

The Efficacy of Protocol of Care on Post Mastectomized Women Outcomes

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Abstract: Modified radical mastectomy is the removal of the breast with its related axillary lymph node and it is associated with many social, emotional, and physical complications.

Aim of the study: is to evaluate the efficacy of protocol of care on women outcomes post mastectomy.

Research design: A Quasi-Experimental design was utilized in this study with a total of 90 women who had primary breast cancer and scheduled for operation at Tanta Cancer Center, affiliated to Ministry of Health, Gharbia governorate, Egypt. Women were approached at the female surgical wards and followed up in the outpatient clinics at the same center. Sample was divided into three groups; control group was received routine hospital care, study group 1 who managed by physical exercises and study group 2 who managed by physical exercises and compression garment postoperatively.

Tools of data collection: Four tools were used

Tool I: Socio-demographic and knowledge assessment structured interview questioner,

Tool II: subjective outcome questioner for upper limb function which include; Shoulder Pain and Disability Index, **Tool III:** Objective outcome measures for upper limb function post mastectomy; which include shoulder Flexibility, grip strength and upper extremity circumferential measurement

Tool IV: upper limb lymph edema observational checklist.

Results indicated that there were statistical significant differences between study and control groups regarding knowledge, subjective and objective outcome measures of upper limb function, with minimal evidence of lymph edema among studied group 1 and no evidence of lymph edema among studied group.

Conclusion: Early post mastectomy exercises program and using of compression garment is very effective on improving upper limb function and prevention of lymph edema after mastectomy.

Recommendation: Complying with early postoperative exercise after mastectomy for at least 6 months, wearing compression garment are effective in preventing lymph edema after mastectomy. Early assessment and prompt detection of arm lymph edema post mastectomy is critical. Further studies are needed with larger sample size, different settings and longer follow up period.

Keywords: lymph edema, compression garment, mastectomy, outcomes

I. Introduction

Cancer is a group of diseases that cause cells in the body to change and grow out of control. Most types of cancer cells eventually form a lump or mass called a tumor, and are named after the part of the body where the tumor originates. Breast cancer begins in the breast tissue that is made up of glands for milk production, called lobules, and the ducts that connect the lobules to the nipples. The remainder of the breast is made up of fatty, connective, and lymphatic tissues (1). Breast cancer is an important global public health problem due to its high incidence and mortality. It is estimated that there will be 16 million new cases annually by the year 2020 world wide. It is expected that about 41.430 deaths will occur annually world wide as a result of breast cancer (2). In Egypt, breast cancer is the most common cancer among women. It represents 18.9 % of total cancer cases (35.1 % in women and 2.2 % in men) among the Egypt National Cancer Institute (NCI) series of 10.556 patients during the year 2001, with an adjusted age rate of 49.6 per 100.000 population (3, 4). A statistical record of Tanta Cancer Center indicated that the number of patients was admitted with breast cancer at 2013 is 578 (5). Surgery is an essential part of all current treatments to cure breast cancer. More than 90 % of women diagnosed with breast cancer undergo operative treatment. Mastectomy is a surgery to remove one or two breasts, there are main types of mastectomy, such as a subcutaneous mastectomy, a total or simple mastectomy and modified radical mastectomy. Modified radical mastectomy continues to be appropriate for some patients and it is the removal of all breast tissue from the affected breast with removal of lymph node from the armpit on the affected side of the body. This surgery typically includes the removal of both the nipples and areola, but the surgery can be performed using skin and nipple sparing techniques (6, 7). Complications of modified radical mastectomy

include seroma formation, wound infection and wound dehiscence, skin flap necrosis, hemorrhage, hematoma formation, paresthesia, muscle paralysis, stiffness, pain, restricted mobility and lymph edema (8). Post mastectomy pain syndrome (PMPS) is a chronic pain condition, typically neuropathic pain in nature, which can occur following surgery to the breast. The exact cause of (PMPS) is unclear, but various etiological theories have been postulated as damage to axillary nerve pathway (9). Many women experience impairment in shoulder movements that can substantially affect their everyday function and quality of life (2). Restriction of shoulder movement is one of the complications following axillary lymph node dissection. It may occur because of tissue and nerve lesions, with prevalence of 7- 36%. This musculoskeletal disorder of the shoulder results in considerable joint debility and pain. The symptoms generally diminish within three months, but they may become chronic, thus interfering with these patients' quality of life (10). Lymph edema is a build-up of lymph fluid in the fatty tissues just under skin. It usually develops slowly over time. The swelling can range from mild to severe. It can start soon after surgery or radiation treatment but it can also begin months or even many years later (11). A recent meta-analysis reports the incidence of breast cancer-related lymph edema to range from 0 to 3% after lumpectomy alone to as high as 65% to 70% after modified radical mastectomy (removal of breast and axillary lymph nodes) with regional nodal radiation (12). The risk of lymph edema is associated with axillary dissection and radiotherapy, obesity, extent of the surgical technique, infection, patient age, number of dissected lymph nodes, number of positive lymph nodes, and level of lymph node dissection (13, 14). Lymph edema may be inherited (primary) or caused by injury to the lymphatic vessels (secondary). In many cancer patients, this condition doesn't develop until months or even years after treatment therapy has concluded. Lymph edema symptoms may include severe fatigue, a heavy swollen limb or localized fluid accumulation in the other body areas, including the head and neck, discoloration of the skin overlying the lymph edema and eventually deformity (elephantiasis) (15). Therapeutic exercise has numerous benefits for all the patients post mastectomy. Exercises are essential to the prevention of shortening of the muscles, prevention of contracture of the joints, and improvement in lymph and blood circulation after mastectomy (6). Compressive bandaging is using low-elasticity bandage rolls. It started on the fingers and then forearm and the upper arm. It is an important technique because it keeps the interstitial pressures in balance. They should be used continuously and only be removed for personal hygiene. The pressure exerted by the bandaging is greater in the distal region and diminishes towards the root of the limb (16). Nurses play an important role in improving shoulder functions and prevention of lymph edema post modified radical mastectomy by giving certain instructions related to postoperative exercises and preventive care measures to prevent lymph edema (17). Therefore, the aim of this study was to evaluate the effect of protocol of care on shoulder pain, function and prevention of lymph edema after mastectomy.

Aim of the study is to evaluate the efficacy of protocol of care on women outcomes after mastectomy.

Research hypotheses

- 1-Women who had mastectomy in the study group who attended the protocol of care for upper limb exercise will exhibit less shoulder pain than control group.
- 2- Women who had mastectomy in the study group who attended early protocol of care will display a greater shoulder range of motion and no evidence of lymph edema compared to the control group.

II. Materials and Method

Materials

Research design: The present study utilized quasi experimental research design.

Setting: This study was conducted at Tanta Cancer Center which is affiliated to Ministry of Health, Gharbia Governorate at the Female Surgical Wards for pre and postoperative period and follow up was done in outpatient clinics at the center mentioned above.

