

Effect of Compression Garment and Low Intensity Exercise on Upper Limb Function and Lymphedema among Post-Mastectomy Women: A quasi-experimental Two Arm Study



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1.ABSTRACT

Background: Lymphedema is one of the riskiest and most prevalent complications post-mastectomy that interfere upper limb function which negatively affect their quality of life. Aim: Evaluate the effect of compression garment (CG) along with shoulder exercise on reducing lymphedema and enhancing upper limb function among post mastectomy women.

Method: Research design: A quasi experimental research design with a control group was used. **Subjects:** A total of 120 women with breast cancer were evenly and randomly allocated to the intervention and control group. Women in the interventional arm were directed to apply compression garment during exercise for six months post operatively. The control group received routine hospital postoperative care. Tools: 1. Demographic and health relevant form, 2. Shoulder Pain and Disability index questionnaire, 3. Shoulder flexibility and grip strength, 4. lymphedema and arm circumference scale. **Results:** At a 6-month interval, the occurrence of lymphedema was markedly lower in the intervention group ($p = 0.000$) compared to their control and there were statistically significant differences between study groups as regard shoulder pain and upper limb function ($p=0.000$).

Conclusion: Post mastectomy exercises combined with compression garment is very effective in preventing lymphedema and improving upper limb function in post-mastectomized women. **Recommendations and Relevance to clinical practice:** Low-intensity exercises and compression garment is a safe, effective, non-invasive method that should be incorporated into the management of post-mastectomy patients to prevent lymphedema and enhance upper limb function.

Keywords: Post-mastectomy women, Compression garment, Low intensity exercise, Upper limb function, lymphedema

2.Introduction:

Breast cancer (BC) is the most common type of cancer worldwide and the death rate is the second highest among women in all cancers. In the last fifty years, advances in diagnosis and treatment have dramatically reduced the mortality rate (Global Burden of Disease Cancer Collaboration, 2019). Despite this, patients who undergo mastectomy have an increased risk of developing breast cancer related lymphedema (BCRL) (Gillespie, Sayegh, Brunelle, Daniell & Taghian, 2018). An estimated incidence rate of 6% to 83% and Approximately 60 percent of patients after mastectomy will eventually develop lymphedema (Di Sipio, Rye, Newman & Hayes, 2019). Breast cancer treatment mainly includes surgery, along with radiotherapy and chemotherapy. A mastectomy is the surgical removal of one or both breasts. The modified radical mastectomy is considered one of the most suitable surgeries for stage I and II BC, in which all breast tissue and lymph nodes of the affected side are removed (McDonald, Clark, Tchou, Zhang & Freedman, 2019). Radiation therapy and modified radical mastectomy are the most common causes of

lymphedema. Muscle stiffness, pain, restricted shoulder movement and lymphedema are among the most common complications of modified radical mastectomy (Freitas-Júnior, Oliveira & Pereira, 2016). Lymphedema is a chronic, debilitating condition in which protein-rich lymph fluid collects in the soft tissues due to obstruction of the lymphatic flow, resulting in increase of 2 cm or more in the girth of the arm. Typical symptoms of lymphedema include swelling, discomfort, pain, heaviness, tightness, shoulder stiffness, decreased sensation in the affected arm, and decreased general daily functions. This condition can significantly affect physical, psychological, and functional abilities subsequently poor quality of life (Vieira et al., 2019). There are certain effective approaches in treating lymphedema, including compression therapy, therapeutic exercise, and low-level laser therapy (Baxter et al., 2017; Shaitelman et al., 2019). Both exercise and CG are fundamental elements of rehabilitation for women with lymphedema (Jeffs & Wiseman, 2019). Several recent results from preliminary research proved the effectiveness of upper extremity

exercises in the treatment of lymphedema, reducing upper extremity morbidity and improves range of motion exercises (Baumann, Reike, Hallek, Wiskemann & Reimer, 2018; Singh, Disipio, Peake & Hayes, 2016). The use of CG for patients with lymphedema is the mainstay of treatment. However, the use of compression garments in the prevention of lymphedema has received relatively little attention from researchers (Rangon, da Silva, Dibai-Filho, Guirro & Guirro, 2021). The role of CG during exercise is not clear. Also, recent clinical trials have not provided sufficient support for this maneuver (Rogan et al., 2016; Singh et al., 2016). Compression garments prevent or treat lymphedema through one or more of the following mechanisms: (1) increase interstitial pressure, (2) increase tissue fluid drainage, (3) stimulate lymphatic contractions, (4) enhance muscle pumping efficacy, and (5) fibrous tissue cracking. Additionally, the use of a compression bandage during exercise in BCRL patients was supported by Rangon et al. (2021).

1.2 Significance of the study

In Egypt, BC most common cancer among women, representing 18.9% of total cancer cases (Bahgat, Elden, Atia, El Shikh & Monera, 2017). Clinical observation illustrated that lymphedema is the most prevalent and a debilitating complication in post-mastectomized women that prompts functional impairment. It is viewed as a challenge to patients and oncology healthcare workers. Proceeding from the fact that drug therapy alone is ineffective in reducing lymphedema and restoring shoulder movement, it is necessary to look for other accessory methods. In this regard, few studies have confirmed the beneficial effect of CG during shoulder exercises in reducing lymphedema and shoulder disability post-mastectomy (Ali, El Gammal & Eladl, 2021). On the other hand, such intervention rarely used with Egyptian women, therefore, we conducted this study.

2.2 Aim of the study

The study aimed to evaluate the effect of compression garment along with shoulder exercise on reducing limb volume, lymphedema self-reported symptoms and enhancing upper limb function among post mastectomy women.

3.2 Research hypotheses

H1. Post mastectomy women who participate in CG and exercise training (Intervention group) exhibited less shoulder pain and disability score than those who did not (control group).

H2. The intervention group show a significant improvement in level of shoulder flexibility and grip strength than the control group.

H3. Post mastectomy women who actively participate in CG and exercise training (intervention group) experienced a low score of lymphedema and arm circumferential measurement than those who did not participate (control group).

