

## Effect of Pre – operative structured exercise protocol on Postoperative Structural and Functional impairments in Modified Radical Mastectomy patients: A Randomized Control Trail.

Dr.Malti V Bhambure<sup>1</sup>, Dr.Trupti S Yadav<sup>2</sup>, Dr. Dhairysheel S Patil<sup>3</sup>,  
Dr.Anand Gudur<sup>4</sup> , Dr.Rashmi Gudur<sup>5</sup>

<sup>1</sup>Senior Resident, Department of Oncology, Krishna College of Physiotherapy, Krishna Vishwa Vidyapeeth Deemed to be University, Karad.

<sup>2</sup>Associate Professor, HOD, Department of Oncologic Physiotherapy, Krishna College of Physiotherapy, Krishna Vishwa Vidyapeeth Deemed to be university, Karad.

<sup>3</sup>Assistant Professor, Department of Oncologic Physiotherapy, Krishna College of Physiotherapy, Krishna Vishwa Vidyapeeth Deemed to be university, Karad.

<sup>4</sup>Head of Department of Radiation Oncology, Krishna Vishwa Vidyapeeth Deemed to be university, Karad.

<sup>5</sup>Associate Professor, Department of Medical Oncology, Krishna Vishwa Vidyapeeth Deemed to be university, Karad.

### Corresponding Author:

Dr.Trupti S Yadav, <sup>2</sup>Associate Professor, HOD, Department of Oncologic Physiotherapy, Krishna College of Physiotherapy, Krishna Vishwa Vidyapeeth Deemed to be university, Karad.

### KEYWORDS

Breast Cancer, Modified Radical Mastectomy, Pre-operative Education, Pre-operative structured exercise protocol, Structural impairments, Functional impairments, SPADI, Quality of Life.

### ABSTRACT

Background:

Pre-operative Education and Pre-operative Exercise Intervention are advised to decrease shoulder morbidity and other associated impairments with breast cancer surgery. These measures will may help to speed up recovery. The goal of the current study was to ascertain the impact of a Pre-operative Structured Exercise Protocol on post-operative structural and functional impairments in patients with modified radical mastectomy in terms of Shoulder Range of Motion, Tightness of Pectoralis minor muscle, Shoulder Pain and Disability Index, Functional Independence, and Quality of Life.

Methods:

94 women with breast cancer were recruited for this study. Further, were randomly assigned into Experimental (n= 47) and Control group (n= 47). Experimental group received pre-operative education, exercise booklet and a Pre-operative Structured Exercise Protocol for a duration of 1 week which was Followed by a post-operative supervised exercise protocol for a duration of 4 weeks. Control group received a supervised post-operative exercise protocol.

Pre and Post assessment was done using Shoulder Range of Motion (Flexion, Abduction, External rotation), Pectoralis minor muscle measurement (PMM), Shoulder Pain and Disability Index (SPADI), Functional Independence Measure self-care scale (FIMS) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ C30). Measures were taken at baseline i.e. before intervention and after completion of rehabilitation i.e. after 4 weeks

Results: All measures significantly improved after completion of Rehabilitation in the Experimental group as compared with control group ( $p < 0.005$ ).

Conclusion: It was concluded that Group A (Experimental) shown a significant improvement in Shoulder Range of motion, Pectoralis Minor Muscle tightness, Shoulder Pain and Disability Index, Functional activities and Quality of Life in patients with Modified Radical Mastectomy as compared to the Control group.

