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Protocol for Randomized Controlled Trial Investigating the Efficacy of Extracorporeal Shockwave Therapy Versus Complex Decongestive Therapy in Breast Cancer Survivors

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A B S T R A C T

This protocol describes a randomized comparative study to evaluate the effectiveness of complex decongestive therapy (CDT) combined with intermittent pneumatic compression therapy (IPCT) versus extracorporeal shock wave therapy (ESWT) in women with postmastectomy lymphedema. Eligible participants will be allocated to either the CDT+ IPCT group or the ESWT group, with both groups also receiving remedial exercises. Primary outcomes will include changes in limb girth, hand circumference, and grip strength, while secondary outcomes will assess shoulder pain and disability, quality of life and chemotherapy induced polyneuropathy symptoms using SPADI, FACT-B, and FACT-GOG NTx scales respectively. This study aims to address a critical gap in the literature by directly comparing these comprehensive rehabilitation strategies, with the goal of identifying optimal, accessible, and holistic approaches for improving physical function and quality of life in breast cancer survivors with lymphedema.

Keywords: Breast cancer, Lymphedema, Extracorporeal Shockwave Therapy, Complex Decongestive Therapy

1. INTRODUCTION

Cancer encompasses a group of disorders characterized by uncontrolled cell division with the potential to invade nearby tissues and metastasize to distant sites. It can arise in virtually any organ or tissue and remains a leading cause of global mortality, influenced by genetic, environmental, and lifestyle factors such as smoking, poor nutrition, and exposure to toxins. Despite advances in early detection and treatment, cancer continues to impose significant social, emotional, and economic burdens worldwide. According to the International Agency for Research on Cancer's GLOBOCAN 2022 data, approximately 20 million new cancer cases were diagnosed globally in 2022, reflecting rising incidence driven by aging populations and lifestyle changes. (1)

Breast cancer is the most common malignancy among women worldwide, with over 2.3 million new cases reported in 2020 and increasing incidence projected to exceed 2 million by 2030. In India, breast cancer incidence has surged markedly, especially in urban areas, now surpassing cervical cancer as the leading female cancer. Advances in early diagnosis and multimodal treatments-including surgery, radiation, chemotherapy, hormone therapy, targeted therapy, and immunotherapy-have improved five-year survival rates to about 90%. (2)

However, treatments often cause side effects such as fatigue, infection, and lymphedema, a chronic condition characterized by lymphatic fluid accumulation leading to swelling, pain, and functional impairment, particularly in the arm or chest on the affected side. Approximately 20% of breast cancer survivors develop lymphedema, with higher risk following axillary lymph node dissection or radiation. Lymphedema not only causes physical symptoms like swelling and heaviness but also psychosocial challenges including anxiety and depression, significantly diminishing quality of life. Early diagnosis through clinical evaluation, limb measurements, and imaging techniques such as lymphoscintigraphy and MRI is critical for effective management. (3-4)

Treatment is multidisciplinary and includes Complex Decongestive Therapy (CDT)-a combination of manual lymphatic drainage, multilayer bandaging, compression garments, remedial exercises, and skin care-which remains the gold standard.(5) Intermittent Pneumatic Compression Therapy (IPCT) offers additional benefits by sequentially applying pressure to facilitate lymphatic drainage. Recently, Extracorporeal Shock Wave Therapy (ESWT) has emerged as a promising, non-invasive modality that reduces tissue fibrosis, stimulates angiogenesis and lymphangiogenesis via VEGF production, and promotes tissue regeneration, thereby improving lymphatic function.(6-7) Given the chronic, progressive nature of breast cancer-related lymphedema and the limitations of existing treatments in terms of cost and time, there is a pressing need for affordable, effective, and accessible therapies. Combining CDT with IPCT or utilizing ESWT represents innovative approaches warranting further investigation to optimize outcomes and enhance quality of life for breast cancer survivors.

2. OBJECTIVES

The objective of this study is to compare the efficacy of Extracorporeal Shockwave Therapy (ESWT) versus Complex Decongestive Therapy (CDT) for breast cancer-related lymphedema. The primary outcomes include measurement of arm circumference using a measuring tape and assessment of shoulder pain and disability using the Shoulder Pain and Disability Index (SPADI). Secondary outcomes focus on hand grip strength measured by a dynamometer, quality of life evaluated through the Functional Assessment of Cancer Therapy - Breast (FACT-B), and neuropathic symptoms assessed by the Functional Assessment of Cancer Therapy/Gynaecologic Oncology-Neurotoxicity (FACT-GOG NTx) scale.

3. METHODOLOGY

Trial design

The trial design is a single blinded Randomized Clinical Trial with parallel groups (CDT group and ESWT group). Sampling method that will be used is Simple random allocation using envelope with an allocation ration of 1:1. Participants will be randomly allocated in either CDT group or ESWT group. Both the groups will receive 9 sessions of treatment, which will be conducted 3 times a week for 3 weeks.

Eligibility criteria:

A total of 22 participants who meet the inclusion criteria will be recruited for the study. The eligible subjects are female breast cancer survivors aged between 18 and above, who have been referred for physiotherapy for lymphedema and have undergone mastectomy surgery at least three months prior. The exclusion criteria include females diagnosed with metastatic cancer, active leukaemia, acute inflammation and infection, severe trauma or disruptive surgery to arm and are pregnant/breast feeding.

Procedure:

Qualified physiotherapists will perform and oversee the intervention. Informed consent will be obtained by one of the primary researchers, beginning with a comprehensive explanation of the study's purpose, procedures, assessments, potential risks, and benefits. Participants will be given ample opportunity to ask questions, ensuring full understanding. Additionally, they will receive a printed copy of the informed consent form to review at their convenience and take home for further consideration if desired.

