

EFFECTS OF STRUCTURED EXERCISE PROGRAM ON TENDERNESS AND CYCLIC MASTALGIA IN OBESE WOMEN:AN EXPERIMENTAL STUDY.

ABSTRACT

BACKGROUND

Cyclic Mastalgia affects women who are menstruating in their 20s, 30s, or 40s. This pain starts about a week before commencing menstruation. During this period, the breasts become sore, tender, and swollen, though symptoms improve later in the cycle or it may be so severe that the patients cannot wear tight fitting clothes or they becomes irritable. The discomfort usually occurs outside and upper portions of both breasts, and it may even affect underarms. Cyclical Mastalgia is a common condition associated with a higher risk of breast cancer. Mastalgia is common ailment that affects about 70% of women and has negative impact on their quality of life. Many scientists believe that the cause of cyclic mastalgia lies in a mix of hormonal activity and something in the breast that reacts to it. Mastalgia is a term used to describe women's discomfort with their breasts., although doctors usually neglect it.

METHODS-Based on the inclusion and exclusion criteria, a total of 30 women will be selected for the study. A questionnaire of breast pain based on the McGill Pain Questionnaire, and a Cardiff chart, will all be employed as outcome measures. The individuals' pre-intervention scores will be collected, and they will be given an exercise routine to follow for four weeks, three times per week. The outcomes of the intervention will be measured afterwards. Our protocol will cover weeks of treatment. Regular assessment will be carried out.

DISCUSSION-This study was done to find out effectiveness of exercise program in obese womens with breast mastalgia and tenderness.

KEYWORDS–Cyclical mastalgia, exercise program, menstrual cycle ,Obese women, breast tenderness, study protocol.

INTRODUCTION-

Mastalgia, also known as mastodynia, is a chronic condition that can be managed with conservative measure. Approximately two third of individuals may be affected through their reproductive age (1). It's a dull, aching pain in the breast tissue that some people describe as heaviness, tightness, pressure, or burning. It might be one-sided or two-sided.It typically begins in the right upper region of the breast and progresses to the ipsilateral arm(2).Mastalgia may usually be managed with basic drugs and reassuring in the majority of cases. Mastalgia can be associated with breast nodules that are either tender or do not have a distinct lump(3).It subsides in 20% of women if no action is taken. Around 60-70 percent of women will suffer breast pain at a certain time in life. Mastalgia is usually moderate, thus no specific therapy is required, and educating and reassuring the patient is beneficial (4).

The four phases of menstrual cycle: follicular, ovulatory, luteal, and menstrual. The first day of menstruation is follicular phase and continues until the menstrual cycle is completed.The luteal phase begins with ovulation and ends with fertilisation (5).

Mastalgia has an etiology that is unknown.Despite the link to the menstrual cycle, hormonal tests for oestrogen, progesterone, and prolactin have found no abnormalities.Pregnancy, lactation, menopause, oral contraceptives, and hormone replacement therapy are all factors that influence the progression of breast pain.While variations in oestrogen and progesterone ratios have been shown to cause pain in women with benign mastopathies, other factors such as smoking, caffeine usage, and obesity can also cause mastalgia(6)-(7) .

Mastalgia has been associated to high stress and anxiety, sadness, chronic fatigue, inflammatory bowel disease, chronic pelvic pain, and various psychiatric issues, implying that this form of pain may have a psychosomatic origin in some persons. Mastalgia has a multifactorial pathogenesis, according to the majority of scholars.Two weeks before menstruation, cyclic breast discomfort starts, diminishes before the onset of menstruation, then resumes during the premenstrual period.

The discomfort is mostly caused by hormones, and that is most noticeable during the luteal phase(8).

Mastalgia is more prevalent in women over the age of 30 and the age range of beginning of breast discomfort is 36 years old. According to Johnson et al Mastalgia was found to be more common in people aged 35 to 55(7). This study shows that weight gain is a risk factor for developing mastalgia and is significant in terms of demonstrating that weight control can be used to avoid breast pain.

Assuring patients knowing they are not suffering from breast cancer and some lifestyle modifications such as stress management, endocrine treatments such as danazol, bromocriptine, and tamoxifen; avoiding caffeine and methylxanthine-containing foods, eating a low-fat diet, and exercising; A range of therapeutic approaches have been tried, including basic analgesics and primrose oil(9). However, the success of various treatments varies. Despite the fact that exercise is widely advocated as a lifestyle modification for mastalgia treatment, there is no concrete data to back it up. With aerobic exercise, pain sensitivity reduces while serum beta endorphin levels, immunoreactivity, sleep quality, and overall happiness all rise(10). Regular physical exercise or activity promote the return of blood to the heart and improve blood circulation throughout the entire body. Literature suggest exercise aid in the regulation of hormones, particularly oestrogen and progesterone, which is one of primary cause of cyclical mastalgias. As a result, exercises aid in regulation of hormonal imbalance and, as a result help in reduction of breast pain. The goal of this study is to see how exercise affects mastalgia patients.

