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The Perioperative Educational Program for Improving Upper Arm Dysfunction in Patients with Breast Cancer at 1-Year Follow-Up: A Prospective, Controlled Trial

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The many women with breast cancer who underwent axillary lymph node dissection (ALND) suffer from the upper arm dysfunction. In this study, we investigated the effectiveness of a perioperative educational program for improving upper arm dysfunction in breast cancer patients following ALND. This study was a sub-analysis of a previous controlled trial with an educational program. The subjects of this analysis included 64 patients following ALND who completed measurements at 12 months. The perioperative educational program consisted of monitoring of arm dysfunction, exercises, massage, and lifestyle adjustments. The intervention group (37 patients) received this perioperative educational program over 12 months, while 27 patients in the control group received written information about shoulder exercise from on-site staff only before surgery. Primary outcomes were shoulder range of motion (ROM), arm girth, and grip strength. Secondary outcomes were evaluated with the Subjective Perception of Post-Operative Functional Impairment of the Arm (SPOFIA) scores, the Disabilities of the Arm, Shoulder and Hand (DASH) scores, and the Medical Outcome Study 36-Item Short-Form Health Survey v2 (SF-36v2). The SF-36v2 measures health-related quality of life (QOL). Primary and secondary outcomes were compared between groups at 1 week (after drainage tube removal) and 12 months after surgery, using the Mann-Whitney U test. The horizontal extension was significantly improved only in the intervention group. Moreover, the SPOFIA score was significantly improved in the intervention group, and other scores of the secondary outcomes were similar between the two groups. The perioperative educational program may improve postoperative upper arm dysfunction and symptoms.

Keywords: breast cancer; controlled trial; education; surgery; upper arm dysfunction
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Introduction

The incidence of upper arm dysfunction, including lymphedema, pain, limited shoulder range of motion (ROM), and muscle weakness, is higher after breast cancer surgery in patients who have undergone axillary lymph node dissection (ALND) as compared to sentinel lymph node biopsy (SLNB) alone (Wilke et al. 2006; Ashikaga et al. 2010; Sagen et al. 2014). Therefore, to reduce these side effects of surgery, the education of risk minimization strategy is important in this population.

The Upper Extremity Rehabilitation Guidelines recommend that rehabilitation be continued for 6 - 8 weeks after breast cancer surgery, and that patients be closely monitored for 12 months after surgery (Harris et al. 2012). In a study involving 330 patients at 2 to 5 years after surgery with ALND, Warmuth et al. (1998) reported that 35% had numbness, 15% had pain, 15% had arm swelling, and 8% had limited shoulder ROM. These chronic symptoms in patients who have undergone ALND have also been reported in other studies (Hack et al. 1999; Voogd et al. 2003; Macdonald et al. 2005; Sagen et al. 2009, 2014). In a cross-sectional study of 150 breast cancer patients within 12 months after surgery, 85.3% of the patients had one or more of the following symptoms: arm swelling; pain; shoulder ROM limited; numbness; arm muscle weakness; and pulling sensation of the arm skin. Furthermore, the more these patients had such symptoms, the lower was their quality of life (QOL) became (Sato and Kuroda 2008). These study findings suggest the importance of continued guidance by healthcare providers to prevent chronic upper arm dysfunction and minimize impairment in daily life after

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surgery in breast cancer patients.

Regarding research on interventions aimed to prevent and improve upper arm dysfunction after breast cancer surgery, Beurskens et al. (2007) investigated the efficacy of physiotherapy advice on exercises for the arm/shoulder for 3 months in patients who underwent breast surgery with ALND in a randomized, controlled trial (15 in the intervention group and 15 in the control group). The study outcomes were pain in the arm/shoulder as recorded on a Visual Analog Scale, shoulder mobility, DASH, edema, grip strength, and QOL. The results showed significant improvement with intervention in pain, shoulder function, and QOL. However, this study had some limitations, such as the follow-up period was too short and the sample size was too small; therefore, further research is needed. In addition, most rehabilitation programs for upper arm dysfunction after breast cancer surgery have been developed with the goals of restoring shoulder ROM and minimizing lymphedema (Box et al. 2002; Harris et al. 2012). Our study outcomes were arm swelling, pain, limited shoulder ROM, numbness, arm muscle weakness, and a pulling sensation of the arm skin. The results of our Perioperative Educational Program evaluated up to 3 months after surgery in ALND and SLNB groups suggest benefits in improving subjective perception of upper arm dysfunction and grip strength in breast cancer patients who have undergone ALND, in whom physical invasiveness is greater than with SLNB alone (Sato et al. 2014). To evaluate behavioral modification and self-care maintenance in patients with chronic diseases, at least 6 months of observation is necessary (Prochaska and DiClemente 1983). Therefore, the benefits of this program to assess a breast cancer patient's ability for symptom management using the education that they have received from before surgery in their current daily life must be continued even later than 3 months after surgery. Moreover, predictive factors for decreased QOL in patients with upper arm dysfunction after breast cancer surgery have been reported in several previous studies (Rietman et al. 2003, 2004; Morgan et al. 2005; Sato and Kuroda 2008; Hayes et al. 2010; Smoot et al. 2010; Nesvold et al. 2011). Therefore, QOL must also be evaluated as an indicator of program effects.