## **Introduction:**

Cancer is the disease defined by uncontrolled spread of cell which can invade and destroy the normal tissue. There are over 200 types of cancer, and each one develops when the body's cells get the capacity to grow and proliferate uncontrollably. It was estimated in the recent studies that 26 million new cancer cases will occur by 2030.<sup>1</sup> The cause of cancer is known to be mutation that either results from inherited factors or is caused by environmental factors, or it may be caused by a replication error in DNA.<sup>2</sup> Annually, 10% of cancers diagnosed in women are breast cancers. Breast cancer is now the most often diagnosed cancer in the world, which places a significant burden on public health.<sup>3</sup> Surgery is the mainstay of the breast cancer treatment. Breast cancer patients have a variety of surgical options, including simple or total mastectomy, radical mastectomy, modified radical mastectomy alone, mastectomy with breast reconstruction, and breast preserving surgery.<sup>4</sup> Modified radical mastectomy is the preferred method for treating breast cancer patients who have clinical nodal involvement and who are having a mastectomy when it is discovered that they have metastatic disease in the sentinel node.<sup>5</sup> Following breast surgery, impairment in upper limb structures and functions may occur, which consists of decreased shoulder mobility, muscular weakness, pain, reduced chest mobility, arm swelling and limitations in the activities of daily living. These impairments can be seen as surgery itself can affect the mobility and flexibility of shoulder joint and arm on the side of surgery. Patients treated with ALND require specific care to diagnose and correct arm and shoulder problems.

In order to understand the impairments related to breast cancer surgery, such as shoulder pain and lymphedema, patients themselves need adequate information.<sup>6</sup>

Preventing or minimizing impairments of breast cancer treatment is the key to optimize function and quality of life after breast cancer treatment. During the development of the self-regulation theory, pre-operative education has become influential. It is believed that individuals tend to cope with illness based on their understanding of it. In contrast to usual care, preoperative education and postoperative physiotherapy may help women improve upper-body symptoms and regain shoulder range of motion after surgery.<sup>7,8</sup>

A preoperative assessment is often accompanied by an educational booklet that includes a summary of advice and precautions to be followed in the period following the surgery. It serves as a reinforcement of the information obtained during the preoperative meeting.

If patients only receive postoperative Physiotherapy and nothing during the vital preoperative time, it is possible that they are missing out on an important component of their care.<sup>9</sup>

Thus, application of this work for betterment of patient care can be done by, preoperative education on prevention and incorporation of Exercise intervention Pre-operatively will help these patients to alleviate surgery-related anxiety, will improve tolerance of treatment, and will prepare them for surgery, as well as teach them about the exercises.<sup>10, 11</sup> Thus, educating patients pre-operatively in person on when and how to perform exercises using an educational booklet with illustrative pictures and incorporation of Pre-operative Exercise Program to prepare them for the surgery along with supervised post-operative exercise protocol is incorporated in this study which may help to alleviate the shoulder morbidity and other impairments resulting from consequence of surgery.

## **Method**

An Experimental study was conducted on the sample of 94 female subjects using simple random sampling technique. Ethical clearance was obtained by primary researcher on 10/08/2022 by the Institutional Ethical Committee of Krishna Vishwa Vidyapeeth, Deemed to be University, Karad. All patients were screened for the inclusion criteria and exclusion criteria. Patients who were planned for modified radical mastectomy with complete axillary lymph node dissection and were between the age group 30-60 years were included in this study.

While those with previous history of trauma to neck or shoulder in past 10 years, physically unable to engage in physiotherapy Protocol, patients on Chemotherapy, and patients with breast reconstruction surgery, patients with Diabetes Mellitus were excluded from this study. Demographic sheets were given to the patients and procedure was explained prior to the assessment. Informed consent was taken before involving them in this study. Patients were then randomly assigned into two groups using simple random sampling technique. Group A (Experimental group), Group B Control group.

**FORMULA:**

$$n = \frac{Z^2SD^2}{(M*\epsilon)^2}$$

$$n = \frac{4*19.2^2}{(7*0.8)^2}$$

**n= 47**

- SD= 19.2 (SPADI, Posttest Pain standard deviation)
- M=7 (Mean Difference was calculated between pre-post mean values of pain)
- Z=2 (Standard score)
- $\epsilon$ = 0.8 % (Precision)

**SAMPLE SIZE:** 94 - 47 (in control group), 47 (in experimental group)

**STUDY DURATION:** 1 year

**Intervention:**

**Group A (Intervention Group) -**

Patients in this group received preoperative planned education on precautions, disease. Each patient was scheduled for pre-operative structured exercise protocol which was carried out for the duration of 1 week when the patients were hospitalized in in-patient department or undergoing investigations on out-patient basis, along with these postoperative exercises were given, which were started on day 3 after surgery. Patients received illustrative guide with pictures for more clarifications of post mastectomy exercises and also education regarding daily functioning. This was done by providing a Booklet for each patient who was opted to undergo modified radical mastectomy. It included written guidelines about post mastectomy exercises.<sup>12</sup>

