

# Enhancing Quality of Life: The Effect of Complete Decongestive Therapy on Jordanian Women With Breast Cancer After Axillary Lymph Node Dissection

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#### ABSTRACT

**Objective:** This study aimed to compare the incidence of breast cancer-related lymphedema (BCRL) between a control group and women with breast cancer who underwent complete decongestive therapy (CDT). Moreover, the quality of life (QOL) was assessed and compared between the intervention group receiving CDT and the control group.

**Materials and Methods:** A quasi-experimental design with a purposeful sampling approach was employed for enrollment. All participants had undergone surgical interventions, specifically axillary lymph node dissection (ALND), for breast cancer at a public healthcare facility between February and July 2023. Over an 18-week period, the intervention group followed a structured CDT protocol, which included receiving skin care instructions, undergoing 30-minute manual lymphatic drainage sessions on the affected arm, wearing compression sleeves for 12 hours daily, and participating in exercise sessions three times per week.

**Results:** In total 180 women, 90 in the CDT group and 90 controls were recruited. The CTD intervention group experienced a notable reduction in the incidence of BCRL development and a significant improvement in QOL across the three assessment times (baseline vs week 9 and week 9 vs week 18) during the study (p<0.001). In contrast, the control group showed an increased rate of BCRL development and a significant decline in QOL when comparing the same three time points (p<0.001).

**Conclusion:** Implementing CDT within the first year following ALND led to a significant reduction in the incidence of BCRL and a marked improvement in the QOL for women with who underwent surgery and ALND for breast cancer.

Keywords: Breast cancer related to lymphedema; complete decongestive therapy; incidence rate; quality of life; breast cancer surgery

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#### **Key Points**

- Complete decongestive therapy (CDT) is a preventative, ameliorating therapy for breast cancer-related lymphedema (BCRL).
- CDT should be used to manage BCRL in the early stage and in high-risk groups to prevent BCRL development under the supervision of a lymphedema expert.
- CDT is considering the best treatment strategy that nurses can use to control BCRL and enhance quality of life for women with breast cancer. It requires less invasive procedures, and can be done at home.
- The benefits of CDT vary based on the level of commitment of patients to perform CDT.
- Lymphedema nurse specialists were essential for close monitoring, supervision and encouragement of women at home to continue CDT as scheduled.
- The findings of this study provide a basic impression and evaluation of actual prevention methods and managing activities in Jordanian public hospitals.

## Introduction

Globally, breast cancer represents the highest annual cancer incidence among women, with 2.26 million documented cases each year, accounting for 24.5% of all cancer types in women (1). In Jordan, 2,403 new cases of breast cancer were reported in 2020, making up 38.5% of all cancer cases among women (2). The rising incidence of breast cancer in Jordan has consequently led to an increase in the number of individuals undergoing treatment.

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Breast cancer therapy, particularly surgical intervention, significantly impacts patients' quality of life (QOL), leading to noticeable physical, psychosocial, and emotional challenges following mastectomy (3). Physically, women treated for breast cancer face a lifelong risk of developing breast cancer-related lymphedema (BCRL), a chronic and potentially debilitating consequence of breast cancer treatment (4). Early-onset BCRL, occurring within 12 months of breast cancer surgery, has been closely associated with axillary lymph node dissection (ALND), with peak onset observed between 6 and 12 months in a cohort of 2,171 prospectively screened women (5). Approximately 21.4% of cases of BCRL were reported following breast cancer surgery (6). In particular, patients who undergo ALND followed by radiation therapy had a greater incidence of BCRL at 19.5% than those who received either treatment alone (7). A variety of risk factors are believed to contribute to the development of BCRL. These include breast cancer surgery particularly modified radical mastectomy (8), supraclavicular fossa radiation, and the use of taxane-based chemotherapy have all been identified as significant contributors (9). In addition, the removal of more than 18 ALN and a higher number of lymph nodes with metastatic involvement have been strongly associated with an elevated risk of BCRL (10, 11).Furthermore, ALND is considered a more substantial risk factor for BCRL compared to sentinel lymph node biopsy (SLNB) (12). ALND is associated with a significantly higher incidence of BCRL, with studies reporting rates ranging from 20% to 40%. This elevated risk is due to the extensive disruption of lymphatic vessels after removal of multiple lymph nodes, which impairs the normal drainage of lymph fluid and increases the likelihood of fluid accumulation in the arm. In contrast, SLNB is associated with a much lower incidence of BCRL, with reported rates ranging from 5% to 10%. This reduced risk is attributed to the removal of fewer lymph nodes (typically 1-3 nodes), which preserves the integrity of the lymphatic system and minimizes disruption to lymphatic drainage (13, 14)

Radiotherapy in general has been linked to an increased risk of BCRL (8). The specific design of the radiation field has also been identified as a contributing factor to the likelihood of BCRL development (10). Notably, the use of 2D radiotherapy techniques demonstrated a significant correlation with a higher incidence of lymphedema when compared to 3D radiotherapy techniques (p<0.001) (15). Furthermore, patients who received conventional radiotherapy exhibited significantly higher rates of lymphedema (42.2%) than those treated with hypofractionated radiotherapy (8.5%) (p<0.001) (16).

