Comparison of Intermittent Pneumatic Compression with Manual Lymphatic Drainage for Treatment of Breast Cancer-Related Lymphedema

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Abstract

Background: The aim of this prospective controlled study was to assess the efficacy of two different combination treatment modalities of lymphedema (LE). Manual lymphatic drainage (MLD) and compression bandage combination (complex decongestive therapy) have been compared with intermittent pneumatic compression (IPC) plus self-lymphatic drainage (SLD).

Methods and Results: Both MLD with compression bandage (complex decongestive therapy) group (Group I, n = 15) and IPC with SLD group (Group II, n = 15) received treatment for LE 3 days in a week and every other day for 6 weeks. Arm circumferences were measured before and the 1st, 3rd, and 6th weeks of the treatment. EORTC-QLQ and ASES-tests were performed to assess the quality of life before and after 6 week-treatment. Patients in both groups had similar demographic and clinical characteristics. Even though both treatment modalities resulted in significant decrease in the total arm volume (12.2% decrease in Group II and 14.9% decrease in Group I) (p < 0.001), no significant difference (p = 0.582) was found between those two groups. Similarly, ASES scores were significantly (p = 0.001) improved in both Group I and II without any significant difference between the groups. While emotional functioning, fatigue, and pain scores were significantly improved in both groups, global health status, functional and cognitive functioning scores appeared to be improved only in patients of group I.

Conclusions: Different treatment modalities consisting of MLD and compression bandage (complex decongestive therapy) or IPC and SLD appear to be effective in the treatment of LE with similar therapeutic efficacy in patients with breast cancer. However, combination modalities including IPC and SLD may be the preferred choices for their applicability at home.

Introduction

Breast cancer, with a lifetime risk of 12%, is the most common cancer among women in the world. Affecting 6%–38% of breast cancer survivors, LE is one of the most serious and life-long complications leading to profound functional and psychological disability in patients treated for breast cancer.1-4 LE is defined as the excessive and persistent accumulation of fluid and extracellular proteins in tissue spaces, due to inefficiency of lymphatic drainage system.5 The incidence and degree of LE correlate to the extent of axillary dissection (ALND) and irradiation to the axilla.2,6-7 LE-associated signs and symptoms are: increased limb diameter, skin tensioning, infection, stiffness and decreased range of motion of the joints, sensory deficit, reduced functional use of the limb, and also aesthetic deformities and psychological stress.8,9

The treatment of LE is difficult, costly, and time consuming. Multidisciplinary approach is necessary. The goals of the therapy are to decrease swelling, restore function and

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complex decongestive therapy, as a multidisciplinary and comprehensive approach, consists of MLD, skin care, bandaging, and exercise. Complex decongestive therapy, as a multidisciplinary and comprehensive approach, consists of MLD, skin care, bandaging, and exercise.

MLD involving mild massage techniques, eliminates the excessive interstitial fluid, softens the fibrotic induration, and increases the lymphatic transport. The direction of the manual massage has to be towards functional lymphoms in order to mobilize the lymphatic fluid from congestive regions to normal tissue.

Self-lymphatic drainage (SLD) is the simple form of MLD, which can be easily carried out by the patient after a short training on self application. SLD can also be applied at home without the need of physiotherapist and without interruption in working.

IPC swabs the collected fluid in tissue and decreases edema by external compression. Pumps with multiple segments exert pressure on extremity with LE, and decrease the pressure gradually from distal to proximal. IPC is an effective treatment model offered to be used in patients with LE.

The aim of this prospective controlled study is to compare the efficacy of complex decongestive therapy (MLD & compressive bandage + skin care + exercise) with IPC & SLD + skin care + exercise, on arm volume and quality of life of patients with LE related to breast cancer treatment.

Material and Methods

This prospective controlled study was carried out at Istanbul Medical Faculty, Istanbul University, in the Breast Unit of the Department of General Surgery. Ethical approval was obtained by the Ethical Committee of the Istanbul Medical Faculty of Istanbul University, and informed consent was taken from each patient.

