Original Article
IASR Multidisciplinary Journal
Website: http://iasrpublication.com/
ISSN(*online*): 2583-0988

Effectiveness of Complete Decongestive Therapy in the Management of Breast Cancer Related Lymphedema in Indian Population

Dr. Himanshu Patidar[1]; Dr. Mayank Pancholi[2]*; Dr. Sanjay Desai[3]; Dr. Vinod Kumar Dhakad[2]; Dr. Simran Behal[4]
[1]Assistant Professor, Department of Surgical Oncology Sri Aurobindo Medical College & PG Institute, Indore (M.P.)
[2]Associate Professor Department of Surgical Oncology Sri Aurobindo Medical College & PG Institute, Indore (M.P.)
[3]Professor Department of Surgical Oncology Sri Aurobindo Medical College & PG Institute, Indore (M.P.)
[4]Tutor, Department of Pharmacology Sri Aurobindo Medical College & PG Institute, Indore (M.P.)

A B S T R A C T

Objective: To evaluate the results of the intensive phase of CDT, including clinical and demographic features, breast cancer and pre and post treatment characteristics of the response to treatment in patients with BCRL.

Method: Total 30 patients were included in this study**.** This study had pre-treatment and post-treatment design and all the measurements were taken at baseline and the duration of the treatment is 6 days, a week for 4 weeks. The participant's intervention has begun the day they visited the clinic. With each intervention session lasting for 45-60 minutes, the participant's attended 6 sessions separated by a one-day break between each week, spread over a period of 4 weeks.

Result: The mean age was 49.5±9.9 and BMI was 28.6 kg/m2. Tumor Involved in breast; 14 (46.6%) cases of right breast and 16 (53.4%) cases of left breast. T stage (Tumor size in the Breast) were seen 1(3.35%) in Tis, T1 (20mm) in 17 (56.7%), T2 (20-50mm) in 11 (36.6%). None of the patient had stage T4. Nodal involvement; 18 (60%) patients had N0 and 12 (40%) had N+ and metastasis was seen 30 (100%) in M0. After 4th week total reduced mean volume of affected arm was 196 mL, total 36.6 % of reduction in the lymphedema volume

Conclusion: Significant difference ($p<0.0001$) was seen in the mean volume of affected arm (pre and post-treatment). And there was no significant difference ($p<0.980$) seen in the mean volume of the normal (pre-treatment and Post-treatment).

Keywords: *Breast Cancer, Lymphedema, CDT, MLD, Modified Radical Mastectomy, Surgery*

Corresponding Author
Dr. Mayank Pancholi
Associate Professor Department of Surgical Oncology Sri Aurobindo Medical College & PG Institute, Indore (M.P.)

INTRODUCTION

Breast cancer is the commonest cancer of urban Indian women and the second commonest in the rural women breast cancer accounts for 14% of cancers in Indian women[1]. Breast cancer has ranked number one cancer among Indian females with age adjusted rate as high as 25.8 per 100,000 women and mortality 12.7 per 100,000 women[2]. The lack of consensus leads to confusion regarding the incidence of lymphedema after breast cancer treatment and difficulty in measuring treatment efficacy[3].

Breast cancer-related lymphedema (BCRL) results from obstruction or disruption of the lymphatic system associated with cancer treatment (removal of lymph nodes and radiotherapy); patient personal factors [obesity or higher body mass index (BMI)] can increase the risk of lymphedema; and infections or trauma can trigger lymphedema[4]. BCRL can occur months or years after treatment. As advances in the treatment of breast cancer continue to progress, health care providers and patients are increasingly focused on post-treatment quality of life[5]. BCRL negatively affects a patient's quality of life, causing elevated rates of depression and anxiety in addition to physical impairment compared to patients without BCRL[6]. Management of lymphedema remains a major challenge for patients and health care professionals. Routine check-ups for lymphedema management, long-term physical therapy, management equipment (compression garments, bandages, special lotions), and repeated cellulitis, infections, and lymphangitis create financial and economic burdens not only to survivors but also to the health care system [7].

The aim of this study was to evaluate the results of the intensive phase of CDT, including clinical and demographic features, breast cancer and pre and post treatment characteristics of the response to treatment in patients with BCRL.