Subjects: All women who met the inclusion criteria were included in the study which yield a convenient sample of 90 adult women who had primary breast cancer and scheduled for mastectomy was selected and divided into three equal groups, 30 women in each group.

Group 1: Control group, 30 pre mastectomy women (received routine hospital postoperative care).

Group 2: Study group; 30 pre mastectomy women who managed by physical exercises postoperatively.

Group 3: Study group; 30 pre mastectomy women who managed by physical exercises and compression garment postoperatively.

Inclusion criteria

Women at the age of 21-60, patients with stage I and II breast cancer, able to communicate, have no previous upper limb disability, undergoing adjuvant chemotherapy and radiotherapy. Women who have D.M, renal failure, heart failure, upper limb injury, trauma, or past shoulder surgery and those who have breast inflammation for any reason were excluded from the study.

Tools: Four tools were used to conduct the study.

Tool (I) Socio-demographic and knowledge assessment structured interview questionnaire". It was consisted of three parts:

Part (1) Socio-demographic data" which include the patient name, age, marital status, educational level, occupation and residence.

Part (2) Health relevant assessment sheet that included the date of admission, past and present medical history, body mass index, stage of breast cancer and the arm affected. This tool was developed by the researcher after reviewing the related literatures ⁽¹⁸⁻²²⁾.

Part (3) Women knowledge assessment; this part was used to elicit subject knowledge regarding post mastectomy exercises and preventive care measures of lymph edema, which was collected from women.

Scoring system

The knowledge sheet consisted of 80 true and false questions, each correct answer was given 1 score, while incorrect or don't know answer was given zero score. The total obtained scores ranged from 0 to 80. Some modifications were done to the Scoring system since a high percentage of the studied women were found to have knowledge level less than 30% ,so the total grades were summed up and converted into total score percentage and calculated as follows:

Poor	< 30%
Fair	≤ 50 %
Good	> 50 % - 64%
Very good	> 65 % - 84%
Excellent	≥ 85 %

Tool II - Subjective outcome questionnaires for upper limb function;

This questionnaire consisted of "Shoulder Pain and Disability Index (SPADI). The SPADI is the only reliable and valid region specific measure for the shoulder. This tool was developed by **Roach (1991)** ⁽²³⁾, adopted by the researcher and translated into Arabic language to assess shoulder pain and shoulder physical functions.

Shoulder Pain Dimension: This part was used to assess the severity of an individual's pain which included five questions related to; (Worst pain, when lying on the involved side, reaching something on a high shelf, touching the back of the neck, pushing with the involved arm). Each question was given an identified score ranging from 0 to 10 and the final scores were interpreted as the following: 0: no pain, 1-3: mild pain, 4-6: moderate pain, 7-9: severe pain and 10 means the worst pain.

Interpretation of scores

Total pain score = Patient score / 50 x 100 = %

(Note: If a person does not answer all the questions, divide by the total possible score, e.g. if 1 question is missed, divide by 40) or total pain score is divided on 5

Shoulder physical functions This part was designed to measure the degree of difficulty an individual has with various activities in daily living that require upper extremity use by using eight questions; (Washing hair, washing back, putting on an undershirt or jumper, putting on a shirt that buttons down the front, putting on pants, placing an object on a high shelf, carrying a heavy object of 10 4.5 kilograms, removing something from back pocket)

Each question was given an identified score ranging from 0 to 10 and the final scores were interpreted as the following: 0: no disability, 1-3: mild disability, 4-6: moderate disability, 7-9: severe disability and 10 means the worst disability.

Total disability score = Patient score / 80 x 100 = %

(Note: If a person does not answer all the questions, divide by the total possible score, eg. if 1 question is missed, divide by 70) or Total disability score divided on 8

Total SPADI score = Patient score / 130 x 100 = %

Tool III: "Objective outcome measures for upper limb function post mastectomy.

This tool consisted of three parts; Shoulder Flexibility, Grip strength, and Upper extremity circumferential measurement

Shoulder Flexibility

This tool was developed by **Heyward (2010)** ⁽²⁴⁾ and adopted by the researcher to measure the multi-rotational components of the shoulder joints. Test the left shoulder by having the woman sit or stand and her right arm is straight up, letting the elbow bend, so the hand comes to rest palm down between the shoulder blades then the woman should reach with the left arm, so the palm is up and the woman attempt to touch the

fingers of the right hand with fingers of the left hand. Repeat the procedure for the other shoulder. Evaluating shoulder flexibility was using the table below.

Scoring system

Good	Fingers can touch
Fair	Fingertips are not touching, but are less than two inches apart
Poor	Fingertips are more than two inches apart

Grip strength

This tool was developed by **Heyward (2010)** ⁽²⁴⁾ and adopted by the researcher .Grip strength by kilogram of hand, measured using the hand-held dynamometer. It was used to measure how much force women exert when closing their hands.

Average Adult Grip Strength in Kilograms (Kg)

Classification	Female, non dominant hand	Female' dominant hand
Excellent	> 37	> 41
Good	34 - 36	38 - 40
Average	22 - 33	25 - 37
Below Average	18 - 21	22 - 24
Poor	< 18	< 22

Upper extremity circumferential measurement

The arm circumference was measured on operated and un-operated extremities at 9 areas (Metacarpal and phalangeal joints, Wrist,10 c.m below wrist, 15 c.m below wrist,20 c.m below wrist, elbow,10 c.m above elbow , 15 c.m above elbow and 20 c.m above elbow) ⁽²⁵⁾.

Tool IV: "Upper limb lymph edema observational checklist"

This tool was developed by the researcher ⁽²⁶⁾ to monitor lymph edema manifestations for post mastectomy. It was covered the following area of monitoring: Arm inspection and observation for signs and symptoms of lymph edema such as swelling in the breast, chest, shoulder, arm, or hand, part of body feels full or heavy, skin changes; texture, feels tight or hard, or looks red, new aching, tingling, or other discomfort in the area, less movement or flexibility in nearby joints, such as shoulder, hand, or wrist, trouble fitting arm into jacket or shirt sleeves and the bra doesn't fit the same, ring, watch, and/or bracelet feels tight, but hasn't gained weight.

Method

1-Administrative process:

A written approval to conduct the study was obtained from the responsible authority of Tanta Cancer Center and Collage of Nursing, Tanta University.

2- Written informed consent:

Informed consent was obtained from the patients and / or their families to participate in the study after explaining the purpose of the study and confidentiality was preserved.

3- Ethical consideration:

Ethical consideration for the privacy and confidentiality of the data and results was concluded and explain the patient' right to withdraw at any time of the study.

4- Validity of the tools

The developed tools (I, II, III, and IV) was tested for content validity by nine experts in the Medical-Surgical, and Oncology field professors and accordingly needed modifications were done.

5- Reliability

Before main data analysis, reliability was tested and Cronbach's alpha was reported as 0.90.

6- A pilot study:

A pilot study was carried out on 9 patients attended the Tanta Cancer Center in the Female Surgical Wards. The purpose of the pilot study was to test the tool for its relevance, clarity and organization and to determine the length of time needed to collect the data from each patient, since only minor modification was done, so the patient of the pilot study were included in the actual study.

