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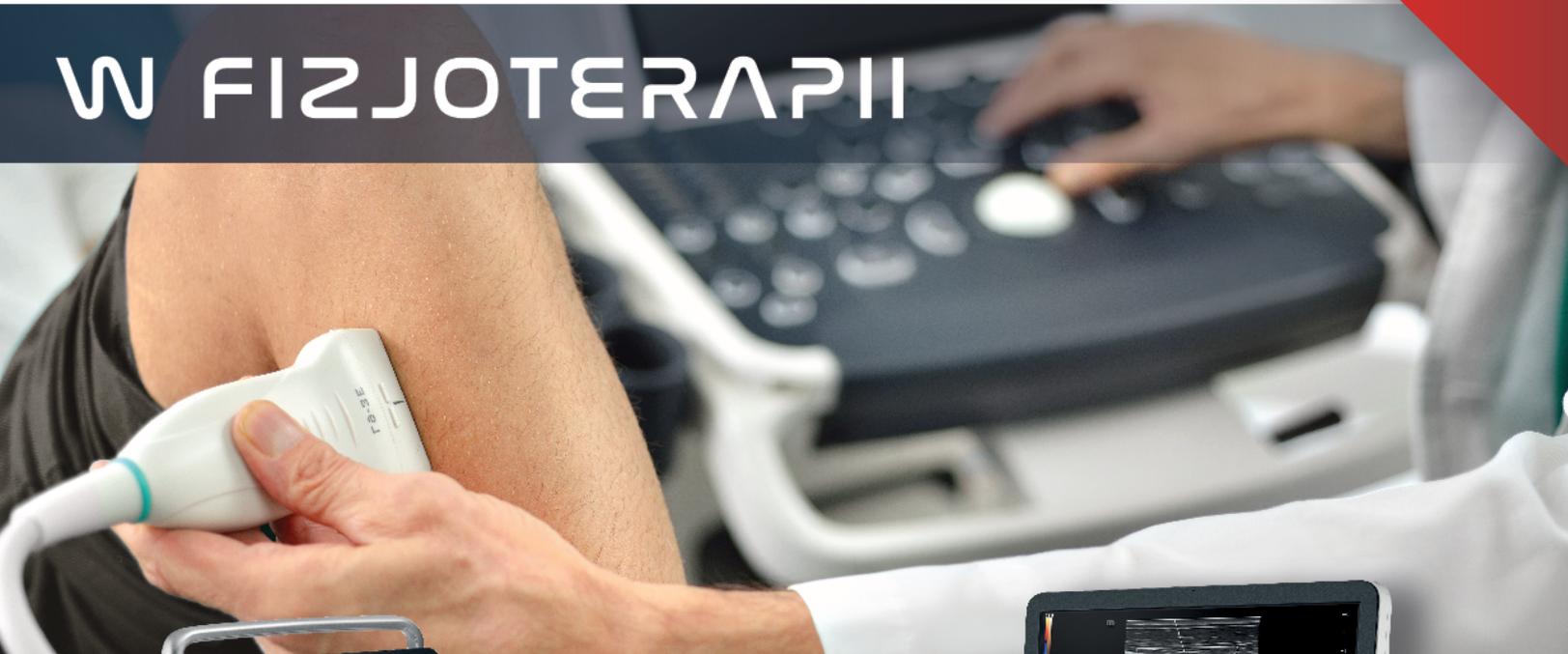
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Pełna oferta:



Effect of kinesiotaping combined with pneumatic compression on function activity in patients with post-mastectomy lymphedema: A Randomized controlled trial

Wpływ kinesiotapingu w połączeniu z kompresją pneumatyczną na aktywność czynnościową u pacjentek z obrzękiem limfatycznym po mastektomii: randomizowane badanie kontrolowane