The purpose of this study was to investigate the effectiveness of a perioperative educational program for improving upper arm dysfunction in breast cancer patients with ALND.

Methods

Study design

This study was a secondary analysis using the data from our original study, "A perioperative educational program for improving upper arm dysfunction in patients with breast cancer: long-term follow-up, controlled trial" (UMIN000018593). This was a non-randomized, controlled trial. The patients were allocated to either the intervention or the control group according to their wishes. This study was conducted with approval from the Ethics Committee of the Research Department at Tohoku University Graduate School of Medicine (Approval numbers 2009-371 and 2010-318).

Participants

Breast cancer patients who provided written, informed consent and were: 1) going to receive surgery; 2) ≥ 20 years old; 3) Eastern Cooperative Oncology Group (ECOG) performance status 0-2; and 4) able to respond to a self-administered questionnaire with no history of a diagnosis or treatment for mental illness, were recruited in Tohoku University Hospital between February 2010 and April 2012. Only patients who underwent ALND, except for those who had bilateral surgery or recurrence, were included in this analysis.

Intervention

Fig. 1 shows the theoretical framework of the "Perioperative Educational Program for Improving Upper Arm Dysfunction in Patients with Breast Cancer (perioperative educational program)" based on the University of California, San Francisco (UCSF) symptom management model (The University of California, San Francisco School of Nursing Symptom Management Faculty Group 1994).

We developed the perioperative educational program to improve postoperative arm swelling, pain, limited shoulder ROM, numbness, muscle weakness, a pulling sensation of the arm skin, and QOL in breast cancer patients. The content validity of this program has been examined for breast cancer patients, healthcare providers, and cancer nursing researchers (Sato 2012).

The intervention group received the educational program from the first author (the investigator) before surgery and 1 week (after drainage tube removal), 1 month, 3 months, 6 months, and 12 months after surgery. The first author is a registered nurse and has been involved in education and research in breast nursing for more than 20 years. We used a pamphlet focusing on the etiology of upper arm dysfunction; the patients practiced the measurement of arm girth and assessment of 15 symptoms to identify changes in their arm; and they were also taught a risk minimization strategy (McLaughlin et al. 2008) including a technique for lymphatic drainage of lymphedema and exercises for shoulder ROM. Telephone consultations were also provided. The control group received written information about shoulder exercise from on-site staff only before surgery.

Measurements

Primary outcomes were arm girth, shoulder ROM, and grip strength. Shoulder ROM (flexion, abduction, and horizontal extension) was measured with a goniometer using standardized methods. Arm girths were measured at 2 points, 10 cm distal to the lateral epicondyle (forearm arm girth) and 15 cm proximal to the lateral epicondyle (upper arm girth) (Kissin et al. 1986; Ivens et al. 1992) with a tape measure. Grip strength was measured in both hands once using a dynamometer in the standing position.

Secondary outcomes were the Subjective Perception of Post-Operative Functional Impairment of the Arm (SPOFIA) score, the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the Medical Outcome Study 36-Item Short-Form Health Survey v2 (SF-36v2).

The SPOFIA is a validated self-reported questionnaire (Cronbach's alpha = 0.92) (Sato 2008). The SPOFIA was constructed of 15 yes (1) and no (0) questions related to swelling, pain, decreased shoulder ROM, numbness, reduced muscle strength of the arm, and pulling feeling in the skin of the arm. The total SPOFIA score was

Symptom experience
1. Presence or absence and severity of lymphedema, pain, limited shoulder ROM, muscle weakness, numbness, and a pulling sensation were measured and assessed by breast cancer patient responses (impact on daily life and work) to a subjective perception scale.
2. Other symptom perception, assessment, patient responses (impact on daily life and work).
3. Measurement of arm girth, grip strength, and shoulder ROM (flexion, abduction, horizontal extension).

