculated the difference between baseline (preoperative) values and values at 7 months after surgery for continuous variables and compared these using independent-samples *t*-tests. For categorical variables, we compared proportions postoperatively using chi-square tests. We evaluated outcomes by two definitions of arm morbidity: (1) a difference in any shoulder ROM for external rotation, shoulder abduction, or shoulder flexion (vs. preoperative measures) of $\geq 10^\circ$, and/or presence of secondary lymphedema as measured by a 2 cm increase in UE circumference between adjacent points, taking into account pre-surgical differences; and (2) a difference in any shoulder ROM for external rotation, shoulder abduction, or shoulder flexion (vs. preoperative measures) of $\geq 20^\circ$, and/or presence of secondary lymphedema as measured by a 2 cm increase in UE circumference between adjacent points, taking into account pre-surgical differences. Using these definitions, we calculated the proportions of participants with arm morbidity at each site and compared these using chi-square tests.

RESULTS

The study enrolled 73 participants, 42 in the experimental group and 31 in the comparison group. One participant did not complete the 7-month follow-up visit and was therefore removed from the data analysis, leaving 41 participants in the experimental group and 31 in the comparison group. For 61 participants (85%), this was their first diagnosis of breast cancer; 11 (15%) had a previous diagnosis of breast cancer. However, 15 participants had had a prior breast-cancer surgery, as some participants had undergone an additional breast surgery (i.e., prior lumpectomy followed by a more extensive surgery) and were recruited at the time of their second surgery. One participant had bilateral breast cancer; for this participant, only data for the side undergoing more extensive surgery were included in our study. Baseline participant characteristics by site are outlined in Table 1. Compared to the comparison group, participants in the experimental group were more likely to undergo a modified radical mastectomy (53.7% vs. 22.6%, $p = 0.03$), to have immediate reconstruction (53.7% vs. 9.7%, $p < 0.01$), to be younger (mean 55.1 [SD 14.8] vs. 62.8 [14.1] years, $p = 0.03$), and to have lower preoperative QOL scores (mean 105.42 [SD 18.3] vs. 117.60 [18.4], $p < 0.01$). Risk factors for secondary lymphedema were similar between

Table 1 Baseline Subject Characteristics by Study Site

Characteristics	No. (%) of patients*		
	Site A (experimental) ($n = 41$)	Site B (comparison) ($n = 31$)	p-value†
Demographic data, mean (SD)			
Age, y	55.1 (14.8)	62.8 (14.1)	0.03
BMI, kg/m^2	27.1 (5.4)	27.0 (4.2)	0.96
Lymph nodes dissected, no.	7.6 (6.3)	9.7 (6.3)	0.16
Lymph nodes positive, no.	1.8 (4.2)	1.4 (3.7)	0.66
Cancer stage			
DCIS or Stage 1	2 (4.9)	2 (6.5)	0.94
Stage II	14 (34.1)	10 (32.2)	
Stage III	19 (46.3)	13 (41.9)	
Unknown	6 (14.6)	6 (19.4)	
Surgery type			
Modified radical mastectomy	22 (53.7)	7 (22.6)	0.03
Simple mastectomy	7 (17.1)	9 (29.0)	
Breast conserving	12 (29.3)	15 (48.4)	
Previous breast surgery‡	9 (22.0)	6 (19.4)	0.79
Treatment			
Reconstruction	22 (53.7)	3 (9.7)	<0.01
Adjuvant radiation	22 (53.7)	14 (45.2)	0.48
Adjuvant chemotherapy	16 (39)	16 (32.3)	0.55
Muscular strength (MMT)			
Shoulder abduction			
<5	11 (26.8)	6 (19.4%)	0.46
5	30 (73.2)	25 (80.6%)	
Shoulder flexion			
<5	10 (24.4)	3 (9.7%)	0.11
5	31 (75.6)	28 (90.3%)	
Shoulder external rotation			
<5	11 (26.8)	5 (16.1%)	0.28
5	30 (73.2)	26 (83.9%)	
Elbow flexion			
<5	10 (24.4)	4 (12.9%)	0.22
5	31 (75.6)	27 (87.1%)	
Risk factors for lymphedema			
Presence of >1 risk factor	19 (46.3)	15 (48.4)	0.85
>5 nodes dissected	22 (53.7)	23 (74.2)	0.08
Postoperative infection	4 (9.8)	2 (6.5)	0.62
Radiation	22 (53.7)	14 (45.2)	0.48
BMI >30	8 (19.5)	6 (19.4)	0.99
Preoperative pain	3 (7.3)	3 (9.7)	0.72