Lymphedema is a severe and distressing side effect of cancer treatment that significantly diminishes the QOL for survivors (17), impacting their physical, social, spiritual, psychological, sexual, and occupational lives (18, 19). Therefore, preventing, managing, and reducing the progression of lymphedema is essential (20). Implementing complete decongestive therapy (CDT) is an effective and safe strategy that has been shown to significantly reduce edema (21) and positively influence all domains of QOL (22).

CDT is one of the most widely recommended therapeutic approaches for managing BCRL. It is a comprehensive program that combines multiple therapeutic modalities, including manual lymphatic drainage, bandaging, compression garments, exercise, and self-care. This method should be administered by a skilled lymphedema therapist who ensures patients are trained in the correct techniques (23). However, there is a lack of studies in Jordan to provide a comprehensive understanding of the incidence of BCRL. To the best of our knowledge and based on an extensive literature review, the present study is the first nursing research in Jordan to implement CDT for BCRL management. Consequently, the aim of this study was to assess the effectiveness of CDT in reducing the development of BCRL and improving QOL among Jordanian women undergoing breast cancer treatment within the first-year post-surgery. Specifically, the study was designed to test the following research hypotheses:

1. The incidence of BCRL is lower in the intervention group who would undergo CDT, compared to the control group who did not have CDT but underwent other normal post-surgical care.

2. Women in the intervention group will experience better QOL outcomes than those in the control group.

## Materials and Methods

### Design

This study adopted a quasi-longitudinal experimental design, which allowed for the examination of changes and outcomes over time within two distinct groups, an intervention group and a control group, without the use of random assignment. This approach was particularly suitable for assessing the long-term effects of CDT on BCRL incidence and QOL among Jordanian women who underwent ALND.

### Participants

The inclusion criteria consisted of Jordanian women with breast cancer who had undergone ALND and who received radiotherapy or adjuvent chemotherapy within the first year after breast cancer surgery. Women were excluded if they had a history of bilateral ALND, previous infections at the surgical site, or a history of heart disease. Using purposive sampling, 180 women who had undergone ALND were recruited, with 90 in the control group and 90 in the intervention group, from a government hospital between February and July 2023. Participants were assigned to groups based on non-random allocation. Each patient had been chosen to be in the control group or an intervention group.

## Intervention

The CDT intervention group received both written materials and verbal instructions on skin care. Participants were provided with compression sleeves to wear for 12 hours daily, starting at the beginning of their exercise routine. Prior to engaging in physical activities, the women were trained to perform manual lymphatic drainage three times a week for 30 minutes. The exercise regimen included an eightstretching routine, consisting of: ball exercise, wand exercise, elbow winging, shoulder blade stretches, shoulder blade squeeze, side bends, chest wall stretch, and shoulder stretch. Each exercise was repeated 5-7 times per session, with stretches held for 15-30 seconds, and the entire routine lasted 15 minutes, performed three days a week over 18 weeks, as previously described (24). In addition, the program incorporated five moderate-intensity resistance exercises for the upper limb (shoulder press, chest press, lateral pulldown, biceps curls, and triceps extension). Each exercise involved 6-10 repetitions, with a 60-90 second recovery period between sets (25). These sessions also lasted 15 minutes and were conducted three times a week for 18 weeks. Throughout the 18-week period, the principal investigator closely monitored each participant in the intervention group every other day via a WhatsApp group.

### Outcomes

Demographic and clinical data were collected through interviews and electronic medical records. At the eighteenth week, the researchers repeated circumferential measurements to evaluate the volume of the affected arm. Participants completed the short form-12 (SF-12) scale tool to assess their QOL (26), and an adherence tool to measure their commitment to the CDT protocol. These assessments were administered every nine weeks throughout the study period.