7- Data collection

The collection of data for the present study was done during the period from November 2014 to November 2015.

8- Protocol of care for post mastectomy was conducted on four phases as follows:

A- Assessment Phase:

Data was collected from women and their current medical records preoperatively as a baseline measures for their knowledge and upper limb function (arm circumference, shoulder joint range of motion, and physical disability by using study tools I, II, III and IV.

B-Planning Phase

Proposed exercises program for upper limb post mastectomy for study group 2 and proposed exercises program with compression garment for study group 3 determining its general and specific objectives was designed based on determined needs, baseline measures, relevant literatures and researches. In order to be implemented using various methods including a booklet contains diagrams and pictures which was designed by researcher in Arabic Language and given to the patients as a guideline.

C- Implementation Phase:

Implementation Phase for group 2: It was included (the schedule of post mastectomy exercises scheme of (Carrle Myers Smith 2001) and other relevant studies ⁽²⁷⁾ and was implemented through 7 sessions; 5 sessions preoperative and 2 sessions postoperative.

Session 1: It was focused on the following:

Introduction about breast cancer, breast cancer treatments, post mastectomy complications, Causes, risk factors and manifestations of lymph edema.

Session 2: It was contained the following:

Introduction about post mastectomy exercises and first operational day exercises.

Session 3: It was included the second, third and fourth operational day exercises.

Session 4: It was contained the fifth operational day exercises which include; hands, chest and shoulder strengthen exercises.

Session 5: It was contained exercises after drain removal which includes; clockwise, wall climbing, hand rope, protraction, hand stick, shoulder elevation and depression, shoulder circumduction and scapula strengthen exercises.

Session 6: It was contained the first part of preventive measures to avoid lymph edema after mastectomy.

-Preventive measures related to extreme heats on affected arm.

-Preventive measures related to extreme effort on affected arm.

Session 7: It was contained the last part of preventive measures to avoid lymph edema after mastectomy.

-Preventive measures related to extreme pressure on affected arm

-Preventive measures related to inflammation and wound on affected arm.

Implementation Phase for group 3: It was contained the schedule of post mastectomy exercises which was implemented through 7 sessions as in group II and one session additional.

Session 8: It contained knowledge, practice and demonstration of compression garment.

D- Evaluation Phase:

It aimed to reassess patients after intervention phase to identify progress in term of differences in patients' level of response from baseline, it was done by the following schedule; post operative first week, 1st month, 3rd month and 6th month by using tools (I, II ,III , IV) for evaluation.

9-The control group received a routine hospital care regarding nursing care after mastectomy and was assessed by the researcher by the same schedule of the study groups II and III and by using tools (I, II, III, IV) for evaluation.

Limitation of the study:

-Unavailability of the compression garment inside Tanta Cancer Center, but the researcher handles this barrier by bought this garment with different size to fit the patient sizes.

-The field of work was exhausting to the researcher, where the place was overcrowded with other patients and visitors.

-There was no special room for women after mastectomy for follow up in outpatient's clinic so the follow up was more difficult to the researcher in the crowded outpatient clinic.

Statistical analysis:

The collected data were organized, tabulated and statistically analyzed using SPSS software (Statistical Package for the Social Sciences, version 16, SPSS Inc. Chicago, IL, USA). For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, comparison between two groups and more was done using Chi-square test (χ^2). Correlation between variables was evaluated using Pearson's correlation coefficient (r). Significance was adopted at $p < 0.05$ for interpretation of results of tests of significance.

III. Results

The results reveals that more than half (60%) of the control group were in age group of 50-60 years compared to half (50%) and third (33.3%) of both the study groups I and II respectively. As for the marital status, majority (73.3%) of the control group were married while minority (16.7%) of both the study groups I and II were widow. In relation to the number of children, about two thirds (66.7%) of the control group have 1-3 children while (23.3%) and (33.3%) of both the study groups I and II have 4-6 children respectively. Regarding to menstruation, majority of the control group (83.3%) were post menopause while minority (16.7%) and half (50%) of both the study groups I and II have regular menstrual period respectively. The difference between the studied groups regarding menstruation was statically significant where $p= 0.006$.

In relation to residence, most of the control group (70%) lives in rural areas compared to near half (46.7%) and more than half (53.3%) of both the study groups I and II respectively. In relation to educational level, more than half (53.3%) of the control group were illiterate compared to third (33.3%) and less than half (40%) of both the study groups I and II respectively while less than half (40%) and more than third (36.7%) of both the study groups I and II have moderate level of education compared to minority (13.3%) of the control group respectively.

Table (1): Levels of the total knowledge about exercises and preventive care measures of lymph edema of women after mastectomy pre and post- protocol of care (n=60).

This table demonstrates levels of the total knowledge about exercises and preventive care measures of lymph edema of women after mastectomy pre and post- protocol of care. It shows that most (70%) of the study group I have poor knowledge pre protocol of care compared to (zero %) post protocol of care. Also ,this table shows that minority (3.3%) of both the study groups I and II pre protocol of care compared to near half (40%) and more than third (36.7%) of both the study groups I and II post protocol of care have a good knowledge respectively. It is also illustrates that there was a significant difference between both the study groups I and II pre and post- protocol of care since $P = 0.0001$.

Figure (1): Mean change of the shoulder pain pre and 6 months post- protocol of care of women after mastectomy.

This figure demonstrates mean change of the shoulder pain pre and 6 months post- protocol of care of women after mastectomy who had primary breast cancer. It reveals that highest decrease in shoulder pain was in the study group I compared to the study group II and the control group where the mean change of shoulder pain scores among the women were (-1.18, - 0.75 and - 0.47) respectively.

Figure (2): Mean change of the shoulder disability pre and 6 months post- protocol of care of women after mastectomy (n=90).

This figure demonstrates mean change of the shoulder disability pre and 6 months post- protocol of care of women after mastectomy. It reveals that there is a decrease in the shoulder disability scores 6 months post protocol of care compared to pre protocol of care mostly in the study group I followed by the study group II since the mean change of the shoulder disability scores were (-1.12 and -0.65)respectively.

Table (2): Levels of the total scores of shoulder flexibility pre and post- protocol of care of women after mastectomy (n=90).

This table shows levels of the total scores of shoulder flexibility pre and post- protocol of care of women after mastectomy who had primary breast cancer. It illustrates in the 1st postoperative week that minority (6.7, %, 16.7% and 6.7%) of the control group and both the study groups I and II have good total scores of shoulder flexibility respectively while majority (73.3, %, 73.3% and 80%) of the control group and both the study groups I and II have fair total scores of shoulder flexibility respectively. As related to the 1st month post operatively; more than a third (36.7, %, 46.7% and 40%) of the control group and the study groups I and II have good total scores of shoulder flexibility respectively compared to a minority (20, %, 3.3% and 6.7%) of the control group and the study groups I and II have poor total scores of shoulder flexibility respectively.