4.2 Operational definition

Upper limb function: Defined according to study's tools to involve 1. Shoulder Pain and Disability Index "SPADI" (subjective upper limb function) 2. Objective upper limb function (Grip strength and shoulder flexibility) (Heyward & Gibson 2014; Roach, Budiman, Songsiridej & Lertratanakul, 1991).

3. Method

1.3 Research design

A quasi-experimental research design with a control group has been used to carry out this study.

2.3 Setting

This research work was conducted at females' surgical wards oncology center Mansoura University Hospital, which provides health services to (200.000) patient a year in Dakahlia governorate and the surrounding areas. It consists of 11 floor and 500 bed, surgical outpatient in second floor and female surgical unit in eighth floor.

3.3 Study sample

A purposive sample of 120 adult mastectomy women was included according to the following criteria:

Inclusion criteria: Adult women aged from 20 to 60 years, undergoing mastectomy, receiving adjuvant chemotherapy and/or radiotherapy, able to speak and willing to take part in the study.

Exclusion criteria: Diabetes mellitus, congestive heart failure, renal impairment, who have any associated disability as upper arm trauma, previous upper limb disability and /or surgery and those who have inflamed breast for any cause and those with psychological disorder.

Sample Size Calculation Formula MedCalc Software as Type I error was (0.05), Type II error (0.20), proportion in group 1 (control group) (36.7%), proportion in group 2 (intervention group) (14.5), ratio of sample size in group 1/ group 2 = 1. So, sample size was 60 for control group and 60 for intervention group which consist of (120) adult women who scheduled for mastectomy.

4.3 Study Tools

Tool I- Patients' demographics and health relevant data form:

Include age, marital status, educational level, residence, and body mass index. Past medical history, stage of breast cancer, the affected arm, receiving preventive measures of lymphatic swelling post- operative or not.

Tool II - Shoulder Pain and Disability Index (SPADI) "subjective upper limb function".

Developed by Roach et al. (1999) and adopted by the researcher to measure shoulder functions and shoulder pain, it consisted of two parts.

Part (1)-Shoulder Pain Dimension: It consisted of (5) items, assess the severity of pain (most painful, when lying on the affected side, when trying to reach an object on a high shelf, pushing the affected arm, palpate back of the neck, pushing with the involved arm). The score ranged from 0 to 10 where: (absence of pain= 0), (mild pain =1-3), (moderate pain =4-6), (severe pain =7-9) and (most painful=10).

Part (2) Shoulder disability index: Consisted of (8) items, developed to assess the degree of difficulty in using the upper arm in activities of daily living (washing hair, back, putting on a jacket, trousers, button-down shirt, reaching for something on a high shelf, lifting

something heavy 4.5kg, taking something out of a pocket). Each item takes a score ranged from 0 (no disability) to 10 (worst disability).

Tool III - Objective upper arm function scale

Developed by Heyward and Gibson (2014) and adopted by the researcher.

Part (1) Shoulder Flexibility: It was developed to assess the ability to rotate the shoulder joint. Test the right shoulder by having the woman stand with her left arm straight, with the elbow bent, the hand reaches between the shoulder bones, trying to touch the fingers of her right hand with the fingers of her left hand. Repeat the action with the other shoulder. The score was given as follow:

- (1) Fingers touching = good,
- (2) do not touch the tips of the fingers and the distance is less than 5 cm = fair,
- (3) do not touch the tips of the fingers and the distance between them is more than 5 cm = poor.

Part (2) Grip strength: Consisted of (2) steps first step for Female non-dominant hand and second step for dominant hand. An adult's grip strength is measured in kilograms from the hand using a manual dynamometer. Measures the force a person exerts to close his or her hand.



Figure (a): Shoulder Flexibility: Bahgat, Z., Alaa Elden, S., Atia, N., El Shikh, E., & Elshemy, M. (2016). The Efficacy of Protocol of Care on Post Mastectomized Women Outcomes. *IOSR Journal of Nursing and Health Science*, 5(5), 49-64.

Grip Strength in Kilogram:

Excellent	> 37	> 41
Good	34 – 36	38 – 40
Average	22 – 33	25 – 37
Less than average	18 – 21	22 – 24
Poor	< 18	< 22



Figure (b): Grip strength: Bahgat, Z., Alaa Elden, S., Atia, N., El Shikh, E., & Elshemy, M. (2016). The Efficacy of Protocol of Care on Post Mastectomized Women Outcomes. *IOSR Journal of Nursing and Health Science*, 5(5), 49-64

Tool IV- lymphedema scale

Part (1) Lymphedema Observational Checklist:

Developed by Bahgat et al. (2016) and adopted by the researcher. It consisted of (11) questions to assess lymphedema manifestations for post mastectomy. It monitors the following area: examination of upper limb and monitor for clinical picture of lymphedema such as enlargement in the shoulder, breast, arm, chest, heaviness in part of the body, redness of the skin, change in texture, lack of movement and flexibility of the wrist, hand or shoulder joint, inability to button the shirt and tightness of the ring bracelet and watch.

Part (2) Arm Circumferential Measurement:

Developed by Czerniec et al. (2011) to determine any changes in arm circumferential measurement and identify lymphedema occurrence at nine areas (Metacarpal and phalanx joints, at the wrist, under the wrist (10 cm, 15 cm, 20 cm and elbow, above the elbow (10 cm, 15 cm and 20 cm).

Validity: Content validity has been done by 9 experts in the medical-surgical nursing, and oncology. The needed modifications were done accordingly. **Reliability:** Reliability tested, and Cronbach's alpha was 0.95 for tool (I & II), 0.90 for tool (III) and 0.87 for tool (IV).

5.3 Pilot Study

A pilot study was conducted on 10% of woman(12woman) attended Mansoura Oncology Center in the Female Surgical Wards to test clarification, suitability and to identify time required to collect data. Minor modification was done, so the piloted patients was included in the actual study.

6.3 Ethical considerations and Human Rights

To conduct the research, the approval of the Scientific Research Ethics Committee was taken at

the Faculty of Nursing, Mansoura University. The women were informed that participation in the study is not compulsory, and they are free to withdraw without giving any reasons. Informed consent was obtained from all participants. The principal investigator also clarified the purpose, benefits, risks, and procedures of the study. Emphasis is placed on ensuring the anonymity and confidentiality of the data and its use for research purposes only.