## Tools

## Short Form-12 Scale

The Arabic version of the SF-12 is a self-reported patient outcome measure designed to evaluate health-related QOL (26). It consists of two main components: the physical component (PC-12), which includes items 1 to 5 and item 8, and the mental component (MC-12), which includes items 6 to 12, excluding item 8. Scores range from 0 to 100, with higher scores indicating better physical and mental functioning. A score of 42 or lower on the MC-12 may suggest "clinical depression", while a score of 50 or lower on the PC-12 has been proposed as a cutoff to indicate a physical health condition (26).

The SF-12 Arabic version has demonstrated strong validity and reliability. The Cronbach's alpha for the SF-12 Arabic was 0.84, indicating high internal consistency. Furthermore, the scales and individual items showed substantial correlations, further supporting its construct validity (26).

## Structured Patients' Adherence Tool

The researchers evaluated patients' adherence to the CDT domains over the 18-week period using a structured questionnaire developed specifically for this study. The questionnaire encompassed four key domains: arm care (18 items), massage steps (11 items), exercise (12 items), and wearing a compression sleeve (1 item). Participants recorded their level of commitment to each domain on a weekly basis from week 1 through week 18.

The pilot study was conducted to determine the feasibility of this research. I gathered information from twenty patients with breast cancer. I distributed all the questionnaires so they could assess their knowledge of all the terms in the tools as well as their understanding the language usage. Following a week, ten patients underwent CDT every other day for one week while ten patients considered as control group. Patients in both groups said they were aware of the terminology, no any vulgar language. Patients in the intervention group carried out CDT without difficulty, and reported this intervention need time. Thus, based on the pilot study results, which showed that CDT could be performed with this study and that it was applicable and feasible, I made the decision to carry out the full investigation like adherence tool. The tool underwent testing for both validity and reliability. A Cronbach's alpha value greater than 0.5 was established as the threshold for acceptable reliability. The tool was distributed to ten women with breast cancer who had undergone ALND, and a Cronbach's alpha score of 0.72 was achieved, indicating good reliability for the Adherence Tool. Additionally, the face validity of the tool was verified and approved by an institutional committee comprising six senior professionals, including medical, surgical, and radiological physicians.

To make sure there was adherence to the program, the researcher followed up with them in the what's up group with close observation every other day (Sunday, Thursday, & Wednesday) the researcher asked the patient to fill out a chart that the researcher had prepared to record the steps of CDT performance, and the researcher encouraged patients to fill out diary or write notes, and take photos by themselves during performing CDT to ensure patients' commitment to the program. The patient had recorded the commitment weekly from week 1 to week 18.

The researcher instructed the patients had put a check mark  $(\checkmark)$  when they adhered to the skin care instructions each week (or) a cross (X) when they did not adhere to the instructions for each item. The second domain was patients adhering to manual massage steps. Patients must adhere to all massage steps to facilitate lymphatic drainage and reduce arm swelling at a rate of three days per week. The researcher instructed the patients to do massage steps three days a week, then the patients wrote the number (3). Also, when patients did the massage steps two days a week, they wrote the number (2). When the patients did massage steps only one day a week, they wrote the number (1) and in cases of non-compliance with taking the steps during the week, patients wrote the number (0). The third domain was exercise. Patients must commit to doing all exercises to maintain the arm and range of motion and prevent lymphedema at a rate of three days per week. When the patients did the exercise three days a week, they wrote the number (3). When the patients did the exercise two days a week, they wrote the number (2). When the patients did the exercise only one day a week, they wrote the number (1), and in the case that patients did not fully commit to doing the exercise during the week, they wrote the number (0). The fourth domain was commitment to wear compression sleeves before exercise and stay 12 hours during the day, three days per week. When patients worn a compression sleeve three days a week, they wrote the number (3). When patients worn the compression sleeve two days a week, they wrote the number (2). When patients worn the compression sleeve one days a week, they wrote the number (1), and in the event of non-compliance with wearing the compression sleeve completely during the week, patients wrote the number (0), as shown in Appendix G.

The researcher calculated the total score of patients adherence tool for all items, which represented the commitment level for patients. The total score for arm care was 18. The total score for massage was 33. The total score for exercise was 36 and the total score for compression sleeve was 3.

The lower total score of the patients adherence to all items indicated minimum commitment specifically. A higher total score of the patients adherence for all items indicated greater commitment of the intervention group to CDT.

### Sample Size

G\*Power software version 3.1 (27) was used to calculate the sample size, with a power of 90%, a significance level (p-value) of 0.05, and a one-tailed independent t-test assuming an effect size of 0.5. Based on these parameters, the minimum required sample size for each group was 70, resulting in a total minimum sample size of 140 breast cancer patients. However, to account for potential attrition and missing data, the actual sample size was increased to 180 participants.