Regarding the 3rd month post operatively; majority (80%) and more than half (63.3%) of the study group I and II respectively compared to less than half (40%) of the control group have good total scores of shoulder flexibility. On the other hand, minority (16.7%) of the control group compared to none of the study groups I and II have poor total scores of shoulder flexibility. Moreover, this table demonstrates that, in the 6th month post operatively, less than half (46.7%) compared to the majority (83.3%) and (73.3%) of the control

group and the study groups I and II have good total scores of shoulder flexibility respectively while minority (10%) of the control group compared to none of the study groups I and II have poor total scores of shoulder flexibility. Furthermore, this table shows statistical significant differences among the three groups in the preoperative, 3rd and 6th months postoperatively where $p = (0.011, 0.002 \text{ and } 0.012)$ respectively.

Table (3): Levels of total scores of Average Adult Grip Strength in Kilograms (Kg) pre and post- protocol of care of women after mastectomy (n=90).

This table reveals levels of total scores of Average Adult Grip Strength in Kilograms (Kg) pre and post- protocol of care of women after mastectomy. It shows that, in the preoperative period, less than half (20%, 40%, 16%) of the control, study I and II group have average total scores of adult grip strength respectively and near half (46.7%) of the control group compared to minority (6.7% and 13.3%) of the both study group I and II who have poor adult grip strength respectively. Regarding the 1st week post operatively, the table proved that a third (33.3%) of the control group compared to minority (6.7%, 13.3%) of both the study groups I and II have poor total scores of adult grip strength respectively while minority (10%), near half (43.3), and more than half (56.7%) of the control, study I and II groups have average scores respectively. Also in the 1st month post operatively, minority (13.3%) of the control group and less than half (40%) of the study groups I and II have average scores while poor total scores of adult grip strength, (23.3%), (0%), and (6.7%) of the control, study I and II groups respectively and remain the same percentage as poor total scores of adult grip strength for the three groups during the following 3rd and 6th month post operatively.

Moreover, the same table reveals that none of the control group have excellent total scores of adult grip strength during the 1st 3rd and 6th months of follow up post-operatively compared to compared to same percent (3%) of both study groups I and II in the 1st, 23.3% and 20% in the 3rd and 33.3% and 26.7% in the 6th month of follow up post operatively. Also, this table shows that there was a significant difference between the control group and the study groups I and II in relation to the total scores of adult grip strength pre, 1st week, 1st, 3rd and 6th months postoperative where $p = (0.002, 0.001, 0.001, 0.0001 \text{ and } 0.0001)$ respectively.

Table (4): Upper limb lymph edema physical finding pre and post- protocol of care of women after mastectomy (n=90)

According to the upper limb lymph edema physical finding pre and post- protocol of care of women after mastectomy, this table presents that more than a third (36.7%) of the control group compared to minority (6.7% and 3.3%) of the study groups I and II respectively have swelling of the breast and chest place and the difference was significant among the three groups where $p = 0.0004$. Also this table shows that about fourth (23.3%) of the control group compared to minority (13.3% and 3.3%) of the study groups I and II respectively have pain and tingling in the injured arm and there was no significant difference among the three groups in relation to pain and tingling in the injured arm where $p = 0.074$.

Furthermore, this table presents that (16.7%, 10% and 3.3%) of the control group and the study groups I and II respectively have a feeling of heaviness in the body or some parts of the body and there was no significant difference among the groups where $p = 0.227$. Finally this table illustrates that (13.3%) of the control group have change the skin feel compared to none of both study groups and the difference between them was significant where $p = 0.015$. Moreover, there was a significant difference among the three groups in relation to the other items of the upper limb lymph edema physical finding where $P = (0.355, 0.074, 0.364, 0.364, 0.364, \text{ and } 1.000)$ for redness and tightness of skin, pain and tingling in the injured arm, lack of close to where the process of joint movement, lack of detailed hand and wrist flexibility, tight clothing and sleeves of the injured arm and narrow rings, bracelets and watch in the injured arm respectively.

Table (5): Correlation between body mass index (BMI) of women and their circumferential measurements of upper extremity of the affected arm at the sixth month post-protocol of care than pre- protocol of care (n=90).

Concerning the correlation between body mass index (BMI) of women and their circumferential measurements of upper extremity of the affected arm at the sixth month post-protocol of care than pre- protocol of care. This table shows that there was a significant positive correlation between body mass index and circumferential measurements of upper extremity in the control group in wrist, 10 cm below wrist, 15 cm below wrist, 20 cm below wrist, elbow, 10 cm above elbow, 15 cm above elbow and 20 cm above elbow where $r = (0.423, 0.422, 0.587, 0.552, 0.464, 0.576, 0.542 \text{ and } 0.455)$ and $p = (0.020, 0.020, 0.001, 0.002, 0.010, 0.001, 0.002 \text{ and } 0.012)$ respectively.

Also, this table illustrates that there was no significant correlation between body mass index and

circumferential measurements of upper extremity of the affected arm at the sixth month post-protocol of care than pre- protocol of care in the study group I while there was a significant positive correlation between body mass index and circumferential measurements of upper extremity in the study group II in 10 cm below wrist where $r=(0.443$ and $p= 0.014)$.

Table (1): Levels of the total knowledge about exercises and preventive care measures of lymph edema of women after mastectomy pre and post- protocol of care (n=60).

Levels of the total knowledge about exercises and preventive care measures of lymph edema pre and post- protocol of care			Study group I (physical exercise management) (n=30)		Study group II (physical exercise & compression garment) (n=30)		χ^2	P
Pre protocol of care :								
Poor	<30%	(0-23)	21	70.0	20	66.7	0.083	0.959
Fair	30-<50%	(24-39)	8	26.7	9	52.9		
Good	50-<65%	(40-55)	1	3.3	1	3.3		
Very good	65-<85%	(56-67)	0	0	0	0		
Excellent	$\geq 85\%$	(68-80)	0	0	0	0		
Post protocol of care :								
Poor	<30%	(0-23)	0	0	0	0	0.087	0.993
Fair	30-<50%	(24-39)	1	3.3	1	3.3		
Good	50-<65%	(40-55)	12	40.0	11	36.7		
Very good	65-<85%	(56-67)	6	20.0	6	20.0		
Excellent	$\geq 85\%$	(68-80)	11	36.7	12	40.0		
χ^2			52.750		52.730			
P			0.0001*		0.0001*			

*Significant (P<0.05)

Figure (1): Mean change of the shoulder pain pre and 6 months post- protocol of care of women after mastectomy (n=90).

