

Outcomes of Rehabilitation on Functional Capacity, Quality of Life among Breast Cancer Survivors with Lymphoedema - An Interim Report

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Breast Cancer cancer-related lymphedema (BCRL) is debilitating morbidity among breast cancer survivors affecting functional outcomes and quality of life. Physiotherapeutic intervention includes complete decongestive therapy (CDT) and sequential Pneumatic Compression therapy (SPCT) are acclaimed to improve arm circumference, functional ability and Quality of Life (QOL) of the survivors. This study aimed to ascertain the effectiveness of sequential pneumatic compression (SPCT) therapy, complete decongestive therapy on lymphedema, functional outcomes, pain, and QOL of breast cancer survivors. A total of 30 women aged between 18 to 72 years with secondary upper extremity lymphedema after mastectomy following breast cancer were included in the study. After the initial assessment, patients were randomly the group treated with CDT, and another group received SPCT. Lymphedema volume was measured by circumferential measurement, shoulder range of motion was measured using Norkin's goniometry, and pain was measured using VAS pain scale. The quality of life was assessed by EORTC QLQ-C30 and breast cancer-specific quality of life questionnaire (EORTC QLQ-Br23). The collected data were organized, tabulated, and statistically analysed using SPSS software.

Following rehabilitation by physiotherapy, there was a decrease in the circumference of the affected limb, an increase in functional outcomes, and an improvement on certain QoL dimensions. The results indicate that sequential pneumatic compression therapy and complete decongestive therapy provide optimum results in treating BCRL.

Key words: Breast cancer, Lymphedema, Sequential Pneumatic therapy, complete decongestive therapy, complex decongestive therapy.

Lymphedema secondary to breast cancer treatment continues to be a global burden and a well-known complication of Breast cancer treatment. Lymphedema (LE) occurs, due to the accumulation of protein-rich fluid in the interstitial space owing to the insufficient lymphatic system. The prevalence rates of LE reported to vary between 5-60% globally and 2%–40% in India among females treated with mastectomy or breast-conserving surgery. Upper extremity lymphedema is a concerning complication caused by surgery and/or radiation therapy involving lymphatic networks of the breast

and axillary areas and considered as a potentially serious and debilitating condition after treatment for breast cancer.

Lymphedema is a chronic condition that cannot be cured but can be managed. Quality of life has become an increasingly important issue in breast cancer treatment. It has been widely reported that breast cancer survivors (BCS) with lymphedema experience a variety of problems, including feelings of discomfort, heaviness, loss of strength, function, psychological distress, depression, low self-esteem, fatigue, neuropathic pain in the affected arm, and an elevated risk of

recurrent infections. The relationship between lymphedema, upper limb function, and quality of life has emerged as an important component in caring for breast cancer survivors.

Management of LE is an essential aspect of breast cancer rehabilitation. Although, various physiotherapeutic interventions have been suggested for the control of symptoms and to minimize complications, by reducing upper limb swelling. Complete decongestive therapy is a non-invasive gold standard of treatment for lymphedema, which includes intensive phase which aim to reduce the lymphedema and the maintenance phase to maintain the reduced limb. A large study on CDT found an average reduction volume of about 59.1% in upper extremity lymphedema. Sequential Pneumatic Compression therapy (SPCT)) is another modality used for controlling lymphedema. SPCT is an inflatable device with different compartments which applies a gradual pressure on the lymph vessels and facilitates the lymph flow. In recent years, advanced pneumatic compression devices has digital programming to mimic manual lymphatic drainage techniques and promote fluid clearance from the proximal trunk and extremity. In order to explore the possible advantages of SPCT in the perspective of Breast Cancer-Related Lymphedema (BCRL), multiple studies and systemic reviews have been performed. A definitive conclusion about the effect of SPCT on BCRL, however, is yet to be reached because the findings of these studies have produced contrasting results. Although current clinical studies showed that completedecongestive therapy and SPCT reduced lymphedema and improved subjective symptoms, however, quality of life, function Capacity should be considered following treatment protocols in the clinic.

