

Study Protocol

A study protocol on the effectiveness of postmastectomy exercises in breast cancer patients on reduction of lymphedema and improving range of motion among patients undergone mastectomy.

ABSTRACT

Background: Breast cancer is the most commonly diagnosed type of cancer in the world, and it is a major stressor in women's lives. Breast cancer cases are increasing in both rural and urban settings. Mastectomy is a procedure that removes the breast to prevent cancer cells from returning. Many complications can develop after a mastectomy, but lymphedema and limited range of motion are the most prevalent. The present study aimed to assess the effectiveness of post mastectomy exercises in breast cancer patients on reduction of lymphedema and improving range of motion among patients undergone mastectomy.

Objectives:

- To assess Pre interventional level of lymphedema among patients undergone mastectomy.
- To assess Pre interventional range of motion among patients undergone mastectomy.
- To evaluate the effectiveness of post mastectomy exercises in reducing lymphedema among patients undergone mastectomy
- To evaluate the effectiveness of post mastectomy exercises in improving range of motion among patients undergone mastectomy.
- To associate demographic variable with post mastectomy exercises.
- To associate correlation of post mastectomy exercise with lymphedema and range of motion.

Methodology: A pre interventional one group pretestposttest design would be adopted to assess the effectiveness of post mastectomy exercises in breast cancer patients on

reduction of lymphedema and improving range of motion among patients undergone mastectomy. In this study interventional analytical study will be used. Purposive sampling technique will be used to collect the data. The study will include 30 patients undergone mastectomy will be assessed by using American lymphology lymphedema scale and Elvaru STJ (Subtalar joint) range of motion and range of motion reliability tool with the help of inch tape and goniometer and then post mastectomy exercises will be teachby researcher as intervention.

Expected Results:The goal of this study is to see how effective post-mastectomy exercises are at reducing lymphedema and improving range of motion in breast cancer patients who had undergone mastectomy. Teaching post-mastectomy exercises can help the respondents reduce lymphedema and improve their range of motion.

Keywords: Effectiveness, Post mastectomy exercises, Lymphedema, Range of motion, Patient's undergone mastectomy

INTRODUCTION

The second most frequent malignancy in India is breast cancer.[1] Cancerous cells in the blood or lymph system can migrate to other parts of the body, causing breast cancer to spread.[2]It is one of the leading causes of cancer deaths among women.[3]

A mastectomy is a procedure that removes all of the breast tissue.A woman's breast is an emotional expression of her pride in her sexuality and motherhood. Various issues can develop after surgery, including a loss of overall fitness, muscle stress, scar tissue prevention, strength loss, and shoulder function loss.[4]The nurses' job is to highlight the patient's positive traits while also providing hope and encouragement.

A woman's risk of acquiring lymphedema after a mastectomy is considerable. It occurs when part or all of the lymph nodes are removed. Lymphedema develops shortly after a mastectomy or within a few days of the procedure. It might be sudden and unpleasant, or it can be gradual and painless. Lymphedema from mastectomy limits range of motion in the shoulder, notably in flexion, abduction, internal or external rotation, and horizontal abduction.[5]Range of motion is the measurement of mobility around a certain joint or bodily component. In order for a joint to have full range of motion, it must be flexible.[6] Post-mastectomy exercises that are performed on a regular basis in the post-operative period can assist to reduce the risk of mastectomy complications.[7]

BACKGROUND OF THE STUDY

Breast cancer is the most commonly diagnosed type of cancer in the world, and it is a major stressor in women's lives. Breast cancer cases are increasing in both rural and urban settings. Mastectomy is a procedure that removes the breast in order to prevent cancer cells from returning. Many complications can develop after a mastectomy, but lymphedema and limited range of motion are the most prevalent.[8] The present study aimed to assess the effectiveness of post mastectomy exercises in breast cancer patients on reduction of lymphedema and improving range of motion among patients undergone mastectomy.