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Abstract

Objective. This study was designed to investigate the effects of Kinesiotaping (KT) combined with intermittent pneumatic compression (IPC) Versus Multilayer bandage (MLB) on Postmastectomy lymphedema on limb volume and function. **Methods.** Forty-Five Female patients with postmastectomy lymphedema were divided randomly into three equal groups. Group "A" received complex decongestive physical therapy (CDP) added to KT combined with IPC, group "B" received CDP added to MLB, group "C" (control group) received CDP only, all groups received treatment three times/week for four weeks. Volumetric Measurement, Anthropometric Limb measure and Disability of Arm, Shoulder, and Hand (DASH) questionnaire for upper limb were used to evaluate subjects at three intervals (pre-treatment, post-treatment and After three months follow-up). **Results.** Statistical analysis showed that there was a significant improvement within-group pre-post treatment in Volumetric measure, Anthropometric Limb measure and DASH at groups A, B and C as ($p < 0.05$), groups A and B were superior to group C. After follow-up there was a significant deterioration in value of all variables in groups B and C as ($p < 0.05$), while there was no significant deterioration in group A. In between-group analysis there was no significant change in pre-treatment value of all variables as ($p > 0.05$), in post-treatment there was no significant change in all variables as ($p > 0.05$) but after follow-up there was a significant change. **Conclusion.** Both KT combined with IPC and MLB are effective methods in the management of subjects with postmastectomy lymphedema with superiority for KT combined with IPC as it has no significant changes after three months follow up.

Key words:

Postmastectomy Lymphedema, Kinesiotaping, Intermittent Pneumatic Compression, Multilayer Bandage

Streszczenie

Cel. Niniejsze badanie zostało zaprojektowane w celu zbadania wpływu kinesiotapingu (KT) w połączeniu z przerywaną kompresją pneumatyczną (IPC) w porównaniu ze stosowaniem bandaży wielowarstwowego (MLB) w przypadku wystąpienia obrzęku limfatycznego po mastektomii na objętość i funkcję kończyny. **Metody.** Czterdzieści pięć pacjentek z obrzękiem limfatycznym po mastektomii podzielono losowo na trzy równe grupy. Grupa „A” była poddawana złożonej fizjoterapii zmniejszającej przekrwienie (CDP) oraz KT w połączeniu z IPC, grupa „B” była poddawana CDP oraz MLB, grupa „C” (grupa kontrolna) była poddawana wyłącznie CDP; wszystkie grupy były poddawane leczeniu trzy razy w tygodniu przez cztery tygodnie. Pomiar objętościowy, pomiary antropometryczne kończyn oraz kwestionariusz DASH dla kończyny górnej zostały wykorzystane do oceny pacjentek w trzech odstępach czasu (przed leczeniem, po leczeniu i po trzech miesiącach obserwacji). **Wyniki.** Analiza statystyczna wykazała, że w grupach A, B i C wystąpiła znacząca poprawa po leczeniu w porównaniu do stanu przed leczeniem w zakresie pomiaru objętości, pomiaru antropometrycznego kończyny i DASH w grupach A, B i C ($p < 0,05$), grupy A i B miały lepsze wyniki od grupy C. Po okresie obserwacji nastąpiło istotne pogorszenie wartości wszystkich zmiennych w grupach B i C ($p < 0,05$), natomiast nie było istotnego pogorszenia w grupie A. W analizie międzygrupowej nie stwierdzono istotnej zmiany wartości wszystkich zmiennych przed leczeniem ($p > 0,05$), po leczeniu nie zaobserwowano istotnej zmiany zmiennych ($p > 0,05$), jednak po okresie obserwacji nastąpiła istotna zmiana. **Wniosek.** Zarówno KT w połączeniu z IPC, jak i MLB są skutecznymi metodami w leczeniu chorych z obrzękiem limfatycznym po mastektomii z przewagą KT w połączeniu z IPC; nie zaobserwowano istotnych zmian po trzech miesiącach obserwacji.

Słowa kluczowe

Obrzęk limfatyczny po mastektomii, kinesiotaping, przerywana kompresja pneumatyczna, bandaże wielowarstwowe

Introduction

Breast cancer is the communist cancer affecting females. One of its dangerous complications is Lymphedema which could continue over a lifetime [1]. Lymphedema is a disease that is persistent increasingly. It characterized by an irregular rise in tissue proteins, edema, chronic inflammation, and fibrosis. Multiple factors associated with lymphatic stagnation, such as invasion of the tumor lymph node, excision of the lymph node, radiotherapy, injury, and infection, are responsible [2]. Lymphedema alters subject's abilities to do his activities and it can impact his relationship quality and whole of his lifestyle and reflects clinical difficulties. Lymphatic-related complications involve pain, feelings of inconvenience and overweight, movement problems, physiological discomfort, chronic infections and loneliness all of which have an adverse effect on lifestyle quality of the subject [3].