METHOD

67 patients were screened and 37 individuals were excluded as they did not meet the inclusion criteria. The 30 participants were made aware of the purpose and procedure of the study. The participants were aged between 25 to 65

years female, and had modified radical mastectomy or lumpectomy and axillary nodal dissection or other (simple mastectomy, tumor excision alone) for breast cancer. This study had pre-treatment and post-treatment design and all the measurements were taken at baseline and the duration of the treatment is 6 days, a week for 4 weeks. The participant's intervention has begun the day they visited the clinic. With each intervention session lasting for 45-60 minutes, the participant's attended 6 sessions separated by a one-day break between each week, spread over a period of 4 weeks. Patients underwent complete physical examination and were evaluated for symptoms such as numbness, tightness, stiffness, and heaviness. On initial assessments, both arms were measured. Patients have completed radiotherapy and chemotherapy sessions. A signed informed consent was obtained from each participant.

Treatment in patients (BCRL)

The affected arm was measured at the start of treatment and weekly during the intensive phase of treatment Component of Decongestive Therapy (CDT)[8]. During the intensive phase, treatment lasts for 1 h daily for up to several weeks depending on the severity and response. (CDT) consists of four components. The first is Manual Lymphatic Drainage (MLD), which causes volume reduction by removing excess fluid and protein. MLD is a skin-stretching form of massage performed to open the lymphatics in unaffected regions to drain fluid from the affected regions and increase lymphatic activity. Second, compression therapy is applied to mobilize the edema fluid after each MLD session for 23 h/d, including weekends. Bandages and specific padding are applied in a precise way to the affected limb using a graded pressure. The bandage material used determines the depth of the compression effect. Short-stretch bandages are primarily used in our institution. Bandage application causes high pressure during activity and relatively low pressure in the limb when the body is resting. The third and fourth components are remedial exercises for the arm and shoulder and deep breathing to help promote venous and lymphatic flow. Patients are instructed about skin and nail care. The home program involves 1 h of training on self-lymphatic drainage and education on scrupulous skin care and remedial exercises. In our study, none of the patients received pneumatic compression therapy. Once the intensive phase was complete, the patient was measured for a custom garment and attended a few sessions to maintain the fluid volume loss until the compression garment was ready to wear (20–30 mm Hg). During the maintenance phase, which is permanent, the patient was instructed to wear the garment daily while awake and to remove it at bedtime. The patient was encouraged to do self-lymph drainage at least once daily.

Inclusion Criteria:

The participants were aged between 25 to 65 years female. Patients have completed radiotherapy and chemotherapy sessions. Patients who developed lymphedema of more than 2 cm compared to the contralateral extremity were included.

Exclusion Criteria:

Participants with primary lymphedema, bilateral lymphedema, pulmonary edema, congestive heart failure or any contraindications limiting CDT were excluded.

Statistical analysis

We applied the chi-squire test and paired t test to the absolute volume in milliliters to evaluate treatment effectiveness. Our data satisfied the assumption of the paired t test. Absolute concordance (degree of difference between the volumes pre and post treatment) was also assessed through the paired t test.

RESULTS

The 30 participants were made aware of the purpose and procedure of the study. The mean age was 49.5±9.9 and BMI was 28.6 kg/m2. Tumor Involved in breast; 14 (46.6%) cases of right breast and 16 (53.4%) cases of left breast. T stage (Tumor size in the Breast) were seen 1(3.35%) in Tis, T1 (20mm) in 17 (56.7%), T2 (20-50mm) in 11 (36.6%). None of the patient had stage T4. Nodal involvement; 18 (60%) patients had N0 and 12 (40%) had N+ and metastasis was seen 30 (100%) in M0. (Table: 1)

Table 1: Demographical Characteristic

Characteristic	
No. of Patient	30
Mean Age	49.5±9.9
BMI (kg/m2)	28.6±4.26
Tumor (Breast Involved)	
Right	14 (46.6%)
Left	16 (53.4%)
T stage (Tumor size in the Breast)	
Tis	1 (3.35%)
T1 (20mm)	17 (56.7%)
T2 (20-50mm)	11 (36.6%)

T3 (>50 mm)	1 (3.35%)
T4	0 (0%)
Nodal involvement	
N0	18 (60%)
N+	12 (40%)
Metastasis	
M0	30 (100%)
M+	0 (%)

14 (46.6%) patients were treated with modified radical mastectomy, 12 (40%) were lumpectomy and axillary nodal dissection, and 4 (13.3%) were simple mastectomy or excision of tumor alone without axillary dissection. 19 (63.3%) were treated with radiotherapy; 12 (63.1%) patients underwent radiation fields 2, 7(36.9%) patients underwent >2 (locoregional) and 15 (50%) treated with chemotherapy. (Table: 2)

