Negative Pressure versus Intermittent Pneumatic Compression on lymphedema Post Mastectomy

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ABSTRACT

Background and Objective: Postoperative lymphedema post mastectomy is a secondary lymphedema that alters lymph drainage of the breast. Its signs and symptoms include increased weight and size of the limb. **Materials and Methods:** Thirty female patients suffering from unilateral upper limb lymphedema post mastectomy. Their ages were ranged from 40 to 60 years. The patients were randomly divided into two equal groups: Group (A)composed of 15 female patients who received negative pressure therapy for 30min in addition to their physical therapy program (elevation and active range of motion exercises), hygiene and skin care. Group (B)composed of 15 female patients who received intermittent pneumatic compression for 30min in addition to their physical therapy program (elevation and active range of motionexercises), hygiene and skin care. Methods of evaluation werecircumference measurement and volumetric measurement.The study conducted six months from July 2019 to December 2019. **Results:** There was a decrease in limb volume and limb circumference post treatment in both groups compared with that pretreatment. There was a significant decrease in limb volume of the group B compared with that of the group A. **Conclusion:** There was a difference between before and after treatment between both groups, but treatment with intermittent pneumatic compression device is effective in reducing limb volume and limb circumference compared with negative pressure therapy so that intermittent pneumatic compression can be considered more effective in reducing lymphedema post mastectomy

Significant statement: This study confirmed that intermittent pneumatic compression is more effective in treatment upper limb lymphedema postmastectomy. The study providing physiotherapist with the effective techniques used for treatment of lymphedema inpost mastectomy breast cancer patients.

Key words: Intermittent pneumatic compression-Lymphedema-Mastectomy-Negative pressure therapy.

INTRODUCTION

Lymphedema is the buildup of tissue-rich protein fluid.The impaired function of lymph vessels interrupts the drainage of the lymphatic system, which is like the arterial and venous structures, a part of the circulatory system. Lymph vessels remove excess fluid from the tissues and return it to circulation.Additionally, immune cell maturation occurs in the lymphatic system; hence, it represents one of the most critical defense mechanisms in the entire body. The capillaries of the lymph are in the dermis, formed like a cobweb, then drained into the subcutaneous plane's lymphatic vessels and eventually into the deeper structure and thoracic duct.Lymphedema may be primary or secondary. Whatever the etiology, it is clinically characterized by chronic swelling, intermittent discomfort, atrophic changes in the skin and secondary infection 1.

Lymphedema involves chronic inflammation of the tissue with tissue changes including accumulation of ex tracellular free fluid, tissue fibrosis an d deposition of fatty tissue2.

Because of lymphedema, arm volume will increase by 44 %, with excess fluid mostly in the subcutaneous tissue 3.

Breast cancer Related lymphedema is detected in 7-77% of patients undergoing axillary lymph node dissection (ALND) due to lymph vessel transection as shown in selected studies4.

Positive modalities of pressure include any treatment that exerts a pushing force on the tissues whereby external tissue pressure exceeds internal tissue pressure. Examples of positive pressure technology include compression bandaging, pressure coatings and pneumatic compression devices, studies have shown that this mechanically results in lower lymphatic load due to reduced edema formation following compression of the blood vessels causing lower venous pressure5.

MATERIALS AND METHODS

Study design:

Pretest – Posttest experimental study.

***Participants*:**Thirty female patients who had undergone modified radical mastectomy involving axillary lymph nodes, and had lymphedema of an

upper extremity as a result. Their ages will be ranged from 40 to 60 years. The participants were selected from Out Patient clinic of Faculty of Physical Therapy and National Cancer Institute, Cairo University.The study conducted six months from July 2019 to December 2019.The patients were randomly assigned into two equal groups(Group A) This group included 15 female patients who received negative pressure therapy for 30min in addition to their physical therapy program (elevation and active range of motionexercises), hygiene and skin care. (Group B) This group included15 female patients who received intermittent pneumatic compression for 30min in addition to their physical therapy program (elevation and active range of motionexercises), hygiene and skin care.

Criteria for the patient selection:

Inclusion Criteria:

The subject selection will be according to the following criteria:

- Female patient their age range between 40-60 years
- Lymphedema of one upper extremity following mastectomy
- No neoplastic disease diagnosed previously, and the breast
- Cancer must not have spread to other tissues
- Difference of 200 mL in size between arms.
- All patients enrolled to the study will have their informed consent.

Exclusion Criteria:

The potential participants will be excluded if they meet one of the following criteria:

- Cardiac diseases.