Symptom outcomes
1. Subjective Perception of Post-Operative Functional Impairment of the Arm (SPOFIA).
2. The Disability of the Arm , Shoulder and Hand (DASH).
3. Measurement of arm girth, grip strength, and shoulder ROM.
4. QOL (SF36v2).
5. Self-care ability (degree of achievement in ability to monitor upper arm function and prevent or improve lymphedema/ impaired motion).

Symptom management strategy

	Preoperative	1 week postoperatively after surgery	1 month, 3 months, 6 months, and 12 months after surgery
Patient/family	Knowledge about symptom mechanisms, ways to monitor arm function changes, and daily living to prevent or improve symptoms.	1. Ability to monitor lymphedema, pain, limited shoulder ROM, muscle weakness, numbness, and pulling sensations. 2. Ability to monitor arm girth for signs of lymphedema. 3. Acquire knowledge and master techniques to prevent or improve lymphedema and limited shoulder ROM.	1. Monitor and report to healthcare providers any lymphedema, pain, limited shoulder ROM, muscle weakness, numbness, or pulling sensations. 2. Monitor arm girth for signs of lymphedema. 3. Practice methods to prevent lymphedema and limited shoulder ROM.
Healthcare providers	Perform together with explanations to patients, including the use of pamphlets, symptom mechanisms, ways to monitor arm function changes, and daily living to prevent or improve symptoms.	1. Examine for limited ROM and edema, assess severity of numbness and pain, and discuss findings. 2. Monitor the course of recovery and provide and discuss information about functional recovery training. 3. Provide support for any discomfort during functional recovery training, discuss types and amount of training, and adjust when necessary. 4. Support and use information resources to evaluate function, improve ADL, and encourage patients to incorporate functional recovery training into their daily lives. 5. Discuss when lifestyle adjustments may be necessary depending on the severity of upper arm dysfunction.	
Healthcare system	Depending on the medical facility systems, information exchange among physicians, nurses, physical therapists, occupational therapists and clinical psychologists to discuss and provide individualized patient support.		

Fig. 1. The Perioperative Educational Program for improving upper arm dysfunction in patients with breast cancer.

calculated, and higher scores indicated worse symptoms. The Japanese Society for Surgery of the Hand (JSSH) version of the DASH questionnaire is a validated self-reported questionnaire (Jester et al. 2005) and evaluates impairments and limitations to activity, in addition to restrictions on participation in both leisure and work activities. The DASH consists of 30 items, and the scores of each item range from 1 to 5: 1, no difficulty; 2, mild difficulty; 3, moderate difficulty; 4, severe difficulty; and 5, inability. A higher score indicates more severe disability (Jester et al. 2005).

The SF-36V2 is a validated comprehensive scale to measure health-related QOL (Fukuhara et al. 1998a, b). This self-reported questionnaire consists of 36 items in 8 subscales: physical functioning, role physical, bodily pain, social functioning, general health perceptions, vitality, role emotional, and mental health. Lower scores indicated a worse condition.

Demographic characteristics were self-reported at the preoperative assessment. Each patient's medical history was taken from the medical records. In the original study, outcomes were measured before surgery, and 1 week, 1 month, 3 months, 6 months, and 12 months after surgery. In this secondary analysis, comparisons were performed between 1 week (after drainage tube removal) and 12 months after surgery.

Statistics

Characteristics of patients were compared between the intervention and control groups using the Mann-Whitney U test or Fisher's exact test. Primary and secondary outcomes were compared between groups at 1 week and 12 months using the Mann-Whitney U test. Differences at 1 week and 12 months after surgery were also compared between groups**.** Statistical analysis was performed using PASW Statistics for Windows version 21.0 (SPSS, Tokyo, Japan). The level of significance was ≤ 5% with two-tailed test.

Results

A total of 71 patients who underwent ALND among the 162 patients who underwent breast surgery were included in this study, and then these patients were allocated into an intervention group (n = 40) or a control group (n = 31) after 1 week (Fig. 2). Three patients in the intervention group dropped out due to loss of contact, mental illness, or death, and four patients in the control group dropped out due to loss of contact for 12 months. Therefore, 64 patients were included in this analysis (37 in the intervention group and 27 in the control group). Table 1 shows the characteristics of the patients and comparisons between the groups before surgery. There were no significant differences between the groups in demographic and clinical characteristics.