NEED OF THE STUDY

Breast cancer is the second leading cause of death. Breast cancer has become most common female cancer worldwide contributing nearly a quarter (25%) of all cancer cases, with an estimated 1.67 million new cancer cases diagnosed in 2012. Less developed countries have a little more number of breast cancer cases (883 000 cases) compared to more developed countries (794 000).[9]

Lymphedema is a common post-mastectomy condition that limits upper-extremity range of motion. To avoid complications, mastectomy patients must be informed about post-mastectomy exercise. Axillary lymph node dissection, obesity, old age, radiation, and surgical complications can all cause lymphedema. Limited knowledge is more dangerous than ignorance since an ignorant person can seek help, whereas someone with little information may not be able to recognise the problem. It may result in a lack of self-care, which is potentially dangerous. During the clinical placement, the researcher noticed that many of the women diagnosed with breast cancer had their breasts removed, resulting in lymphedema and decreased range of motion.[10] Following a thorough review of the literature and consultation with experts, the investigator concluded that there is a high demand for post-mastectomy exercises to be taught to patients who have had a mastectomy in order to reduce post-mastectomy complications such as lymphedema and improve range of motion.

METHODOLOGY

A one group pre-testpost-test design will be used. Purposive sampling technique will be used to collect the data. Prior to beginning of the study, the nature of the study will be explained to study participants in the Marathi language and written informed consent will be taken from study participants. Confidentiality regarding each and every participant's personal

identity and privacy will be strictly maintained. Sample size for the study is calculated by Cochran's formula. Selected 30 patients who have had undergone mastectomy will be assessed using the American lymphology lymphedema scale and the Elvaru STJ (Subtalar joint) range of motion and range of motion reliability tool with the aid of an inch tape and goniometer, and then post mastectomy exercises will be taught to the sample as an intervention on 2nd post-operative day and instructed to be performed for 30 minutes morning and evening for 7 post-operative days. After 7th day using the same tool the lymphedema and range of motion will be assessed to see the effectiveness of post mastectomy exercise. IEC approval was obtained from Institutional Ethics Committee, Data Meghe Institute of Medical sciences (Deemed to be University)/IEC/2021/280).

CRITERIA FOR SAMPLE SELECTION

INCLUSION CRITERIA:

- The women who undergone mastectomy had lymphedema and decreased range of motion
- The women who are willing to participate
- First time operated for mastectomy of one side breast.

EXCLUSION CRITERIA:

- Women who are not cooperating.
- Already undergone mastectomy

RANDOMIZATION

All the patients undergone mastectomy will be assigned randomly by sequential numbered system.

INTERVENTION

Assess the effectiveness of post mastectomy exercises under the guidance of the Associate Professor of Medical Surgical Nursing.

STATISTICAL ANALYSIS

Statistical analysis done by descriptive and inferential statics with the help of SPSS 20.0 software.

ETHICAL ASPECTS

Study was approved by the Institutional Ethics Committee (letterno–DMIMS (DU)/IEC/2021/280) and the study will be conducted in accordance with the ethical guidelines prescribed by institutional Ethics Committee on Human Research.

EXPECTED OUTCOME/ RESULTS:

The goal of this study is to see how effective post-mastectomy exercises are at reducing lymphedema and improving range of motion in breast cancer patients who had a mastectomy. Teaching post-mastectomy exercises can help the respondents reduce lymphedema and improve their range of motion.

DISCUSSION:

The study findings would be supported through the studies conducted worldwide. A study conducted by Ashwini.K.N, Satynarayana T.Ein 2018 on assess the video-assisted teaching on knowledge regarding post mastectomy exercises among breast cancer patients. They assessed knowledge of post-mastectomy exercises using self-prepared structured questionnaires. As a result of the study, patients' knowledge of post-mastectomy exercise improved when video-assisted education was used. However, it is recommended that patients' knowledge of post-mastectomy complication reduction to be assessed.[11]As a result,the current study aimed to assess the effectiveness of post mastectomy exercises in breast cancer patients on reduction of lymphedema and improving range of motion among patients undergone mastectomy. Contributing to a better knowledge of the effects of post-mastectomy exercises on lymphedema and range of motion. Similar research on post-mastectomy exercises have also been reported. Sri Aurobindo Prasad Das and SathasivamSureshkumar published a study titled "Effect of exercise on shoulder function and morbidity following mastectomy with axillary dissection in patients with breast cancer" (et.al in 2018). [12]A systemic review conducted on effectiveness of exercise programmes on shoulder mobility and lymphedema after axillary lymph node dissection for breast cancer in which researcher found that early rather than delayed onset of training did not affect the incidence of postoperative lymphedema, but early introduction of exercises was valuable in avoiding deterioration in range of shoulder motion.[13], [14]

CONCLUSION:Final conclusion will be drawn from final result of the statistical review.

REFERENCE:

1. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries - Sung - 2021 - CA: A Cancer Journal for Clinicians - Wiley Online Library [Internet]. Available from: <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21660>
2. Breast Cancer - Metastatic: Introduction | Cancer.Net [Internet]. Available from: <https://www.cancer.net/cancer-types/breast-cancer-metastatic/introduction>
3. Gaikwad IS, Dandekar PD. Knowledge, awareness and attitude about Breast lump among females An observational study. *Int J Ayurvedic Med.* 2020 Oct 2;11(3):554–8.
4. Mastectomy [Internet]. Available from: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/breast-cancer/mastectomy>
5. Hamner JB, Fleming MD. Lymphedema Therapy Reduces the Volume of Edema and Pain in Patients with Breast Cancer. *Ann Surg Oncol.* 2007 Mar 8;14(6):1904.
6. The efficacy of physiotherapy recovery after a modified radical mastectomy: A Case Report [Internet]. Available from: https://scholar.google.com/citations?view_op=view_citation&hl=en&user=yRddpdIAAAAJ&citation_for_view=yRddpdIAAAAJ:Y0pCki6q_DkC300115615priya.pdf [Internet]. Available from: <http://repository-tnmgrmu.ac.in/11714/1/300115615priya.pdf>
7. CHIRIAC V-F, BABAN A, DUMITRASCU DL. Psychological stress and breast cancer incidence: a systematic review. *Clujul Med.* 2018;91(1):18–26.
8. Anand AS, Shinde RK. To Compare the Effects of Adjuvant and Neoadjuvant Chemotherapy on Outcome of Stage III Carcinoma Breast. *J Evol Med Dent Sci.* 2020 Feb 24;9(8):496–501.
9. Prevalence of upper extremity lymphedema and risk factors in patients with mastectomy: Single-center, observational, cross-sectional study [Internet]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7538822/>
10. (PDF) A Study to Assess the Effectiveness of Video Assisted Teaching on Knowledge Regarding Post Mastectomy Exercises among Breast Cancer Patients at Kidwai

Memorial Institute of Oncology, Bangalore | International Journal of Health Sciences and Research (IJHSR0Academia.edu[Internet]. Available from: https://www.academia.edu/43751877/A_Study_to_Assess_the_Effectiveness_of_Video_Assisted_Teaching_on_Knowledge_Regarding_Post_Mastectomy_Exercises_among_Breast_Cancer_Patients_at_Kidwai_Memorial_Institute_of_Oncology_Bangalore

11. Das et al. - 2018 - Effect of exercise on shoulder function and morbid.pdf [Internet]. Available from: <https://www.ijsurgery.com/index.php/isj/article/viewFile/3359/2330>
12. Chan DNS, Lui LYY, So WKW. Effectiveness of exercise programs on shoulder mobility and lymphoedema after axillary lymph node dissection for breast cancer: a systematic review. *J Adv Nurs*. 2010;66(9):1902–14.
13. Birelliwari, Aachal. Evaluation of Posture and Quality of Life in Females Undergone Modified Radical Mastectomy: A Research Protocol; 963-965:

UNDER PEER REVIEW

Fig 1. Schematic diagram of study methodology