Table 2: Treatment and Surgery type

Treatment/ Surgery type	
Modified Radical Mastectomy	14 (46.6%)
Lumpectomy and axillary nodal dissection	12 (40%)
Other (simple mastectomy, tumor excision alone)	4 (13.3%)
Radiotherapy	19 (63.3%)
Radiation fields 2	12 (63.1%)
>2 (locoregional)	7(36.9%)
Chemotherapy	15 (50%)

In the affected arm the pre-treatment mean volume was 2357 mL (range, 1472–5878 mL) and in normal arm the pre-treatment mean volume was 1822 mL (range, 1321–4297 mL). The difference arm volume at baseline was 535 mL, and the standard deviation was 254 mL. There was significant difference ($p<0.0001$).

Post-treatment affected arm mean volume was 2024 mL (After 4th week total reduced mean volume of affected arm was 196 mL,) total 36.6 % of reduction in the lymphedema volume. Significant difference ($p<0.0001$) was seen in the mean volume of affected arm (pre and post-treatment). And there was no significant difference ($p<0.980$) seen in the mean volume of the normal arm pre-treatment 1822 mL vs Post-treatment 1802 mL. (Figure: 1)

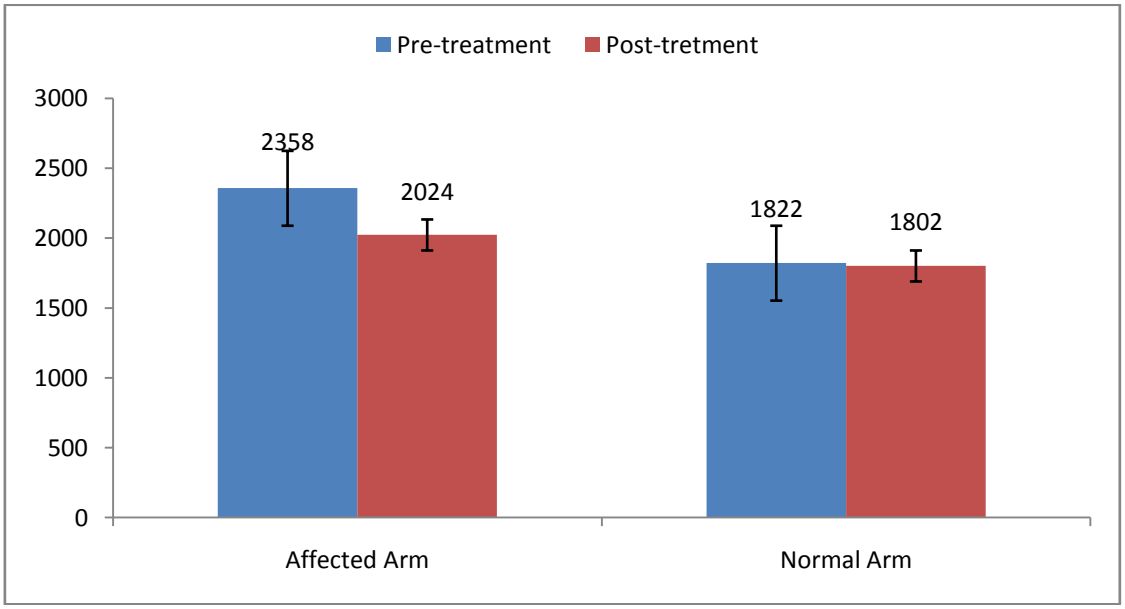

Figure 1: Comparison of arm volumes pre and post-treatment
Affected arm (196mL; p<0.0001), Normal arm (20mL; p<0.980)