#### **Statistical Analysis**

The researchers used IBM SPSS, version 25, for data analysis (IBM Inc., Armonk, NY, USA). Descriptive statistics were employed to summarize the demographic and clinical characteristics of the patients and their disease profiles. To identify cases of BCRL, the researchers considered a difference of 2 cm or more in at least one measurement

location between the affected and unaffected arms in both groups. Differences in QOL between the intervention and control groups were assessed using an independent t-test. In addition, repeated measures ANOVA was conducted to analyze changes in patients' QOL at nineweek intervals, enabling intragroup comparisons over time.

#### **Ethical Consideration**

The study was conducted in the oncology department of a leading government hospital in Jordan. Approval for data collection was granted by the Institutional Review Board, as well as the scientific research ethics committee of the hospital. Written informed consent was obtained from all participating patients prior to their involvement. The research adhered to the ethical standards outlined by followed Good Clinical Practice guidelines throughout the study. The researcher had obtained approval from the scientific research Ethics Committee in this Government Hospital to collect the data at February 1, 2023, approval number was MOH/REC/2023/33.

## Results

There were 183 women in the study sample. Based on non-random criteria, it was split into two groups: 91 women in the CTD intervention group and 92 women in the control group. Due to their incapacity to pay for their hospital treatment, two women in the control group were dropped from the follow-up at week nine. At week nine, one woman in the CTD intervention group was hospitalized due to pulmonary edema. The final sample consisted of 180 women, 90 in each group, as shown in the flow chart of participants (Figure 1).

## Baseline and Week Nine Demographic and Clinical Comparison

The demographic and clinical characteristics of the participants and their disease profiles are outlined in Table 1. The mean age of the women was 48.97 years (standard deviation  $\pm$  6.92), and the mean number of ALN dissected was 11.49 ( $\pm$ 6.33). The majority of women (118 out of 180, 65.6%) had positive cancer cells detected in their ALN. The majority had metastatic internal mammary lymph node involvement (n = 150, 83.2%). Approximately 50% (83 women) underwent radiation therapy as part of their treatment regimen. Those patients received a total radiation dose ranging from 40 to 50 Gy. The radiation was administered over 15, 19, or 20 sessions, reflecting the use of both hypofractionated and moderate-course treatment schedules (Table 1).

The incidence rate of developing BCRL was markedly lower in the intervention group (n = 15; 16.6%) compared to the control group (n = 58; 64.5%) in the first nine weeks of the study.

## Comparison Between the Intervention and Control Groups at Week Nine and Eighteen

The QOL, encompassing both physical and mental components, demonstrated significant differences between the intervention and control groups ( $p \le 0.001$ ). The incidence rate of developing BCRL was notably lower in the intervention group (n = 5; 5.6%) compared to the control group (n = 69; 76.7%) (Table 1). Similarly, the QOL, including both its physical and mental dimensions, varied significantly between the CTD intervention and control groups ( $p \le 0.001$ ) (Table 2).

# Patient's Adherence to CDT Domains from Week One to Week Eighteen

From week one to week eighteen, 90% of the women demonstrated commitment to CDT. Specifically, 96% adhered to their skin care regimen, 87.5% performed the recommended massages, 90% participated in the 12 prescribed types of exercise, and 87% consistently used compression bandages. This implies a high level of compliance with the intervention protocol (Table 3).

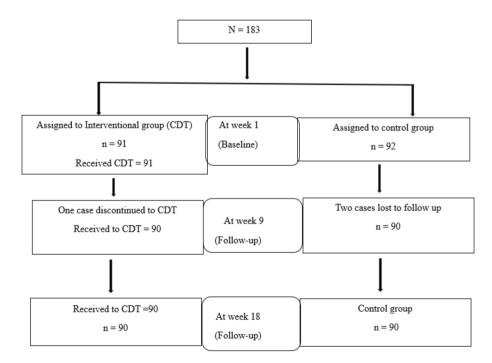


Figure 1. The flow diagram illustrating the progression of participants through the study groups