Complex decongestive physiotherapy (CDP) is accepted as an international traditional technique for lymphedema management. These strategies involve Manual lymphatic drainage (MLD), compression, workout, and caring of the skin [1]. In the area of physical management of lymphedema, Intermittent Pneumatic Compression (IPC) is frequently recommended. The simplest concept of the IPC is that it depends on applying force to an edema to allow removal of its contents to the physiological drainage methods as much as possible: venous, lymphatic, interstitium [4].

A new option in the area of physiotherapy is kinesiotaping (KT) for lymph drainage. KT consists of cotton fibers 100% and heat sensitive glue made of acrylic. This methodology is still ongoing to improve for its division. Applying KT will have physiological effects such as, reducing discomfort, encouraging muscle mobility, preventing lymphatic fluid congestion or hemorrhages under the skin, and correcting joint misalignment. The taped area will form convolutions after applying KT to increase the gap between the skin and muscles. When the skin is lifted, blood and lymphatic fluid flow is facilitated [2].

Multilayer Bandaging (MLB) is gradient pressure with higher compression distally than proximal parts of the extremity. Applying more than one elastic martial layer over the other alter its flexible feature become more rigid because of layers contact. MLB can be helpful in controlling complications in the patients with complex medical conditions with lymphedema. Low stretch bandages pressure treatment is used to preserve MLD results. MLB performed during dense management period [5].

Previous Studies supports that there is no cure for post-mastectomy lymphedema and the goal of treatment is to decrease the excess volume as possible and maintain best function of the limb. Reviews by Feldman, et al [6] shows that there is a suitable position for the use IPC equipment as a successful alternative lymphedema treatment. Another studies as Hassan M. and Ismail S. [7] found Compression therapy improve level of edema rather than KT while KT more comfort and functional than compression therapy. There was lake of studies that combining methods of KT and IPC. So, this study conducted to combine KT with IPC to get most effective methods on upper limb volume and function.

Material and Method

Design of the study

A prospective, pre-test post-test, randomized controlled clinical trial to compare the effects of KT combined with IPC versus MLB on female patients with unilateral postmastectomy lymphedema. This study was conducted between December 2018 and August 2019. The research related to human use has been approved by the authors institutional review board at the Faculty of Physical Therapy, Cairo University with a reference number P.T.REC/012/001655. and registered at Pan African Clinical Trial Registry with identification number: PACTR201902658798814.

Participants

A convenient sample of Forty-five Female patients participated in this study with unilateral upper extremity post-mastectomy lymphedema (15 right side and 30 left side). Their age ranged 49-60 years old. Fifty-eight patients recruited through a flayer, from Bahya foundation for early detection of breast cancer, Giza, Egypt and National Cancer Institute (NCI), Cairo University, Egypt. They were screened and assessed before starting of study for their eligibility. Two male patients were excluded because study designed for only female patients, three patients refuse to be participated in this study. After assessment for eligibility for the remain (Fifty-three) participants eight patients of them were excluded because they had marked increase the limb size after control period of this study, as shown in Figure 1.

Inclusion criteria for this study were; all patients had Unilateral postmastectomy upper extremity lymphedema, they were stage II of lymphedema, all patients were selected from females only, and they were medically stable and do not suffer from any other diseases which might affect the trial results. While the exclusion criteria: Congestive heart failure, renal failure, taking anticoagulant drugs, marked increase in upper limb size by the end of four weeks of the control period, having surgery on arm, malignant lymphedema, infection in the arm, intolerable bandage, skin redness, and intense itching as a result of bandages, and lack of cooperation from the patient.

Randomization

Consenting participant were assigned randomly into, (group A) KT combined with IPC group, (group B) MLB group and (group C). A randomized table by SPSS software version 26, was the method used to implement randomization. Each participant had an identification number. These IDs were assigned by SPSS into three equal groups (n = 15). Every participant ID had written in an index card sequentially. A blinded, independent research assistant opened the sealed envelope and allocated participants into their groups Figure 1.