Based on their extensive clinical expertise and the available literature, the research team as a whole contributed to the finalization of the booklet, which was created by the lead researcher. The Oncologist Opinions, inquiries, queries, and remarks about this material of exercises for breast cancer surgery were taken into consideration by the researcher when creating the instructional material. The first draught of the information was then submitted to the study's co-author and head of the department of oncologic physiotherapy, who has experience delivering physiotherapy care to patients having breast cancer surgery, for evaluation.

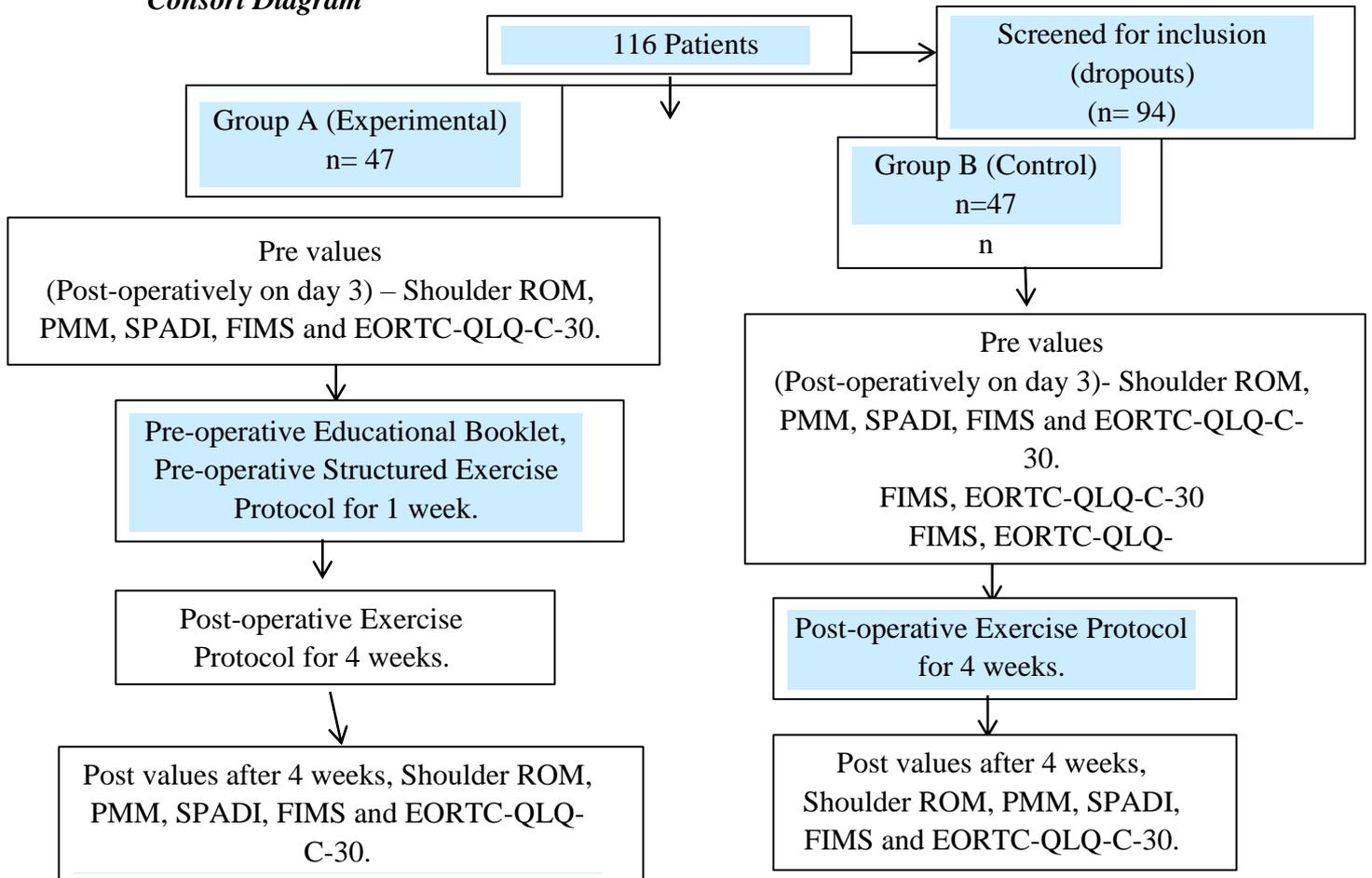
The educational material was then printed once the professionals had acknowledged their remarks, revisions, and modifications. The printed educational material contains illustrative images, is comprehensible to readers, and is written in English and local regional language of the study area (Marathi) which is why, it was simple and easy for them to understand. This