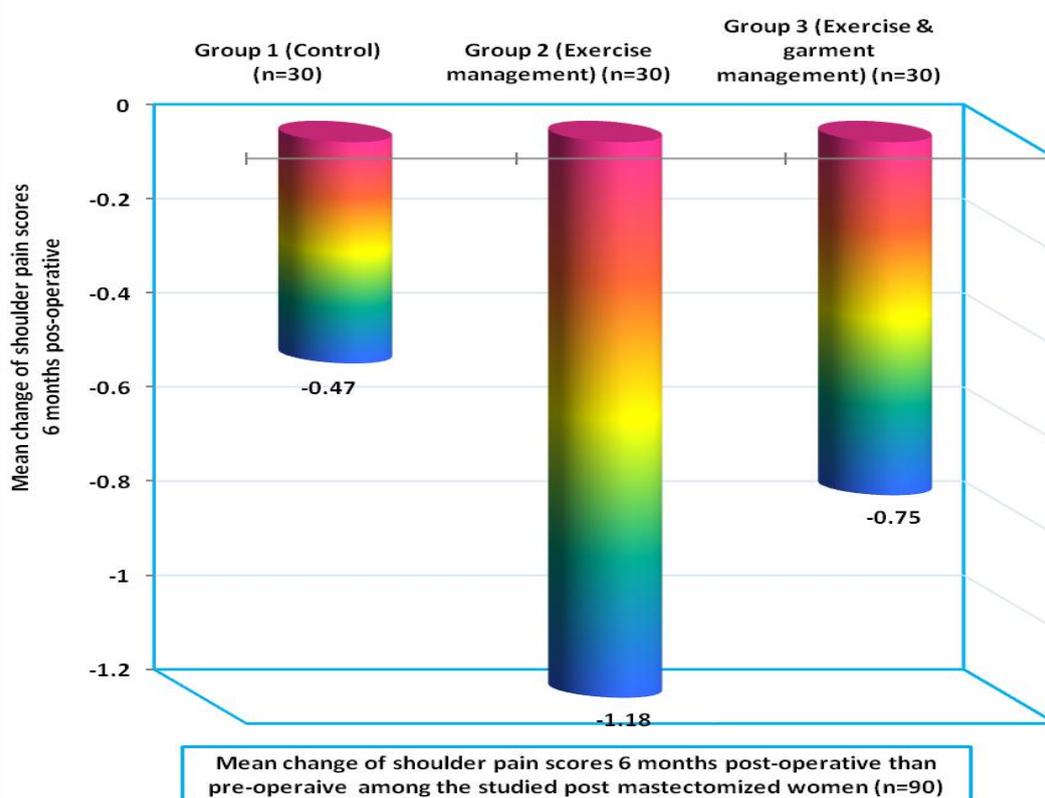


Figure (2): Mean change of the shoulder disability pre and 6 months post- protocol of care of women after mastectomy (n=90).

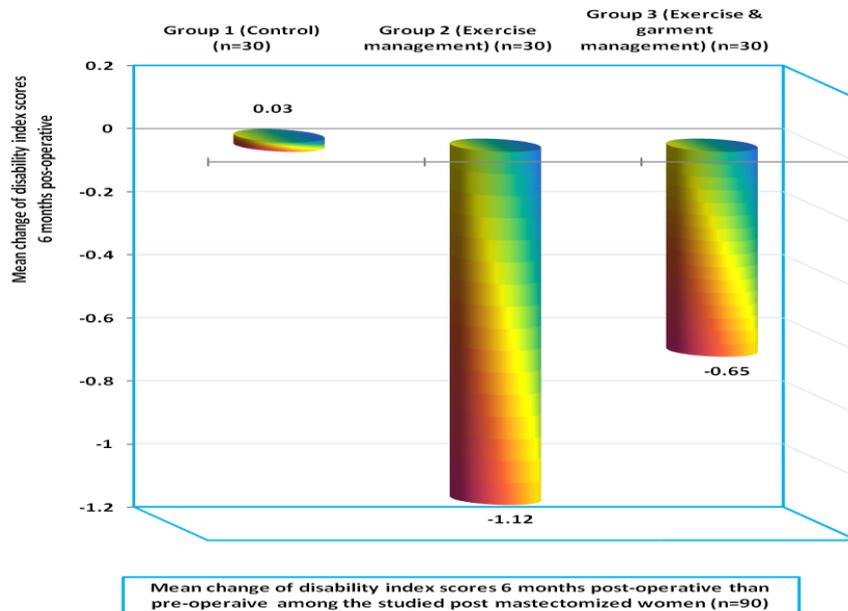


Table (2): Levels of the total scores of shoulder flexibility pre and post- protocol of care of women after mastectomy (n=90).

Levels of the total scores of shoulder flexibility pre and post- protocol of care	Mastectomized women (n=90)						χ^2 P
	Control group (Routine hospital care) (n=30)		Study group I (physical exercise management) (n=30)		Study group II (physical exercise & compression garment) (n=30)		
	n	%	n	%	n	%	
Preoperative:							
Good	19	63.3	22	73.3	22	73.3	13.143
Fair	5	16.7	8	26.7	8	26.7	0.011*
Poor	6	20.0	0	0	0	0	
Postoperative:							
1st week							
Good	2	6.7	5	16.7	2	6.7	3.195
Fair	22	73.3	22	73.3	24	80.0	0.526
Poor	6	20.0	3	10.0	4	13.3	
1st month							
Good	11	36.7	14	46.7	12	40.0	5.363
Fair	13	43.3	15	50.0	16	53.3	0.252
Poor	6	20.0	1	3.3	2	6.7	
3rd month							
Good	12	40.0	24	80.0	19	63.3	16.564
Fair	13	43.3	6	20.0	11	36.7	0.002*
Poor	5	16.7	0	0	0	0	
6th month							
Good	14	46.7	25	83.3	22	73.3	12.950
Fair	13	43.3	5	16.7	8	26.7	0.012*
Poor	3	10.0	0	0	0	0	
χ^2	25.484		43.438		42.859		
P	0.001*		0.0001*		0.0001*		

Table (3): Levels of total scores of Average Adult Grip Strength in Kilograms pre and post- protocol of care of women after mastectomy (n=90).

Levels of total scores of Average Adult Grip Strength in Kilograms (Kg) pre and post-protocol of care	Women after mastectomy (n=90)						χ^2 P
	Control group (Routine hospital care) (n=30)		Study group I (physical exercise management) (n=30)		Study group II (physical exercise & compression garment) (n=30)		
Pre-operative							
Excellent	2	6.7	1	3.3	1	3.3	24.585
Good	2	6.7	0	0	2	6.7	0.002*
Average	6	20.0	12	40.0	16	53.3	
Below average	6	20.0	15	50.0	7	23.3	
Poor	14	46.7	2	6.7	4	13.3	
Postoperative:							
1st week							
Excellent	0	0	0	0	0	0	23.586
Good	3	10.0	0	0	0	0	0.001*
Average	3	10.0	13	43.3	17	56.7	
Below average	14	46.7	15	50.0	9	30.0	
Poor	10	33.3	2	6.7	4	13.3	
1st month							
Excellent	0	0	3	10.0	3	10.0	27.560
Good	3	10.0	9	30.0	8	26.7	0.001*
Average	4	13.3	12	40.0	12	40.0	
Below average	16	53.3	6	20.0	5	16.7	
Poor	7	23.3	0	0	2	6.7	
3rd month:							
Excellent	0	0	7	23.3	6	20.0	31.354
Good	2	6.7	9	30.0	10	33.3	0.0001*
Average	7	23.3	11	36.7	7	23.3	
Below average	14	46.7	3	10.0	5	16.7	
Poor	7	23.3	0	0	2	6.7	
6th month							
Excellent	0	0	10	33.3	8	26.7	36.400
Good	5	16.7	12	40.0	13	43.3	0.0001*
Average	5	16.7	7	23.3	3	10.0	
Below average	13	43.3	1	3.3	4	13.3	
Poor	7	23.3	0	0	2	6.7	
χ^2	20.921		67.857		47.906		
P	0.182		0.0001*		0.0001*		