Table 2 shows the comparisons between groups at 1 week after surgery. Only grip strength was significantly different between the groups (p = 0.037). This indicates that the control group (median = 3.0; IQR = −1.5-6.2) had a greater difference in grip strength between the unaffected arm and the affected arm than the intervention group (median = 0.0; IQR = −1.3-2.2).

Table 3 shows the comparison between the groups at 12 months after surgery. The SPOFIA score was signifi-

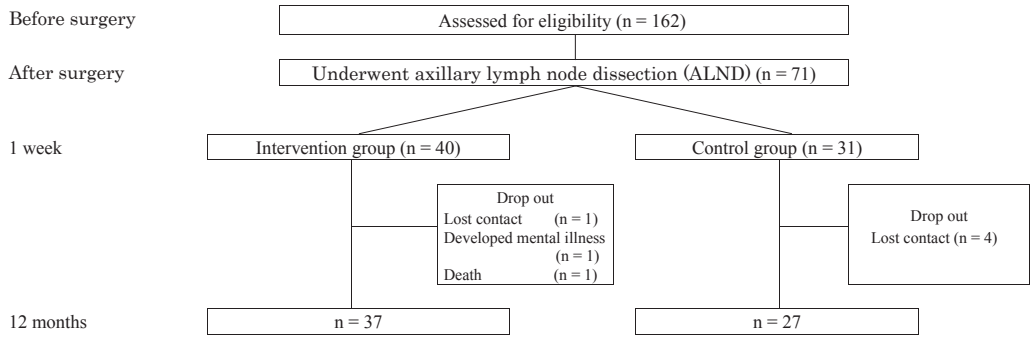

Fig. 2. Flow-chart of the analysis.

Table 1. Characteristics of the patients by group (n = 64).

Characteristics	Intervention n = 37	Control n = 27	p
Age, Median (IQR[a])	51.0 (45.0-61.5)	50.0 (46.0-58.0)	.80
Married, %	75.7	59.3	.38
Employed, %	35.1	51.9	.21
Stage, %			
0	0.0	3.7	
I	8.1	18.5	
II	43.2	55.6	.14
III	40.5	22.2	
IV	8.1	0.0	
Type of surgery, %			
Lumpectomy	43.2	59.3	.31
Mastectomy	56.8	40.7	
Level of Axillary lymph node dissection, %			
I	24.3	44.4	
II	56.8	37.0	.20
III	18.9	18.5	
Adjuvant treatment, %			
Radiotherapy	70.3	85.2	.38
Chemotherapy, targeting therapy	78.4	88.9	.35
Endocrine therapy	83.8	66.7	.14

Age, Mann-Whitney U test; other characteristics, Fisher's exact test.
[a]IQR, interquartile range.

cantly lower (p = 0.037) in the intervention group (median = 2.0; IQR = 1.0-4.0) than in the control group (median = 3.0; IQR = 1.0-7.0). Examining the difference between 1 week and 12 months after surgery, horizontal extension was significantly improved in the intervention group (p = 0.020). Furthermore, horizontal extension was better in the intervention group (median = −4.0; IQR = −10.5-0.0) than in the control group (median = 0.0; IQR = −4.0-6.0).

Discussion

The present intervention program improved the SPOFIA scores, representing subjective symptoms, and horizontal extension of shoulder ROM. The SPOFIA scale used in the present study included symptoms such as pain, numbness, and a pulling sensation of the arm skin, which are only subjective experiences reported by patients. These subjective symptoms and objective evaluations such as arm girths, ROM, and grip strength often did not match. Subjective symptom experience is the most important parameter for assessing physical function (Segerström et al. 1991) and is often a major source of discomfort for patients (Petrek et al. 2000). The more the patients perceive a certain symptom, the more likely they will behave to avoid that symptom (McLaughlin et al. 2008). Our education program might have helped patients understand the symptoms related to breast surgery and made them check their symptoms in daily life. This may have led patients to start self-care activities for their symptoms.

Table 2. Comparison of intervention and control groups 1 week after surgery.