7.3 Data collection procedure

Once the official approval was obtained to proceed with the proposed study. Participating women who met sampling standards and agreed to engage in the study were individually invited by the researcher's assistant to inform them the aim of the research and collect data pertinent to study. The process of collecting data for the study took nine months, from the first of March 2020 until the end of November 2020. The study sample was randomly divided into 2 equal groups, intervention, and control group. The women in intervention group were trained before the operation how to apply CG during physical exercise and continue to do so for six months after mastectomy. The control group received routine hospital postoperative care. The study passed through the following phases.

Assessment: Data was collected preoperatively as a baseline measure for further comparison using tools (I, II, III and IV).

Planning: In the present study, the protocol of care was designed for BC women guided by recent studies which has shown significant efficacy of CG and physical exercise in improving shoulder function and lymphedema post-mastectomy (Nadal Castells et al.,2022). The program content was developed and revised in collaboration with oncology specialist based on the women's needs. The content validity of the program was assured by

three oncology specialist and two medical surgical nursing professors. Different teaching and learning methods were used as interactive, demonstration, pictures, videos, and printed booklet was given to the women as well.

Implementation of the intervention group:

It was carried preoperatively, included post-mastectomy exercise and CG implemented through two sessions; theoretical session lasted about 45 minute and practical session lasted one hour. In theoretical session, the researcher used power point presentation, figures and flip chart contains the following: preface about breast cancer, treatments modalities, causes, risks, and clinical signs of BCRL. lymphedema preventive measures post-mastectomy related to extreme heat, extreme effort, extreme pressure on the affected arm, and wound in the affected arm. The last related to compression garment. The practical session focused on post-mastectomy exercises on (1st, 2nd, 3rd, 4th, and 5th postoperative day) include exercises to strengthen the shoulders, hands and chest. It contained clockwise post-drain removal exercises, wall climbing and shoulder girth exercises. The researcher stressed on the importance of follow up and active participation. Five videos were prepared by the research to guide women in the intervention group. The first video concerning the 1st day exercises post-operative, the 2nd video explained the 2nd, 3rd and 4th day post-operative exercise, the 3rd video demonstrated the 5th day exercise, and exercise after removing drain was clarified in the 4th video. The 5th video explained post-mastectomy lymphedema preventive measures. Three groups of what's App were established for intervention group to facilitated communication, follow up and enhance relationship between study participants and through which the researcher, remember woman to practice exercise at time by sending notifications on WhatsApp.

Evaluation and follow up: The baseline data of both groups were compared post operatively after one week of implementing CG and exercise and at 1st, 3rd and 6th month using tool (II, III and IV).

The control group assessed by the same schedule of the intervention group. After data analysis, control arm was received an educational guide and videos provided to intervention group.

8.3 Statistical analysis

Statistical analysis was performed according to the latest valid and reliable statistical tests. The collected raw data was encoded and entered into SPSS system files (SPSS package version 23).

After those checks were done to avoid any error during data entry. The data were analyzed and interpreted using appropriate statistical methods. Qualitative data were presented as number and percent. The mean and standard deviation were used for quantitative data. Chi-square was used to compare the two groups in categorical data. Mann-Whitney U test was used to compare the differences between two non-parametric continuous variables between unrelated groups. Friedman test was used to test differences on ordinal and non-parametric continuous variables between repeated situations. Cochran's Q test was used to test differences on a dichotomous variable between three or more related groups. P-value was significant at $p < 0.05$.

4. Results

Participation Characteristics

A total of one hundred and twenty patients were enrolled in the study 60 in each arm, underwent mastectomy and received chemotherapy and radiotherapy based on the eligibility criteria. Patients' characteristics and disease related data of study groups were illustrated in table 1. There was no significant difference in demographics and clinical data between the intervention and control group ($p < 0.05$). Table 1. showed that (30 %) of the intervention and (16.7%) of control group aged between 30 to less than 40 years old. According to marital status, (71.7%) of both groups were married. Regarding to children's numbers more than half of the intervention and control group (55 % & 61.7%) respectively have (1-3) child. It was found that (53.3 %) of the intervention group and (51.7%) of the control group in menopausal phase. In relation to residence, (51.7%) of intervention and (68.3%) of control group were lived in rural areas. Concerning the level of patients' education, it was found that (45%) of the intervention and (41.7 %) of control groups were intermediate education. Regarding to patient's body mass index (BMI), overweight patients represented by (51.7% & 36.7%) in intervention and control group respectively. Additionally, (61.7) of intervention group and (45%) of control group have no family history of BC. According to the stage of breast cancer (60% & 46.7%) of intervention and control group were in the second stage of breast cancer respectively. More than half of the study participants in the intervention and control groups (65% and 50%), respectively, had their right arm affected. This table also portrayed that, the majority of sample (95.0%) of the intervention group and (98.3 %) of the control group did not receive

lymphedema preventive measures from the medical team.

Improvement in shoulder pain during study period

Table 2. revealed a highly significant changes between the intervention and control group in relation to the total scores of shoulder pain at 1st week, 1st, 3rd. and 6th months postoperatively where $p < 0.05$. Also, it clarified that the pain mean score was reduced significantly in the intervention group in all study' phases as follow (12.60±6.49"1st week", 0.20±1.00,"1st month" 0.00±0.00,"3rd month " and 0.08±0.64 6th month") more than the control group (32.20±12.68, 27.40±11.98, 20.61±9.42, 19.30±10.13). Accordingly, A significant reduction of shoulder pain was observed after study period in intervention groups when compared to their control $p < 0.05$. Furthermore, there was a significant reduction in the total score of shoulder pain post- 6 month of mastectomy compared to the 1st week, 1st and 3rd month in both study groups, $p < 0.001$.

Shoulder Disability during study phases

Table 3. clarified that there was a highly statically significant difference in physical disability mean score between the control and intervention group during all phases of the study period where p value < 0.001 . It revealed that shoulder disability mean score was markedly reduced in the intervention group (13.50±8.47, 0.38±1.80, 0.00±0.00, 0.00±0.00) than the control group (34.88±13.99, 25.95±14.02, 20.52±13.11, 17.41±12.92) at 1st week, 1st, 3rd. and 6th months postoperatively. It is also emphasized that there was a significant reduction in the total score of shoulder disability post- 6 month of mastectomy compared to the 1st week, 1st and 3rd month within the study groups $p < 0.001$.

