A RANDOMIZED STUDY COMPARING MANUAL LYMPH DRAINAGE WITH SEQUENTIAL PNEUMATIC COMPRESSION FOR TREATMENT OF POSTOPERATIVE ARM LYMPHEDEMA

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ABSTRACT

We compared manual lymph drainage (MLD) with sequential pneumatic compression (SPC) for treatment of unilateral arm lymphedema in 28 women previously treated for breast cancer. After 2 weeks of therapy with a standard compression sleeve (Part I) with maintenance of a steady arm volume, each patient was randomly assigned to either one of two treatment regimens (Part II). MLD was performed according to the Vodder technique for 45 min/day and SPC was performed with a pressure of 40-60 mmHg for 2 hours/day. Both treatments were carried out for 2 weeks. Arm volume was measured by water displacement. Arm mobility, strength, and subjective assessments were also determined.

Lymphedema was reduced by 49 ml (7% reduction) (p=0.01) in the total group during Part I. During Part II, the MLD group decreased by 75 ml (15% reduction) (p<0.001) and the SPC group by 28 ml (7% reduction) (p=0.03). The total group reported a decrease of tension (p=0.004) and heaviness (p=0.01) during Part I. During Part II, only the MLD group reported a further decrease of tension (p=0.01) and heaviness (p=0.008).

MLD and SPC each significantly decreased arm volume but no significant difference was detected between the two treatment methods. Postoperative arm lymphedema is a common complication of breast cancer treatment. The incidence during the last 10 years varies widely from 0 to 60% in Europe (1-8) depending on treatment and the method for measuring and defining lymphedema. Axillary dissection (1,2,4,8,9) and irradiation (1,3,4,8) are known as key predisposing factors. The volume of arm lymphedema correlates with subjective sensations such as tension and heaviness (10). The swollen arm is cosmetically unappealing and it often is difficult to find suitable clothes, disabilities that contribute to emotional distress (11).

Arm lymphedema is difficult to manage and often requires life-long physiotherapy as treatment (12). Without treatment, lymphedema tends to worsen and with fibrosis becomes intractable (12). In rare instances, a highly malignant lymphangiosarcoma is associated with longstanding lymphedema (13).

Various methods for treatment have been proposed. In most western countries, nonoperative treatment with manual lymph drainage (MLD) (12,14-16) or sequential pneumatic compression (SPC) (14,17,18) is used either separately or together and commonly combined with bandaging or a compression sleeve. Arm volume reducing effect of MLD when combined with bandaging is reported to be 20% (16), and for MLD in conjunction with an elastic sleeve or benzopyrone administration is reported as

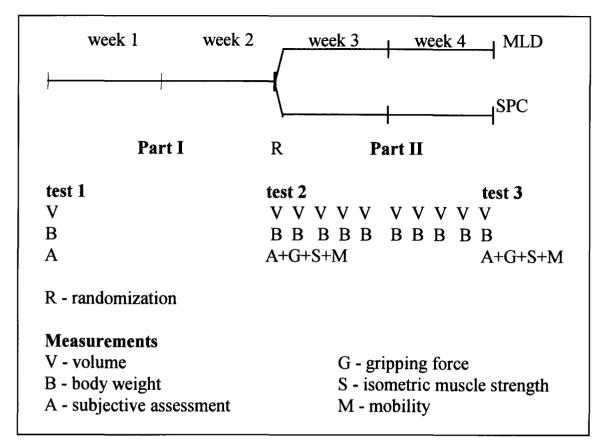


Fig. 1. Study Design: For the first 2 weeks, only a standard compression sleeve garment was used. Thereafter the patients were randomized to either manual lymph drainage (MLD) or sequential pneumatic compression (SPC).

25% (14). SPC also reduces arm volume by 5-45% depending on the pressure applied and the treatment time (14,17-19). The use of a standard elastic sleeve alone is reported to give a volume reduction of 25% (20). However, the volume reducing effect of MLD and SPC individually and compared to each other without adjuvant compression or drug treatment has not been examined.