*Significant (P<0.05)

Table (4): Upper limb lymph edema physical finding pre and post- protocol of care of women after mastectomy (n=90)

Upper limb lymph edema observational physical finding pre and post- protocol of care	Women after mastectomy (n=90)								χ^2 P
	Control group (Routine hospital care) (n=30)		Study group I (physical exercise management) (n=30)		Study group II (physical exercise & compression garment) (n=30)		Total (n=90)		
	n	%	n	%	n	%	n	%	
•Swelling of the breast and chest place	11	36.7	2	6.7	1	3.3	14	15.5	15.390 0.0004*
•Swelling of the shoulder, arm, or hand	0	0	0	0	0	0	0	0	0
•Feeling of heaviness in the body or some parts of the body	5	16.7	3	10.0	1	3.3	9	10.0	2.960 0.227
•Changing the skin feel	4	13.3	0	0	0	0	4	4.4	0.370 0.015*
•Redness of the skin and tighten	2	6.7	1	3.3	0	0	3	3.3	2.070 0.355
•Pain and tingling in the injured arm	7	23.3	4	13.3	1	3.3	12	13.3	5.190 0.074
•Lack of close to where the process of joint movement, such as the shoulder joint	1	3.3	0	0	0	0	1	1.1	2.020 0.364
•Lack of detailed hand and	1	3.3	0	0	0	0	1	1.1	2.020

wrist flexibility									0.364
•Tight clothing and sleeves of injured arm	0	0	0	0	1	3.3	1	1.1	2.020
									0.364
•Tight bra	0	0	0	0	0	0	0	0	0
•Narrow rings, bracelets and watch in the injured arm	2	6.7	2	6.7	2	6.7	6	6.7	0.000
									1.000

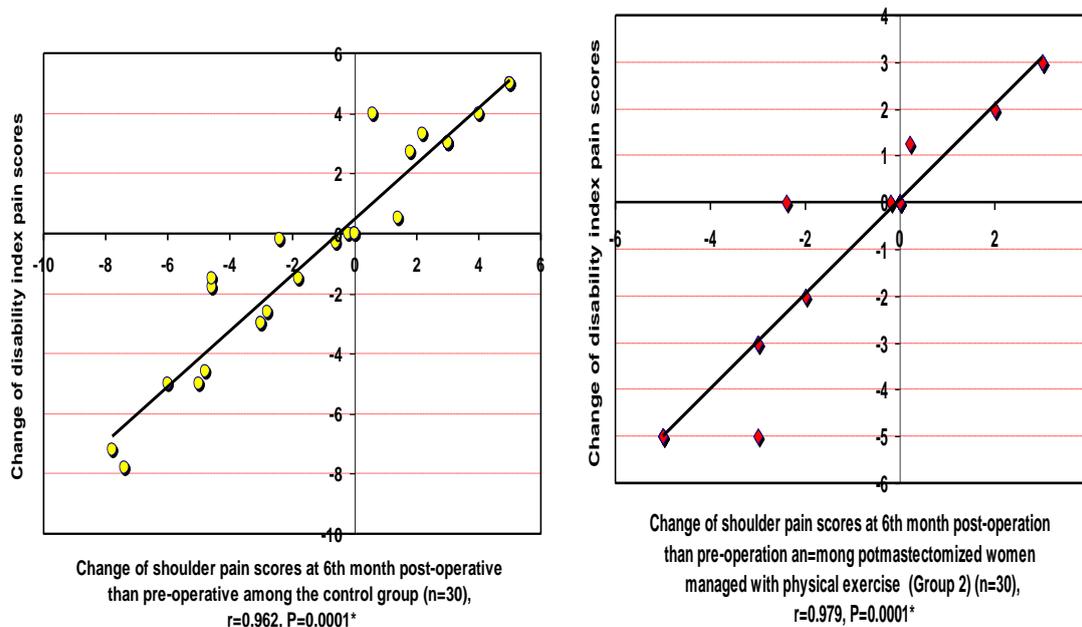
*Significant (P<0.05)

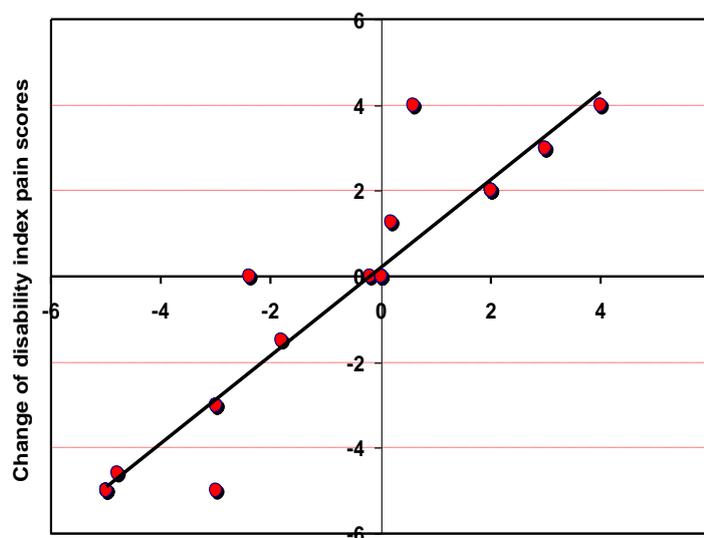
Table (5): Correlation between body mass index (BMI) of women after mastectomy and their circumferential measurements of upper extremity of the affected arm at the sixth month post-protocol of care than pre- protocol of care (n=90).

Values of upper extremity circumferential measurements at the sixth month post-protocol of care than pre- protocol of care	Correlation between the 3 groups of women regarding body mass index (BMI) (n=90).		
	Control group (Routine hospital care) (n=30)	Study group I (physical exercise management) (n=30)	Study group II (physical exercise & compression garment) (n=30)
	r P	r P	r P
•Fingers	0.151 0.427	0.197 0.296	0.280 0.134
•Wrist	0.423 0.020*	0.086 0.650	0.198 0.295
•10 cm below wrist	0.422 0.020*	0.353 0.056	0.443 0.014*
•15 cm below wrist	0.587 0.001*	0.332 0.073	0.322 0.082
•20 cm below wrist	0.552 0.002*	0.184 0.331	0.216 0.251
• elbow	0.464 0.010*	0.026 0.991	0.033 0.862
•10 cm above elbow	0.576 0.001*	0.002 0.991	0.096 0.614
•15 cm above elbow	0.542 0.002*	0.006 0.974	0.095 0.616
•20 cm above elbow	0.455 0.012*	0.048 0.803	0.218 0.246

*Significant (P<0.05)

Figure (3): Correlation between change of shoulder pain and shoulder disability scores of women at sixth month post-protocol of care than pre- protocol of care (n=90).