- Patient with deepvenous thrombosis.
- Other diseases that cause significant swelling.
- Pregnancy.
- Cellulitis.

I. Measurement procedures:

All patients in this study were subjected to the following:

- **Full history taking and complete clinical examination:**
- **For measurement of limb Volume** we used water displacement method which based on quantum of water overflowing from fully filled container when measured limb is inserted[6].

The container is emptied at the beginning of the measurement and the tube is filled with water, as water starts floating through the spillway. We wait for the spilled water to drop away completely. The measured limb is then inserted into the tube up to the indicated edge of region of interest or drowns entirely. We wait as long as the spilled water drops away completely. The amount of spilled water in grams is the volume value in milliliters [7].

- **For measurement of limb circumference** we used Tape measurement,

The method for measurement of lymphedema as the subject in sitting position with forearm pronated and the lymphedema was measured at3 levels,5cm below elbow, elbow and 5cm above elbow[8].

Fig.1: Measuring 0f U.L circumference

II. Treatment procedures :

Group (A) Negative pressure therapy

The level of negative pressure can be accurately quantified at the tissue interface from 20-250 mmHg applied for 30min in addition to their physical therapy program which included elevation and active range of motionexercises[9]as shown in Fig1.

Fig.2:Negative pressure application

Group B: Intermittent pneumatic compression therapy:

Segmented IPC's are fitted with several pneumatic pump outflow ports that inflate sequentially from the lower extremity to the upper extremity until all segments are inflated. After this phase, all compartments deflate simultaneously with pressure from 25 to 50 mmHg mmHg applied for 30min in addition to their physical therapy program which included elevation and active exercise range[10]as shown in Fig2.

Fig. 3: Intermittent compression application

Physical therapy program for both groups:

All patients were advised to perform daily limb exercises (active range of

motion and elevation), hygiene and skin care

Active range of motion:

Active range of motion (AROM) is a movement of a segment within the unrestricted range of motion that is produced by active contraction of the muscles crossing that joint.

Hygiene and skin care: Advice the patients to:

- Avoid sun beds, steam rooms, and saunas.
- Avoid taking very hot baths or showers.
- Avoid wearing tight-fitting clothes.
- Avoid wearing tight-fitting jewelry.
- Look for changes or breaks in the skin.
- Keep skin supple by moisturizing it every day.
- Keep nails short.[11]

Data Analysis:

- Statistical package for social studies (SPSS) 25 version for windows (IBM SPSS, Chicago, IL, USA) was used. (*P*- value, mean, unpaired t-test, standard deviation, t-value and mean difference)

RESULTS

The purpose of this study was to investigate the effect of negative pressure versus intermittent pneumatic compression on lymphedema post mastectomy.

Data obtained from both groups before initiation of treatment (Pretreatment) and after eight weeks of treatment (post treatment) regarding limb size and limb volume and were statistically analyzed and compared with level of significance for all tests was set as ($p \leq 0.05$).

The analysis of data revealed the following findings:

- Subjects demographic data:

There was no significance difference between both groups in the mean age values (p = 0.22).(table1,figure 4)

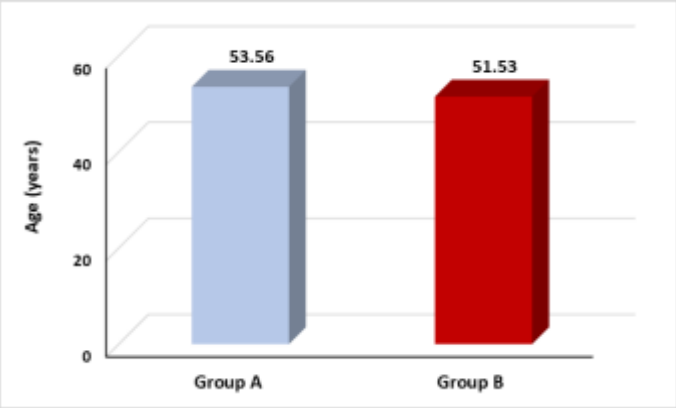

Figure (4). Mean age of the group A and B.

Table1:Descriptive statistics and t test for the mean age of the group A and B.

Age (years)	**Group A**	**Group B**
$\bar{x}$**± SD**	53.56 ± 3.83	51.53 ± 5.01
Maximum	60	60
Minimum	48	44
MD	2.03	
t-value	1.24	
p-value	0.22	
Significance	**NS**	

$\bar{X}$: Mean
SD: Standard deviation
MD: Mean difference
t value:Unpaired t value
p value: Probability value
NS: Non significant

I-Limb volume

Pretreatment mean values of limb volume of both groups (A and B):

- There was no significant difference in the limb volume between the group A and B pre treatment (p = 0.24). (Table 2, figure 5.