Outcome measures

All measurements were done pre, post treatment and after 3 months follow-up. Upper extremity size and function was assessed pre, post treatment and after 3 months of follow-up for each subject by using:

1. Volumetric measurement method which is accepted as golden standard as it reflects the changings on lymphedema better

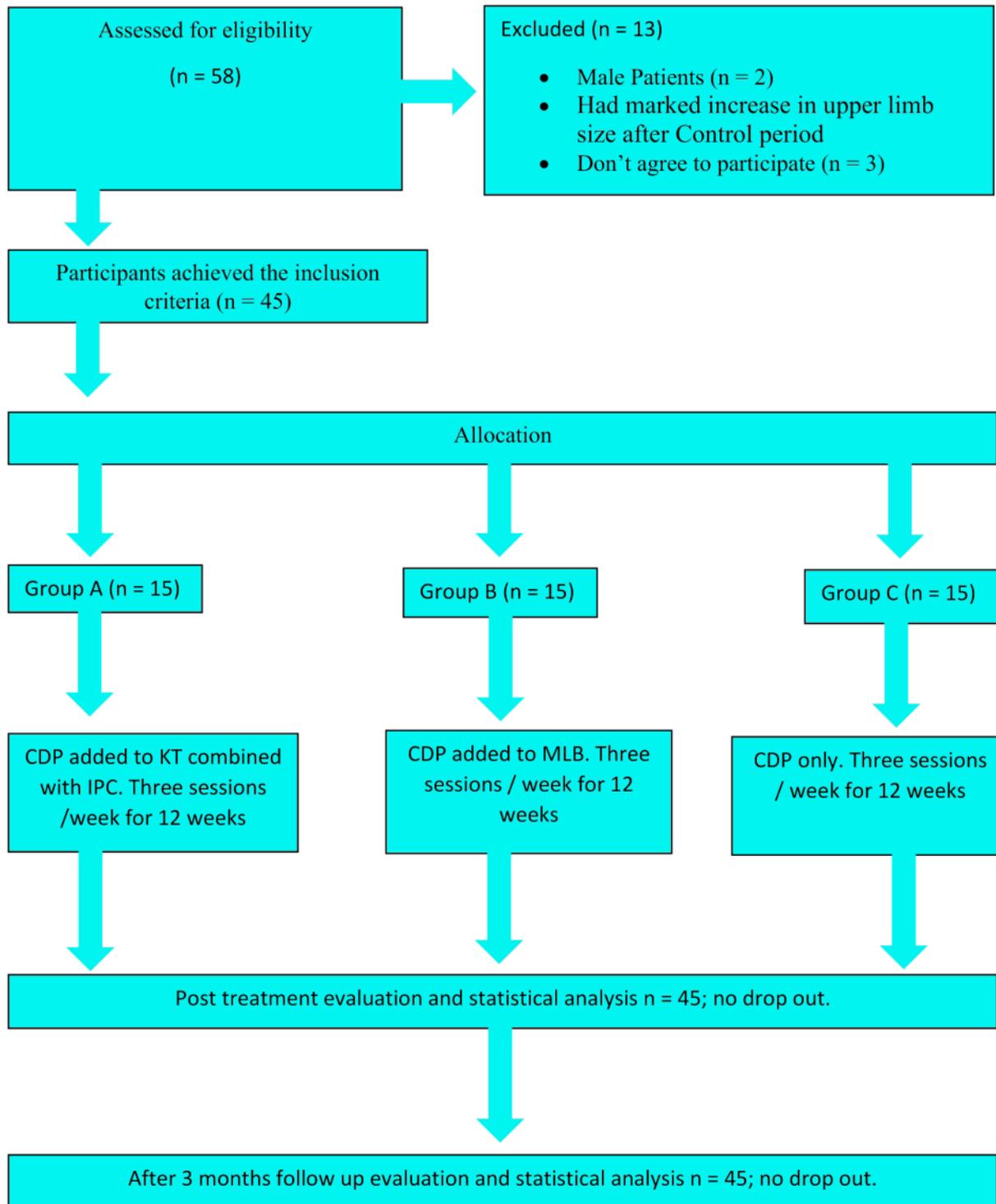


Figure 1. Flow chart of the study

than others as it shows if there is weight gaining or losing [9]. For the arm measurements, participants were instructed to lower the arm slowly into the volumeter until it came in contact with the axilla. The water flow from volumeter was measured using a graded tape [1].