Improvement upper limb function among the studied groups during different phases of the study

Table 4. illustrated that, there was a highly statically significant difference in shoulder flexibility level between the study groups during all stages of the study period where p value < 0.001 . It also revealed that, the percentage of shoulder flexibility was significantly improved to a good level at 1st week ,1st 3rd and 6th month in the

intervention group as follow (1.7% ,80.0%, 98.3% & 100%) respectively compared to (0.0% 1.7%, 8.3%, & 46.7%) in the control group, p value < 0.0001 . It also clears from table 4. that there was a statistically significant difference within study groups as regard shoulder flexibility at 1st week, 1st, 3rd. and 6th months post-mastectomy p value < 0.0001 .

Table 5. demonstrated levels of grip strength in kilograms (Kg) post compression garment and exercise training, it shows that in the 1st week post operatively (46.7%) of the intervention group and (10.0%) of the control group have average grip strength scores $p < 0.0001$. At 1st and 3rd month post operatively, it also proved that (75.0% & 65.0%) of the intervention group and (8.3% & 23.3%) of their control have good scores. Moreover, the table illustrated that, at 6th month (56.7%) of the intervention group and only (1.7%) of the control group have excellent scores. Therefore, this table presented a marked changes between the studied groups regarding total adult grip scores over the study periods. It also clears from the table that there was a statistically significant difference within study groups as regard grip strengths during 1st week, 1st, 3rd. and 6th months postoperative.

Table 6. briefly illustrated a statistically significantly higher proportion of upper limb lymphedema physical findings in control group compared to intervention group during 1st week, 1st, 3rd and 6th months postoperative where $p < 0.0001$. It is noted in the table that there was a considerable change within study groups regarding upper limb lymphedema physical findings over study course $p < 0.0001$.

Table 7. Showed that, there was significantly increase in wrist, elbow, and above elbow measurements mainly in control group and not seen in intervention group. There was increasing in lymphedema occurrence during different phases of study in control group rather than intervention group $p < 0.0001$. This table also showed that, overtime there is slight clinical change with a no statistically differences in the arm measurements within the intervention group.

Table (1): Demographic characteristics and health relevant data of the studied groups (n=120) Data are expressed as frequency (percentage). P value by Chi-Square Test.

Demographic variables	Intervention group (n=60)		Control group (n=60)		χ^2 / p
	No	%	No	%	
Age (years)					
20 < 30	11	18.3	5	8.3	7.22/0.06
30 < 40	18	30.0	10	16.7	
40 < 50	15	25.0	20	33.3	
50- 60	16	26.7	25	41.7	
Marital Status					
Single	7	11.7	2	3.3	4.77/0.18
Married	43	71.7	43	71.7	
Divorced	9	15.0	11	18.3	
Widowed	1	1.7	4	6.7	
Residence					
Rural	31	51.7	41	68.3	3.47/0.06
Urban	29	48.3	19	31.7	
Educational level					
Illiterate	11	18.3	16	26.7	8.13/0.09
Basic education	4	6.6	11	18.3	
Intermediate education	27	45.0	25	41.7	
Higher education	18	30.0	8	13.3	
Menopause					
Yes	32	53.3	31	51.7	0.03/0.85
No	28	46.7	29	48.3	
Body mass index (BMI)					
<18.5 (Underweight)	1	1.7	1	1.7	5.39/0.25
18.5-24.9(Normal weight)	5	8.3	2	3.3	
25.0-29.9 (Overweight)	31	51.7	22	36.7	
30 To 39.9 (Obese)	19	31.7	30	50.0	
Family history of breast cancer					
Never	37	61.7	27	45.0	7.33/0.12
Mother	8	13.3	7	11.7	
Sisters	8	13.3	15	25.0	
The aunt	4	6.7	10	16.7	
Grand mother	3	5.0	1	1.7	
Stage of breast cancer					
First stage	24	40.0	32	53.3	2.14/0.14
Second stage	36	60.0	28	46.7	
The affected arm					
Right	39	65.0	30	50.0	2.76/0.09
Left	21	35.0	30	50.0	
-Received measures related to lymphedema prevention					
Yes	3	5.0	1	1.7	1.03/0.31
No	57	95.0	59	98.3	

Table (2): Comparison between the patients in intervention and control group regarding overall shoulder pain during the different phases of the study (n=120)

Overall shoulder pain	Intervention group (n=60)		Control group (n=60)		χ^2 / p	z-value/p
	No	%	No	%		
Pre-operative						
No pain	60	100.0	60	100.0		
Mean±SD	0.00±0.00		0.00±0.00			0.00/1.00
Post-operative						
1 st week						
No pain	3	5.0	0	0.0	66.83/ 0.000**	
Mild pain	50	83.3	9	15.0		
Moderate pain	6	10.0	22	36.7		
Severe pain	1	1.7	19	31.7		
Worst pain	0	0.0	10	16.7		
Mean±SD	12.60±6.49		32.20±12.68		10.65/ 0.000**	7.87/0.000**
1 st month						
No pain	58	96.7	1	1.7	108.95/ 0.000**	
Mild pain	2	3.3	16	26.7		
Moderate pain	0	0.0	23	38.3		
Severe pain	0	0.0	16	26.7		
Worst pain	0	0.0	4	6.7		
Mean±SD	0.20±1.00		27.40±11.98		17.51/ 0.000**	9.85/0.000**
3 rd month						
No pain	60	100	3	5.0	108.57/ 0.000**	
Mild pain	0	0.0	21	35.0		
Moderate pain	0	0.0	32	53.3		
Severe pain	0	0.0	3	5.0		
Worst pain	0	0.0	1	1.7		
Mean±SD	0.00±0.00		20.61±9.42		16.95/ 0.000**	9.97/0.00 0**
6th month						
No pain	59	98.3	3	5.0	104.71/ 0.000**	
Mild pain	1	1.7	28	46.7		
Moderate pain	0	0.0	26	43.3		
Severe pain	0	0.0	1	1.7		
Worst pain	0	0.0	2	3.3		
Mean±SD	0.08±0.64		19.30±10.13		14.65/ 0.000**	9.92/0.00 0**
Friedman χ^2 / p	218.09/0.000**		189.85/0.000**			
Friedman χ^2 / p (Mean±SD)	231.08/0.000**		181.00/0.000**			