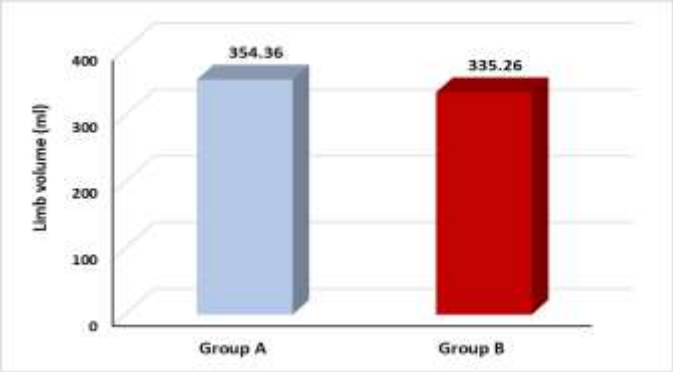

Figure (5). Pre treatment mean values of limb volume of group A and B.

Table2. Comparison of pretreatment mean values of limb volume between group A and B.

	Limb volume (ml)	**MD**	**t- value**	**p-value**	**Sig**
	$\overline{X}$ **± SD**				
Group A	354.36 ± 38.74	19.1	1.19	0.24	**NS**
Group B	335.26 ± 48.47				

$\overline{X}$: Mean, SD: Standard deviation , MD: Mean difference NS: Non significant

t value: Unpaired t value *p* value: Probability value

Post treatment mean values of limb volume of both groups (A and B):

- There was a significant decrease in the limb volume of the group B compared with that of group A post treatment (p = 0.01). (Table 3, figure 6).

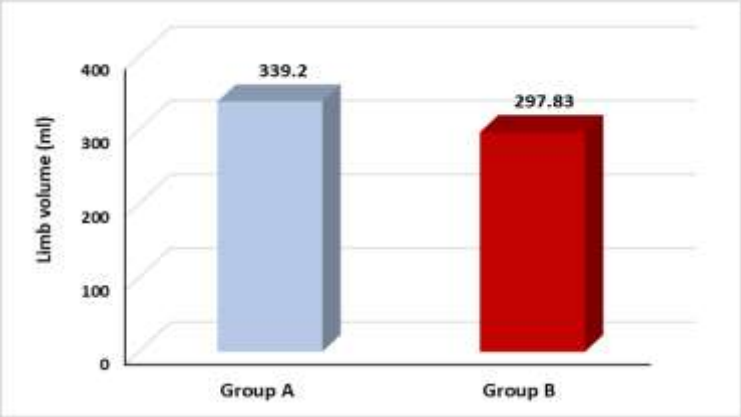

Figure 6. Post treatment mean values of limb volume of group A and B.

Table 3. ***Comparison of post treatment mean values of limb volume between group A and B.***

	Limb volume (ml)	**MD**	**t- value**	**p-value**	**Sig**
	$\overline{X}$ **± SD**				
Group A	339.2 ± 39.07	41.37	2.57	0.01	**S**
Group B	297.83 ± 48.55				

$\overline{X}$: Mean, MD: Mean difference, p value: Probability value , SD: Standard deviation

t value: Unpaired t value, NS: Non significant

II-Limb circumference

Pretreatment mean values of limb circumference of both groups (A and B):

Below elbow 5 cm

- There was no significant difference in the limb circumference at 5 cm below elbow between group A and B pre treatment (p = 0.47). (Table 4, figure 7).

At elbow level

- There was no significant difference in the limb circumference at elbow level between group A and B pre treatment (p = 0.42). (Table 4, figure 7).

Above elbow 5 cm

- There was no significant difference in the limb circumference at 5 cm above elbow between group A and B pre treatment (p = 0.79). (Table 4, figure 7).

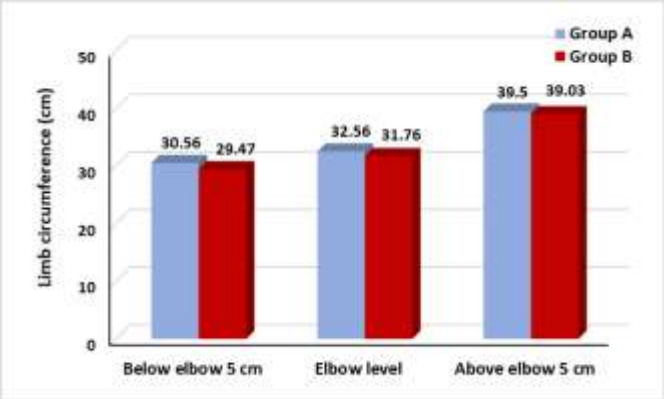

Figure (7). Pre treatment mean values of limb circumference of group A and B.