Accordingly, we determined the effects of treatment with MLD and SPC individually and by comparison with each other regarding changes in arm volume, shoulder mobility, isometric muscle strength and subjective assessment of arm function including feelings of heaviness, tension, pain, and paresthesia of the lymphedematous arm in women after treatment for breast cancer.

Clinical Population

In this prospective study, 28 consecutive women with unilateral arm lymphedema after a breast cancer operation with axillary nodal dissection was studied over a 2.5 year period. Each patient had been operated upon in the Department of Surgery, University Hospital, Lund, Sweden. In Lund, the incidence of lymphedema, with or without radiotherapy, is 13% two years after the operation for treatment of breast cancer (unpublished observations 1991). No patient had arm edema before breast cancer treatment. Lymphedema was defined as >10% difference in volume between the abnormal and normal (contralateral) arm (21) as measured by volumetry (22).

	MLD (n-12)	SPC (n=12)
	median (q1-q3)	median (q ¹ -q ³)
Age & years)	64.0 (52.5-69.5)	57.5 (47.5-69.5)
Duration of edema after op (months)	9.0 (6.0-45.8)	10.5 (4.8-29.3)
Duration of edema (months)	14.0 (3.0-76.5)	6.5 (2.3-68.3)
	number	number
Right/Left arm lymphedema	6/6	7/5
Dominant arm lymphedema	5	7
Partial mastectomy/mastectomy	1/11	2/10
Radiotherapy	10	8

TABLE 1

The study design (Fig. 1) included two weeks of treatment with a hand/wrist-toshoulder compression sleeve of standard type (Rehband Anatomiska AB, Sollentuna, Sweden) for all 28 patients (Part I) to maintain a steady volume level of arm edema before instituting the treatment regimen. The time was chosen according to the results of a previous study (23) of four weeks of treatment including massage, isometric exercises, and wearing of an elastic sleeve. The earlier results showed that the greatest edema volume reduction was during the first week, whereas over the course of the next three weeks, the therapeutic benefit decreased sharply. Any patients who after Part I did not fulfill the criteria of lymphedema (21) were excluded from Part II. After written and oral consent, the patients were randomly allocated to either MLD or SPC therapy for two weeks (Part II). Before and six months after the study period, the patients had a clinical examination including X-ray of the lungs and mammography. The study was approved by the Lund University research ethics committee.

Exclusion criteria included previous contralateral breast disease or intercurrent disease affecting the swollen arm, difficulties in participating in the study such as dementia, and complete resolution of arm edema after compression sleeve treatment in Part I. One patient was excluded because of resolution after compression during Part I. Two patients in each group were dropped during Part II; two because of recurrent breast cancer, and one because of erysipelas during the period of treatment and one who was unable to participate in repeated measuring. Demographics of the remaining 24 women are shown in Table 1. There were no differences between the two groups.

Physiotherapeutic Treatment

MLD or SPC treatment was administered for two weeks, 5 days a week, at approximately the same time of the day. The time chosen was based on the results of an earlier study (23) of four weeks of treatment, where the greatest edema volume reduction was recorded during the first week of therapy. MLD was carried out according to the massage technique of Vodder (24). In theory, MLD massage mechanically stretches underlying epifascial lymph collectors (25), promotes greater frequency of lymphangion contractions (26) and increases pressure in the lymph collectors (27), thereby improving the lymph transport capacity (28). Massage is applied with low pressure in a proximal direction, starting at the trunk bordering the edematous area, slowly moving more distally and ending with the hand. MLD was performed for 45 min/day by one physiotherapist specially trained in this technique. Treatment with SPC was provided using Lympha-Press employing 9 compression cells (Liljenberg Medical AB, Malmö, Sweden). According to standard practice, a pressure of 40-60 mmHg was applied for 2 hours/day. Each patient was instructed to wear the compression sleeve during the daytime in order to maintain a similar compression level during both Part I and Part II phases of the study.