Trial Registration:

The study is prospectively registered with the Clinical Trials Registry- India.

Outcome Measures:

Arm circumference will be measured at four specific points (wrist, elbow, 10 cm above the wrist, and 10 cm above the elbow) and at the hand using a figure-of-eight technique with a measuring tape. Each measurement will be taken three times for both the affected and unaffected limbs, and the average value will be used to determine the degree of edema by comparing differences between limbs.[8]

The Shoulder Pain and Disability Index (SPADI), a reliable patient questionnaire with strong psychometric properties, will be used to assess pain and functional limitations in daily activities involving the upper limb, with higher scores indicating greater disability.[9] Hand grip strength will be evaluated using a hand-held dynamometer, with patients performing three maximal squeezes in a standardized position; the mean value will be recorded, reflecting the method's excellent reliability.[10]

Quality of life will be assessed by the Functional Assessment of Cancer Therapy-Breast (FACT-B), a 37-item tool with robust internal consistency, covering physical, emotional, social/family, and functional well-being. Neuropathic symptoms will be measured using the FACT-GOG NTx, an 11-item module specifically targeting sensory, motor, and auditory neuropathy issues, which also exhibits high internal consistency and strong correlation with other validated cancer quality of life instruments.[11-12]

Intervention

Participants in the ESWT group will undergo treatment with the Gymna Shockmaster 500 device, set at an intensity of 0.056–0.068 mJ/mm², 2 bar pressure, and 4 Hz frequency. Each session will deliver 2,500 shocks-1,000 to the most fibrosed area and 1,500 to the cubital lymph node and arm-three times a week for three weeks, totalling nine sessions, with patients lying comfortably in a supine position and no local anaesthesia administered.[13]

The CDT group will receive a comprehensive protocol including intermittent pneumatic compression therapy (IPCT) using the ITO Medomer CP-110 A at 45 mmHg for 40 minutes per session, manual lymphatic drainage (MLD) with Vodder techniques for 15 minutes, multilayer bandaging, compression garments, and prescribed exercises, all performed three times weekly for three weeks.[14]

Additionally, all participants will be instructed to follow a daily home program consisting of diaphragmatic breathing, pumping, and active range of motion exercises for the elbow and shoulder, along with self-care guidance on hygiene, skin protection, and limb safety, to optimize lymphatic drainage and support recovery.[15]

Criteria for Discontinuing or Modifying Allocated Interventions

Discontinuation of the intervention will be upon participant request, or in the presence of any adverse effect.

Sample Size Calculation

To determine sample size, technique of estimating sample size for Paired "t" test was used where significance level of 5%, Power of 80%, anticipated dropouts of 5% was considered, and the total sample size was calculated as 22, that is 11 in each group.

Data collection and Management

Data collection and management will be conducted by a physical therapist specialized in cancer rehabilitation, who will contact patients to assess outcomes at baseline and during follow-up visits. All data will be recorded anonymously in an Excel spreadsheet, with both control and experimental groups assigned numeric codes to maintain blinding during statistical analysis. Information will initially be gathered using printed questionnaires and subsequently entered the electronic dataset. A designated monitor will oversee data completeness and ensure diligent patient follow-up. Statistical analyses will include descriptive statistics such as means, standard deviations, medians, interquartile ranges, and frequencies, as well as inferential statistics performed using the SPSS® software. Analyses will be conducted within and between groups for all measured parameters.

4. DISCUSSION

This research outlines a protocol for a prospective randomized clinical trial aimed at examining the efficacy of ESWT versus CDT in breast cancer related lymphedema. This protocol employs validated and reliable instruments-SPADI, FACT-B, and FACT-GOG NTx-to comprehensively measure pain, disability, quality of life, and neuropathic symptoms in breast cancer-related lymphedema (BCRL) patients. By implementing standardized exercise protocols uniformly across both treatment arms (ESWT and CDT combined with IPCT), the study aims to minimize exercise-related confounding factors, thereby isolating and clarifying the distinct therapeutic effects of each intervention and enhancing methodological rigor. Repeated follow-up assessments will enable detailed tracking of immediate and short-term clinical and functional outcomes, consistent with established research standards.

Preliminary evidence indicates that ESWT is safe for use in BCRL patients, with no adverse events reported, underscoring its practical viability in clinical settings. The patient-centred design, which addresses common barriers such as cost and travel, supports the feasibility and accessibility of these rehabilitation protocols in real-world oncological care environments.[8,16]

The anticipated outcomes include significant improvements in limb circumference, grip strength, shoulder pain and disability, and overall quality of life in both treatment groups, aligning with prior research demonstrating the efficacy of CDT, IPCT, and ESWT in managing lymphedema symptoms. Notably, while physical, emotional, and functional quality of life domains are expected to improve, social and family well-being may remain unchanged in the short term, reflecting the complex nature of psychosocial factors and the need for longer-term supportive interventions.[17]

Furthermore, both interventions are projected to alleviate chemotherapy-induced peripheral neuropathy symptoms, as measured by FACT-GOG NTx, potentially through mechanisms such as enhanced lymphatic drainage and modulation of neural inflammation. This study will contribute valuable comparative data on the relative effectiveness of CDT+IPCT versus ESWT, supporting their integration into multimodal rehabilitation strategies for BCRL.[18]

While sample size and follow-up duration may limit generalizability, the protocol lays a strong foundation for future large-scale, multicentre trials with extended follow-up to confirm the durability of benefits and elucidate underlying neurophysiological mechanisms. Overall, this investigation aims to advance evidence-based, accessible, and effective rehabilitation approaches to improve functional outcomes and quality of life for breast cancer survivors experiencing lymphedema.

The proposed study received ethical clearance from the institutional ethics committee of KLE Institute of Physiotherapy on 25/06/24, SI no- 806.

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