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Efficacy of the modified Buerger-Allen exercise with Epsom-salt foot bath for the management of chemotherapy-induced peripheral neuropathy in breast cancer patients: a treatment comparative randomized clinical study protocol†

Original article

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Abstract: **Objective:** Breast cancer in India is growing at an alarming rate, and the fact that it is currently being detected more frequently in the younger age groups is even more concerning. In India, a woman dies of breast cancer every 8 min, which is a terrible situation. Breast cancer claims one life for every two women who are diagnosed with it. However, the morbidity level is gradually increasing due to advanced medical treatment, but we need to be aware and alert.

Methods: The research has been structured as a randomized controlled trial. A total of 180 breast cancer patients were taken from Acharya Vinoba Bhave Rural Hospital (AVBRH), Cancer Center Sawangi Meghe for the study as per inclusion and exclusion criteria. With intervention, the period of the study was 11 months. A signed consent form was taken from each participant and based on the answers before, during, and after the trial the data were analyzed using IBM SPSS v29.

Results: The investigator believes that the Buerger-Allen exercise and Epsom salt foot bath will improve the symptoms in the symptomatic group of breast cancer patients and will prevent or delay the occurrence of peripheral neuropathy symptoms among the asymptomatic group as well as improve the overall quality of life (QoL). However, during the trial, if any of the study participants developed any side effects, they would be identified early and prompt treatment would be initiated.

Conclusions: This study protocol aims to evaluate and compare the non-pharmacological treatment options for chemotherapy-induced peripheral neuropathy (CIPN) and to develop a new treatment option that will pave the way to lead a new non-pharmacological cost-effective treatment option for breast cancer patients which also could improve the QoL.

Keywords: *breast cancer • Buerger-Allen exercise • chemotherapy-induced peripheral neuropathy • Epsom-salt foot bath • non-pharmacological treatment*

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1. Introduction

The "battle against cancer" is far from over. Cancer is a multifactorial complex disease[1] and is currently one of the biggest causes of death worldwide, with approximately 10 million deaths in 2020.[2] India in fact is a vastly diverse subcontinent in terms of ethnicity, culture, religion, economics, as well as healthcare infrastructure. The healthcare institution layout is varied, with many areas where the benefits of early detection, multidisciplinary treatment, and awareness initiatives have yet to be realized. According to a recent report, the number of cancer cases in India increased by an average annual rate of 1.1%–2% between 2010 and 2019. During the same period, the average annual rate of cancer-related deaths in the country jumped from 0.1% to 1.0%. Predictions from another study show that India could have 1,392,179 cancer patients by the end of 2020. According to research, the breast, lung, mouth, cervix, uterus, and tongue were the five most common sites for the disease. Moreover, the Cancer Statistics Report, 2020, says the projected incidence of cancer for men was 94.1 per 100,000 people, while for women it was 103.6 per 100,000 people.[3] Among all cancers, breast cancer is rising at an alarming rate in India. According to Globocon, every 4 min, a woman is diagnosed with breast cancer in India, with over 178,000 new cases identified each year.[4]

Scientists have made great progress in understanding this complexity over the past 50 years through coordinated studies, including fundamental and clinical experts in cancer. The Cancer Genome Atlas and Pan-Cancer Analysis of Whole Genomes investigations have shed light on the intricate nature of cancer as well as valuable clues toward new treatments. Basic cell cycle research has resulted in the creation of anticancer medicines that target certain cell-cycle proteins.[5]

Cancer still poses a challenge to contemporary medicine despite the enormous number of research that has been conducted in the past 10 years. It is fatal, especially when not detected at an early stage or made worse by comorbidities, difficult to treat, if not impossible to cure, and has a significant impact on the patient's quality of life (QoL). There are few available treatments (chemotherapy, radiation therapy, or surgical removal of the tumors), which are all expensive and have side effects (e.g., chemotherapy-induced nausea and vomiting, immuno- and myelosuppression, cardio-, hepato-, or nephrotoxicity).[6]