CTD: Complete decongestive therapy

## Table 1. Descriptive statistics of demographic and clinical characteristics for women with breast cancer (n = 180)

Variable	CTD intervention group n=90		Control group n=90		Total sample n=180	
	Frequency	%	Frequency	%	Frequency	%
Age in years (M ± SD) Intervention = 48.3±7.3 Control = 49.6±6.5 Marital status						
Married	69	76.7	68	75.6	137	76.1
Divorced	4	4.4	12	13.3	137	8.9
Widowed	7	4.4 11.1	6	4.4	18	8.9 7.8
Single	10	7.8	4	4.4 6.7	14	7.2
Education level	10	7.0	4	0.7	21	1.2
Secondary	41	45.6	38	42.2	79	43.9
Illiterate and primary	19	21.1	29	42.2 32.3	48	43.9 32.3
Diploma	19	18.9	15	52.5 16.7	32	52.5 17.8
University degree	13	14.4	8	8.9	21	11.7
Side of breast cancer	15	14.4	0	0.9	21	11.7
Right side	46	51.1	49	54.4	95	52.8
Left side	40	48.9	41	45.6	85	47.2
TNM staging	44	40.9	41	45.0	65	47.2
Stage 1	6	6.7	4	4.5	10	5.6
Stage 2	31	34.4	31	34.4	62	34.4
Stage 3	42	46.7	46	51.1	88	48.9
Stage 4	11	12.2	9	10	20	11.1
Grading		12.2	-	10	20	
Grade 1	5	5.6	7	7.8	12	6.7
Grade 2	55	61.1	48	53.3	103	57.2
Grade 3	30	33.3	35	38.9	65	36.1
Estrogen receptor						
Positive	68	75.6	75	83.3	143	79.4
Negative	22	24.4	15	16.7	37	20.6
Progesterone receptor						
Positive	60	66.7	70	77.8	130	72.2
Negative	30	33.3	20	22.2	50	27.8
Human epidermal receptor 2						
Positive	45	50	40	44.4	85	47.2
Negative	45	50	50	55.6	95	52.8
Type of breast surgery						
Breast conserving surgery	52	57.8	53	58.9	105	58.3
Modified radical mastectomy	33	36.6	31	34.4	64	35.6
Simple mastectomy	5	5.6	6	6.7	11	6.1
Positive cancer cell in ALN	56	62.2	62	68.9	118	65.6
Negative cancer cell in ALN	34	37.8	28	31.1	62	34.4
Number of ALN dissected Mean ± SD	11.54	11	11.44	12	11.49	6.33

## Table 1. Continued

Variable	CTD intervention n=90	CTD intervention group n=90		Control group n=90		Total sample n=180	
	Frequency	%	Frequency	%	Frequency	%	
Location of metastatic LN							
Supraclavicular LN	1	1.1	1	1.1	2	1.1	
Mediastinal (chest) regions	5	5.6	4	4.4	9	5	
Retroperitoneal LN	3	3.3	2	2.2	5	2.8	
Pelvic LN	2	2.2	2	2.2	4	2.3	
Internal mammary LN	73	81.1	77	85.7	150	83.2	
No LN metastatic	6	6.7	4	4.4	10	5.6	
Total radiation dose							
Did not receive RT	51	56.7	46	51.1	97	53.9	
Received 40 Gray RT	27	30	29	32.2	56	31.1	
Received 50 Gray RT	12	13.3	15	16.7	27	15	
Total radiation session							
Did not receive radiation	51	56.8	46	51.1	97	53.9	
Received 15 radiation session	22	24.4	29	32.2	51	28.8	
Received 19 radiation session	12	13.3	9	10	21	11.7	
Received 20 and more	5	5.5	6	6.7	11	5.6	
Incidence of BCRL week 1							
No BCRL	56	62.2	56	62.2	112	62.2	
BCRL present	34	37.8	34	37.8	68	37.8	
Incidence of BCRL at week 9							
No BCRL	75	83.3	32	35.6	107	59.4	
BCRL present	15	16.7	58	64.4	73	40.6	
Incidence of BCRL at week 18							
No BCRL	85	94.4	21	23.3	106	58.9	
BCRL present	5	5.6	69	76.7	74	41.1	

TNM staging: T: Tumor; N: Lymph node; M: Metastatic; ALN: Axillary lymph node; RT: Radiotherapy; BCRL: Breast cancer-related lymphedema; SD: Standard deviation; CTD: Complete decongestive therapy; LN: Lymph node

## Table 2. Comparison of outcome variables between groups at weeks 9 and 18

Variable	CTD intervention group n = 90		Control group n = 90		t	df	P
	Mean	SD	Mean	SD			
Total score of outcome variables at week 9							
SF-12 (QOL)	61.70	17.82	38.84	17.15	-8.77	178	< 0.001
Physical components SF-12	61.02	21.58	38.72	19.79	-7.23	178	< 0.001
Mental components SF-12	62.38	19.32	38.96	19.49	-8.10	178	< 0.001
Total score of outcome variables at week 18							
SF-12 (QOL)	74.99	14.90	33.03	17.33	-17.42	178	< 0.001
Physical components SF-12	75.42	17.80	32.55	20.77	-14.87	178	< 0.001
Mental components SF-12	74.56	18.46	33.52	18.03	-15.09	178	< 0.001