Table 4. Comparison of pre treatment mean values of limb circumference between group A and B:

Limb circumference (cm)	Group A	Group B	MD	t- value	p-value	Sig
	$\overline{X}$ ±SD	$\overline{X}$ ±SD				
Below elbow 5 cm	30.56 ± 3.45	29.47 ± 4.67	1.09	0.72	0.47	**NS**
Elbow level	32.56 ± 2.61	31.76 ± 2.77	0.8	0.81	0.42	**NS**
Above elbow 5 cm	39.5 ± 3.12	39.03 ± 6.1	0.47	0.26	0.79	**NS**

$\overline{X}$: Mean, MD: Mean difference, p value: Probability value , SD: Standard deviation

t value: Unpaired t value, NS: Non significant

Post treatment mean values of limb circumference of both groups (A and B):

Below elbow 5 cm

- There was no significant difference in the limb circumference at 5 cm below elbow between group A and B post treatment (p = 0.21). (Table 5, figure 8).

At elbow level

- There was no significant difference in the limb circumference at elbow level between group A and B post treatment (p = 0.09). (Table 5, figure 8).

Above elbow 5 cm

- There was no significant difference in the limb circumference at 5 cm above elbow between group A and B post treatment (p = 0.19). (Table 5, figure 8).

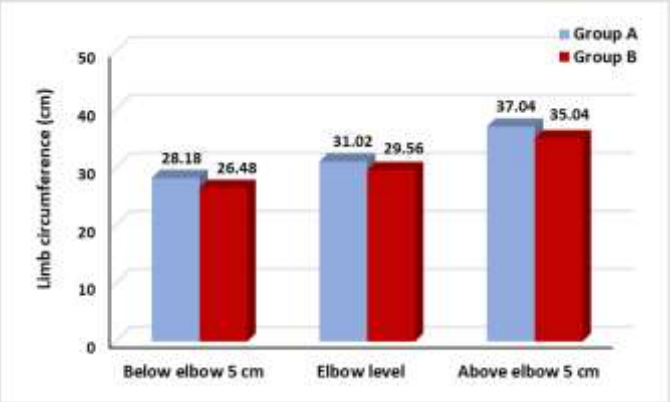

Figure (8). Post treatment mean values of limb circumference of group A and B.

Table 5. ***Comparison of post treatment mean values of limb circumference between group A and B:***

Limb circumference (cm)	Group A	Group B	MD	t- value	p-value	Sig
	$\overline{X}$ ±SD	$\overline{X}$ ±SD				
Below elbow 5 cm	28.18 ± 2.95	26.48 ± 4.19	1.7	1.28	0.21	**NS**
Elbow level	31.02 ± 1.84	29.56 ± 2.73	1.46	1.71	0.09	**NS**
Above elbow 5 cm	37.04 ± 3.07	35.04 ± 4.96	2	1.32	0.19	**NS**

$\overline{X}$: Mean, MD: Mean difference, p value: Probability value , SD: Standard deviation

t value: Unpaired t value, NS: Non significant

DISCUSSION

This study was designed to investigate the effect of negative pressure versus intermittent pneumatic compression on lymphedema post mastectomy by using circumference measurement and volumetric measurement as methods of evaluation.

Regarding the effects of Negative Pressure in group A

According to limb volume and circumference of lymphedema pre and post treatment in group A

There was a significant decrease in the limb volume in the group Apost treatment compared with that pretreatment (p = 0.0001)andthe percent of change was 4.28%,There was a significant decrease in the limb circumference at 5 cm below elbow post treatment compared with that pretreatment (p = 0.0001), at elbow level there was a significant decrease in the limb circumference post treatment compared with that pretreatment (p = 0.0001), at 5 cm above elbow there was a significant decrease in the limb circumference post treatment compared with that pretreatment (p = 0.0001).