Lymphedema has been considered as a severe adverse effect of breast cancer treatment. However, effective treatments for

preventing its progression include early intervention using CDT and SPCT. Therefore this study aims to compare the effects of CDT and SPCT in reducing volume of post mastectomy lymphedema.

Method

Research design:

A pre-test & post-test design was adopted for this study to compare the effectiveness of SPCT and CDT.

Study setting:

General setting: The study was conducted at the Cancer Institute (WIA) in Chennai, Tamil Nadu, India. The Ministry of Health and Family Welfare, Government of India, has revered this institution as a non-profit organisation as a regional cancer centre of excellence in both cancer treatment and research.

Specific setting: The study was carried out in the Department of Physiotherapy, Cancer Institute (WIA). It is a fully equipped unit for Onco- rehabilitation and also renders training to the Physiotherapy interneers in Onco-rehabilitation.

Sample:

Breast cancer survivors aged 18 years and above having completed treatment with minimum 1 year disease-free survival following mastectomy or breast conservation surgery, who are reporting for follow-up at the outpatient department of Cancer Institute (WIA) were included for the study. The physiotherapist screened the BCS for Lymphedema and those found to have more than 2cm difference in circumference between affected and normal limb has been classified as lymphedema. A total of 36 Survivors were found with clinical evidence of lymphedema during the study period of which 30 patient who consented for the study were recruited consecutively, the remaining 6 survivors were not fitting into the inclusion

criteria. Survivors with evidence of loco regional recurrence of carcinoma, bilateral breast cancer and edema due to filariasis, primary lymphedema, deep vein thrombosis, congestive heart diseases, recently underwent breast cancer surgery on ipsilateral side, survivors without axillary lymph node dissection, with bilateral breast cancer, systemic conditions such as uncontrolled diabetes mellitus and hypertension, pain score >5 on a visual analogue scale, and any related contraindication to physiotherapy were all excluded from the study.-

Ethical clearance for the study was obtained from the ethics committee in the hospital before the commencement of the study. All survivors were informed about the nature of the study, and their informed consent was obtained according to the study Protocol.

Variables and measures:

Demographic and clinical characteristics

The socio-demographic characteristics such as age, height, weight, BMI, Occupation, education, and clinical characteristics such as type of surgery, treatment status, stage of the disease, personal habits, and previous therapies, were collected from the hospital registry and case record. Functional outcomes such as Lymphedema, Shoulders Flexion, Shoulder Abduction, elbow flexion, hand grip strength, pain and quality of life were studied.

Lymphedema measurement

Limb girth of both arms was measured using a flexible measuring tape. The upper limb will be fragmented down into segments (cones), starting from the level of the wrist and moving upwards, till the axilla. Limb volume will be calculated using geometrical method of estimation of arm volume (truncated cone method)(16). The volume for each cone was calculated using the formula

$V = h (C_1^2 + C_1 C_2 + C_2^2) / 12\delta$ where V- volume, H-height of the segment (cone), and C1, C2 are the limb circumference at the either ends of the segment.

The volume obtained was compared with the volume of the opposite upper limb and the difference was calculated as Volume difference. The volume was recorded before and after 3 weeks of CDT.

Functional Capacity

The functional capacity of arm was assessed by their Range of motion and Grip Strength. Range of motion assessment for Shoulder (Abduction / Flexion), Elbow (Flexion) was assessed using goniometer and grip strength using Digital hand dynamometer (Best of three assessments) dominant hand will be specified.

Quality of Life

The QoL was recorded using the EORTC QLQ C30 and EORTC QLQ-BR 23 questionnaire. The EORTC is an integrated system for assessing the health related quality of life (QOL) of cancer patients participating in international clinical trials. The EORTC-C30 questionnaire consists of 30 questions and assesses symptoms that occurred in the previous two weeks (17). Answers are displayed in a Likert scale: 1 – not at all, 2 – a little, 3 – quite a bit, 4 – very much; except for the global health scale, which is composed by 2 questions asking patients to classify their general health and quality of life in the previous week, by rating it from 1 to 7, in which 1 means poor and 7, excellent. The questionnaires are divided into 3 scales: global health scale (GHS), functional scale (FS) and symptom scale (SS). The EORTC questionnaire – BR 23 comprises 23 questions (questions 31 to 53), supplementing the general questionnaire. Its answers are also displayed in a Likert scale. This questionnaire contains 2 scales, namely the functional scale and the symptom scale.