Measurements and Assessments

The study design is outlined in *Fig. 1.* Objective measurements and subjective assessments were uniformly performed before the daily treatments in Part II.

Volume of the arm: The affected and unaffected arm were each submerged in a container with water and the volume displacement was measured in ml. The method has been described by Kettle (22), who found a standard deviation of 1.5% from the mean volume. The unaffected arm was used as a control. The change in lymphedema volume was obtained by comparing the difference in volume between the affected and unaffected arm and the change expressed both in ml and as percent reduction in lymphedema for purposes of comparison with other studies. Thus.

% edema reduction = $\frac{\text{diff test } 2 - \text{diff test } 3}{\text{diff test } 2} \times \frac{100}{100}$

where diff = volume of affected arm – volume of unaffected arm.

Body weight was also recorded.

<u>Passive mobility</u>: In a supine position, flexion of the elbow and flexion, abduction and in- and outward rotation of the shoulder at both sides was measured with a goniometer. The mobility was expressed in degrees (29). We estimate the test-retest error at ~ 5 degrees.

<u>Isometric muscle strength</u>: In a supine position, the flexors, abductors, and adductors of the shoulder on the affected side were measured in kp with a dynamometer. The device was placed at the wrist with the arm straight in 90° flexion of the shoulder, and a breaking force technique was employed. The method is highly reliable with significant correlations (p<0.01) for repeated measurements (30). The gripping force of the hand on the affected side was measured with a Jamardynamometer with the patient in a sitting position, and the arm held close to the body with a 90° flexion of the elbow. The highest value of three was registered for each test.

<u>Subjective assessment</u>: The function, heaviness, tension, pain and paresthesia of the affected arm were each scored by the patient on a 100 mm horizontal visual analogue scale (VAS) anchored by "worst imaginable" (0 mm) and "no discomfort" (100 mm). Each patient was asked to consider the subjective sensations during the week before each scoring (tests 1, 2 and 3). The initial scores from test 2 were made available to the patient on the third occasion (31).

Statistics

Student's t-tests for paired samples was performed to calculate differences within the group during Part I and within the groups MLD and SPC in Part II. t-tests for independent samples were performed to calculate differences between the two groups (MLD and SPC).

A check with Wilcoxon signed rank tests and Wilcoxon rank sum tests for paired and

TABLE 2Arm Volumes in mL (Mean ± SD)Before and After Treatment(see Fig. 1 for time intervals of test 1-3)				
	MLD (n=12)	SPC (n=12)		
test 1	3025±328	2708±458		
test 2	2960±335	2740±433		
test 3	2866±322	2683+420		

independent samples respectively was performed. A p<0.05 level was taken as significant.

RESULTS

Volume of the Arm

In the total group (n=24), the mean value \pm SD of the volume of the arm was 2850 \pm 81 ml on the affected side and 2355±79 ml on the unaffected side in test 1. The difference was significant (p<0.001). The mean lymphedema arm volumes on the different test occasions for the MLD group and the SPC group are shown in Table 2. During Part I when each patient was wearing a compression sleeve, a significant reduction of 49±87 ml (p=0.01) for the total group and a %reduction of 7 ± 18 (p=0.05) were seen from test 1 to test 2. There were no significant volume differences between the two groups in test 2 at the start of Part II (p=0.09) (Table 3). During Part II, there was a reduction in lymphedema volume from test 2 to test 3 in both the MLD group (mean=75 ml, p<0.001) and the SPC group (mean=28 ml, p=0.03). The % reduction in lymphedema was 15% in the MLD group (p<0.001) and 7% in the SPC group (n.s.). No significant difference

(Affected Minus Unaffected Arm) (Mean ± SD) Before and After Treatment				
	MLD (n=12)	SPC (n=12)		
test 1	657±308	431±201		
test 2	579±258	411±203		
test 3	504±252	382±193		

between the two treatments was found either in ml (p=0.11) or in % reduction (p=0.36).