Thirty-four patients, who evolved LE after operated for breast cancer, were enrolled in the study. LE developed in all patients after 6 months of surgery. One patient with less than 2 cm difference between two arm circumference measurements, two patients with bilateral LE, and one patient with her own accord, were excluded from the study. Thirty patients with LE were randomized to two different treatment protocols (groups 1 and 2). The patients, who were eligible for the study, were randomized either to the group I or the group II using a computer-derived random number sequence in a ratio of 1:1. No lymphangitis and no progression in LE was observed during the study.

Sociodemographic and clinical characteristics and risk factors related to LE of the patients (age, marital status, educational level, dominant hand, body mass index, cigarette smoking, co-morbid diseases as diabetes mellitus (DM), hypertension (HT), type of surgery, radiation therapy (RT) fields, time to LE and previous therapies, previous infections) were assessed and recorded. While 15 patients in group I were applied to MLD and compression bandage, 15 patients in groups II were applied to SLD and IPC (Flowpress Sequential Compression Pump, England). Both groups had continued to wear compression garments at the end of the therapy. Patients in both groups were trained and informed before the study to do upper extremity active exercises by themselves and skin care regularly during the study. Exercise programs of both groups included regular joint motions, with 10 repetitions of every motion (flexion, abduction, internal and external rotation, horizontal abduction and adduction of shoulder, flexion and extension of elbow and wrist, supination and pronation of forearm) for 15 minutes, twice a day. All the patient’s daily records of their exercise performance at home were checked weekly by a physiotherapist.

Treatment protocols were arranged as every other day method for 6 weeks in both groups. MLD was performed by the mild pressure of fingers and hand (nearly 30 mmHg), and rhythmic skin stretching for 30 min in every treatment period. In the first stage of the MLD, compressive stimulation of the nearby healthful lymphatic drainage regions such as cervical and opposite axillary regions was achieved. In the second stage, MLD was performed by manual decongestion of the affected trunk, shoulder, arm, forearm, wrist, consecutively. Short-stretch compression bandages were applied to the patients in MLD-group during the study to achieve optimal volume reduction for 21–24 hours in a day, except the periods of MLD performance.

IPC and SLD programs were applied to the patients in group two. IPC, with a long arm muffle, stimulates the lymphatic flow, from distal to proximal region of the extremity with LE, by compression-decompression periods with 25 mmHg pressure and different cyclic manner. IPC was applied to the patients with a 45 min duration for every treatment period. All the patients in group II were trained for SLD by the same physiotherapist, and performed self-diversion of lymphatic fluid from the effected edematous region to healthy region of the arm at home. Patients performed SLD everyday for 15 min at home during the study. The daily records on SLD of the patients were checked weekly by physiotherapist.

Arm circumference measurement

Bilateral arm circumference measurements were performed for four times to calculate arm volume, before and after the LE treatments (at the beginning and 1st, 3rd, and 6th weeks of the treatments). Measurements were done at 6 points of segments between wrist and shoulder with 10 cm distance (at 0, 10, 20, 30, 40, 50 cm from wrist to shoulder) by the same physiotherapist. Arm circumference measurements were also done on the healthy arm, for one time at the beginning of the study to compare the arm with LE. The measurements of the arm circumference were switched to arm volume values by formulas. Initially the volumes for every arm segment were calculated separately by formula of V1s: L/12 II (C1, C2 + C3) (C, circumference; L, segment length; s, segment; V, volume) afterwards, total arm volume was calculated by a formula as described before: Total Volume = V1s + V2s + V3s + V4s + V5s + V6s. The severity of LE was calculated by using total volumes of the lymphedema arm (VLE) and normal arm before treatment (VN). The Stillwell Classification for Lymphedema was used to classify lymphedema in the study (Table 1). The lymphedema rate was calculated by formula of (VLE - VN)/VN × 100.