QOL: Quality of life; SD: Standard deviation; CTD: Complete decongestive therapy; SF-12: Short Form-12

**Discussion and Conclusion** 

## Results of Intragroup Comparisons Over the Three Time Points of the Study

A repeated measures ANOVA was used to evaluate changes in general, physical, and mental QOL across the three time points of the study (baseline vs 9 weeks vs 18 weeks). The results revealed that in the CTD intervention group, general, physical, and mental QOL significantly increased over the three time points (p<0.001 for all three). However, in the control group, QOL significantly decreased over the same periods (p<0.001). There were significant differences in general QOL (p<0.001), physical QOL (p<0.001), and mental QOL (p = 0.016) between week 1 and week 9. Significant differences were also observed in general QOL (p<0.001), physical QOL (p = 0.002), and mental QOL (p = 0.003) between week 9 and week 18. Thus, the changes in general, physical, and mental QOL were statistically significant (p<0.001) between week 1 and week 18 (Table 4).

This study is probably the first quasi-experimental investigation into the effects of CDT following breast cancer surgery with SLND conducted in a government hospital setting in Jordan. The primary objective was to explore the impact of CDT on both the incidence rate of BCRL and the QOL among patients. By addressing these important outcomes, the study provides valuable insights into the potential benefits of CDT as an intervention for improving patient well-being and managing post-surgical complications. The findings and broader implications of these results are elaborated upon in the following sections, shedding light on the significance of incorporating CDT into standard post-operative care practices for breast cancer patients in similar settings.

#### Table 3. Adherence of CDT for the intervention group (n = 90) from week one to week eighteen

Domains of CDT	% week 1 to 9	% week 10 to 18	% week 1 to week 18
Arm care	96%	96%	96%
Massage	91%	84%	87.5%
Exercise	93%	87%	90%
Wearing sleeve compression	91%	84%	87.5
The total score of 4 domains	93%	87.5%	90.25
CTD: Complete decongestive these			

CTD: Complete decongestive therapy

Table 4. Comparison of the intervention and control groups in terms of QOL at the three times of the study (week 1, 9 & 18)

		CTD intervention group		Control group		
Outcome variable	Phases of study	Mean ± SD	Changes at different three phases of the study <i>p</i> -value	Mean ± SD	Changes at different phases of the study <i>p</i> -value	
	Week 1	44.75±20.31	<0.001	45.88±19.03	<0.001	
	Week 9	61.70±17.82	W18 > W9 > W1	38.84±17.15	W1 > W9 > W18	
SF-12 (General QOL)	Week 18	74.99±14.90	W1 < W9 (<0.001) W9 < W18 (<0.001) W1 < W18 (<0.001)	33.03±17.33	W1 > W9 (<0.001) W9 > W18 (<0.001) W1 > W18 (<0.001)	
	Week 1	45.51±24.74	<0.001	47.31±22.76	<0.001	
Physical	Week 9	61.02±21.58	W18 > W9 > W1	38.72±19.79	W1 > W9 > W18	
Physical components of S-12 (QOL)	Week 18	75.42±17.80	W1 < W9 (<0.001) W9 < W18 (<0.001) W1 < W18 (<0.001)	32.55±20.77	W1 > W9 (<0.001) W9 > W18 (0.002) W1 > W18 (<0.001)	
			<0.001		≤0.001	
Mental components of S-12 (QOL)	Week 1	44.00±21.04	W18 > W9 > W1	44.44±20.43	W1 > W9 > W18	
			W1 < W9 (<0.001)		W1 > W9 (0.016)	
			W9 < W18 ( <i>p</i> ≤0.001) W1 < W18 ( <i>p</i> ≤0.001)		W9 > W18 ( $p = 0.003$ )	
			π1 < w10 (μ=0.001)		W1 > W18 ( $p \le 0.001$ )	
OOL: Quality of life: SE	). Standard deviation: (	CTD. Complete dec	oppositive therapy: SE-12, Short Form	-12		

QOL: Quality of life; SD: Standard deviation; CTD: Complete decongestive therapy; SF-12: Short Form-12