The EORTC questionnaire – BR23 comprises 23 questions (questions 31 to 53), supplementing the general questionnaire. Its answers are also displayed in a Likert scale. This questionnaire contains 2 scales, namely the functional scale - body image, sexual functioning, sexual enjoyment and future perspective) and four symptom scale (Systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss).

Pain

The pain was assessed using visual analogue scale varying from 0-10 where 0 is no pain and 10 is severe pain.

Procedure

All the 30 BCS who consented were recruited for the study were randomly assigned to Intervention Group (CDT) and standard care group (SPCT). Patients assigned to both the group underwent therapy every day for 45min 5 days a week for three weeks. Pre & post therapeutic assessment were assessed, recorded and documented prior to the physiotherapeutic intervention, and post-therapy. Assessment were done using the same protocol after the completion of the 3-week intensive programme on the fourth week.

Intervention

Sequential Pneumatic compression therapy (SPCT)

The SPCT is the standard care of therapy administered for survivors with lymphedema using Sequential Pneumatic Compression Device. The Sequential Pneumatic Compression Device consists of a gradient, sequential pneumatic compressor with an adjustable range between 20 to 90 mmHg in a gradient, to enhance distal to proximal flow. Patient assigned in this group will be checked for any skin damage or any other injury in the upper limb before commencing SPCT.

The patient is then made to sit in a chair and the hand is placed over a table with a pillow just above the chest height. The patient will be advised to wear a stockinet over the hand and then a zipped compression garment will be fixed to the arm that needs to be treated. The treatment duration will be 45 minutes to one hour for five days a week for three weeks. On completion of therapy every day the patient will be advised to wear the compression garment for 18-20 hours a day for seven days a week and also do exercises. Skin care will be advised.

Complete Decongestive Therapy (CDT)

Patients were treated with Manual lymphatic drainage (MLD) in the beginning of the therapy followed by multi-layered bandaging, active assisted exercises and skin care. MLD was performed by using mild pressure of fingers and hand with rhythmic skin stretching for 20 min in every treatment period. MLD is a compressive stimulation of the nearby healthy lymphatic drainage regions such as cervical, opposite axillary regions, affected trunk, shoulder, arm, forearm, wrist, consecutively followed by multi-layered bandaging (MLB). At the start of Multi-layered bandaging, cotton tube stockinet was placed on the arm and a layer of gauze was applied to the fingers and hand. A layer of foam padding was placed on the hand and wrapped around the arm. Short stretch bandages of different sizes were sequentially placed around the limb with the first starting at the hand, the second at the wrist and the third starting below the elbow. Gradient pressure was achieved by applying more layers distally, gradually reducing the number as well as overlap of bandages applied proximally along the arm. All the survivors were advised about the do and don'ts following lymphedema and were given a hand out of the exercises to be followed at home during maintenance Phase.

Statistical Analysis

Statistical Package for the Social Science (SPSS) Version 20 was used for statistical analysis. Demographic & Clinical characteristics were analysed using descriptive statistics such as median and range. Paired sample 't' test was performed to study the effectiveness of pre and post assessment score of CDT and SPCT for the variables such as lymphedema, shoulder range of movement, hand grip and QoL.

Results

Among the 30 survivors included in the study, the median age of the participants was 52 years (range = 27 to 72 years). The majority of participants were between 45 to 54 years (30%), followed by 35 to 44(26.7%), and 55 to 64(23.3).Majority of the survivors (76.7%) had attained menopause and 70%had completed their Secondary and Higher secondary school education followed by36.7% with either their Primary or College and above education. The mean of body mass index was 28.31kg/m² and revealed that 43.3% survivors were obese and 33.3% & 23.3% were normal and overweight respectively. T-stage 2 was observed in 36.7% of the cohort, while T-stages 1, 3, and 4 constituted the remaining 63.3%.Neo-adjuvant therapy was administered to 60% of patients across the spectrum of treatment modalities, whereas hormonal therapy was administered to 45% of the participant population. According to the hormone receptor analysis, 76.7% of people had tumours that tested positive for oestrogen receptors (ER), while 70% had tumours that tested positive for progesterone receptor (PR). Of all, 43.3% had node involvement ranging between 1-10 whereas 56.7% had no nodes involved. (Table 1)