There is currently an enormous amount of concern about the toxicity of chemotherapy in Indian women, which has been investigated in various trials. Chemotherapy-induced peripheral neuropathy (CIPN) has been linked to some of the most popular breast cancer chemotherapy medications, including platinum (70%–100%) and taxane (11%–87%). As far as we currently know, numerous underlying causative mechanisms of CIPN have been identified by researchers, including mitochondrial and vascular dysfunction, oxidative stress, DNA damage, and neuroinflammation.[7] According to recent research studies, the prevalence of CIPN is around 68.1% during the first month of chemotherapy, 60.0% at 3 months, and 30.0% at 6 months, which poses a serious health concern. Chronic pain and irreversible nerve damage are among the symptoms that can range in severity and duration from acute to chronic, fleeting hot sensations, to persistent abnormalities in the peripheral nerves.[8]

Cancer patients, cancer survivors, and medical professionals need to be very cautious about CIPN symptoms, because there is currently no single, proven gold standard method to prevent it, and the options for treating the symptoms are extremely limited. Throughout the continuum of chemotherapy, CIPN also affects 11%–80% of breast cancer patients.[9,10] Chemotherapy-related neurotoxicity is now more widely recognized than ever before. It is predicted that neurotoxicity will be present in some form in 60% of the patients receiving neurotoxic chemotherapeutic agents.[11] As we have seen in the past few years, treating CIPN symptoms is becoming increasingly challenging. As a result, other researchers and scientists have been able to further develop and test a variety of non-pharmacological interventions, such as exercise, cryotherapy, acupuncture, and scrambler therapy, which have produced superior results to traditional pharmacological treatment in treating CIPN symptoms.[12,13] But despite many negative side effects, chemotherapy remains one of the main cancer treatments.[14]

There is no denying that the number of women in India who are newly diagnosed with breast cancer is rapidly increasing. Also, India has a predominantly younger population, so without doubt we are bound to see more breast cancer cases in younger women.[15] Although some of these cancer survivors may have ended up winning their battle with cancer, many of them suffer from poor outcomes as a result of multiple treatment-related side effects or complications that reduce their QoL and lead them to frequently experience pain for a very long time after finishing their cancer treatment.[16] It is a dire need now to explore different treatment modalities, especially non-pharmacologic approaches to treat CIPN symptoms among breast cancer patients in an aspect of improving the QoL, which could open a new window for breast cancer peripheral neuropathy symptom management in the near future.

2. Methods

2.1. Study type and design

This is a randomized clinical trial, and the design adapted for the study was a three-arm, single-blinded, triple-parallel randomized clinical study. Keywords used in this study were (Buerger-Allen exercise, Epsom-salt foot bath, peripheral neuropathy, neuropathy, management of chemotherapy-induced peripheral neuropathy, breast cancer, randomized controlled trial, non-pharmacological treatment modalities of breast cancer) related to Buerger-Allen exercise and Epsom-salt foot bath on peripheral neuropathy epidemiology, and we did a thorough search of the PubMed, Research Gate, Cinhal, and Google Scholar databases to find the related research.

2.1.1. Study setting

The study was conducted at Acharya Vinoba Bhave Rural Hospital (AVBRH), Cancer Center, Wardha, Maharashtra, under DMIHER (deemed to be a university), Sawangi Meghe Wardha.

2.1.2. Study participant

In total, 180 breast cancer patients were enrolled in the study with the use of a non-probability purposive sampling technique.

2.1.3. Recruitment of samples

Recruitment of the samples was based on the inclusion and exclusion criteria.

(1) Inclusion Criteria:

- **Inclusion criteria for symptomatic patients**
  1. Patients who consent to participate in the study.
  2. Breast cancer patients over the age of 18 years, medically stable, and able to understand and follow verbal instructions.
  3. Breast cancer patients who are having CIPN symptoms such as pain, numbness, and burning sensation in the lower extremities after receiving a minimum of two cycles of chemotherapy.
  4. Breast cancer patients who are willing to participate in the study.
  5. Cases with moderate CIPN on NCI-CTCAE V5.0 scale.
- **Inclusion criteria for asymptomatic patients**
  1. Patients who consent to participate in the study.
  2. Breast cancer patients who are indicated for chemotherapy with neurotoxic drugs.
  3. Breast cancer patients who have not yet developed CIPN symptoms.

(2) Exclusion criteria:

1. Patients who are terminally ill and have psychiatric conditions.
2. Patients who are suffering from diabetes, diabetic neuropathy, and other neurological disorders.