booklet is copyright registered (Registration Number: L-121417/2023) Under Copyright Office, Government of India in 2023 named “STANACHYA KARKAROJACHYA SHASTRAKRIYE NANTAR VYAYAMASATHI TUMCHE MAGADARSHAK”.

**Group B (Control Group) -**

Patients in this group received a supervised routine postoperative protocol which was started after day 3. Regular follow up was taken in each week.

**Consort Diagram**



**Standard Programme Components:**

Intervention	Focus
Education	<ul style="list-style-type: none"> <li>• Early signs and symptoms of lymphedema.</li> <li>• General Precautions to be followed following surgery.</li> <li>• Instructions for risk reduction on lymphedema.</li> </ul>
General Post-Operative Exercises	Exercise Protocol of 4 weeks

**Post Mastectomy Exercises to perform during first day -7 days after surgery:**

- Deep breathing
- Pump hand up
- Shoulder shrugs and circles
- Thoracic mobility exercises

- Shoulder blade squeeze
- Wand exercises

(Perform 5 repetitions of each exercise for 3-4 times a day)

**2 weeks-3 weeks after surgery:**

- Arm reach
- Active range of motion exercises of shoulder, wrist, elbow, neck
- Chest stretch
- wall climbing
- side wall stretches
- Scapular stabilization exercise

(Perform 5 repetitions of each exercise 1-2 times a day)

**4 weeks after surgery:**

Strengthening exercises for shoulder, elbow, wrist

(3 sets of 10-15 reps using yellow colored Resistive band, Gradual progression to next color when individual is able to easily complete 3 sets of 10-15 repetition)

Color Progression : Yellow → Red → Green → Blue → Black → Silver

**Statistical Analysis:**

Statistical data was summarized using descriptive statistics including percentage, frequencies, mean and standard deviation. Analysis of data was done using SPSS software for windows version 18.

To compare the outcomes post-rehabilitation, we calculated the difference between baseline (pre-rehabilitation) values and after 4 weeks after completion of rehabilitation by using paired test within the groups and used unpaired t test to compare the values between the groups. Values were significant if  $p < 0.005$ .

**Results:**

**Table 1. Baseline patient demographics and clinical characteristics (n = 94)**

Demographics/characteristic	n (%)
<b>Age</b>	
18-35	10
36-53	46
54-70	38
Total	94
<b>Body Mass Index</b>	
Underweight	4
Normal	56
Overweight	27
Obese	7
Total	94
<b>Operated side</b>	

Left Breast Cancer	32
Right Breast Cancer	62
Total	94

**INTERPRETATION:** This graph represents the Age of the patients included in this study. 10% of population were between age group 18-35, 48% of population were of 36-53 years age group and 40% population were between 54-70 years age group. And about the Body Mass Index of patients included in this study. 4% of population were underweight, 59% had normal BMI, and 28 % were overweight while 7 % were obese. And the last part is about the operated side of breast of patients involved in this study.32% were operated for left Cancer, while 62% were operated for right breast Cancer.