AIM

The Aim of this research is to see how a structured exercise programme affected cyclical mastalgia and tenderness in obese women.

OBJECTIVES

1. Analyzing the effect of structured exercise program on cyclical mastalgia
2. Analyze the effect of structured exercise program on tenderness in obese women.

MATERIAL AND METHODOLOGY:-

Material required:-

McGill Pain Questionnaire, Cardiff chart.

Methodology:-**Study Setting:-**

The participants would be recruited from the physiotherapy OPD of Acharya Vinoba Bhave Rural Hospital, Sawangi Meghe, Wardha, Maharashtra, after receiving approval from the Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences, Deemed to be university. Participants will be informed about the study's goals and approaches before being accepted, and they will sign a written consent form.

STUDY DESIGN AND SAMPLE SIZE

Study Design:- Cross sectional

Study Type:-Interventional study

Duration of study: 6 months

Sample size: 30

Sampling technique: Convenient sampling

Allocation: convenient selection of patients.

Sample Size Calculation:-

Sample size was calculated by using G power analysis. There will be total 30 participants.

Sample Size:-

n= 30patients needed

PARTICIPANTS-

The inclusion criteria of participants are under-

- Obese Women's with BMI greater than $30\text{kg} / \text{m}^2$ who are complaining of breast tenderness.
- Age between 25-35.

The excluding criteria of participants are under-

- Individual on hormone therapy
- Mastalgia medications
- Breast pain caused by a lump
- Diagnosed with breast cancer or any other undetected illness.
- Premenstrual syndrome

PARTICIPATION TIMELINE

As study duration is of 6 months and intervention duration is 6 weeks so participant will be enrolled mostly during first 4 months of study so 6 week intervention will be completed successfully. Assessment will be done on 1 st day of visit then in 3 rd week and last on 6 th week of intervention. Participant will have to visit 5 days a week for 6 weeks for treatment.

RECRUITMENT

Prospective patients should be referred to the physiotherapy department at RNPC Sawangi Meghe Wardha by health care practitioners working under the DMIMSU. Before allocation, informed patient agreement will be obtained once the study's purpose, technique, potential benefits, and post-intervention effects have been explained. Participants will be included if they meet the study's inclusion and exclusion criteria.b

Blinding:-

The subjects will be assigned to one or more testers.

DEPENDENT VARIABLES:-Education,sufficiency of income for expenses,pain,tenderness.

INDEPENDENT VARIABLES:-age,menarche age,marital status, body mass index,type of breast cancer,structured exercise program.

Study Procedure:-.

- Patients will be assessed before starting the treatment and then the patients will be given following exercises:

1)Pectoral stretching

2)Retractor strengthening

3)Jacobsons relaxation

4)Yoga

Pectoral stretching: Patients will be given a pectoral stretch in sitting position with 30 second hold for 4 repetitions

Retractor strengthening (wall push-ups): Participants palms facing the wall with their feet apart, shoulders flexed to 90 degrees, and hands on the wall. The participants will be instructed to bend their elbows and lean forward toward the wall and hold the position for 30 second and return to normal (11). Repeat for 3 times

Relaxation techniques: Jacobson's relaxation technique can provide relief.

Yoga which includes pranayam, paschimottasana and gomukhasanas will be performed by the patients. Pranayama is a technique for slowing down breathing by adjusting the ratios of intake, expiration, and breath retention. It is a practise of pranamaya kosha. (12). paschimottanasana and gomukhasana are performed which reduces the negative effects of induced stress to immune system. In gomukhasana patient will be made to sit down on floor with legs stretched and bending the kness with one knee stacking over other. Arms taking overhead with elbows bending towards back. This position is holded for 30 seconds. paschimottanasana is done by sitting on floor with legs stretched out straight toes are flexed. Patient is asked to bend forward to rest head just beyond the knees. This position is hold for 30 sec and bought back to starting position.

For the next six weeks, all workouts will be delivered three times a week.

OUTCOME MEASURE-

- The Breast Pain Questionnaire (BPQ), a self-reporting measure of pain derived from the McGill Pain Questionnaire, is utilised for patients with a variety of illnesses. It evaluates both the severity and the quality of subjective pain.
- Cardiff chart-For each day of the month, a cardiff chart is a normal table with 31 columns. Participants will be asked to fill in each column based on the explanations provided for each cell in terms of pain intensity. The nominal day breast pain (NDBP) score will be used to calculate the pain severity score.
$$[(\text{number of days of mild or moderate pain} \times 1) + (\text{number of days of severe pain} \times 2)] \times 28 \div \text{total number of days in cycle that pain is recorded}$$
 is the formula for calculating the score. Pain is documented for a total of 28 days in a cycle. A score of less than 7 indicates light pain, a score of

7 to 14 suggests moderate pain, and a score of more than 14 indicates severe pain, according to the calculations.