Table 1: The personal and clinical characteristics (n=30)

Variables	Category	Frequency (n)	Percentage (%)
Age (y)Mean (±SD)	52.55(±11.72)		
BMI (Kg/m ²) mean(±SD)	28.31(±4.53)		
Age (in years)	18-34	1	3.3
	35-44	8	26.7
	45-54	9	30.0
	55-64	7	23.3
	> 64	5	16.7
Education	Primary	4	13.3
	Secondary	15	50.0
	Higher secondary	6	20
	Graduate and above	5	16.7
BMI	Normal (BMI 18.5 - 24.9)	7	23.3
	Overweight (BMI 25.0 - 29.9)	10	33.3
	Obesity (BMI > 30)	13	43.3
Menopausal	Postmenopausal	23	76.7
	premenopausal	7	23.3
Comorbid	No comorbid	10	33.3
	Comorbid	20	66.7
T- Stage	1	4	13.3
	2	11	36.7
	3	7	23.3
	4	8	26.7
Types of Treatment	Adjuvant	12	40
	Neo-adjuvant	18	60

Hormonal therapy	YES	9	45
	No	11	55
Er	Positive	23	76.7
	Negative	7	23.3
Pr	Positive	21	70
	Negative	9	30
Hers2	Positive	21	70
	Negative	9	30
Nodes Involved	0	17	56.7
	1-5	10	33.3
	6-10	3	10.0

Note: BMI-Body mass index , Er –Estrogen receptor , Pr-Progestron receptor

The mean volume of the limbs was evaluated both pre and post therapy in order to determine the effectiveness of therapy. Notably, after a 3-week therapy period, there was a significant reduction in the volume of the affected upper limb in both groups was found.

The effects of SPCT and CDT on upper limb function are displayed in Table 2. The SCPT resulted in statistically significant improvements in shoulder flexion ($Z=2.07$, $p < 0.03$), shoulder abduction ($Z=3.33$, $p < 0$

.00), elbow flexion ($Z=3.46$, $p < 0.00$) and in VAS pain ($Z = 2.12$, $p < 0.03$) when compared to the baseline. However, there was no significant increase in handgrip strength between baseline and post assessment ($Z=0.31$, $p > 0.05$). Similarly, when compared to the baseline, survivors who underwent CDT showed significant improvements post treatment. Significant improvements were observed in shoulder flexion ($Z=2.12$, $p < 0.03$), shoulder abduction ($Z=3.49$, $p < 0.00$), elbow flexion ($Z=3.40$, $p.001$) and VAS pain ($Z =2.13$, $p < 0.03$). (Table 2)

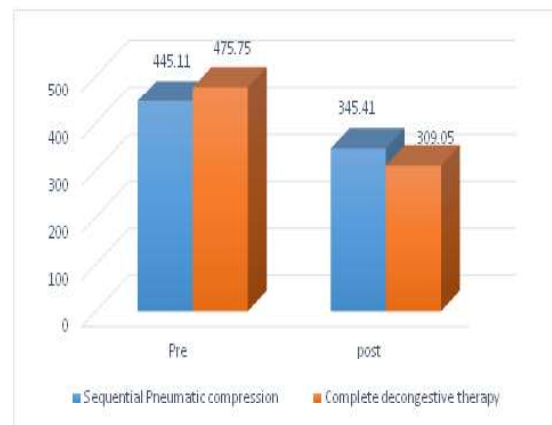


Figure 1 Changes in the volume of upper limb pre and post treatment between sequential Pneumatic compression therapy and complete decongestive therapy:

Table 2: Comparison between the Pre-test and Post Test within sequential pneumatic compression therapy and complete decongestive therapy