Data are expressed as frequency (percentage). P value by Chi-Square Test. Mean± Standard Deviation

**Highly Significant p <0.01

Table (3): Overall shoulder physical disability levels among both studied groups in the different phases of the study (n=120)

Overall shoulder physical disability	Intervention group (n=60)		Control group (n=60)		χ^2 / p	z-value/p
	No	%	No	%		
Pre-operative						
No disability	60	100.0	60	100.0		
Mean±SD	0.00±0.00		0.00±0.00			0.000/1.00
Post-operative						
1 st week						
No disability	19	31.7	0	0.0	58.83/	

Mild disability	34	56.7	13	21.7	0.000**	
Moderate disability	7	11.7	37	61.7		
Severe disability	0	0.0	9	15.0		
Worst disability	0	0.0	1	1.7		
Mean±SD	13.50±8.47		34.88±13.99		10.13/0.000**	8.25/0.000**
1 st month						
No disability	58	96.7	3	5.0	101.11/ 0.000**	
Mild disability	2	3.3	29	48.3		
Moderate disability	0	0.0	23	38.3		
Severe disability	0	0.0	5	5.3		
Mean±SD	0.38±1.80		25.95±14.02		14.01/0.000**	9.83/0.000**
3 rd month						
No disability	60	100.0	4	6.7	105.00/ 0.000**	
Mild disability	0	0.0	41	68.3		
Moderate disability	0	0.0	12	20.0		
Severe disability	0	0.0	3	5.0		
Mean±SD	0.00±0.00		20.52±13.11		12.13/0.000**	9.96/0.000**
6 th month						
No disability	60	100.0	9	15.0	88.69/ 0.000**	
Mild disability	0	0.0	41	68.3		
Moderate disability	0	0.0	8	13.3		
Severe disability	0	0.0	1	1.7		
Worst disability	0	0.0	1	1.7		
Mean±SD	0.00±0.00		17.41±12.92		10.44/0.000**	9.93/0.000**
Friedman χ^2 / p	159.56//0.000**			176.75/0.000*		
Friedman χ^2 / p (Mean±SD)	231.08/0.000*			186.34/0.000**		

Data are expressed as frequency (percentage). P value by Chi-Square Test. Mean± Standard deviation ** Highly Significant p <0.01

Table (4): Shoulder flexibility level in both studied groups during the different phases of the study (n=120)

Shoulder flexibility	Intervention group (n=60)		Control group (n=60)		χ^2 / p
	No	%	No	%	
Pre-operative					
Good	60	100.0	60	100.0	
Post-operative					
1 st week					
Poor	12	20.0	46	76.7	38.78/ 0.000**
Fair	47	78.3	14	23.3	
Good	1	1.7	0	0.0	
1 st month					
Poor	0	0.0	14	23.3	78.18/ 0.000**
Fair	12	20.0	45	75.0	
Good	48	80.0	1	1.7	
3 rd month					
Poor	0	0.0	6	10.0	97.64/ 0.000**
Fair	1	1.7	49	81.7	
Good	59	98.3	5	8.3	
6 th month					
Poor	0	0.0	5	8.3	43.63/0.000**
Fair	0	0.0	27	45.0	
Good	60	100.0	28	46.7	
Friedman χ^2 / p	206.17 / 0.000**		186.23 / 0.000**		

Table (5): Grip strength among studied groups over the course of the study period (n=120)

Grip strengths	Intervention group (n=60)		Control group (n=60)		χ^2 / p
	No	%	No	%	
Pre-operative					
Good	27	45.0	30	50.0	0.30/ 0.58
Excellent	33	55.0	30	50.0	
Post-operative					
1 st week					
Poor	5	8.3	33	55.0	35.75/ 0.000**
Below average	25	41.7	20	33.3	
Average	28	46.7	6	10.0	
Good	2	3.3	1	1.7	
1 st month					
Poor	0	0.0	6	10.0	59.69/ 0.000**
Below average	3	5.0	26	43.3	
Average	12	20.0	23	38.3	
Good	45	75.0	5	8.3	
3 rd month					
Poor	0	0.0	4	6.7	71.27/ 0.000**
Below average	0	0.0	11	18.3	
Average	2	3.3	31	51.7	
Good	39	65.0	14	23.3	
Excellent	19	31.7	0	0.0	
6 th month					
Poor	0	0.0	4	6.7	57.75/ 0.000**
Below average	0	0.0	4	6.7	
Average	1	1.7	21	35.0	
Good	25	41.7	30	50.0	
Excellent	34	56.7	1	1.7	
Friedman χ^2 / p	198.25/0.000**		192.20/0.000**		

Lymphedema occurrence and physical findings

Table (6): Comparison of patients in both studied groups regarding upper limb lymphedema physical findings during the different phases of the study period (n=120)

Physical findings of lymphedema	Phases of intervention	Intervention group (n=60)		Control group (n=60)		χ^2 / p
		No	%	No	%	
1. Swelling of the breast and chest place	Pre-operative	0	100.0	0	100.0	16.87/0.000**
	Post 1st week	3	5.0	21	35.0	
	Post 1st month	1	1.7	19	31.7	
	Post 3rd month	0	100.0	12	20.0	
	Post 6th month	0	100.0	11	18.3	
Cochran's Q / p		9.17/0.04*		33.62/0.000**		
2. Swelling of the shoulder, arm or hand	Pre-operative	0	100.0	0	100.0	3.92/0.04*
	Post 1st week	2	3.3	8	13.3	
	Post 1st month	0	100.0	12	20.0	
	Post 3rd month	0	100.0	17	28.3	
	Post 6th month	0	100.0	19	31.7	
Cochran's Q / p		800/0.09		43.54/0.000**		
3. Feel heaviness in the body or some body parts	Pre-operative	0	100.0	0	100.0	13.88/0.000**
	Post 1st week	14	23.3	34	56.7	
	Post 1st month	4	6.7	34	56.7	
	Post 3rd month	1	1.7	32	53.3	
	Post 6th month	2	3.3	30	50.0	
Cochran's Q / p		41.54/0.000**		82.98/0.000**		
4. Change skin texture	Pre-operative	0	100.0	0	100.0	8.07/0.004**
	Post 1st week	7	11.7	20	33.3	