Evaluation of quality of life by EORTC-QLQ and ASES tests

EORTC-QLQ and ASES tests were applied to each patient in both groups. The ASES test is a subjective test to measure
quality of life (QOL), consisting of 10 questions about the effective use of the arm during the day (as combing hair or dressing). The answers were scored and the total score for every patient was recorded. The ASES test were applied bi-

effective use of the arm during the day (as combing hair or

cal). The ASES test were applied bi-

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effective use of the arm during the day (as combing hair or

The EORTC-QLQ-C30 test was performed for twice on all the patients in both groups. The first one was just before the study, and the second one was at the sixth week, at the end of the study. It is a subjective worldwide test to assess the QOL of cancer patients including 30 items generic HRQOL instrument evaluating the physical, psychological, and social functions.\(^{22}\) It is composed of nine multi-item scales including five functional (physical, role, emotional, cognitive, social), a global (QQOL), and three symptomatic (fatigue, pain, nausea and vomiting) scales. Additionally it has five single symptomatic scales (dyspnea, insomnia, loss of appetite, constipation, and diarrhea). At the final section of the test, the financial effect of the illness was evaluated by a financial impact scale. The first 28 items of the test are rated on a response scale of “not at all”=1 point, a little=2 points, fairly=3 points and very much=4 points”. The last two items are scored between 1 (very poor) to 7 (excellent) points.

The statistical analysis was performed by using 15.0 SPSS statistical computer program for Windows. Sociodemographic characteristics were evaluated by descriptive methods. The continuous variables such as the EORTC-QLQ-C30 scores were compared by Student t-test or Mann-Whitney-U, or Wilcoxon signed tests.

Results

The median age of patients was 55 (31–74) years. The median detection time of lymphedema was 18 months (range, 6–72 months). All patients had levels I and II axillary lymph node dissection for breast cancer treatment, and had radiotherapy to the involved breast and regional lymphatics. All patients had received no treatment for LE before. None of them had remote organ metastases and there were no significant differences between groups in respect of breast cancer stage (\(p=0.826\)). Venous doppler ultrasonography revealed no venous thrombosis among all the patients before the study. In group II: 5 patients had hypertension (HT), 2 patients had DM (diabetes mellitus), and 3 patients had smoked cigarettes. In group I: 4 patients had HT, 2 had DM, and 4 patients had smoked cigarettes. No significant differences could be found between two groups including their socio-demographic characteristics (Table 2).

There was no statistically significant difference of the BMI (body mass index) of two groups (\(p=0.356\)). Fifteen (50%) patients had mild LE and 15 (50%) patients had severe (moderate + marked) LE; [8 patients (26.7%) had moderate, 7 patients (23.3%) had marked] according to the Stillwell Classification for LE. Patients with BMI above 30 kg/m\(^2\) had more severe LE than patients with BMI level 30 kg/m\(^2\) or below (\(p=0.016\)). Mean BMI level was 32.8 kg/m\(^2\) (SD 5.2) in severe LE patients and 29.2 kg/m\(^2\) (SD 4.7) in mild LE patients. Morbid obese patients had worse treatment outcomes than nonmorbid obese patients (\(p<0.001\)). There were no significant differences in mean arm volumes of the groups initially (3533±739 and 3581±783 ml in group I and II, respectively). LE differences between both arms were greater than 10% in all patients initially \([\text{V}_{\text{LE}} - \text{V}_{\text{N}}]/\text{V}_{\text{N}}]\). Significant differences were determined between the initial and 1, 2, 6 weeks of arm volumes in both groups, separately (\(p<0.001\)). The decrease in total arm volumes as a result of treatment protocols were 529 ml (14.9%) and 439 ml (12.2%) in

### Table 1. Stillwell Classification for Lymphedema

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant</td>
<td>0–10% &gt; normal arm</td>
</tr>
<tr>
<td>Slight</td>
<td>11–20% &gt; normal arm</td>
</tr>
<tr>
<td>Moderate</td>
<td>21–40% &gt; normal arm</td>
</tr>
<tr>
<td>Marked</td>
<td>41–80% &gt; normal arm</td>
</tr>
<tr>
<td>Severe</td>
<td>More than 80% &gt; normal arm</td>
</tr>
</tbody>
</table>