DATA COLLECTION AND MANAGEMENT

DATA COLLECTION

The data for the evaluation will come from a pre-made spreadsheet with varied baseline attributes. The results of the research will be stored in a secure database. Hard copies of evaluation forms, signed informed consent, and other non-electronic documents will be safely preserved in the study setting.

DATA MANAGEMENT

Under the direction of the lead investigators, data will be collected and reported. The accuracy of the research papers must be double-checked. At the conclusion of the study, the Excel spreadsheet will be published and delivered to the statistician for the appropriate analysis. A checklist can be used to prevent data loss due to erroneous staff processes.

STATISTICAL ANALYSIS PLAN

Data analysis will be undertaken utilizing qualitative and interpretation statistical data through using chi-square test. The device used for interpretation will be SPSS 27.0 Version.

BIAS

To avoid attrition bias, reminder calls will be made before to each intervention, and travel help will be provided to those who require it. As a result, we anticipate a low number of dropouts.

RESULT:

The study will be carried out to see efficacy of exercise program on cyclical mastalgia and tenderness in obese women.

As this is the study protocol the results are yet to be drawn, but as per the hypothesis we can provide with the positive impact of structured exercise program on breast tenderness.

DISCUSSION

Mastalgia is a most prevalent condition in females but because of embarrassment women doesn't report such problems. Also it is a self limiting condition. As a result, there are limited studies on mastalgia treatment in the literature. But this condition affects the women psychologically and can affect their QOL. Physiotherapy can help the patient to relive their pain and to improve QOL. So exercises are recommended for the treatment of mastalgia.

In several research, Physical activity has been linked to a better quality of life, such as chronic fatigue syndrome, low back pain, and fibromyalgia. Yoga Therapy can help with menstrual abnormalities as well as mental illnesses including anxiety and stress, as well as overall quality of life. Because the majority of women experience breast discomfort on a monthly basis, yoga practise benefits in the decrease of breast cancer worries. Yoga therapy has been discovered to create a balanced interaction between the mind and the body. As a result, psychosomatic and somatopsychic illnesses can be avoided. Physical activity has indirect physical health benefits in addition to the direct physical health advantages (13). Cancer of breast is the often diagnosed cancer. The cancer usually grows in the lobules or the breast ducts. The most prevalent subtype is infiltrating ductal carcinoma. Symptoms include a tumor or mass, alteration in the skin or nipple, a breast rashes or redness, and lymphadenopathy (14). Inflammatory cytokines have been linked to pain modulation, and various research have looked into this cytokine response in mastalgia patients (14). Ramakrishnan et al. He compared the expression of cytokines (IL-1, IL-6) in breast tissue from pain-affected women to pain-free controls. They came to the conclusion that these cytokines had no role in the development of mastalgia.

Cyclical mastalgia is a frequent complaint that has been implicated in the development of breast cancer. Recent case-control studies have reported that cyclical mastalgia could have been an only risk factor for breast cancer (15). Breast cancer is the most common cancer among women in urban regions, but it is the second most common disease among women in rural areas,

accounting for 27% of all cancers. It is anticipated to become the most common type of cancer in the decades ahead. (16). The cancer usually grows in the lobules or the breast ducts. The most prevalent subtype is infiltrating ductal carcinoma (17). Breast cancer treatment has advanced over time to include surgery that is less invasive. Clinically management encompasses a wide range of strategies that puts together the skills of a variety of medical professionals in order to ensure a successful therapeutic outcome in terms of survival and quality of life. (18).

The focus of the research is to see how a planned exercise programme affects pain, discomfort, and quality of life in female subjects presenting with cyclic mastalgia. According to the recent research, regular physical activity or workouts encourage the return of blood flow to the heart and improve blood circulation throughout the body. Other theory has been that exercise increases the flow of prostaglandins through into body, reducing or eliminating discomfort and other unpleasant sensations (19).

CONCLUSION

Structured exercise program will be effective in obese women with cyclical mastalgia and tenderness.

Ethical approval and dissemination:-

The study's participants and the DMIMSU, which will support it, will be able to access the study's findings. Data will be stored in the DMIMSU data repository after the study is completed and the results are published.

Patient consent:-

The principal investigator will get the participant's written informed permission on a printed form (in the local language) with signatures and provide confirmation of confidentiality.

Confidentiality:-

The participant will be informed about the study protocol, and the primary investigator will collect subjective data. The confidentiality declaration, as well as the signatures of the principle investigator, the patient, and a witness, will be included on the permission form. If it is necessary to release some information for the study, the patient's agreement will be obtained with complete assurance of his privacy.

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