2. Anthropometric limb volume measured by taking round measures of 6 points at landmarks on an arm (mid palm, wrist, 10 cm above the wrist point, elbow, 10 cm above elbow

and axilla), each segment volume calculated by truncated cone formula:

$$Vs = h \frac{(Ct^2 + Ct \times Cb + Cb^2)}{12\pi}$$

As Vs was volume of a segment, h was the distance between two points of a segment, Ct was the circumference at the top point and Cb was the circumference at the base of the segment. Sum of five segments of an arm to calculate its volume. This technique is valid in many studies [10].



Figure 2. Volumetric measure

3. Additionally, Disability of Arm, Shoulder and Hand (DASH) is a self-administered outcome measure that assesses disability in patients with various upper extremity conditions. It engages the patients in the evaluation process and considers the perceptions of their status. The DASH-Arabic is a reliable,

valid and responsive upper extremity outcome measure for patients whose primary language is Arabic; it can be used to document patient status and outcomes and support evidence-based practice [11].



Figure 3. Anthropometric limb volume

Intervention

The study was divided into three consecutive periods; (1) Control Period was 4 weeks, (2) Intervention Period was 4 weeks also and (3) followed by 3 months of follow up Maintenance period [8].

Control period: was four weeks patients were assessed pre and post this period with no intervention, the main aim of this period was to exclude patients with marked increase in upper limb size.

Intervention period: was four weeks, the participated patients were divided randomly into three groups as mentioned before.

1. (Group A) received CDP which includes (MLD technique and lymphatic exercises as (Abdominal Breathing Exercises, Pelvic Tilt, Partial Sit Up with Breathing, Neck Rotation, head tilt, shoulder shrug, shoulder rolls, shoulder blade squeeze, isometric hand press, elbow bend, wrist circles, fist clench and active finger movement)) in addition to KT (the tape is applied in a proximal-to-distal direction and positioning the body in where skin is stretched during application while the base and anchors are always rounded and unstretched when applying tape) combined with IPC (a four-chamber pneumatic sleeve and a pump set at 40 mm Hg pressure for 30 minutes was used) by 3 sessions per week for four weeks.

2. (Group B) received CDP as previous in addition to MLB technique (bandages wrapped just tight enough to stay in place without tug or stretch while wrapping. To prevent occur-

rence of pain, numbness, tingling or a cold feeling in hand or fingers) by 3 sessions per week for four weeks.

3. (Group C) control group received only CDP by 3 sessions per week for four weeks.

Maintenance period: was 3 months of follow-up, in this period of treatment all patients of the three groups finished their intervention sessions and received only lymphatic exercise and garment to maintain intervention results. Patients were reassessed by the end of this period.

Statistical Analyses

The obtained data were analyzed by the Statistical Package for the Social Sciences (SPSS) software, version 26. Prior to analysis, data were assessed for normality, homogeneity, and occurrence of extreme scores. Descriptive statistics and ANOVA test was conducted for comparison of the subject characteristics between the three groups. Mixed ANOVA was conducted to compare the effect of treatment on mean values of Volumetric measures and DASH questioner. The level of significance for all statistical tests was set at $p < 0.05$.

Results

Comparing the general characteristics of the participants among the three groups revealed that there were no statistical significant differences among groups in the mean age, weight, height and BMI ($p > 0.05$) (Table 1).

Table 1. Physical characteristics of participants in studied groups

	Group A	Group B	Group C	Comparison		Significance
	KT Mean ± SD	MLB Mean ± SD	Control Mean ± SD	f-value	p-value	
Age [years]	52.80 ± 2.651	54.40 ± 3.043	55.13 ± 2.642	2.754	0.075	NS
Weight [kg]	72.47 ± 2.125	72.33 ± 1.62	71.87 ± 2.1252	0.383	0.684	NS
Height [cm]	159.40 ± 2.694	159.07 ± 2.187	158.53 ± 2.642	0.452	0.639	NS
BMI [kg/m ²]	28.53 ± 0.878	28.60 ± 0.737	28.60 ± 0.619	0.039	0.962	NS