	1week after surgery		
	Intervention	Control	p
	n = 37	n = 27	
	Median (IQR[a])		
Arm girth[b]			
Upper arm	0.5 (−0.1-1.3)	0.5 (−0.3-1.3)	.690
Forearm	0.3 (−0.4-1.1)	0.0 (−0.3-0.8)	.531
Shoulder ROM[c]			
Flexion	20.0 (7.5-53.0)	18.0 (9.0-48.0)	.843
Abduction	18.0 (10.5-52.0)	20.0 (8.0-64.0)	.940
Horizontal extension	3.0 (−0.5-8.5)	1.0 (−1.0-4.0)	.100
Grip strength[d]	0.0 (−1.3-2.2)	3.0 (−1.5-6.5)	.037*
SPOFIA (0-15)[e]	6.0 (4.5-8.0)	6.0 (4.0-9.0)	.800
DASH (0-100)[f]	19.2 (11.7-33.3)	22.5 (15.0-36.7)	.391
SF36v2 (0-100)[g]			
Physical functioning	80.0 (70.0-95.0)	80.0 (65.0-85.0)	.311
Role physical	75.0 (50.0-96.9)	62.5 (50.0-93.8)	.873
Bodily pain	52.0 (41.0-84.0)	64.0 (41.0-74.0)	.503
Social functioning	75.0 (50.0-100)	62.5 (50.0-100)	.983
General health perceptions	57.0 (52.0-69.5)	57.0 (50.0-72.0)	.978
Vitality	62.5 (53.1-75.0)	62.5 (50.0-75.0)	.864
Role emotional	75.0 (50.0-100)	75.0 (50.0-91.7)	.512
Mental health	70.0 (55.0-80.0)	60.0 (45.0-85.0)	.553

Mann-Whitney U test.
[a]IQR, interquartile range.
[b]Arm girth (cm) = affected arm girth − unaffected arm girth.
[c]Shoulder ROM (°) = unaffected arm − affected arm.
[d]Grip strength (kg) = unaffected arm − affected arm.
[e,f]Higher scores indicate a worse condition.
[g]Lower scores indicate a worse condition.
*$p < 0.05$.

The Perioperative Educational Program is based on a symptom management model that attaches importance to a patient's experience. The causes and mechanisms of symptom onset were explained before surgery. This explanation included a pamphlet and demonstrations based on individualized patient assessment, including the level of ALND and whether there was nerve resection, symptom duration, symptoms that may occur in the future, and lifestyle and preventive methods to help avoid these symptoms. At 1 month after surgery, the need for lifestyle adjustments was discussed based on each patient's symptom experience, symptom strategy, and symptom outcomes. Assistance was provided to patients so that they could decide further symptom strategies for themselves. This process for continued intervention increases a patient's ability for symptom management, which is reflected by a decrease in the SPOFIA score and improvement in horizontal extension.

The Perioperative Educational Program proposes a strategy based on providing breast cancer patients with information about symptom management whenever necessary and encouraging patients to feel free to report their symptoms to healthcare providers. These strategies help to relieve the anxiety that breast cancer patients may have about symptoms and can be applied to symptom management strategies. Our program also includes abdominal breathing exercises, as well as massage of the upper arm and area around the mastectomy site. These techniques can improve relaxation and circulation, as well as other symptoms such as heaviness, fatigue, and swelling and numbness in the arms. Active stretching exercises of the upper arm are recommended starting 1 week after surgery or after drains have been removed, and they should be continued until full ROM is achieved (Harris et al. 2001). However, after hospital discharge, when interventions by healthcare providers decrease, patients must understand the importance of continuing rehabilitation through self-care. There might not have been education or follow-up in the control group about the need to continue active stretching exercises

Table 3. Comparison of intervention and control groups 12 months after surgery.