2.2. Research hypothesis

1. There is a significant relief in the symptoms of peripheral neuropathy in the combination of Modified BAE and Epsom salt foot bath as compared with Modified BAE and Epsom salt foot bath alone in delaying or preventing symptoms of CIPN between the control and experimental asymptomatic groups.
2. There is a significant improvement in the symptoms of peripheral neuropathy in the combination of Modified BAE and Epsom salt foot bath as compared with Modified BAE and Epsom salt foot bath alone in alleviating the symptoms of CIPN between the control and experimental symptomatic groups.

2.3. Null hypothesis

1. There is no significant relief in the symptoms of peripheral neuropathy in the combination of Modified BAE and Epsom salt foot bath as compared with Modified BAE and Epsom salt foot bath alone in delaying or preventing the symptoms of CIPN between the control and experimental asymptomatic groups.
2. There is no significant improvement in the symptoms of peripheral neuropathy in the combination of Modified BAE and Epsom salt foot bath as compared with Modified BAE and Epsom salt foot bath alone in alleviating the symptoms of CIPN between the control and experimental symptomatic groups.

2.4. Data analysis

Descriptive analysis such as frequency, percentage, standard deviation, and mean were used. To determine the efficacy, a t-test was be utilized. Furthermore, to make a comparison between the experimental and control groups, the chi-squared test or Fisher's exact test, whichever was applicable, was used. SPSS v29 was used for data analysis. Adjusted odds ratios (AORs) and 95% confidence intervals (CIs) were adapted. A two-sided *P*-value of <0.050 was considered statistically significant.

2.5. Informed consent

Informed consent was obtained from the breast cancer patients. The consent form was prepared by the researcher and was attached to the validated tools. Instructions were given to the patients to not use reference material or discuss with their friends to find the correct answer.

2.6. Ethical consent

This randomized clinical trial was conducted in the AVBRH, Cancer Center, at Datta Meghe Institute of Higher Education and Research, deemed to be university Wardha, Maharashtra, and the study proposal was approved by the Institutional Ethical Committee on May 9, 2023, with the letter Ref. No. DMIHER(DU)/IEC/2023/22. Furthermore, this clinical trial is also registered in the Clinical Trial Registry of India (CTRI) with the Registration No: CTRI/2023/07/055716. Written informed consent was obtained along with a comprehensive explanation of the study objectives prior to commencing the study.

2.7. Intervention

There were 18 breast cancer patients in each group, which were divided into six equal groups: first time receiving chemotherapy but yet to develop the symptoms of CIPN (asymptomatic), and multiple time received chemotherapy with mild to moderate CIPN symptoms (symptomatic) in each of the experimental and control groups. Group 1 received both modified Buerger-Allen exercise with Epsom-salt foot bath; Group 2 received modified Buerger-Allen exercise; and Group 3 received Epsom-salt foot bath. For 5 days, three times a day for 20 min at intervals of 3 h, the Buerger-Allen exercise was administered and Epsom salt foot bath entailed immersion of the feet and legs to a depth of 4 inches (10 cm) above the ankles in water at 40°C for 20 min.

Participants had the right to withdraw from the study in case any adverse reaction developed. During this time the reason for discontinuation or intervention modification would be properly documented. Participants were also advised to record their daily experience after the procedure to find out whether or not the QoL had improved.

2.7.1. To avoid turnover, we implemented the following strategies

1. Regular in-hospital contact with the patients will be made and remind them for treatment routine and procedures.
2. Monitoring of participants and advice to family members to continuously look after the patients during and after the procedure in both the experimental and control groups.
3. The study team and participants stayed in constant contact to resolve any queries or concerns regarding the intervention.

2.7.2. Enrolment

Various strategies were used to ensure sufficient participant enrolment:

- Health education and public awareness was created in the daycare center along with the hospital's outpatient department of the cancer care center.
- Working together with medical and nursing staff in the surgical, general, and daycare wards to make patient recruitment easier.
- Making sure prospective participants are made aware of the inclusion and exclusion criteria in a clear and understandable manner.

2.7.3. Allocation

The biostatistician created a pattern for random allocation. The primary research investigator enrolled the participants in different groups, and the interventions were done by the research associates along with the primary investigator. In this study, participants were blinded. In case of an emergency health situation or, regarding the safety of the patients, unblinding would be taken into consideration.