NS: Not significant, SD: Standard deviation, p: probability value f: ANOVA test

Mixed ANOVA was used to compare the effect of treatment on mean values of Volumetric measures and DASH questioner. Within group analysis, Volumetric measures scores showed that there was a significant statistical reduction ($p < 0.05$) in post-treatment scores compared with that of the pre-treatment at the three groups, groups A and B had superiority than group C. And there was significant statistical negative increase ($p < 0.05$) in After follow-up scores compared with that of the post-treatment at the three groups, while group A had superiority. Also, in measurements of the anthropometric limb volume there was a significant statistical reduction ($p < 0.05$) in post treatment scores compared with that of the pre-treatment at all groups, groups A and B had superiority than group C. While there was no significant statistical negative increase ($p > 0.05$) in after follow-up scores compared with that of the post-treatment at group A only. Fi-

nally, in measurements of the DASH questioner there was a significant statistical reduction ($p < 0.05$) in post treatment scores compared with that of the pre-treatment at all groups, groups A and B had superiority than group C. While there was no significant statistical negative increase ($p > 0.05$) in after follow-up scores compared with that of the post-treatment at group A only. Comparing the results among the three tested groups, there was no significant difference ($p > 0.05$) in the post-treatment mean values of volumetric measures between the All groups, while there was a significant difference ($p < 0.05$) in the after follow-up scores only between groups (A) and (B). As well as, in measurements of the anthropometric limb volume. There was no significant difference ($p > 0.05$) in the post-treatment mean values and in after follow-up of DASH among three groups the (Table 2).

Table 2. The HbA1c and fibrinogen levels for both groups

		Group (A) (n = 15)	Group (B) (n = 15)	Group (C) (n = 15)	Group A Vs. B p-value*	Group A Vs. C p-value*	Group B Vs. C p-value*
Volumetric measures	Pre	2.64 ± 0.27	2.75 ± 0.13	2.5 ± 0.33	0.710 ^{NS}	0.795 ^{NS}	0.074 ^{NS}
	Post	2.17 ± 0.27	2.28 ± 0.14	2.3 ± 0.29	0.627 ^{NS}	0.237 ^{NS}	0.999 ^{NS}
	p-value	0.0001 ^S	0.0001 ^S	0.0001 ^S			
	Follow-up	2.25 ± 0.29	2.57 ± 0.14	2.43 ± 0.3	0.003 ^S	0.153 ^{NS}	0.418 ^{NS}
	Post vs follow-up p-value	0.0001 ^S	0.0001 ^S	0.0001 ^S			
DASH	Pre	75.4 ± 2.33	75.8 ± 2.70	73.7 ± 4.32	0.999 ^{NS}	0.459 ^{NS}	0.256 ^{NS}
	Post	39.76 ± 3.4	33.2 ± 2.38	61.8 ± 2.44	0.0001 ^S	0.0001 ^S	0.0001 ^S
	p-value	0.0001 ^S	0.0001 ^S	0.0001 ^S			
	Follow-up	41.6 ± 2.79	54.7 ± 3.20	69.1 ± 2.47	0.0001 ^S	0.0001 ^S	0.0001 ^S
	Post vs follow-up p-value	0.054 ^{NS}	0.0001 ^S	0.0001 ^S			
Anthropometric limb volume	Pre	6.42 ± 0.69	6.83 ± 0.39	6.13 ± 0.86	0.295 ^{NS}	0.731 ^{NS}	0.091 ^{NS}
	Post	5.34 ± 0.66	5.67 ± 0.36	5.67 ± 0.73	0.414 ^{NS}	0.423 ^{NS}	0.999 ^{NS}
	p-value	0.0001 ^S	0.0001 ^S	0.0001 ^S			
	Follow-up	5.41 ± 0.70	6.36 ± 0.41	5.91 ± 0.77	0.001 ^S	0.132 ^{NS}	0.188 ^{NS}
	Post vs follow-up p-value	0.055 ^{NS}	0.0001 ^S	0.0001 ^S			

S: Significant, NS: Not significant, SD: Standard deviation, P: probability value

Discussion

The aim of the study is to compare the effects of kinesiotaping combined with pneumatic compression versus multilayer bandage on post-mastectomy lymphoedema. The results of the study showed that there was a significant improvement in the volumetric measurement post-treatment in all groups, while in the follow up measurements, there was significant deterioration in all groups. The superiority was to group A. While there was no significant difference in the post-treatment measures between the three groups. In the follow up measurements, there was significant difference only between groups A and B with more improvement in group A. Regarding to the DASH questioner, there was a significant improvement in the post-treatment in the three groups with superiority to groups A and B rather than group C. In follow up measurement, there was no significant deterioration only in group A while, groups B and C showed significant deterioration. While, between groups there was no significant difference in the post-treatment mean values and in after follow-up of DASH among three groups.