Body Weight

The mean \pm SD of the body weight in test 1 was 72 \pm 11 kg for the total group and did not change significantly during the study.

Shoulder Mobility

In test 2, there was reduced arm mobility compared to the unaffected contralateral arm in the total group (*Table 4*). Treatment with MLD or SPC did not change arm mobility from test 2 to test 3.

Isometric Muscle Strength

Mean \pm SD for the total group in test 2 for shoulder flexion on the affected side was 7.5 \pm 1.8 kg, for abduction 7.0 \pm 1.7 kp, for adduction 5.8 \pm 1.6 kp and for gripping force 36.7 \pm 13.2 kp/cm². No significant changes over time were seen for any of these in the two groups in test 3.

Subjective Assessment

During Part I, a significant decrease of

TABLE 4Arm Mobility (in degrees) of the Edematous (Affected) andNon-edematous (Unaffected) Arm in All Women (n=24) at Test 2					
Joint mobility (°)	Unaffected mean±SD	Affected mean±SD	Diff (x) 95% CI	p-value	
Elbow					
flexion	147±6	144±4	2 (-0.3 - 5)	=0.08	
Shoulder					
flexion	164±12	149±18	15 (10 - 20)	<0.001	
abduction	151±27	122±37	30 (19 - 41)	<0.001	
inward rotation	70±17	58±15	12 (4 - 19)	=0.006	
outward rotation	83±16	71±22	11 (2 - 21)	=0.02	

feeling of tension (p=0.004) and heaviness (p=0.01) in the arm was found in the total group. In Part II, only the MLD group showed a further decrease of tension (p=0.01) and heaviness (p=0.008). In a separate analysis, the data were stratified to exclude patients who had scored 100 (no discomfort) on the scales in test 2. The results revealed the significance to be greater but still only for MLD as regards tension and heaviness. There was no significant difference between the two groups in Part II.

DISCUSSION

We compared two nonoperative methods for treatment of arm lymphedema, namely manual lymph drainage and sequential pneumatic compression, and determined changes in arm volume, shoulder mobility, isometric muscle strength as well as subjective assessment of arm function, feeling of heaviness, tension, pain, and paresthesia. Each method was effective in reducing arm volume, but no significant differences between the treatment regimens was seen.

Limb volume measurement is the most common approach to quantify the extent of

lymphedema. In this study, we used volumetry by water displacement for objective measurements of changes in arm volumes because it is a simple method with high reliability (22). Yet there is normally a small biological fluctuation of arm volume over a given time period. This variation has been documented in a study by Swedborg et al (19). Over a 2 week period, there was a mean range of variation of 100.5 ml in ten normal women with a mean arm volume of 2058 ml (4.8%). This physiological variation should be taken into account when measuring edema volume as done in this study, as in others (1,5,6,19) by determining the volume difference between the affected and unaffected arms. This calculation is based on the assumption that the arm volume variations are similar bilaterally. In the 24 women studied, the mean \pm SD volume variation of the unaffected (non-edematous) arm during Part II was very low (24±44 ml or 1±2%) and there was no significant difference between the two groups. This low variation of the unaffected arm, together with the fact that there was no significant change in body weight, leads us to conclude that the reduction of arm volume in the affected arm after

treatment is truly attributable to a reduction in edema fluid.

Differences in volume between a dominant and non-dominant arm have been shown by Godal et al (33). They noted significant asymmetry of arm volume, with the dominant right arm slightly larger than the left (1.6%). For the ambidextrous or dominant left arm, the right arm was slightly smaller (0.1% and 1.4%, respectively). No correction was made for asymmetry in our patients, as there were no significant differences between the groups in regards to operation on the right or left side or dominant to non-dominant arm.

We measured the shoulder and elbow mobility to determine whether edema reduction increased the range of motion by softening the tissues or altering the joints. Whereas no differences were discernible, perhaps if the volume differences between the affected and the unaffected arm were larger to begin with, a greater functional influence on the affected arm or an effect of treatment may have been seen.