**Table 2- Comparison of Shoulder Range of Motion between and within Experimental group and Control group.**

<u>Shoulder Flexion</u>	Experimental group	Control group	p value
Pre	73.681 ± 17.434	72.340 ± 13.267	0.6759
Post	132.68 ± 16.374	78.234 ± 13.054	<0.0001*
p value	<0.0001*	0.0006	
<u>Shoulder Abduction</u>	Mean ± SD	Mean ± SD	p value
Pre	56.106 ± 11.775	56.170 ± 11.257	0.9785
Post	96.723 ± 15.427	66.489 ± 14.822	<0.0001*
p value	<0.0001*	<0.0001*	
<u>Shoulder External Rotation</u>	Mean ± SD	Mean ± SD	p value
Pre	35.128 ± 7.054	35.426 ± 6.046	0.8265
Post	62.174 ± 10.448	42.766 ± 5.983	<0.0001*
p value	<0.0001*	<0.0001*	

**INTERPRETATION:**

The present table represents comparison of Mean value and Standard Deviation of Shoulder Flexion Range of Motion. The pre-intervention Mean ± SD was 73.681 ± 17.434 whereas post-intervention was 132.68 ± 16.374 for Experimental group which was statistically significant and 72.340 ± 13.267 pre-intervention and 78.234 ± 13.054 post- intervention in the control group which was statistically not significant when compared using Student’s Paired t test. While even the post-post values were statistically significant when compared using unpaired t test.

**Table 3 - Comparison of Pectoralis Minor Measurement between and within Experimental group and Control group.**

Pectoralis Minor Muscle Measurement	Experimental Group	Control Group	p value
	Mean ± SD	Mean ± SD	
Pre	49.340 ± 5.418	49.362 ± 4.949	0.9842
Post	25.362 ± 5.256	33.447 ± 5.200	<0.0001*
p value	<0.0001*	<0.0001*	

**INTERPRETATION:**

The present table represents comparison of Mean value and Standard Deviation of Pectoralis Minor Muscle Measurement. The pre-intervention Mean ± SD was 49.340 ± 5.418 whereas post-intervention was 25.362 ± 5.256 for Experimental group which was statistically significant and 49.362 ± 4.949 pre-intervention and 33.447 ± 5.200 post- intervention in the control group which was statistically not significant when compared using Student’s Paired t test. Post-post values showed a statistically significant difference between the groups when compared using unpaired t test. The Mean Difference for pre-post values for the experimental group was 20.808 while for the control group it was 15.182.

**Table 4- Comparison of Functional Independence Measure Self-care subscale within Experimental group.**

Domain	Eating	Grooming	Bathing	Dressing - Upper Body	Dressing - Lower Body	Toileting
Pre	3.000 ± 1.251	3.149 ± 1.161	3.170 ± 1.110	5.149 ± 1.318	4.745 ± 1.823	4.170 ± 1.672
Post	6.979 ± 0.1459	5.936 ± 0.9870	6.085 ± 1.039	6.404 ± 1.262	5.957 ± 1.301	6.553 ± 0.6530
P value	0.0011	0.0003	<0.0001*	<0.0001*	0.0003	<0.0001*

**INTERPRETATION:**

The present table represents Functional Independence Self-care subscale of the Experimental group. Pre and post mean values within the group were compared using Student’s paired t

test. The pre-intervention Mean  $\pm$  SD when compared was statistically significant for all the domains within Experimental group

**Table 5- Comparison of Functional Independence Measure Self-care subscale within Control group.**

Domain	Eating	Grooming	Bathing	Dressing - Upper Body	Dressing - Lower Body	Toileting
<i>Pre</i>	3.957 $\pm$ 1.546	4.745 $\pm$ 1.010	4.195 $\pm$ 1.231	5.213(1.503)	4.085 $\pm$ 1.442	5.319 $\pm$ 1.270
<i>Post</i>	5.489 $\pm$ 1.780	4.532 $\pm$ 1.780	5.362 $\pm$ 1.309	5.149 $\pm$ 1.532	6.170 $\pm$ 1.007	5.978 $\pm$ 1.053
<i>P value</i>	0.0222	0.4490	0.0724	0.8308	0.0058	0.0085

**INTERPRETATION:**

The present table represents Functional Independence Self-care subscale of the Control group. The pre and post mean values within the group were compared using Student’s paired t test. Mean Difference for Functional Independence Measure Self-care subscale in Control group was statistically significant for the domains like Eating, Dressing lower body and toileting. There was no significant difference seen for the domains like grooming, bathing and dressing upper body in the control group.