Functional outcomes	Sequential Pneumatic compression therapy				Z value	p-value	Complete decongestive therapy				Z value	p-value
	Pre test		Post test				Pre-Test		Post Test			
	Median	Range	Median	Range			Median	Range	Median	Range		
Shoulder Flexion	162.00	151-167	163.00	151-167	2.07	.03	165	158-168	165	159-169	2.12	.03
Shoulder Abduction	161.00	155-167	163.47	157-169	3.33	.00	160	157-165	162	160-167	3.49	.00
Elbow flexion	143	140-145	145	142-148	3.46	.00	143	139-148	145	141-14	3.40	.00
Hand grip	21.20	11.4-50.0	21.00	10-54	.31	.75	18.00	8-43	17.00	10-41	.43	.66
Vas Pain	1	0-3	.67	0-2	2.12	.03	1.20	0-4	.33	.61	2.13	.03

With regard to the differences in QoL, the findings indicate that there were no statistically significant differences in the functional scale domains of the EORTC QLQ C30 ($p > 0.05$). The EORTC QLQ C30 symptom scale revealed a significant change in the pain domain ($U = 67.00, p < 0.05$). Furthermore, only the sexual function ($U =$

$52.00, p < 0.05$) and sexual enjoyment ($U = 49.50, p < 0.05$) domains of the EORTC BR23 functional scale showed statistically significant changes, while the remaining domains of the functional scale and symptom scale did not show any statistically significant differences. (Table 3)

Table 3: Differences between sequential pneumatic compression therapy and complete decongestive therapy at post therapy on EORTC QLQ C 30 and EORTC BR23.

EORTC QLQ C 30		Sequential pneumatic compression therapy		Complete Decongestive therapy		U value	p-value
		Median	Range	Median	Range		
Functional scale ¹	Physical Functions	93	80-100	93.00	80-100	94.50	.42
	Role Functions	100	67-100	100	50-100	92.50	.34
	Emotional Function	83.00	67-100	92	67-100	91.00	.35
	Cognitive function	100	67-100	100	67-100	85.50	.19
	Social Functioning	100	67-100	100	67-100	112.50	1.00
SYMPTOMS SCALE ²	Fatigue	11	0-44	.00	0-33	88.50	.28
	Nausea and Vomiting	.00	0-17	.00	0	105.00	.31
	Pain	17	0-50	.00	0-33	67.00	.02*
	Dyspnoea	.00	0-33	.00	0	105.00	.31
	Insomnia	.00	0-100	.00	0	100.00	.54
	Appetite Loss	.00	0-33	.00	0	105.00	.31
	Constipation	.00	0	.00	0	112.50	1.00
	Diarrhoea	.00	0-33	.00	0	105.00	.31
	Financial difficulties	33	0-33	.00	0	105.50	.74
	Global Health	83	67-100	83	83-100	80.50	.14
EORTC - BR23							
Functional scale ¹	Body Image	100	75-100	92	83-100	88.50	.25
	Sexual Function	67	0-100	100	67-100	52.00	.00**
	Sexual Enjoyment	67	0-100	100	67-100	49.50	.00**
	Future perspective	100	33-100	100	33-100	84.50	.16
SYMPTOMS SCALE ²	Systemic therapy						
	Side effects	5.00	0-24	5	0-14	108.50	.86
	Breast symptoms	.00	0-33	.00	0-8	75.00	.06
	Arm symptoms	11	0-44	11.00	0-33	85.00	.22
	Upset by hair loss	.00	0-67	.00	0-100	89.00	.18

Discussion

The findings of the study revealed that the treatment of BCRL using CDT and SPCT not only significantly reduced limb volume, but also showed significant improvement in the function capacity such as shoulder and elbow ROM, and in pain levels. This study did not indicate significant improvement in EORTC-QLQ- C30 functional scale's domain whereas in the EORTC QLQ C30 symptom scale it revealed significant decrease in pain score. In addition, there was significant difference observed in functional capacity in survivors who had undergone CDT and SPCT. However there was no significant difference observed in hand grip in both the groups.