*Unless otherwise specified.
†Based on independent samples t-test for continuous variables and chi-square tests for categorical variables.
‡Either another primary on same side or second surgery for same cancer diagnosis (e.g., modified mastectomy following lumpectomy).
BMI = body mass index; DCIS = ductal carcinoma in situ; MMT = manual muscle testing.

the groups, although more women in the comparison group than in the experimental group had >5 lymph nodes removed during breast surgery (74.2% vs. 53.7%, $p = 0.08$; see Table 1).

The mean number of physiotherapy visits for the experimental group was 2.73 (SD 2.16), including the 2 monitoring visits and any additional required visits. The number of additional physiotherapy visits varied from 1 to 10. Twelve of the 41 participants (29%) required additional visits: 4 (10%) required 1 additional visit, 5 (12%) required 2, 2 (5%) required 6, and 1 (2%) required 10. Reasons for these additional visits were decreased ROM, decreased strength, increased limb girth, decreased scar mobility, poor posture, axillary web syndrome, increased pain, or any combination of these outcomes; the most frequent reason cited for additional visits was decreased ROM. The treatment time required for the additional visits was between 30 and 45 minutes.

Table 2 Effect of the intervention on arm morbidity

	Group; no. (%) of patients*						
	Experimental ($n = 41$)			Comparison ($n = 31$)			
Characteristics	Baseline	7 months	Change	Baseline	7 months	Change	p-value†
Mean shoulder range of motion (SD), degrees							
Abduction	157.5 (21.1)	158.2 (19.7)	0.45 (9.68)	156.0 (11.3)	151.8 (16.4)	−4.23 (13.62)	0.11
Flexion	149.7 (16.3)	150.1 (14.6)	0.63 (9.44)	152.5 (14.2)	146.4 (18.1)	−6.06 (14.98)	0.03
External rotation	93.5 (19.4)	94.9 (14.4)	1.43 (13.77)	85.7 (7.5)*	82.9 (10.9)	−2.71 (11.08)	0.17
Muscular strength							
Shoulder abduction							
Increase strength	NA	3 (7.5)	NA	NA	4 (12.9)	NA	0.50
Decrease strength	NA	7 (17.5)	NA	NA	2 (6.5)	NA	0.17
Shoulder flexion							
Increase strength	NA	5 (12.5)	NA	NA	2 (6.5)	NA	0.40
Decrease strength	NA	3 (7.5)	NA	NA	1 (3.2)	NA	0.44
Shoulder external rotation							
Increase strength	NA	3 (7.5)	NA	NA	0 (0)	NA	0.12
Decrease strength	NA	4 (10.0)	NA	NA	1 (3.2)	NA	0.27
Elbow flexion							
Increase strength	NA	6 (15.0)	NA	NA	1 (3.2)	NA	0.10
Decrease strength	NA	1 (2.5)	NA	NA	1 (3.2)	NA	0.90
Lymphedema	NA	1 (2.5)	NA	NA	3 (9.7)	NA	0.19
DASH Score, mean (SD)	13.6 (17.7)	18.3 (18.7)	4.76 (16.56)	11.8 (14.0)	13.7 (15.1)	1.86 (13.69)	0.27
DASH >25	NA	7 (18.4)	NA	NA	4 (13.8)	NA	0.61
DASH ≤ 25	NA	31 (81.6)	NA	NA	25 (86.3)	NA	NA
FACT-B+4, mean (SD)	102.3 (18.8)	105.42 (18.3)	1.92 (16.21)	120.0 (12.2)	117.60 (18.4)	−1.35 (16.05)	0.43
Pain (VAS), mean (SD) cm							
At rest	0.07 (0.3)	7.8 (15.5)	7.5 (15.3)	0.10 (0.30)	8.9 (11.9)	8.5 (11.8)	0.74
With activity	NA	16.6 (23.4)	NA	NA	24.6 (27.1)	NA	0.20