**Table 6 - Comparison of SPADI, Experimental group and Control group.**

SPADI TOTAL SCORE		EXPERIMENTAL GROUP	CONTROL GROUP	<i>p value</i>
	<b>Pre value</b>	97.576 $\pm$ 16.546	98.596 $\pm$ 9.414	0.9571
	<b>Post value</b>	35.489 $\pm$ 10.683	99.723 $\pm$ 9.638	<0.0001*
	<b><i>p value</i></b>	<0.0001*	0.1993	

**INTERPRETATION:**

The present table represents comparison of Mean value and Standard Deviation of Shoulder Pain and Disability score in Breast Cancer patients. The pre-intervention Mean  $\pm$  SD was 97.576  $\pm$  16.546 whereas post-intervention was 35.489 for Experimental group which was statistically significant and 98.596  $\pm$  9.414 pre-intervention and 99.723  $\pm$  9.638 post-intervention in the control group which was statistically not significant when compared using Student’s Paired t test.

**Table 7- Comparison of EORTC-QLQ C-30 , Experimental group and Control group.**

EORTC-QLQ-C-30	Item	Pre value	Post value	P value
		Mean ± SD	Mean ± SD	
Experimental Group	Global Health	49.085 ±9.974	72.617±12.536	0.0710
Control Group	Global Health	49.297±10.986	49.277±13.297	0.9930
p value		0.9219	<0.0001*	
Experimental Group	Functional Scale	75.383±9.088	41.170±13.436	<0.0001*
Control Group	Functional Scale	76.468± 9.899	72.617±13.271	0.767
p value		0.5812	<0.0001*	
Experimental Group	Symptom Scale	78.426±8.295	39.702±10.762	<0.0001*
Control Group	Symptom Scale	77.170±12.457	65.745±16.736	<0.0001*
p value		0.5667	<0.0001*	

**INTERPRETATION:** The present table represents comparison of Mean value and Standard Deviation of EORTC-QLQ C-30 for quality of life in Breast Cancer patients. The pre-intervention Mean ± SD was 49.085 ±9.974 whereas post-intervention was 72.617 ± 12.536 for Global Health, for Functional scale it was 41.170 ± 13.436 and for Symptom scale it was 78.426 ±8.295 pre-intervention and 39.702 ± 10.762 which was statistically significant when compared using Student’s paired t test

**INTERPRETATION:** The present table represents comparison of Mean value and Standard Deviation of EORTC-QLQ C-30 for quality of life in Breast Cancer patients. The pre-intervention Mean ± SD was 55.170 ± 10.027 whereas post-intervention was 56.191±12.761 for Global Health and for Functional scale it was 76.468 ± 9.899 which was not statistically significant when compared using Student’s paired t test. The pre-intervention Mean ± SD was 77.170 ± 12.457 whereas post-intervention was 65.745 ± 16.736 for Symptom Scale which was statistically significant using Student’s paired t test

**Discussion:**

This Randomized Control Trail was aimed to examine the effect of pre-operative structured exercise protocol followed by post-operative physical therapy protocol in patients with Modified Radical Mastectomy.

The Mean age of patients in our study was 49.893 ± 11.281. This result may be seen as breast cancer incidence in India is stated to be in early thirties and to peak during 50-64 years.<sup>13</sup> In the present study majority of women’s were of normal and overweight Body Mass Index which was more than 25.0 kg/m<sup>2</sup>. Previously, a similar result was found by the study conducted in India with Higher proportion of women’s with body mass index (BMI)>25.0 kg/m<sup>2</sup>.<sup>14</sup> The risk of Breast Cancer was found to be associated with increased BMI levels. Thus, the present study might have reflected more prevalence of women’s having overweight BMI.

In relation to the side of breast affected to our knowledge this is the first study, which evaluated the incidence of Right breast cancer to be more than 50%. Research suggests that

breast cancer is more common in the left breast than the right breast, but the reason for this is still unknown. Some hypotheses suggest that the larger size of the left breast. But, most women naturally have one breast bigger in size, even if it is of right side it is considered normal. This asymmetry might be due to hormonal changes that occur in women's.