### The Incidence of BCRL

Within the first year following breast surgery, the incidence of BCRL was 37.8% in both the CTD intervention and control groups at week one. By comparison, a review of 84 cohort studies involving 58,358 breast cancer patients reported an overall lymphedema incidence of 21.9% (28). Furthermore, a meta-analysis and systematic review of 16 studies with 3,515 breast cancer patients found the occurrence of lymphedema after ALND within one year to be 16.5% (29). The incidence of BCRL observed in our cohort was notably higher than reported in previous studies. Several factors may explain this increased incidence. Patients in both groups had predisposing factors associated with cancer treatment that contributed to the development of BCRL. Over one-third underwent modified radical mastectomy, 65.6% had positive lymph nodes, and approximately half had right-sided breast cancer; all factors linked to a higher rate of BCRL.

In the CTD intervention group, adherence to CDT domains was associated with a reduced rate of BCRL, dropping from 37.8% at week one to 5.6% by the end of week 18. This outcome was attributed to continuous monitoring by a lymphedema nurse specialist, regular follow-ups to ensure proper implementation of CDT, and participants recording their adherence in diaries. In contrast, the control group experienced a significant increase in BCRL development, with a rate of 76.7% by week 18. This rise may have been due to the absence of written health education about CDT, lack of supervision by a lymphedema nurse specialist, and/or no referrals to the physiotherapy department for BCRL prevention or management.

# Complete Decongestive Therapy Adherence in the Intervention Group

We believe the 90% commitment level to CDT was achieved through close supervision by the lymphedema nurse specialist. This specialist conducted follow-ups every other day via a dedicated WhatsApp group. These follow-up sessions addressed questions, provided guidance and encouragement, and monitored progress. All CDT-related equipment, such as compression sleeves and bandages, was provided to all patients free of charge, eliminating financial barriers and further contributing to the high commitment rate. These combined factors ensured consistent participation and adherence to the therapy protocol throughout the study period.

## General QOL (Physical and Mental)

The results revealed that the general QOL, encompassing both physical and mental components, showed significant variations both within and between groups at weeks 9 and 18. Within the CTD intervention group, there was a notable improvement in mean QOL scores across all three time-points of the study. In contrast, the control group experienced a decline in QOL over the same period. The decline in QOL observed in the control group is in keeping with the findings of a systematic review and meta-analysis encompassing 39 studies. These studies demonstrated that patients with BCRL experienced significant reductions in QOL, with the most pronounced negative impacts on physical well-being, functional abilities, and social domains (30). Specifically, when the SF-12 tool was used, patients with BCRL reported deterioration in both the physical and mental aspects of QOL (30). The reasons for this decline in QOL among BCRL patients include factors such as advanced age, lower education levels, unemployment, reduced family income, and psychological distress (10). Notably, all these predictive factors were present in the study sample of the present study, which helps explain the poorer QOL

observed in the control group. The improvement in QOL observed in the intervention group is consistent with the findings of a metaanalysis that highlighted the positive impact of CDT on QOL (31). Further studies have corroborated that CDT significantly enhances QOL for patients with BCRL, particularly when initiated in the early stages (32). Notably, these benefits were especially evident when CDT was performed at home under supervision via a mobile application, emphasizing the effectiveness of remote monitoring and guidance (33). Some prior studies have reported mixed findings regarding the impact of CDT on QOL. For instance, one study found only a 5% improvement in QOL among patients who received CDT and this improvement was not significant (34). The lack of significance was attributed to factors including a smaller sample size and lower levels of patient commitment to the CDT protocol. While other studies have consistently validated that CDT positively influences QOL, the duration and design of those studies may have limited their ability to detect significant changes.

In contrast, the present study spanned 18 weeks and was structured into three distinct phases, allowing for a more comprehensive evaluation of the effects of CDT. The extended duration and phased approach provided sufficient time to observe meaningful improvements in QOL, leading, in our opinion, to more accurate and robust conclusions than those drawn from prior research. This methodological rigor highlights the reliability of the findings and the importance of adequate study length and patient adherence in assessing the effectiveness of CDT.

### Axillary Lymph Node Surgery (ALND vs SLND)

In the present study the surgeon was questioned about their decision to perform ALND. The surgeon explained that the decision was based on literature review and evidence-based practice. Specifically, ALND is typically performed when SLNB had revealed the presence of cancer in the sentinel lymph node(s), as this indicates a higher likelihood of additional nodal involvement (35). Moreover, ALND was more likely when there was clinical or imaging evidence of lymph node involvement prior to surgery, such as palpable lymph nodes or suspicious findings on ultrasound, MRI, or positron emission tomography-computed tomography scans (35). In addition, most of the women in this study were at advance stages (3&4), where ALND is often included as part of the surgical plan to ensure the comprehensive removal of cancerous tissue and to achieve optimal disease control (36). This approach aligns with current guidelines and clinical practices, which emphasize the importance of tailoring surgical interventions to the individual patient's disease characteristics and stage (35, 36).