2.7.4. Follow-up

The following plan was implemented to avoid patient turnover and to complete follow-up.

- Collecting patient information that included a contact number and an updated record of all participants.
- Regular follow-up appointments and interaction between the research group and patients necessary to complete the study.
- Thoroughly stating the significance of ongoing involvement and the possible repercussions of not finishing the informed consent stage.

2.7.5. Blinding (masking)

Trial participants were blinded after they were assigned to treatment.

2.8. Data collection methods

Official permission was sought from the hospital medical superintendent as well as from the head of the breast

cancer department. The investigator introduced himself to the participants and informed about the purpose of the study. Sample selection was done according to the inclusion criteria. Samples were allocated to both the experimental and control groups under Groups 1, 2, and 3, after collecting informed consent before the study. After identifying the symptomatic and asymptomatic CIPN cases, the intervention groups received treatment, and the control group received the routine standard hospital treatment. For the symptomatic cases in the experimental group, observation was done till the sixth cycle, whereas for the asymptomatic group of patients, observation was done till the 4th cycle.

2.9. Data management

Proper coding and indicators were applied to the master sheet during the data collection and were stored by the investigator. Data confidentiality was maintained.

3. Results

The study findings are unique as there is no similar study done in an Indian setting or anywhere in the world. So the evidence generated from the comparison between the Buerger-Allen exercise (Modified version) with Epsom salt foot bath as against modified BAE and Epsom salt foot bath alone will help to understand the new non-pharmacological treatment modality for CIPN symptoms for breast cancer patients and will also pave the way to understand the overall QoL of breast cancer patients during chemotherapy.

3.1. Statistical analysis

Every research participant with no missing values for any of the dataset's parameters was included in the whole analytic dataset. Those who met the inclusion and exclusion criteria were the study participants.

Outcome variables:

1. National Cancer Institute (NCI)-CTCAEv5.0 toxicity criteria.
2. Functional assessment of cancer therapy/gynecology oncology group—Neurotoxicity (FACT/GOG-NTX) scale 13-item version.

All the data were summarized with baseline characteristics for demographic variables described by the frequency and percentage for categorical data and with mean and standard deviation for continuous data. Outcome variables were analyzed over continuous variables, which were summarized with the minimum, maximum, mean, standard deviation, standard error, and CI at 95% for parametric data. Data over the continuous outcome variables were first tested using normality test using Kolmogorov–Smirnov test at 5% level of significance ($P \leq 0.05$). If rejected, data were considered as normal, otherwise nonparametric test was used for finding the significance. *T*-test was used to find the significant difference at the 5% level ($P \leq 0.05$) for comparative groups: (1) Modified BAE and Epsom salt foot bath against control group, (2) Modified BAE against control group, and (3) Epsom-salt foot bath against control group.

Non-normal data were described by mean, median, lower, and upper quartiles for using non-parametric test and testing significance was done using Mann–Whitney test.

Categorical variables were summarized by frequency (N) and percentage values (%). Efficacy over the categorical variable were analyzed by chi square analysis for finding efficacy.

4. Discussion

Currently, there is no known method of treatment or prevention for the adverse effects of chemotherapy. Most treatments additionally fail to address the potential long-term effects or secondary reactions, which might lead to discomfort in the patient. There has been considerable concern about the toxicity of chemotherapy in Indian women and this has been addressed in numerous trials. In India, we do not have any proper protocol to manage CIPN symptoms among breast cancer patients receiving paclitaxel and taxane chemotherapy. However, some research has found that non-pharmacological therapy is far more effective and useful to manage CIPN symptoms compare with the traditional pharmacological intervention.

A comparative study conducted by Park and Park[17] examined the comparison of foot bathing and foot massage in CIPN. A total of 48 patients participated in the study and the intervention consisted of foot bathing or massage for 2 weeks and 30 min per session on every alternate day.