	Post 1 st month	1	1.7	18	30.0	18.07/0.000**
	Post 3 rd month	0	100.0	11	18.3	12.11/0.001**
	Post 6 th month	0	100.0	10	16.7	10.91/0.001**
Cochran's Q / p		24.80/0.000**		42.89/0.000**		
5. Redness and tightening of the skin	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	7	11.7	22	36.7	10.23/0.001**
	Post 1 st month	1	1.7	19	31.7	19.44/0.000**
	Post 3 rd month	0	100.0	5	8.3	5.22/0.02*
	Post 6 th month	0	100.0	5	8.3	5.22/0.02*
Cochran's Q / p		24.80/0.000**		64.62/0.000**		
6. Pain and tingling in the affected arm	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	58	96.7	60	100.0	2.03/0.15
	Post 1 st month	2	3.3	59	98.3	108.33/0.000**
	Post 3 rd month	0	100.0	57	95.0	108.57/0.000**
	Post 6 th month	0	100.0	55	91.7	101.53/0.000**
Cochran's Q / p		244.41/0.000**		212.39/0.000**		
7. Lack of movement operative joint	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	39	65.0	53	88.3	9.13/0.003**
	Post 1 st month	1	1.7	49	81.7	78.99/0.000**
	Post 3 rd month	0	100.0	48	80.0	80.00/0.000**
	Post 6 th month	0	100.0	42	70.0	64.61/0.000**
Cochran's Q / p		152.15/0.000**		162.84/0.000**		

Table (6 cont.): Comparison of patients in both studied groups regarding upper limb lymphedema physical findings during the different phases of the study period (n=120)

Physical findings	Phases of intervention	Intervention group (n=60)		Control group (n=60)		χ^2 / p
		No	%	No	%	
8. 8.Disability of wrist and wrist joint	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	4	6.7	23	38.3	17.25/0.000**
	Post 1 st month	0	100.0	21	35.0	25.45/0.000**
	Post 3 rd month	0	100.0	17	28.3	19.81/0.000**
	Post 6 th month	0	100.0	15	25.0	17.14/0.000**
Cochran's Q / p		16.00/0.003**		49.82/0.000**		
9. 9.Tight clothes and sleeves with affected arm	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	7	11.7	4.82/0.03*
	Post 1 st month	0	100.0	10	16.7	10.91/0.001**
	Post 3 rd month	0	100.0	15	25.0	17.14/0.000**
	Post 6 th month	0	100.0	14	23.3	15.84/0.000**
Cochran's Q / p		4.00/0.41		34.14/0.000**		
10.10.Tight bra	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	0	100.0	9	15.0	9.73/0.002**
	Post 1 st month	0	100.0	11	18.3	12.11/0.001**
	Post 3 rd month	0	100.0	12	20.0	13.33/0.000**
	Post 6 th month	0	100.0	13	21.7	14.57/0.000**
Cochran's Q / p				24.00/0.000**		
11.11.Tight rings, watch and bangles in the affected arm	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	0	100.0	8	13.3	8.57/0.003**
	Post 1 st month	0	100.0	7	11.7	7.43/0.006**
	Post 3 rd month	0	100.0	9	15.0	9.73/0.002**
	Post 6 th month	0	100.0	10	16.7	10.91/0.001**
Cochran's Q / p				20.25/0.000**		

Data are expressed as frequency (percentage). P value by Chi-Square Test. *Significant p <0.05 /**Highly Significant p <0.01

Figure 1. showed that (70%) of control group had lymphedema post 6th months of mastectomy while only (3.3%) of intervention group developed lymphedema.

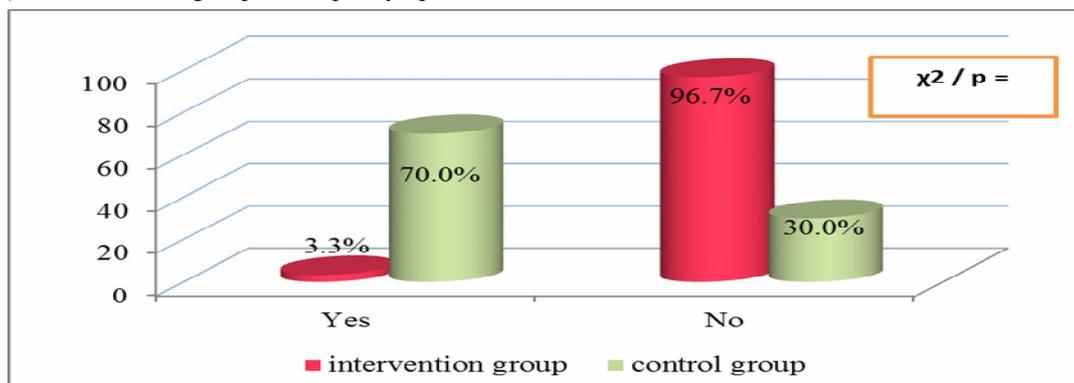


Figure (1): Lymphedema occurrence in the intervention and control group after 6th month of mastectomy

Table (7). Comparison of patients in both studied groups regarding upper extremity circumferential measurements during different phases of study period (n=120)