DISCUSSION

Lymphedema may result in cosmetic deformity, loss of function, physical discomfort, and recurrent episodes of erysipelas. Patients with lymphedema are at risk of clinical, as well as psychological consequences that are debilitating and patients may be frustrated as they face a major problem, yet cannot find an answer to reduce a swollen limb[9]. In our study the mean age was 49.5±9.9 and mean BMI (kg/m2) was 28.6±4.26. Tumor Involved in breast; 14 (46.6%) cases of right breast and 16 (53.4%) cases of left breast. Breast cancer-related lymphedema was defined in the five controlled studies by arm size difference, but not in either descriptive study,[10,11] using various diagnostic criteria recognized by the lymphedema community:[12] two studies[13,14] defined lymphedema as >10% excess arm volume and one study[15] as >20% excess arm volume; one study[16] defined BCRL as >150 ml difference between arms; one study[17] In our present study in the affected arm the pre-treatment mean volume was 2357 mL (range, 1472–5878 mL) and in normal arm the pre-treatment mean volume was 1822 mL (range, 1321–4297 mL). Post-treatment affected arm mean volume was 2024 mL (After 4^{th} week total reduced mean volume of affected arm was 196 mL,) total 36.6 % of reduction in the lymphedema volume. Significant difference ($p<0.0001$) was seen in the mean volume affected arm (pre and post-treatment). And there was no significant difference ($p<0.980$) seen in the mean volume of the normal arm pre-treatment 1822 mL vs Post-treatment 1802 mL. Four studies categorized severity of swelling at baseline, either according to the International Society of Lymphology staging,[15,18] or relative (%) excess arm volume:[11,13,16] Dayes *et al.[13]* categorized severity as 10% to <20%, 20% to <30%, and ≥30% excess arm volume, McNeely *et al.[16]* categorized severity as mild (<15% excess arm volume), moderate (16–37%), or severe (>37%), and Hwang *et al.* stratified severity as <20% or ≥20% excess arm volume. Treatment of lymphedema is difficult, multidisciplinary in nature, and, even in the best outcomes, costly and time consuming [19]. The goal of lymphedema therapy is to reduce swelling, restore function, and improve the cosmetic outcome of the affected limb. In published reports, several common modalities have been used, in various combinations, but the quality of data demonstrating efficacy of the different treatments has been inconsistent. Most breast cancer patients undergo some form of surgery. Axillary dissection is often done as a staging procedure to guide adjuvant treatment. Although the trial of sentinel lymph node biopsy demonstrated an overall reduction in the incidence of lymphedema.[20] Multiple large series of patients with mild to severe lymphedema who underwent an intensive 2–3 weeks of CDT have documented striking results. Despite this success, neither CDT nor its components have been subjected to proper randomized clinical trial. In current study, CDT was offered according to the discretion of the therapists to patients with moderate to severe lymphedema. These patients had a maximal response after treatment. Patients who were enrolled in the home program had mild lymphedema and had a less dramatic response to therapy. The therapeutic benefit of CDT has been documented for >30 years and is in use as the standard treatment in North America. Drugs, such as diuretics, benzopyrones, antimicrobials, and mesotherapy (injection of hyaluronidase), have not been proved to have therapeutic value against uncomplicated lymphedema [21]. Surgical techniques such as the Charles debulking and microlymphatic venous anastomosis have also been used, but long-term follow-up data are not available to prove their efficacy [22]. However, because of these conflicting results, no consensus has yet been reached regarding a standard treatment of lymphedema. The findings of this study, indicated that the subjects had showed an after 4^{th} week significant effective reduction in lymphedema volume (total 36.6 % of reduction in the lymphedema volume). Williams et al. conducted a randomized control crossover study and found that MLD significantly reduced the limb volume and dermal thickness[23].

CONCLUSION

The study indicated that the subjects had showed an after 4^{th} week significant reduction in lymphedema mean volume in affected arm, pre and post-treatment total 36.6 % of reduction in the lymphedema volume. And there was no significant difference ($p<0.980$) seen in the mean volume of the normal arm pre-treatment 1822 mL vs Post-treatment 1802 mL.

REFERENCE

1. Agarwal G, Ramakant P(2008). Breast Cancer Care in India: The Current Scenario and the Challenges for the Future. Breast Care (Basel); 3(1):21-27. doi: 10.1159/000115288. Epub 2008 Feb 22. PMID: 20824016; PMCID: PMC2931014.
2. Malvia, S., Bagadi, S. A., Dubey, U. S., & Saxena, S. (2017). Epidemiology of breast cancer in Indian women. *Asia-Pacific Journal of Clinical Oncology*, *13*(4), 289-295.
3. Brennan, M. J., & Miller, L. T. (1998). Overview of treatment options and review of the current role and use of compression garments, intermittent pumps, and exercise in the management of lymphedema. *Cancer: Interdisciplinary International Journal of the American Cancer Society*, *83*(S12B), 2821-2827.
4. Lawenda, B. D., Mondry, T. E., & Johnstone, P. A. (2009). Lymphedema: a primer on the identification and management of a chronic condition in oncologic treatment. *CA: a cancer journal for clinicians*, *59*(1), 8-24.
5. Erickson, V. S., Pearson, M. L., Ganz, P. A., Adams, J., & Kahn, K. L. (2001). Arm edema in breast cancer patients. *Journal of the National Cancer Institute*, *93*(2), 96-111.
6. Chachaj, A., Małyszczak, K., Pyszel, K., Lukas, J., Tarkowski, R., Pudełko, M., ... & Szuba, A. (2010). Physical and psychological impairments of women with upper limb lymphedema following breast cancer