*Unless otherwise specified.
†Difference from baseline to 7-month follow-up.
NA = not applicable; DASH = Disabilities of the Arm, Shoulder and Hand; FACT-B+4 = Functional Assessment of Cancer Therapy—Breast; VAS = visual analogue scale.

At 7 months after surgery, shoulder ROM had returned close to baseline values in the experimental group, as indicated by positive changes in postoperative ROM measurements (see Table 2). In contrast, postoperative ROM measurements were lower than baseline in the comparison group. This finding was consistent across all ROM measures, although only reaching statistical significance for measurement of shoulder flexion ROM (+1° [SD 9°] vs. −6° [SD 15°], $p = 0.03$). We did not detect a statistically significant difference in change in QOL postoperatively in the experimental group versus the comparison group (+1.9 [SD 16.2] vs. −1.4 [SD 16.1], $p = 0.43$). We also observed a lower proportion of participants who developed lymphedema in the experimental group than in the comparison group, although this difference was not statistically significant (2.5% vs. 9.7%, $p = 0.19$; see Table 2).

Using the study definitions for arm morbidity, we observed a lower proportion of women experiencing arm morbidity in the experimental group than in the comparison group; however, this difference was not statistically significant. Specifically, using the first definition (ROM difference $\geq 10°$ from baseline and/or lymphedema), arm morbidity was observed in 26.8% of participants in the experimental group and 32.3% in the comparison group ($p = 0.62$); using the second definition (ROM difference $\geq 20°$ from baseline and/or lymphedema), arm morbidity was observed in 9.8% of participants in the experimental group and 16.1% in the comparison group ($p = 0.42$).

DISCUSSION

Persistent arm morbidity after breast-cancer surgery was observed in as many as 32% of women in our study at 7-month follow-up, depending on the study site and the definition of arm morbidity used. This finding highlights the need for more effective management to identify and treat UE impairments following surgery for breast

cancer. In this study, we attempted to separate the effect of preoperative education, prospective monitoring, and early physiotherapy from preoperative education alone on arm morbidity after breast-cancer surgery. Our main findings include a deficit in shoulder ROM and higher incidence of arm morbidity in the comparison group than in the experimental group. Overall, the main goal of this pilot study was to generate estimates for our composite outcome measure of arm morbidity, which can be used to provide insight for a sample-size calculation as part of planning a larger definitive study. While only the outcome of shoulder flexion ROM reached statistical significance, trends across all other outcomes were better among participants in the experimental group. These results suggest a possible benefit of physiotherapy preoperative teaching, postoperative monitoring, and early physiotherapy intervention that warrants further investigation. It should also be noted that when a need for additional physiotherapy was identified, the majority of participants needed only one or two additional visits to address the issue, which suggests that this is a very efficient treatment approach.

Almost half of the sample in this pilot study consisted of women who had fewer than 5 axillary lymph nodes removed. This patient group has a lower incidence of lymphedema-related arm morbidity than women who have more lymph nodes removed.[25] Therefore, our sample may have been at a lower risk of arm morbidity. A larger sample size may be needed to show changes in this lower-risk population.