Change of shoulder pain scores 6th month post-operative than pre-operative among potmastectomized women managed with physical exercise and garment (group 3) (n=30), r=953, P=0.0001*

IV. Discussion

Modified radical mastectomy is a type of mastectomy and is the most widely used surgical procedure to treat operable breast cancer. It combines the removal of all breast tissue from the affected breast with lymph node removal from the armpit on the affected side of the body. It results in physical and psychological problems. It often involves a deterioration of postoperative function; decreased shoulder and arm mobility, strength, pain, decreased range of motion, and muscle weakness⁽²⁸⁻³⁰⁾.

Regarding to biosocio-demographic data, the finding of the present study revealed that the majority of women in the control group and the study group (I&II) ranged in the age between 40-60 years. This finding is justified by longer life expectancy, as well as increases in breast cancer incidence of women over 40 years due to changes in reproductive patterns, menopausal hormone use, the rising prevalence of obesity and genetic damage (mutations) in the body at this age⁽³¹⁾.

This finding was in agreement with **Shabaan (2013)**⁽⁶⁾ in a study carried out about "Effect of educational program regarding therapeutic exercises for women undergoing mastectomy", who mentioned that the majority of studied samples ranged in age between 40-55 years. Also, this finding was in line with **Hussien (2007)**⁽³²⁾ in a study entitled about "Nurse's Role in Early Detection of Breast Cancer through mammography and genetic screening and its impact on patients Outcomes" and found that the highest percentage of the studied women were above 40 years.

In relation to the marital status, the present study showed that the majority of women in the control group and the study group (I&II) were married. This result was similar with **Pakseresht et.al (2009)**⁽³³⁾ in a study conducted about "Risk Factors with Breast Cancer among women in Delhi", who found that the majority of the women in both groups were married. Also, the current results reported that the majority of women undergoing modified radical mastectomy have from 1 to 3 children. This finding contradicted with **Mahdy and Ali (2012)**⁽³⁴⁾, in a study investigating; "Effect of Pre-discharge Guidelines on Women's Knowledge and Self-Care Practices Regarding Arm Lymphedema Prevention Post mastectomy", who found that more than two thirds of participated women were having more than 3 children.

Considering the incidence of menopause, this study reveals that the majority of the control group were post menopause while more than half of the study group I and II have a regular menstrual period. This may be interpreted that about half of the study group aged less than 50 years while more than half in the control group were aged more than 50 years. This finding was accepted with **Parvee et.al (2007)**⁽³⁵⁾ in a study carried out for "Prognostic factors in stage-I breast cancer" who found that less than a third of women were premenopausal.

Moreover, in the current study more than half of the control group and about half of the study group were living in rural areas. This finding was supported with **Sim et.al (2006)**⁽³⁶⁾, in a study carried out about "Ethnic differences in the time trend of female breast cancer incidence", who reported that women with breast cancer came from rural areas. This finding of the present study contradicted with **Pakseresht et.al (2009)**⁽³³⁾,

who stated that a large number of breast cancer patients were living in urban areas.

Also, the current study showed that more than half of the control group were illiterate while one third of the study groups have a moderate level of education. This is congruent with **Abd El-Razik (2010)**⁽³⁷⁾, in a study carried out about “The Effect of Educational Program on Quality of Life for Patients with Cancer Undergoing Chemotherapy”, who reported that the highest percentage of the studied groups were illiterate. This is supported with **Ali (2010)**⁽³⁸⁾, in a study carried out about “Informational needs and concerns among women with breast cancer after surgery”, who found that more than one quarter of the study sample were illiterate.

This finding contradicted with **Beiki et.al (2012)**⁽³⁹⁾, in a study conducted about “Breast cancer incidence and case fatality among 4.7 million women in relation to social and ethnic background”, who revealed that women with the highest educational level had a significantly higher incidence of breast cancer compared to those with lower education.

Regarding to levels of the total knowledge about exercises and preventive care measures of lymph edema of mastectomized women pre and post- protocol of care, the finding of the present study revealed that more than half of the study group I have a poor knowledge pre protocol of care compared to no one post protocol of care. Also, this current study found that only minority of the study groups I and II have knowledge about exercises and preventive care measures of lymph edema of mastectomized women pre and post- protocol of care compared to about half of the study groups I and II post protocol of care who gain and have a good level of knowledge, so this study showed that there was a significant difference between the study groups I and II pre and post- protocol of care.

This goes in the same line with **Paskett and Stark (2000)**⁽⁴⁰⁾ who pointed out, in the study entitled “Lymph edema: Knowledge, Treatment, and Impact among Breast Cancer Survivors.”, that overall women knew little or nothing about lymph edema before they developed it. Additionally this finding similarly with **Fu et.al (2010)**⁽⁴¹⁾ who found, in the study entitled “The Effect of Providing Information about Lymph edema on the Cognitive and Symptom Outcomes of Breast Cancer Survivors”, that patients who received information reported significantly a higher score in the knowledge test.

Regarding to degrees of the shoulder pain pre and post- protocol of care of mastectomized women who had primary breast cancer, the current study reported that the majority of women in the control group and the study groups (I&II) had a mild pain in the 1st week postoperatively but the minority of the control group had a severe pain compared to none of the study groups (I&II) in the 3rd month postoperatively. In addition, the current study represented that one quarter of the control group had no pain in the 6th month postoperatively compared to more than half of both the study groups (I&II) in the same period. There is a significant difference between the control group and the study group (I&II) in relation to pain in the postoperative 6th month.

This result accepted with **Mahdy (2014)**⁽⁴²⁾, who reported that both study groups had less pain at the last measurement period (1st postoperative year) than the first postoperative period of measurement (1st week). It is thought that the study group of patients had a lower score of pain at the last period than the control group.

With regard to the preoperative shoulder disability among the control group and the study groups (I&II) this result found that the majority of women in the control group and the study groups (I&II) had no shoulder disability preoperatively. Also, this result represented that more than half of the study groups (I&II) had a moderate shoulder disability in the 1st week postoperatively but minimal improvement was observed in the study group (I&II) in which more than half of them had mild shoulder disability in the 1st month postoperatively. Finally this result presented that a minority of the control group had a severe shoulder disability in the 6th month postoperatively compared to none of both the study groups (I&II) in the same period of time.