treatment. *Psycho-Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer*, *19*(3), 299-305.
7. Shih, Y. C., Xu, Y., Cormier, J. N., Giordano, S., Ridner, S. H., Buchholz, T. A., ... & Elting, L. S. (2009). Incidence, treatment costs, and complications of lymphedema after breast cancer among women of working age: a 2-year follow-up study. *Journal of clinical oncology*, *27*(12).
8. Liao, S. F., Huang, M. S., Chou, Y. H., & Wei, T. S. (2003). Successful complex decongestive physiotherapy for lymphedema and lymphocutaneous reflux of the female external genitalia after radiation therapy. *Journal of the Formosan Medical Association*, *102*(6), 404-406.
9. Tobin, M. B., Lacey, H. J., Meyer, L., & Mortimer, P. S. (1993). The psychological morbidity of breast cancer–related arm swelling. Psychological morbidity of lymphoedema. *Cancer*, *72*(11), 3248-3252.
10. Haghighat, S., Lotfi-Tokaldany, M., Maboudi, A. K., Karami, M., Bahadori, A., & Weiss, J. (2013). Predictive factors of response to phase I complete decongestive therapy in upper extremity lymphedema following breast carcinoma in Iran. *Lymphology*, *46*(2), 97-104.
11. Hwang, J. M., Hwang, J. H., Kim, T. W., Lee, S. Y., Chang, H. J., & Chu, I. H. (2013). Long-term effects of complex decongestive therapy in breast cancer patients with arm lymphedema after axillary dissection. *Annals of Rehabilitation Medicine*, *37*(5), 690.
12. Armer, J. M., & Stewart, B. R. (2005). A comparison of four diagnostic criteria for lymphedema in a post-breast cancer population. *Lymphatic research and biology*, *3*(4), 208-217.
13. Dayes, I. S., Whelan, T. J., Julian, J. A., Parpia, S., Pritchard, K. I., D'Souza, D. P., ... & Levine, M. N. (2013). Randomized trial of decongestive lymphatic therapy for the treatment of lymphedema in women with breast cancer. *Journal of clinical oncology*, *31*(30), 3758-3763.
14. Kaviani, A., Fateh, M., Nooraie, R. Y., Alinagi-zadeh, M. R., & Ataie-Fashtami, L. (2006). Low-level laser therapy in management of postmastectomy lymphedema. *Lasers in Medical Science*, *21*(2), 90-94.
15. Gradalski, T., Ochalek, K., & Kurpiewska, J. (2015). Complex decongestive lymphatic therapy with or without Vodder II manual lymph drainage in more severe chronic postmastectomy upper limb lymphedema: a randomized noninferiority prospective study. *Journal of pain and symptom management*, *50*(6), 750-757.
16. McNeely, M. L., Magee, D. J., Lees, A. W., Bagnall, K. M., Haykowsky, M., & Hanson, J. (2004). The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. *Breast cancer research and treatment*, *86*(2), 95-106.
17. Sim, Y. J., Jeong, H. J., & Kim, G. C. (2010). Effect of active resistive exercise on breast cancer–related lymphedema: a randomized controlled trial. *Archives of physical medicine and rehabilitation*, *91*(12), 1844-1848.
18. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema: 2013 consensus document of the International Society of Lymphology. Lymphology; 46 1:1–11.
19. Rockson, S. G. (1998). Precipitating factors in lymphedema: myths and realities. *Cancer: Interdisciplinary International Journal of the American Cancer Society*, *83*(S12B), 2814-2816.
20. Clarke D, Khonji NI, *et al*(2004). Sentinel node biopsy in breast cancer. *Ann Surg Oncol*; 11(3 Suppl.):208S–2010S.
21. Passik, S. D., & McDonald, M. V. (1998). Psychosocial aspects of upper extremity lymphedema in women treated for breast carcinoma. *Cancer: Interdisciplinary International Journal of the American Cancer Society*, *83*(S12B), 2817-2820.
22. Földi, E. (1998). The treatment of lymphedema. *Cancer: Interdisciplinary International Journal of the American Cancer Society*, *83*(S12B 12B), 2833-2834.
23. Williams, A. F., Vadgama, A., Franks, P. J., & Mortimer, P. S. (2002). A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. *European journal of cancer care*, *11*(4), 254-261.