Following surgery, patients undergo certain complications like pain; decreased range of motion of shoulder, weakness of muscles etc. which in turn leads to functional limitations and affects the activities of daily living of these individuals.

Post-operative Exercises can thus, routinely practiced to prevent or minimize these complications and thus optimizing the quality of life. Thus, based on the previous study results, this study was conducted to provide a more effective design of Exercise program for post-operative patients. In the present study the Group A (Experimental group) which included pre-operative education and Exercise training along with booklet with supervised post-operative physiotherapy protocol showed a significant improvement in all the variables used i.e. Shoulder ROM, PMMM, FIMS, SPADI and EORTC-QLQ C-30  $p < 0.005$ . when compared to the control group.

The findings of the present study showed that there was a statistically significant difference present in pre-post intervention regarding the shoulder range of motion in both the groups but the Mean Difference was significantly higher in the experimental group. This result might have seen as both the groups received the same Exercise intervention. The result of this study is in same line with study by Y.Lokapavani et.al<sup>15</sup> which concluded that preoperative education along with Exercise influence the postoperative shoulder ROM and functional activities after modified radical mastectomy.

The previous study by Chung Ho et.al<sup>16</sup> concluded that chest tightness is increased after surgery and is also related to the upper limb dysfunction. The length of the Pectoralis minor muscle is reliable measure of chest tightness that indicates postural abnormality and muscle imbalance in the upper extremity. Thus, Pectoralis Minor Muscle Measurement evaluation was undertaken pre and post intervention. There was statistically difference present for both the groups. This result might have seen as both the groups received same intervention which included the retraction Exercises of scapula and even certain stretches which must have contributed in decreasing the protracted shoulder posture among these patients.

Though, the Mean Difference for PMMC was statically higher in the Experimental group. This result may have seen as a result of additive effect of incorporating Pre-operative Education and Rehabilitation in this group. To our knowledge this was the first study that evaluated the effect of any intervention on PMMM in post-operative breast Cancer patients. Bendz I et.al<sup>17</sup> concluded that the post-operative rehabilitation Exercises should be initiated 1-3 days postoperatively, which was considered in the present study. This might have shown the positive results in the present study.

There are various studies in support with the use of pre-operative Exercise intervention as a part of Rehabilitation and the results of these studies are in line with the present study. A study by Karin Valkenet et.al.<sup>18</sup> concluded that Preoperative exercise therapy can be effective for reducing postoperative complication rates and length of hospital stay after cardiac or abdominal surgery. The study has certain lacunas such as smaller sample size, and was conducted in different group of population.

Another study in accordance to the use of Pre-operative education by Chairi Singh et.al<sup>19</sup> concluded that clinical care pathway that includes preoperative education, prospective monitoring and early physiotherapy addresses the arm morbidity following surgery for breast is beneficial. Although this was a pilot study and no educational material was provided to the patients.

It is believed that this effect of pre-operative education and exercise can be seen to be more effective as it provides a clear picture to the patients about the post-operative presentation. In this aspect, present study was conducted to focus on preoperative education on prevention and guided exercises which can help these patients to alleviate surgery-related anxiety, will improve tolerance of treatment, and will prepare them for surgery, as well as teaches them when and how to do exercises. And, thus, improve quality of life among these patients. The key feature of the present study it is that it included the women's of different geographical area. Thus, the results of this study can be generalised to the overall population of patients with Modified Radical Mastectomy.

Based on the findings of the present study there are several recommendations which can be carried out in the future studies: Booklet can be provided as a home based exercise guide to the control group, the study can be replicated using a larger sample size with weekly follow-up to with regular follow-up to determine how long the training effect endures, would prove beneficial in the future.

### **Conclusion:**

It was concluded that the Group A (Experimental) which was treated with pre-operative education and Pre-operative Structured Exercise Protocol with post-operative supervised physiotherapy protocol for a duration of 4 weeks shown a significant improvement in Shoulder Range of Motion, Pectoralis Minor Muscle Measurement, Shoulder Pain and Disability Index, Functional activities and Quality of Life in patients with Modified Radical Mastectomy.

**Conflict of Interest:** Nil.

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