The limb volume is the most common used parameter in assessing lymphedema. There are several different measurement methods capable of determining arm size including water displacement methods, such as perometer, bioimpedance spectroscopy (BIS) and circumference measurements.(19, 20). This study adopted specific formulas to calculate the limb volumes from the measurements of limb circumferences. In our study, the statistical evaluations revealed a highly significant decrease in limb volumes in both groups. The volume of the affected upper limb decreased significantly in both the groups when compared to baseline assessment after 3 weeks of therapy. The finding was in line with that of earlier studies conducted by Bhavna Anand ,et.al.,(2020) & Hilal Ye°il,et.al.,(2021), which revealed a significant improvement post intervention followed with CDT and SPCT. Similarly Sibel Ozkan Gurdal, M.D.(2012), in his study revealed that both treatment modalities resulted in significant decrease in the total arm volume by 14.9% in CDT and 12.2% in IPC. Hwang et al (2013) retrospectively investigated the effect of CDT in 59 patients with BCRL and reported a volume reduction from 41.9% to 28.8%. Similarly, Gradalski et

al compared 2-weeks of CDT with compression bandaging alone and bandaging with MLD and obtained 47% edema volume reduction in both groups. Using MLD, lymphedema was found to decrease by 7% after 2 weeks using a standard compression sleeve, and 15% after assignment to a treatment regimen consisting of MLD or SPC. All these findings strongly indicate the impact of CDT and SPCT in managing lymphedema, as the present study.

This present study showed that there was significant difference in ROM in both groups post therapy. This finding is also supported by the literature wherein a study conducted by Szuba et al., revealed uniform improvement in ROM from baseline to post-treatment gradually among patients receiving SPCT and CDT for initial volume reduction, but there were no significant differences among the changes observed at the conclusion of treatment. Similarly in a trial conducted by Moattari et al. (2013) and J.H. Do., et.al (2015), ROM increased significantly in the CDT group along with muscular strength, and QOL in breast cancer patients with arm lymphedema. These findings emphasize that the CDT and SPCT are a significant therapeutic approach to improve ROM among patients.

Lymphedema is a potentially debilitating problem and can produce significant impairments on functional status and QoL. However, the literature indicated limited number of studies evaluating the effects of combined CDT on QoL and functional status measures in addition to volume reduction. Gurdal et al. (2012) revealed that there was significant improvement in emotional functioning, fatigue, and pain scores in both CDT and IPC group, while the global health status, functional and cognitive functioning scores were improved only in patients who had undergone CDT. Similarly Kim et al. also showed that during the maintenance phase of CDT, QoL significantly improved and it was

correlated with the reduction in limb volume. The present study findings are in line with the previous studies which indicate a relationship between changes in volumes and QoL and functional scores. Although study by Jaafari, Hashemifard, and Mehri (2020) revealed that CDT and compression pumps had a positive impact on body image among patients with BCRL, the present study revealed significant improvement in emotional function pain, sexual function, future perspective and arm symptom. Similarly Atalay et al. in his study indicated the positive effects of 20 sessions CDT on physical functioning and depression levels. Karadibak et al. reported similar findings with the 36-session CDT in patients with BCRL during 12 weeks of treatment.

It is possible that even though patients demonstrated a reduction in lymphedema in their affected arm, this reduction is not associated with QoL. This inference is supported by literature also showing that regardless of a reduction in excess volume of lymphedema between upper limbs, there were no association with QoL and its domains with BCRL survivors undergoing complex physical therapy. Improvements in QoL following CDT was found to occur in the maintenance phase alone due to a decrease in limb volume. Earlier studies have shown that, a reduction in the size of the upper extremity was associated neither with the QoL nor with the upper extremities function. Mondry et al. also with 2 to 4 week of CDT in patients with BCRL, demonstrated that the degree of the decrease in girth had a significant correlation with the reduction in pain VAS scores, but not with the increase in QoL.

Conclusion

This study has revealed that quality of life, emotional function and pain had improved in CDT groups. Although current Interim report show that CDT and IPC reduced lymphedema

and improved functional capacity, neither of the methods was superior to the other. Therefore, clinical economics, patients' wishes and QoL should also be considered for the selection of the 2 methods before starting the therapy. Our results and those of many other outcomes still need to be confirmed by large-sample and or multicentre RCTs.

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