Areas of circumferential measurement	Phases of intervention	Lymphedema occurrence				χ ² / p
		Intervention group (n=60)		Control group (n=60)		
		No	%	No	%	
1. Metacarpal and phalangeal joints	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	0	100.0	0	100.0	
	Post 1 st month	0	100.0	0	100.0	
	Post 3 rd month	0	100.0	0	100.0	
	Post 6 th month	0	100.0	0	100.0	
2. Wrist	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	0	100.0	0	100.0	
	Post 1 st month	0	100.0	3	5.0	3.07/0.08
	Post 3 rd month	0	100.0	5	8.3	5.21/0.02*
	Post 6 th month	1	1.7	5	8.3	2.81/0.09
3. Under the wrist ,10 c.m	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	2	3.3	5	8.3	1.36/0.24
	Post 1 st month	0	100.0	5	8.3	5.22/0.02*
	Post 3 rd month	0	100.0	5	8.3	5.22/0.02*
	Post 6 th month	0	100.0	5	8.3	5.22/0.02*
4. Under the wrist ,15 c.m	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	2	3.3	0.34/0.56
	Post 1 st month	0	100.0	2	3.3	2.03/0.15
	Post 3 rd month	0	100.0	4	6.7	4.13/0.04*
	Post 6 th month	0	100.0	3	5.0	3.07/0.08
5. Under the wrist ,20 c.m	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	2	3.3	0.34/0.56
	Post 1 st month	1	1.7	2	3.3	0.34/0.56
	Post 3 rd month	1	1.7	2	3.3	0.34/0.56
	Post 6 th month	1	1.7	2	3.3	0.34/0.56
6. Elbow	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	1	1.7	0.00/1.00
	Post 1 st month	0	100.0	1	1.7	1.01/0.31
	Post 3 rd month	0	100.0	5	8.3	5.22/0.02*
	Post 6 th month	0	100.0	4	6.7	4.13/0.04*
7. Above elbow, 10 c.m	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	3	5.0	1.03/0.31
	Post 1 st month	0	100.0	2	3.3	2.03/0.15
	Post 3 rd month	0	100.0	6	10.0	6.32/0.01**
	Post 6 th month	0	100.0	9	15.0	9.73/0.002**
8. Above elbow, 15 c.m	Pre-operative	0	100.0	0	100.0	
	Post 1 st week	1	1.7	5	8.3	2.81/0.09
	Post 1 st month	1	1.7	7	11.7	4.82/0.03*
	Post 3 rd month	1	1.7	12	20.0	10.44/0.001**

9. Above elbow, 20 c.m	Post 6th month	1	1.7	13	21.7	11.64/0.001**
	Pre-operative	0	100.0	0	100.0	
	Post 1st week	1	1.7	8	13.3	5.8/0.02*
	Post 1st month	0	100.0	13	21.7	14.57/0.000**
	Post 3rd month	0	100.0	17	28.3	19.81/0.000**
	Post 6th month	0	100.0	19	31.7	22.57/0.000**

Data are expressed as frequency (percentage). P value by Chi-Square Test. *Significant p <0.05 /**Highly Significant p <0.01

5. Discussion

The aim of this research work was to study the effect of exercise combined with CG on improving lymphedema and shoulder function in post-mastectomy women. The women participating in the intervention and control group were identical in all major baseline demographic and clinical characteristics with no statistically significant differences. The finding of the current study revealed that, more than half of the studied women aged between 50 -60 years old. This result justifies the life expectancy, also the prevalence of breast cancer in women over the age of forty may be due to hormonal changes, menopause and increased genetic mutations at this age. These findings agreed with Ahmed, Mekkawy and Sayed (2017) in a study entitled "Effect of applying shoulder exercise on shoulder function after modified radical mastectomy" who mentioned that more than half of the women of both groups, their ages ranged between (40 to 60) years. This means that both the immune response and the hormonal changes with aging can be associated with breast cancer. More than two third of both groups were married. This result come along with Bozdemir and Aygin (2021) in a study entitled "Effect of structured training program on arm dysfunction, lymphoedema and quality of life after breast cancer surgery" who reported that two third of both groups were also married. It was found that more than half of menopausal women live in rural areas. These results were consistent with Omar et al. (2020). Similar finding was obtained in this study.

Considering level of patients' education, less than half of both groups were intermediate education this could be due to our low socioeconomic status community policies in graduating quickly from school and this helps in further employment or marriage. This is congruent with several recent studies who found that, almost half of studied subjects were having middle education (Aboul-Enien et al., 2018; El-feqi, et al., 2020). Regarding body mass index (BMI), slightly more than half of the intervention arm and nearly half of control arm were overweight this could be due to unhealthy lifestyle. This finding in harmony with Kabak et al. (2020) and Kilbreath et al.

(2020). Increasingly, more than two third of studied groups have negative family history of cancer. The same findings were reported by kim et al. (2019).

Around half of studied women were in the first stage of BC and their right upper limb was affected. This can be explained from the researcher point of view as, the women discovered breast cancer in its early stages because of the initiative of 100 million Seha sponsored by the Egyptian President and Ministry of Health for early detection and diagnosis of cancer. Similar findings were reported by Bozdemir and Aygin (2021). Most of the studied groups had no information about preventive measures of lymphatic swelling. Alsharif et al. (2021) supported this finding in their study. This could be interpreted by that, the physician and the nurse focused on providing brief instructions just before discharge.

Improvement in shoulder function

a. Shoulder pain and disability index

In terms of shoulder pain and disability score after intervention the present study revealed that there was a marked reduction in shoulder pain and disability index in the intervention arm more than their control in repeated measurement during study intervals with a statistically significant differences p< 0.001. Moreover, there was a trend toward a significant change in shoulder pain and disability within the intervention group after 6 months of training program (table. 2&3). This might be attributed to the warmth produced during exercise and CG, it is believed to help dispel allosteric chemicals and enhance muscle relaxation.