### Table 2. Patient Characteristics of the Randomized Treatment Groups: Manual Lymphatic Drainage (MLD) and Compressive Bandage vs. Intermittent Pneumatic Compression (IPC) and Self-Lymphatic Drainage (SLD)

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (MLD)</th>
<th>Group 2 (IPC)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ±SD)</td>
<td>58.13 ± 10.54</td>
<td>50.13 ± 10.83</td>
<td>0.068</td>
</tr>
<tr>
<td>BMI (mean ±SD)</td>
<td>30.71 ± 5.63</td>
<td>31.39 ± 4.91</td>
<td>0.356</td>
</tr>
<tr>
<td>Surgery (n (%))</td>
<td></td>
<td></td>
<td>0.269</td>
</tr>
<tr>
<td>BCS + ALND</td>
<td>5 (33.3)</td>
<td>8 (53.3)</td>
<td></td>
</tr>
<tr>
<td>Mastectomy + ALND</td>
<td>10 (66.7)</td>
<td>7 (46.7)</td>
<td></td>
</tr>
<tr>
<td>RT (n (%))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No RT</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>RT</td>
<td>15 (100.0)</td>
<td>15 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Dominant hand (n (%))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>15 (100.0)</td>
<td>15 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>8 (53.3)</td>
<td>9 (60.0)</td>
<td>0.666</td>
</tr>
<tr>
<td>Cigarette smoking (n (%))</td>
<td></td>
<td></td>
<td>0.146</td>
</tr>
<tr>
<td>Never smoked</td>
<td>11 (73.3)</td>
<td>12 (80.0)</td>
<td></td>
</tr>
<tr>
<td>Ever smoked</td>
<td>4 (26.7)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Co-morbidities (n (%))</td>
<td></td>
<td></td>
<td>0.153</td>
</tr>
<tr>
<td>CHF</td>
<td>—</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td>HT</td>
<td>4 (26.7)</td>
<td>5 (33.3)</td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>2 (13.3)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>—</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>9 (60.0)</td>
<td>4 (26.7)</td>
<td></td>
</tr>
<tr>
<td>Marital status (n (%))</td>
<td></td>
<td></td>
<td>0.624</td>
</tr>
<tr>
<td>Never married</td>
<td>2 (13.3)</td>
<td>3 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>13 (86.7)</td>
<td>12 (80.0)</td>
<td>0.568</td>
</tr>
<tr>
<td>Education (n (%))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No education</td>
<td>1 (6.7)</td>
<td>2 (13.3)</td>
<td>0.563</td>
</tr>
<tr>
<td>High school</td>
<td>11 (73.4)</td>
<td>11 (73.4)</td>
<td>0.624</td>
</tr>
<tr>
<td>University</td>
<td>3 (19.9)</td>
<td>2 (13.3)</td>
<td>0.210</td>
</tr>
<tr>
<td>Working status (n (%))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never worked</td>
<td>11 (73.4)</td>
<td>9 (60.0)</td>
<td>0.439</td>
</tr>
<tr>
<td>Ever worked</td>
<td>4 (26.6)</td>
<td>6 (40.0)</td>
<td>0.365</td>
</tr>
</tbody>
</table>

ALND = axillary lymph node dissection; BCS = breast conserving surgery; BMI = body mass index; CHF = congestive heart failure; DM = diabetes mellitus; HT = hypertension; LE = lymphedema; RT = radiotherapy.
groups I and II, respectively. Although a greater decline was observed in group I, there was no statistically significance between two groups (p = 0.582) (Table 3).

The initial ASES test scores were significantly lower at the affected arm than the nonaffected arm in both groups of patients (p = 0.039). The initial mean ASES scores of the arms with LE in group I and II (8.73 ± 6.98 and 13.27 ± 4.09, respectively), was significantly increased (18.47 ± 6.93 and 19.20 ± 4.65) by treatment protocols at the end of the study in both groups (p < 0.001). However, no significant differences could be detected between the groups in respect of ASES scores (Table 4).