From the same result, it can be also concluded that; there was no statistical significant differences between the three groups regarding shoulder disability scores in the 1st week, 1st, 3rd, or 6th months. This result was in respect with **Cinar et.al (2008)**⁽⁴³⁾, who found that recovery of functional capacity of shoulder in the treatment group is better throughout the follow up period (after 6 months). Also this result accepted with **Fung et.al (2011)**⁽⁴⁴⁾ in the result of the study entitled “Efficacy of modified 3 phases exercise program for patient following breast cancer surgery”, who concluded that physiotherapy program was proved to be safe and effective in improving shoulder function without major complications.

Regarding changes of shoulder flexibility the current study proved that in the 1st week postoperatively, only a small proportion of the control group and the study groups (I&II) have good total scores of shoulder flexibility scale while majority of them have fair total scores of shoulder flexibility scale but in the 3rd month post operatively, majority of the study group I compared to more than half of the study group II have good total scores of shoulder flexibility scale. Finally, at the 6th month post operatively the results demonstrated that majority of the study groups (I&II) have good total scores of shoulder flexibility scale compared to less than half of the control group who have good total scores. A significant Statistical difference was found among the

three groups in the 3rd and 6th months postoperatively and within the same group in different times of follow up.

This result was similar to **Bendz & Olse (2002)** ⁽⁴⁵⁾ in their result entitled “Evaluation of immediate versus delayed shoulder exercises after breast cancer surgery including lymph node dissection” ,which concluded from their study that in both a short term as well as a long term, early onset of exercises is valuable in avoiding deterioration in a range of shoulder motion. This result was also corresponding with **Park et .al (2006)** ⁽⁴⁶⁾ in the result entitled “The effects of a rehabilitation program on physical health, physiological indicator and quality of life in breast cancer mastectomy patients” , which revealed a significant increase in flexion, internal rotation and external rotation of shoulder in the study group compared to the control group. This result contradicted with **HASSAN et.al (2015)** ⁽⁴⁷⁾ in their result entitled “Kinesio Tape Versus Compression Garment on Post Mastectomy Lymphedema” ,which concluded from their study that a significant improvement of shoulder range of motion in Kinesio Tape group more than Compression Garment group on Post operative Mastectomy Lymphedema.

Regarding the changes of grip strength post- protocol of care than pre protocol of care, the present study revealed that, in the 1st week post operatively, a tenth of the control group have good scores of adult grip strength compared to none of both the study groups (I&II) but in the 6th month postoperatively, the improvement was observed in the study groups (I&II) than the control group in which about half of the study groups (I&II) have good scores of adult grip strength compared to a small proportion of the control group. Also ,the result showed that there was a significance difference between the control group and the study groups (I&II) in relation to the total scores of adult grip strength pre, the 1st week, 1st, 3rd and 6th months postoperatively. In addition, there was a significant difference between the same study groups (I&II) during the entire period of follow up.

This result is in line with **Cho (2004)** ⁽⁴⁸⁾ ,in his result entitled “Effects of a comprehensive rehabilitation program for mastectomy patients” ,who revealed a significant increase in hand grip strength of operated side compared to the control group. This result is in contrast with **Beurskens et.al (2007)** ⁽⁴⁹⁾ , who conducted a study in order to investigate “The efficacy of physiotherapy treatment of shoulder function, pain and quality of life in patients who have undergone breast cancer surgery and axillary lymph node dissection” , which declared that there was no significant improvement in handgrip strength between groups .

According to the upper limb lymph edema physical finding pre and post- protocol of care, the result presented that one third of the control group have a sign of lymph edema as swelling of the breast and chest area, pain and tingling in the injured arm, a feeling of heaviness in the body or some parts of the body and have changes in the skin texture compared to a tenth in the study group I and less than a fifth in the study group II.

This result is in line with Sandra et.al (2008) ⁽⁵⁰⁾ , in a study carried out about “Lymph edema in Breast Cancer Survivors: Incidence, Degree, Time Course, Treatment, and Symptoms” , who mentioned that one third of the sample have pain and Skin felt tired/thick/heavy while one quarter of the sample have too tight Jewelry compared to a small proportion of the sample have too tight clothing and skin felt different. Also, this result is in accordance with **Chung et.al (2011)** ⁽⁵¹⁾ , in a study carried out about “lymph edema, upper limb morbidity, and self management in women after breast cancer treatment” , who stated that one third or more of the women complained of pain in the upper arm, armpit, and shoulder.

Regarding correlation between body mass index (BMI) of women who had mastectomy and their circumferential measurements of upper extremity of the affected arm at the sixth month post-protocol of care than pre- protocol of care this result showed that there was a significant positive correlation between body mass index and circumferential measurements of upper extremity in the control group and the study group II. This result is in agreement with **Pinto et.al (2013)** ⁽⁵²⁾ , who conducted a study in order to “investigate upper limb disability and perceived Health Related Quality of Life (HRQOL) ” that found in a group of women with breast cancer related lymphedema (BCRL), compared with a group without lymph edema and clarified that women with BMI ≥ 30 , the presence of co morbidities and radical mastectomy had an influence on the extent of the functional limitation, linked to the presence of the lymphedema.

As well, the current result was supported by Vignes et al. (2007) ⁽⁵³⁾ , in a study carried out about “Long-term management of breast cancer-related lymphedema after intensive decongestive physiotherapy” , which stated that body mass index was found to be significantly higher in the women with lymphedema than those without. Twenty one of the 31 women who had a BMI over 30, and thus would be considered to be “obese” , were in the lymphedema group.

V. Conclusions

Based on the findings of the present study, it can be concluded that early post mastectomy protocol of care is more effective on improving upper limb function and prevention of lymph edema after mastectomy in the study groups than the control group. Also the findings concluded the importance of using compression garment in the prevention of lymph edema post mastectomy in study group II than study group I. Moreover, the findings concluded that the educational program regarding therapeutic exercises and preventive measures have a significant positive impact on women's information and practice regarding decreasing of shoulder pain, stiffness and prevention of lymph edema in the study groups post program than preprogram.

1-Recommendation for patients

- All women who had mastectomy must perform early postoperative exercises and complying with them for at least 6 months after mastectomy.
- All women who had mastectomy must wear compression garment as a prevention from lymph edema after mastectomy.

2- Recommendation for nurse

- Nursing staff must focusing on early assessment of women who had mastectomy and prompt detection of arm lymph edema post mastectomy.
- Protocol of nursing care for upper limb exercise to exhibit less shoulder pain and display greater shoulder range of motion and prevention of lymph edema post mastectomy.
- Planned pre discharge education should be prepared and given to women who had mastectomy as well as systemic education during the period of follow up.
- Provide compression garment to each women after modified radical mastectomy for prevention of lymph edema.
- -Conducting of comprehensive health educational programs for women following breast cancer to maintain good adherence to self- care practices for arm lymph edema prevention.

4-Recommendations for further research studies:-

- Further studies are needed to increase follow up period post mastectomy.
- The study should be replicated on large sample and different hospitals setting in order to generalize the results.
- Assessment of problems faced oncology nurse and their effect on her performance and satisfaction.
- Development of written copy of the interventions and distribution to involved hospital related oncology for application and demonstration.

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