In this context, recent RCT conclude that, exercises and CG program is an effective tool for preventing upper extremity dysfunction and pain in breast cancer patients (Corrado, Ciardi, Servodio & Arpino, 2018; Gamee, Shaaban & Ali, 2019; Giacalone, Alessandria & Ruberti, 2019). This was in line with kim et al. (2019) who study the effectiveness of self-exercises for improving shoulder disability and pain in breast cancer survivors after lymph node dissection and recognized that the conservative self-exercise appeared to be more effective after 6 weeks because of it decreased pain and disability level. Also, these results were in harmony with Appavu

(2021) and Paolucci et al. (2021) who explore the efficacy of post mastectomy exercises program in reducing shoulder pain without analgesics. The same result concluded in other recent studies by El-Feqi et al. (2020) and Giacalone et al. (2019). All these findings support the first hypothesis, proposed that " Post mastectomy women who participate in CG and exercise training (Intervention group) exhibited less shoulder pain and disability score than those who do not (control group) ".

b. Shoulder flexibility

When considering the efficacy of CG and shoulder exercise on enhancing shoulder flexibility post-mastectomy over the different phases of study, the current study proved that there was a highly statistically significant differences in shoulder flexibility level between the intervention and control group at 1st week, 1st, 3rd, and 6th month post-intervention and within the same groups in a repeated measurement where $p < 0.0001$. In the 1st month, majority of intervention group have good score of shoulder flexibility compared to only one woman in their control. Finally, post six months all women in intervention group have good shoulder flexibility, unlike the control group less than half of the participants had improvement with a statistically significant difference (Table.4). This goes in the line with Das, Sureshkumar, Vijayakumar, Kate, and Srinivasan (2018) who emphasized that post-mastectomy protocol of care improved shoulder ROM and lowered ADL impairment. In this regard, similar studies concluded the same results (Majed et al., 2020; Omar, Gwada, Omar, El-Sabagh & Mersal, 2020).

c. Grip strength

When comparing changes in grip strength in the affected arm post-intervention, the present study, illustrate improvement in the total scores of adult grip during study intervals in the interventional arm more than a control arm with a highly statistically significant differences $p < 0.0001$. Crucially, the majority of the intervention group had excellent grip strength, unlike their control, only one woman who scored this value at the end of six month of follow up, $p < 0.0001$. It also clears from the study that there was a statistically significant difference within study groups as regard grip strengths in repeated measurements, during 1st week, 1st, 3rd and 6th months postoperatively $p < 0.0001$ (table 5). This result is Congruent with Bahgat et al. (2016) and Cho (2004) who clarified a considerable improvement in handgrip strength of the affected limb of study group than the control group.

From the results of the current study regarding shoulder function (a,b & c), can conclude that there were marked improvement in overall shoulder function in terms of shoulder pain & disability index, shoulder flexibility and grip strength in intervention group compared to control group over the study course. The changes between the study groups were considerably evident especially at 1st week to the end of the study after 6-month $p < 0.0001$. This means that the intervention group attained shoulder function more than the control group post-mastectomy. The rationale behind this effect was that, using a compression garment and exercises improves blood flow in the affected arm and decreases the pain perception, hence the patient can actively perform a range of motion to the shoulder joint. It also helps to eliminate lactate, muscle-cellular proteins, and inflammatory process. These results agreed with the 2nd hypothesis of the study, which assumes that the intervention group would show a significant improvement in level of shoulder flexibility and grip strength than the control group.

Lymphedema prevention and arm circumferential measurement

When investigating the effect of CG combined with exercise on lymphedema, the findings of this study emphasized that; the lymphedema was significantly low with a marked difference between the control and interventional arms. Briefly, the present study showed that, majority of control group developed lymphedema after 6 months of mastectomy compared to only two women in intervention group with a statistically significant differences $p < 0.0001$. In details, a third of the control group had clinical manifestations of lymphedema, changes in the skin texture, flexibility of wrist and feeling of tight bra, sleeves, and ring. Additionally, most of them feel heaviness in some body parts, pain and tingling in the affected arm, and shoulder disability, compared to only two women in intervention group feel heaviness in the body $p < 0.0001$ (table 6). The reduction in lymphedema may be attributable to lymph dynamics because the CG pressure was more than the venous pressure. This can also be caused by low or negative lymphatic pressure. These mechanisms lead to the opening of the lymph capillaries (Tantawy, Abdelbasset, Nambi & Kamel, 2019). Current findings are supported by recent reports who found a considerable difference in the incidence of lymphedema between patients who underwent mastectomy and received a lymphedema prophylaxis protocol compared with those who did not at $p < 0.05$ (Ali et al., 2021;

Saragih & Harahap, 2021; Thomis et al., 2020). Notably, the previous findings are proportionate with Omar et al., (2020) who suggested the efficacy of low-intensity resistance training with a garment in improving lymphedema and its associated symptoms (pain, heaviness, and tightness), thus reducing the size of the affected arm. Similar finding was concluded by Gursen et al. (2021) and Kilbreath et al. (2020).

When considering changes in affected upper-limb circumferential measurements post mastectomy, in this study, the circumferential measurements of the interventional arm remained stable throughout the study phases, thus suggesting the effectiveness of shoulder exercise and CG in preventing lymphedema. There was significantly increase in measurements of wrist, elbow, and above elbow mainly in control group compared to intervention group in a repeated measurements during different phases of study $p < 0.0001$. Interestingly over the study period, there is slight clinical change in the arm measurements within the intervention group with no significant differences (table 7). These results proportionate with Hawash et al. (2018) who concluded that, the mean arm circumferential differences were increased in control group while in study group no change in arm measurement from baseline, post and at follow up until the end of study period. A similar trial carried out by Tendero-Ruiz et al. (2020) concluded a decreased in upper limb volume in post-mastectomized women received compression garment compared to the control group. Decisively, we can accept the 3rd hypothesis that proposed " Post mastectomy women who actively participate in CG and exercise training experienced a low score of lymphedema and arm circumferential measurement than those in control group.

6. Conclusion

Crucially, the present study concluded that, compression garment combined with low-intensity exercises are an effective way to enhance shoulder function and reduce lymphedema during the first 6 months post-mastectomy in breast cancer women. Moreover, should be incorporated into the management of postmastectomy lymphedema as a safe, effective, and non-invasive technique.

7. Recommendations

1. Low-intensity exercises and compression garment is a safe, effective, non-invasive method that should be incorporated into the management of post-mastectomy patients to prevent lymphedema and enhance upper limb function.

2. It is recommended to increase the follow-up period in post-mastectomized studies.
- 3- Replicated the study in a large probability sampling and several hospitals to generalize the results.
4. Assessment of the obstacles facing the oncology nurse and their impact on patient satisfaction.

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9. Adherence to Ethical Criteria

Conflict of Interest: The authors absolve themselves of any conflict of interest.

Ethical Approval: The study procedures were in accordance with the ethical standards of Mansoura University and the Declaration of Helsinki.

Informed Consent: Informed consent was obtained from all participating women included in the study.

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Nil.

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