## **Radiation therapy**

Radiotherapy, in general, has been associated with a heightened risk of BCRL (8). Among 1,052 women who underwent breast-conserving therapy (BCT) with adjuvant radiotherapy, 9.6% experienced BCRL. This study highlighted several significant risk factors associated with the onset of BCRL, including the administration of adjuvant chemotherapy (37). These findings align with the present study population, in which women undergoing adjuvant chemotherapy were included, and approximately half of them also received radiation therapy and underwent BCT.

Most of women received 15 sessions of radiotherapy in this study. The primary difference between patients who received 15, 19, or 20 radiation sessions after breast cancer surgery lies in the total dose of radiation delivered, the treatment duration, and potentially the treatment intent (curative *vs.* palliative) (38). The 15 sessions are

ideal for low-risk patients, offering a shorter, more convenient treatment schedule, patients reported cancer control, late side effects, better QOL and fewer disruptions to daily activities compared to those receiving more sessions (15, 38). The 19 or 20 sessions are used for intermediate-risk patients and the choice of regimen is patient-specific, emphasizing personalized care to optimize outcomes and QOL (15).

#### Strengths

The study benefited from an adequate sample size and duration, ensuring robust results. A high level of adherence to CDT was achieved, supported by the use of self-recorded diaries to monitor commitment. In addition, the presence of a lymphedema nurse specialist provided continuous supervision, encouragement and guidance to patients in performing CDT.

## **Study Limitations**

The study employed a quasi-experimental design and was conducted at a single governmental hospital, limiting the generalizability of the findings. Patients also reported that CDT required considerable time and effort to perform correctly, which may have influenced adherence and outcomes.

#### Implications

This study has significant implications for clinical practice and patient care, particularly in the context of breast cancer treatment and post-operative management. The findings demonstrate that implementing CDT within the first year following breast cancer surgery in women who underwent ALND and received adjuvant chemotherapy or radiotherapy can substantially reduce the incidence of BCRL and enhance patients' QOL. The CDT intervention group, under the supervision of a lymphedema nurse specialist, showed a marked reduction in BCRL incidence and significant improvements in QOL, while the control group experienced an increasing BCRL rate over the study period and a concurrent decline in QOL. These results underscore the importance of early intervention, structured follow-ups, and patient adherence to CDT protocols. The study also highlights the potential benefit of having lymphedema nurse specialists to providing continuous monitoring, education, encouragement and support, which we believe were key to achieving high adherence rates and positive outcomes in our study. Furthermore, the rigorous design, spanning 18 weeks with three distinct phases, provided robust evidence for the effectiveness of CDT, offering a model for integrating such interventions into standard post-operative care. However, the quasi-experimental design and single-site setting limit generalizability, suggesting the need for broader, multi-centre studies to validate these findings. Overall, this study advocates for the adoption of CDT in clinical practice, emphasizing the need for dedicated resources, patient education, and specialist involvement to improve long-term health outcomes for breast cancer survivors.

Implementing CDT within the first year following breast cancer surgery was shown to significantly reduce the incidence rate of BCRL and enhance patients' QOL in a single center in Jordan. Early intervention with CDT helps mitigate the risk of lymphedema development and addresses symptoms before they become severe, leading to better physical, emotional, and social outcomes for patients. A key factor in the success of CDT may be the involvement of lymphedema nurse specialists, who are dedicated to delivering consistent follow-up, providing tailored therapies and encouragement, and ensuring patients adhere to the treatment protocol. This expertise and ongoing support not only improve treatment efficacy but also empowers patients to manage their condition effectively, ultimately contributing to improved long-term health and well-being.

#### Ethics

**Ethics Committee Approval:** The researcher had obtained approval from the scientific research Ethics Committee in this Government Hospital to collect the data at February 1, 2023, approval number was MOH/REC/2023/33.

**Informed Consent:** Written informed consent was obtained from all participating patients prior to their involvement.

#### Footnotes

#### **Authorship Contributions**

Surgical and Medical Practices: S.S.; Concept: S.S.; Design: S.S., M.A.; Data Collection or Processing: S.S.; Analysis or Interpretation: S.S., M.A.; Literature Search: S.S.; Writing: S.S., M.A.

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