	12 months after surgery			The difference between 1week and 12 months after surgery *Δ*		
	Intervention	Control	p	Intervention	Control	p
	n = 37	n = 27		n = 37	n = 27	
	Median (IQR[a])			Median (IQR[a])		
Arm girth[b]						
Upper arm	0.5 (−0.1-1.1)	0.3 (−0.3-1.5)	.610	−0.1 (−0.6-0.6)	−0.1 (−0.9-0.4)	.844
Forearm	0.0 (−0.5-1.5)	0.0 (−0.6-0.7)	.586	−0.2 (−0.7-0.6)	−0.2 (−0.7-0.6)	.854
Shoulder ROM[c]						
Flexion	6.0 (−6.0-14.0)	5.0 (0.0-12.0)	.559	−18.0 (−49.5-−2.5)	−15.0 (−39.0-−1.0)	.913
Abduction	6.0 (−8.5-15.0)	10.0 (3.0-17.0)	.174	−15.0 (−55.5-−7.0)	−11.0 (−31.0-11.0)	.392
Horizontal extension	−2.0 (−4.0-2.0)	1.0 (−2.0-5.0)	.074	−4.0 (−10.5-0.0)	0.0 (−4.0-6.0)	.020*
Grip strength[d]	−0.5 (−2.3-1.7)	0.1 (−2.6-2.7)	.227	−0.9 (−1.8-0.8)	−1.8 (−5.6-1.7)	.121
SPOFIA (0-15)[e]	2.0 (1.0-4.0)	3.0 (1.0-7.0)	.037*	−4.0 (−5.0-−1.0)	−2.0 (−5.0-1.0)	.065
DASH (0-100)[f]	5.8 (2.9-12.9)	13.3 (3.3-20.8)	.077	−14.2 (−23.8-−5.8)	−10.0 (−20.0-−1.7)	.484
SF36v2 (0-100)[g]						
Physical functioning	90.0 (85.0-95.0)	85.0 (80.0-95.0)	.116	10.0 (0.0-20.0)	10.0 (0.0-15.0)	.978
Role physical	93.8 (75.0-100)	87.5 (68.8-100)	.405	12.5 (−3.1-43.8)	18.8 (0.0-25.0)	.924
Bodily pain	84.0 (67.0-90.0)	84.0 (62.0-90.0)	.569	21.0 (0.0-35.0)	10.0 (−18.0-38.0)	.151
Social functioning	100 (81.3-100)	100 (75.0-100)	.408	12.5 (0.0-43.8)	25.0 (0.0-37.5)	.890
General health perceptions	57.0 (51.0-77.0)	57.0 (52.0-72.0)	.193	0.0 (−5.0-15.0)	0.0 (−5.0-10.0)	.490
Vitality	68.8 (59.4-75.0)	62.5 (56.3-75.0)	.981	−6.3 (−12.5-18.8)	6.3 (−18.8-12.5)	.753
Role emotional	100 (83.3-100)	100 (66.7-100)	.463	8.3 (0.0-45.8)	8.3 (0.0-25.0)	.929
Mental health	80.0 (70.0-90.0)	75.0 (60.0-85.0)	.356	10.0 (−5.0-25.0)	10.0 (0.0-25.0)	.692

Mann-Whitney U test.
[a]IQR, interquartile range.
[b]Arm girth (cm) = affected arm girth − unaffected arm girth.
[c]Shoulder ROM (°) = unaffected arm − affected arm.
[d]Grip strength (kg) = unaffected arm − affected arm.
[e,f]Higher scores indicate a worse condition.
[g]Lower scores indicate a worse condition.
*$p < 0.05$.

until shoulder ROM fully recovered to the level before surgery. In fact, despite limited shoulder ROM, there were even some patients in the intervention group who discontinued exercises because they felt that their daily activities were not impaired or that they were just too busy. This underscores the significance of continued intervention to measure shoulder ROM and re-educate patients. The movement of horizontal extension is used less often in daily life than flexion or abduction. However, limitation of horizontal extension interferes with patients' ability to wash their back and wear a brassiere.

Next, one must consider the fact that measurements of arm girth and grip strength between the affected and normal sides were not significantly different between 1 week and 12 months after surgery. In a study of patients who underwent ALND similar to the present study, the results of the same program were analyzed by two-way ANOVA for repeated measurements of changes from before surgery to 1 week, 1 month, and 3 months after surgery. The analysis showed that grip strength improved significantly in the intervention group compared to the control group (Sato et al. 2014). The grip strength in affected side was significantly lower in control group compared to intervention group. However, careful interpretation is needed as there was a significant difference between the groups at baseline. In addition, this study was limited by a small sample size and lack of randomization.

There was no significant difference between groups in arm girth, but long-term follow-up is needed, since the onset of lymphedema after more the 10 years has been reported (Petrek et al. 2001). No residual deficits in this study were reported in either the control or the intervention group after the 12-month period. However, a multi-center, blinded, randomized, controlled trial of this program is needed in the future.

Conclusion

The effectiveness of a perioperative educational program for improving upper arm dysfunction in breast cancer patients with ALND was investigated between 1 week and 12 months after surgery. The SPOFIA score and horizontal extension were significantly improved only in the intervention group. This program may improve upper arm dysfunction and symptoms in this population.

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Conflict of Interest

We declare no conflict of interest.

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