The visual analogue scale (VAS) was used to evaluate subjectively arm function, heaviness, tension, pain, and paresthesia. VAS, to our knowledge, has been typically used to test for pain. Accordingly, the validity of the correlation between edema volume reduction and the assessments determined has not been verified. Nonetheless, a correlation between edema volume reduction and the feeling of tension and heaviness has been demonstrated by Swedborg et al (10) using a Borgscale (34). Our results also suggest a correlation between volume reduction and experience of heaviness and tension but the patient population was too small to substantiate this impression, and this area needs further investigation.

Although there was no significant difference between the two treatment methods (MLD and SPC), there was a tendency favoring MLD as seen in the percent reduction in lymphedema volume. For MLD during Part II, it was 15% but for compression sleeves during Part I and SPC during Part II, it was only 7%. However, the poorer outcome for SPC may be attributable to the time duration of treatment which was only 2 hours/day. Richmand et al (18) found an average reduction of arm lymphedema (n=7) of 30% using SPC for 24 hours with a pressure of 80-130 mmHg (individual tolerance). The theory of longer duration daily treatment is also supported by Zanolla et al (14) who found a volume reduction of 21% after 6 hours with a pressure of 90 mmHg (n=20).

The pressures used in the two previous studies (14.18) were higher than that used in our study. However, SPC treatment under low pressure (35-60 mmHg) has also shown a significant decrease of volume (17) with a daily treatment time of 6 hours in 54 patients. As to why both higher and lower pneumatic pressures each vield similar results may have an explanation in a recent study of manual massage of edema in dogs with a pressure of 70-100 mmHg (35). Higher pressure seems to promote damage to the lymphatics, particularly its endothelial lining, which may be assumed to worsen edema. On the other hand, such pressure loosens the connective tissue, encourages the formation of large tissue channels, and facilitates uptake of lipid droplets into initial lymphatics (35), which may be favorable for patients with lymphedema with a tendency to accumulate fat and fibrous tissue in the interstitium. As the magnitude of the reduction and the dimension of the arm are directly related to the degree of subcutaneous fibrosis (assessed by xeroradiography) (32), the outcome of higher or lower pressure treatment may depend on the severity of fibrosis in the different patient populations. Only clinical examination by palpation was performed on the patients in our study but no marked fibrosis was verified, suggesting that the low pressure that we chose was adequate for edema mobilization in this patient population. We favor that edema be diagnosed and treated at an early stage when fat and collagen deposition is at a minimum and where low pressure application is preferably irrespective of whether MLD or SPC is chosen for treatment.

There was no difference in arm "tension" and "heaviness" in the MLD compared with the SPC cohort. Like arm volume differences, perhaps more prolonged daily treatment may have also improved the subjective assessments.

In our study, overall lymphedema volume reduction was 15%. Zanolla (14) also tried MLD using the Vodder technique (n=20) and found a reduction of 25%. However, the treatment was used in combination with benzopyrone and compression sleeves, although the compression sleeve was not applied for a period of time before MLD as done in our study. Hutzschenreuter et al (16) found a reduction of 20% using MLD, but in combination with compression bandaging therapy. The 15% volume reduction by MLD together with the 7% reduction by compression sleeve in our study (i.e., 22%) supports the results of the two previous studies (vide supra).

Hutzschenreuter et al (16), using low stretch bandages, confirms our clinical impression that bandaging provides better remodeling of arm volume and shape after each MLD or SPC treatment session, compared with that of a standard elastic sleeve alone.

In summary, we determined that manual lymph drainage or sequential pneumatic compression, when applied in conjunction with a compression sleeve, each resulted in a notable reduction of arm lymphedema in women previously treated for breast cancer. Manual lymph drainage showed a decrease of subjective sensation of tension and heaviness in the affected arm, but overall this limited study showed no notable difference between the two treatment regimens.

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