The EORTC-QLQ-C30 test results are shown in Table 4. In the MLD group: the scores of the global health status (p = 0.03), social functioning (p = 0.01), physical functioning (p = 0.006), emotional functioning (p = 0.01), cognitive functioning (p = 0.02), social functioning (p = 0.005) were significantly increased, whereas fatigue (p = 0.002) and pain (p = 0.001) were found to be significantly decreased after the treatment. In the IPC group: scores of emotional functioning (p = 0.03), social functioning (p = 0.003) was significantly increased, whereas fatigue (p = 0.003) and pain (p = 0.005) were significantly decreased after the treatment (Table 5).

It has been established that the quality of life of patients was improved by treatment protocols in both study groups. Although the improvement was better in MLD group, this difference was not found to be statistically significant.

Discussion

LE is a common problem for the patients with breast cancer. Patients with LE have been confronted with functional and psychological disabilities related to LE in addition to problems with cancer follow up.2,3

Table 4. Changes in ASES Scores in Different Treatment Groups after Therapy: Manual Lymphatic Drainage (MLD) and Compressive Bandage vs. Intermittent Pneumatic Compression (IPC) and Self-Lymphatic Drainage (SLD)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean Volume before Treatment (mL)</th>
<th>Mean Volume after Treatment (mL)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (MLD)</td>
<td>3533</td>
<td>3004</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group II (IPC)</td>
<td>3581</td>
<td>3142</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The higher values indicate higher level of functioning and quality of life, min: 0, max: 100.

The higher values indicate a greater degree of symptoms, min: 0, max: 100.

*p Mann-Whitney U test; **p Wilcoxon signed ranks test.

Table 3. Changes in Arm Volumes in Different Treatment Groups after Therapy: Manual Lymphatic Drainage (MLD) and Compressive Bandage vs. Intermittent Pneumatic Compression (IPC) and Self-Lymphatic Drainage (SLD)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean Volume before Treatment (mL)</th>
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The higher values indicate higher level of functioning and quality of life, min: 0, max: 100.

The higher values indicate a greater degree of symptoms, min: 0, max: 100.

*p Mann-Whitney U test; **p Wilcoxon signed ranks test.

ASES = American Shoulder and Elbow Surgeons.
The incidence of LE in breast cancer patients ranges from 6% to 38%, depending on the extent of axillary surgery and radiotherapy. Penzer and colleagues reported the rate of LE as 25% in women above ages of 60, while it was 7% in women below ages of 60. Kiel and Rademacker, however, reported that age was most important parameter for LE and found that the incidence of LE was 56% in women above age of 55. Köçak and Overgaard suggested that incidence of the LE was increased due to decrease of lymphatic anastomosis with age. The median age of patients in our study was 55 in concordance with this data. Although there is no consensus on obesity as a risk factor for LE, Werner and colleagues declared that patients whose BMI were higher than 29.2 kg/m² had higher incidence of LE. In another study by Soran and colleagues, BMI was 26.1 kg/m² for the control group, 29.0 kg/m² for the mild LE group, and 30.9 kg/m² for the severe LE group. Nearly 75% of their patients with LE were overweight or obese (BMI greater than 25 kg/m² or 30 kg/m²). In the present study, the BMI was higher than 29.1 kg/m² in 56.6% of the patients. Patients with BMI above 30 kg/m² had more severe LE than patients with BMI level 30 kg/m² or below (p = 0.016). Mean BMI level was 32.8 kg/m² (SD 5.2) in severe LE patients and 29.2 kg/m² (SD 4.7) in mild LE patients. Patients with morbid obesity had worse treatment outcomes than nonmorbid obese patients (p < 0.001). Surgery in the axilla of the dominant site, or overuse of the arm at the operated site, are also found as risk factors for LE. LE was seen in 56.6% of our patients at the dominant site arm. In this study, both two groups’ characteristics were not statistically different than each other, but the reason of the lymphedema was not the main subject of this study. We discussed the response rate of the lymphedema patients to the different treatment modalities, in this study.