According to the findings of the research, the authors concluded that foot bathing was more effective than foot massage, which can also be used for supportive care and QoL among cancer patients. Another experimental study was conducted by Emine and Gulbeyaz,[18] to see the effect of salt water baths in the management of treatment-related peripheral neuropathy in cancer patients receiving taxane and platinum-based treatment, where a total of 103 cancer patients participated in the study, and the participants were divided into two groups, namely, 1–warm salt water and 2–cold salt water. Every other day for 14 days, the participants in the warm salt

water group were instructed to apply 41°C warm water to their hands and feet, whereas the participants in the cold water group were instructed to use 23–26°C cold water. The result shows that the severity of peripheral neuropathy decreased and the QoL increased in the cold-water salt bath group as compared with the control group. We have also seen that the foot bath has been rigorously used in many societies in many countries since ancient times. Some studies have also suggested that foot baths also give fruitful results in the treatment of various skin diseases, fatigue, infection control, pain, and psychiatric symptoms.[19–22]

Many pharmacological studies have been done to manage peripheral neuropathy symptoms all around the world, but the amount of non-pharmacological studies done compared with pharmacological studies is very less. Some of the studies show that exercise, foot bath therapy, Epsom salt foot bath, and Buerger-Allen exercise are very helpful to improve symptoms of peripheral symptoms. Buerger-Allen exercise was also considered as an effective non-pharmacological treatment for peripheral neuropathy in diabetes mellitus cases, but more research in this aspect is needed.

Radhika et al.[23] set out to investigate the effectiveness of Buerger-Allen exercise on lower extremity perfusion and peripheral neuropathy symptoms among patients with diabetes mellitus. Fifty patients participated in the study, and it revealed that mildly impaired perfusion was decreased and the normal perfusion was increased by 34%–36%. Therefore, the authors concluded that Buerger-Allen exercise can be an effective exercise for diabetes mellitus patients suffering from peripheral neuropathy. A similar study was done by Irhas et al.[24] and Hafid et al.[25] and they found that Buerger-Allen exercise improves lower extremity perfusion and reduction of peripheral neuropathy in diabetes mellitus cases. However, as most of the studies have a very less sample size and also do not have control groups, hence it was advised to do more research in the future to have a proper non-pharmacological therapy for peripheral neuropathy.

The QoL of breast cancer patients is also one of the crucial aspects to consider. In addition, there were only a few high-quality researches done to generate evidence on the QoL. A patient-reported outcome study was done by Carreira et al.[26] In the United Kingdom, where 356 breast cancer survivors and 252 women with no history of cancer participated in the research, the research was conducted to compare the QoL and mental health of breast cancer survivors with non-cancer controls. It turned out that when compared with the women with no history of cancer, breast cancer survivors exhibit more issues with sexual function, fatigue, anxiety, and cognitive function, particularly as the cancer stages progressed and when on chemotherapy medication. Therefore, this study aimed to develop a new treatment protocol and also quantify patient-reported outcomes of QoL among breast cancer patients.

5. Conclusions

Cancer still poses a challenge to contemporary medicine despite the enormous number of research that has been conducted in the past 10 years. The side effects and long-term effects of anti-cancer chemotherapy continue to be a significant challenge for both patients and oncologists, despite improvements in the treatment which enhance cancer survival. The author hopes this PhD research study will help breast cancer patients to improve their neuropathy symptoms and QoL.

5.1. What are known about the topic

- Female breast cancer has now overtaken lung cancer as the most commonly diagnosed cancer, with an estimated 2.3 million new cases.
- One of the most common side effects of anti-neoplastic drugs in breast cancer is CIPN.
- The incidence of paclitaxel-induced neuropathy (all grades) is approximately 10%–12%, with <2% of patients developing Grade III or IV neuropathy. Also, platinum (70%–100%) or taxane (11%–87%) has been identified to cause CIPN.
- There is no gold-standard method to treat CIPN symptoms yet.

5.2. What this study adds

- This is the first comprehensive study done in India as well as around the world to find out the effectiveness of two combined treatments to check the improvement of CIPN in breast cancer patients.
- The evidence generated from the comparison between the Buerger-Allen exercise (modified version) with Epsom salt foot bath as against modified BAE and Epsom salt foot bath alone will help to understand the new non-pharmacological treatment modality for CIPN symptoms in breast cancer patients and will also pave the way to understanding the overall QoL of breast cancer patients during chemotherapy.

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Ethical approval

This study proposal was approved by the Institutional Ethical Committee on May 9, 2023, with the letter Ref. No. DMIHER(DU)/IEC/2023/22. Furthermore, this clinical trial is also registered in the Clinical Trial Registry of India (CTRI) with the Registration No: CTRI/2023/07/055716. Ethical issues are not involved in this paper.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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