There was few researches that support effect of Negative Pressure on lymphedema post mastectomy as:

The result of this study showed agreement Iivarinen et al., 20139study suggested that negative pressure therapy is a successful form of treatment for patients with lymphedema. The study showed that the approach of negative pressure brought about improvements in the parameters of length, MRI and tissue stiffness. Most of the observed changes can be taken as positive. Results of the study suggest that the negative pressure approach is more effective in treating edema than conventional manual lymphatic drainage therapy. This caused greater decreases in muscle tissue edematous volume (7 %) and tissue stiffness (9.2 %). It also resulted in greater improvement in the Quality of Life variable of patients (14 %).

Regarding the effects of intermittent pneumatic compression in group B

According to limb volume and circumference of lymphedema pre and post treatment in group B

There was a significant decrease in the limb volume in the group Bpost treatment compared with pre treatment (p = 0.0001) and the percent of change was 11.16%.

There was a significant decrease in the limb volume of the group B compared with that of group A post treatment (p = 0.01),there was a significant decrease in the limb circumference at 5 cm below elbow post treatment compared with that pretreatment (p = 0.0001), at elbow level there was a significant decrease in the limb circumference post treatment compared with that pre treatment (p = 0.0001), at 5 cm above elbow there was a significant decrease

in the limb circumference post treatment compared with that pre treatment ($p = 0.0001$)

This result agree with Ridner et al.,200812as they retrospectively studied home-based lymphedema treatment and reported changes in clinical use behaviours. Ninety-five per cent of the participants reported an outcome of positive limb volume perceived by themselves. Forty-two percent reported this result in agreement with self-perceived volume of limbs decreases just as much as 20%, and an additional 20% reported decreases of less than 20%. They found a statistically significant decrease in the use of MLD administered by clinicians from a rate of 60% MLD-usage before using a programmable IPC device to a 13% MLD-usage rate at follow-up. The application of compression bandages and the teaching of self-MLD also decreased.

Results showed similarity with Hammond.,200913 also reported that the use of a programmable IPC system to treat arm-breast cancer-related lymphedema was documented in five patients. After undergoing 2 months of in-clinical decongestive therapy, including in-home self-treatment with the IPC system, patients reported decreased arm swelling, softening of fibrotic tissue, reduction of pain, and increased mobility and flexibility.The patients reported improved compliance with their self-treatment program within the home.

Agreement also with Pilch et al .,200914 as They found that the extent of edema was reduced by IPC, with no significant differences between the type of IPC device used. They hypothesize that the IPC wave in sequential compression is centripetally directed, unlike MLD where lymphatic pressure is applied from proximal to distal parts of the extremity, but begins in the distal parts of the limb.If any mechanical block interferes with the outflow of the lymph, the pressure wave moves to the proximal extremity sections, unless the proximal lymph vessels are drained.

Also Pilch et al .,200914 state that another explanation, independent of the compression series, for a significant reduction in lymphedema may include the physiological mechanism of IPC. IPC functions as a "muscle pump" that encourages lymph flow to the lymphedema.Another explanation, independent of the compression series, for a significant reduction in lymphedema may include the physiological mechanism of IPC. IPC functions as a "muscle pump" that

encourages lymph flow to the lymphedema.

Study supported by Rashmi et al.,200715 who stated that 250 patients surer from upper limb lymphedema post mastectomy managed with IPC, manual lymph drainage alone and home program.the absolute volume of the affected arm and nonaffected arm was reduced by pvalue ($p<0.0001$) which mean that IPC combined with manual ltmph drainage and exercises were associated with reduction of lymphedema volume.

On the other hand, the results of this study contradict with:

Al-Reefy and Parsa Nezhad.,201416who reported that secondary arm lymphoedema occurs in post-breast cancer following negative pressure therapy session as a bruising and swelling has been identified as a common side effect of this procedure, cupping is not used to treat lymphoedema due to the risk of further injury.

Study also unsupported by Vanscheidt et al .,200917 study of compression therapy, two patients reported a 60 mmHg discomfort when treated with intermittent pneumatic compression but not 40 or 50 mmHg compression. One patient treated with sustained pneumatic compression had skin irritation, and at least once had three subjects reporting discomfort. It can be concluded that the IPC devices have little detrimental effect on patient safety under these controlled circumstances.

Finally, the results of this study revealed a significant decrease in limb volume and limb circumference post treatment in the group A and B compared with that pretreatment.There was a significant decrease in limb volume of the group B compared with that of the group A.

CONCLUSION

Intermittent pneumatic compression was more effective in reducing limb volume and limb circumference than negative pressurein case of upper limb lymphedema post mastectomy.

ACKNOWLEDGMENT

Authors express appreciation to all staff corporate in this study.

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