The improvement in the results of the three groups post treatment may be attributed to the mechanism of action of the different interventions, in the previous study which compare between the KT versus IPC on post-mastectomy Lymphedema concluded that, both methods have a positive effect with no significant difference between them, So Combination therapy is recommended to achieve better improvement [12].

Low pressure produced by KT on the skin by its active elastic acts upon the lymphatic system improves lymphatic flow and reduces its congestion which decreases the circumference of the affected limb [13]. KT applications pull the skin slightly, creating more space between the dermis and fascia. Lymphatic

ping is thus quite similar to lymphatic drainage, though it allows patients to receive therapeutic benefits 24 hours a day. Based on analysis of physiological effects it can also be argued that KT is more similar to compression therapy in that it reduces capillary filtration [14].

Intermittent Pneumatic Compression (IPC) in controlling lymphedema by exerting pressure on the extremity move edema proximally. It has been accepted that pneumomassage moves the affected limb edema to adjacent trunk quadrant which belongs to dependent area of the axillary lymph nodes [15].

Multilayer Bandaging (MLB) used in lymphedema management decreasing the volume and hardness of the edema by producing gradient compression which allow movement of lymphatic liquid towards the central circulation [16]. A multilayer bandage slightly stretched for preserving the effect of manual lymphatic drainage. MLB produce mild pressure at rest and creates higher one muscle active so lymphatics pressed between the muscle and the bandage, leading to manual pump of them [17].

In agreement with the current study, the results of the study conducted by Tsai et al, reported that there was significant reduction of lymphedema and lymph circumference in both groups receiving KT and Pressure Garment, but a higher percentage of reduction was recorded in the KT group [8]. Also, Tantawy et al., concluded that, there was statistically significant difference in the KT group when compared with the bandage group. As KT technique facilitates lymph circulation and lymph flow in lymph capillaries as mentioned in this study [18]. Bosman [19] suggests KT is helpful in hot and humid conditions while bandages were uncomfortable and problematic Finnerty et al. [20]. Similarly, Pyszora and Kranjik [21] recommend KT in the palliative treatment

of advanced lymphedema as bandaging method is painful or affect subject's quality of life (QoL).

On the other hand, there were previous studies come in contrast with the results of the current study. Tsai et al. [8] reported function improvement post-treatment in the KT group while deteriorated after follow-up period, but improved in the compression group. And there was improvement in both groups after follow-up. Pekyavas et al. [22] also showed that function was improved significantly by bandaging while KT did not at the end of treatment and follow-up periods. Also in the physical parameter scores a trend towards improvement was seen in the bandaging group. KT had no effect on QoL in their patients. In summary, two of the studies which reported patients' QoL showed an improvement in emotional function scores in the bandaging groups. These findings are inconsistent with the notion that KT has a more beneficial effect on QoL than bandaging.

In their case report Kaya et al. [23] used KT under the compression garment to treat lymphoedema. However, in their report this was ineffective for a patient with mild post-mastectomy lymphoedema. While four of the five RCTs included in the meta-analysis that conducted by Gatt et al. [24] found greater limb volume reductions with bandaging compared to KT, no statistically significant differences could be demonstrated. The findings of this review are in general agreement with the systematic review of Kalron and Bar-Sela [25] who reported that the effectiveness of KT is inconclusive for lymphatic disorders. Similarly, Morris et al. [26], in their systematic review, state that there is limited to moderate evidence that KT is not more effective than sham or bandage in clinical practice.

The contradiction of the results of these previous studies with the current study may be explained as the previous studies used the KT alone in comparison with the bandage but in the current study the KT was used in combination with the pneumatic compression which may explain the superiority of the KT group over the bandage group in the follow up measurements.

This study was limited by psychological and physiological condition of patients that may affect their performance during the study. Skin disorders interrupted and avoid applying treatment program in many times during the study. In sometimes, some patient may not be compliant with the treatment program.

Conclusion

On basis of the present study, it was possible to conclude that, using KT combined with IPC added to CDP program and MLB added to CDP program for postmastectomy lymphedema has the same improvement for posttreatment in the upper limb size and its function compared with CDP program only, while after three months follow up the superiority was for KT combined with IPC added to CDP program as it was less deterioration.

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