Given the quasi-experimental design of our study, the risk of arm morbidity may have differed between the two groups because of differences in age and surgical treatment between the two clinical sites. In observational research, a higher risk of arm morbidity has been consistently associated with axillary dissection,[4,13,18] removal of a greater number of lymph nodes,[3,33,34] infection in the arm on the side of breast surgery,[3,18,35,36] axillary radiotherapy,[3,13,37] overweight/obesity,[3,33,34,36] and greater age.[4] While women at Site B (the comparison group), were older and might therefore be considered at higher risk for arm morbidity, women at Site A (the experimental group) were more likely to receive more extensive surgery and more likely to undergo immediate reconstruction, both factors that are associated with a higher risk for arm morbidity and postoperative pain.[38–40] Since the experimental group had a non-significant lower incidence of arm morbidity than the comparison group, we speculate that the intervention was effective in lowering the incidence of arm morbidity at 7 month after surgery, despite the experimental group's more extensive surgery and greater likelihood of undergoing immediate reconstruction. In the absence of randomization, however, this cannot be confirmed.

We chose not to include a measure of arm volume in this study because it is not part of a clinical diagnosis of lymphedema at our clinical sites. Arm volume can be calculated from arm circumference measures[41] or can be measured through water displacement[42,43] or using a perometer.[30,44] Arm volume may be a more sensitive way to detect early changes in the arm consistent with the development of lymphedema; therefore, the calculation or direct measurement of arm volume may be a valuable addition to future studies.

LIMITATIONS

We believe that our findings provide preliminary evidence for the positive effect of prospective monitoring and early physiotherapy intervention on arm morbidity, but the study is limited by several factors. First, our last data measurement took place 7 months after surgery; a longer follow-up period may be necessary to understand the true incidence and time course of arm morbidity. One recent study demonstrated that the average time to the development of postoperative lymphedema was 6.9 months,[9] while others have demonstrated the development of lymphedema between 6 and 12 months after surgery.[8]

Furthermore, the quasi-experimental study design meant that the subjects in this study were not randomized to the experimental or comparison group. As a result, the two groups were at unequal risk of developing arm morbidity because of differences in patient characteristics and surgical approaches at the two study sites. Sub-group analysis by specific risk factor (e.g., radiation, $\geq$5 nodes removed, or modified radical mastectomy) was not possible because of the small number of events in each treatment group and the uneven distribution of events between sites.

Finally, the physiotherapists who carried out the 7-month follow-up assessments were not blinded to group assignment, since the assessors worked at one of the two study sites and therefore were aware of which study arm the participants at each site belonged to.

Recommendations for future research include a larger sample size, longer follow-up, random allocation of subjects, and use of independent assessors blinded to group allocation. In addition, examination of the influence of surgical approach should be included in the statistical analysis plan. Using a conservative estimate of expected incidence of arm morbidity at 12 months after surgery—25% for the comparison group (based on this pilot study) and 10% for the experimental group (based on published intervention studies[10,22,29])—a sample size of 97 participants per group, or 194 in total, is needed to detect a minimal clinically important difference of 15% between groups (two independent proportions null case). To accommodate one stratification factor of immediate reconstruction surgery at 2 levels (Y/N) and an anticipated 10% dropout rate, a sample size of 109 participants per group, or 218 in total, is required.

CONCLUSION

A clinical care pathway that includes preoperative education, prospective monitoring, and early physiotherapy shows promise to address arm morbidity following surgery for breast cancer. This pilot study provides the foundation for a larger, definitive randomized controlled trial.

KEY MESSAGES

What is already known on this topic

The majority of women report at least one persistent arm issue after surgery for breast cancer. Detecting arm morbidity, especially lymphedema, early is ideal, so that treatment can resolve the condition before it becomes chronic. Physiotherapy treatment has been shown to improve arm function postoperatively and to better identify lymphedema at its earliest stage. Prospective monitoring for early identification of arm morbidity is not common practice in the outpatient clinical setting, and even when issues are identified, access to appropriate and timely physiotherapy services may be limited.

What this study adds

Our pilot study examined a clinical care pathway focusing on preoperative education, early identification of postoperative arm issues and physiotherapy treatment compared to preoperative education alone for reducing arm morbidity, and improving QOL. Initial results are promising and support feasibility of integrating this approach into follow-up care. While the initial results are promising, a randomized controlled trial is needed to definitively address this question.

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