The combined treatment modalities have been shown to be superior to physiotherapy alone in treatment of LE. Complex decongestive treatment as an extensive multidisciplinary approach includes skin care, exercise, MLD, and bandaging. This approach has been reported to decrease LE by a rate of 22%–73%. IPC is another option of treatment for LE. Several controlled studies have documented its effectiveness when used continually and in combination with other options. Szuba and colleagues demonstrated the improved therapeutic effect of IPC when combined with complex decongestive treatment. Didem and colleagues reported that, while complex decongestive therapy alone was decreasing LE by 26%, the decrease was 45% when it was combined with IPC. In contrast to these, another study demonstrated that the use of CDT alone, or in combination with IPC, significantly reduced limb volume in patients with post mastectomy lymphedema. In the present study, we showed a significant improvement in LE, by IPC combined with SLD, skin care, and exercise which were applied with an excellent accordance of the patients without affecting their daily activities. The limb volume is the most common used parameter in assessing LE. The measurements of limb circumference or water displacement are both certain methods for volume calculations. We used specific formulas to calculate the limb volumes from the measurements of limb circumferences. In our study, the statistical evaluations revealed a highly significant decrease in limb volumes by different treatment combinations in both groups with similar therapeutic efficacy. The volume decreases had been reported to be as 48% and 25% by MLD and by IPC, respectively. In another comparative study, although MLD was superior to IPC method in regards to volume decrease (75 and 28 ml), this difference was not found to be significant (p = 0.11). Our better results might be due to the use of combined treatments instead of using only one treatment modality.

LE negatively affects the quality of life, the body image, and the ambition to cope with the diseases. Sensory disorders, strength loss, decreased range of motion, oversensitivity of the skin, and predisposition to infections are the other possible serious side effects of LE. In our study, the ASES test scores of the arm with LE were significantly lower than the opposite side before the treatment, and significant improvements of ASES test scores were achieved by both treatment modalities. However, no significant difference was found between these 2 groups in terms of treatment efficacy. Our results therefore suggest that both treatment modalities improve quality of life with similar efficacy.

It is important to evaluate patients for psychosocial changes as much as physical and functional changes. Body image, personal respect, social support, and strength in the battle of life can also be affected adversely by LE. Tobin and Carter demonstrated psychological morbidity in patients with LE, just as in anxiety and depression. The psychological benefit of massage including reduction of anxiety, stress, and pain, is demonstrated. In our study, while quality of life was found to be improved after MLD, no significant difference could be detected after IPC. When physical and cognitive functions were assessed, a significant difference was also confirmed in the MLD group, whereas no significant changes was found after IPC. However, a significant improvement was detected in emotional and social functions in both treatment groups. In assessing symptomatic scale parameters, while symptoms of fatigue and pain significantly decreased in both groups, no significant changes were recorded in symptoms of insomnia or loss of appetite in both treatment groups.

The limitations of this study were that the sample size was small, and this study was not a randomized controlled study. It was only a prospective study, and patients were included in the study consecutively. Furthermore, this study was not a double blinded study, and the measurements and the exercise and the massage were performed by the same physiotherapist. Another limitation was that, although a standardized educational program was applied, there may be some variations depending on the individual performance.

Conclusion

In conclusion, our results suggest that the combination treatment modalities including IPC with SLD, and MLD with compression bandage, are both effective and tolerable modalities, along with skin care and exercises in the treatment of LE caused by breast cancer treatment. Gautam et al. demonstrated that the individualized home-based exercise program led to improvement in affected upper-limb volume and circumference and QOL of postmastectomy lymphedema patients. Even though MLD and compression bandage therapy seems to be slightly superior in terms of some quality of life scores, the IPC with SLD can be the choice of treatment in LE for applicability at home without interruption of regular life. Studies should be done comparing effects of home-based versus institution-based exercise programs.
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