A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema

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This paper describes a randomized controlled crossover study examining the effects of manual lymphatic drainage (MLD) in 31 women with breast cancer-related lymphoedema. MLD is a type of massage used in combination with skin care, support/compression therapy and exercise in the management of lymphoedema. A modified version of MLD, referred to as simple lymphatic drainage (SLD), is commonly taught as a self-help measure. There has been limited research into the efficacy of MLD and SLD. The study reported here explores the effects of MLD and SLD on a range of outcome measures. The findings demonstrate that MLD significantly reduces excess limb volume (difference, $d = 71$, 95% CI = 16–126, $P = 0.013$) and reduced dermal thickness in the upper arm ($d = 0.15$, 95% CI = 0.12–0.29, $P = 0.03$). Quality of life, in terms of emotional function ($d = 7.2$, 95% CI = 2.3–12.1, $P = 0.006$), dyspnoea ($d = –4.6$, 95% CI = –9.1 to –0.15, $P = 0.04$) and sleep disturbance ($d = –9.2$, 95% CI = –17.4 to –1.0, $P = 0.03$), and a number of altered sensations, such as pain and heaviness, were also significantly improved by MLD. The study provides evidence to support the use of MLD in women with breast cancer-related lymphoedema. The limitations of the study are outlined and future areas for study are highlighted.

Keywords: manual lymphatic drainage (MLD), breast cancer-related lymphoedema, lymphoedema management, lymphoedema therapy, combined decongestive therapy (CDT), massage.

INTRODUCTION

Secondary lymphoedema develops in one in four women treated for breast cancer (Kissin *et al*. 1986; Mortimer *et al*. 1996), usually as a result of surgery, radiotherapy or advanced disease. Swelling commonly affects the arm, although oedema of the adjacent trunk area and breast is often present as these areas drain via similar lymphatic pathways. Problems associated with lymphoedema include altered sensations such as discomfort and heaviness (Woods 1993), psychological distress (Tobin *et al*. 1993), difficulties with physical mobility (Sitzia & Sobrido 1997) and an increased risk of recurrent infection (Mortimer 1995).

The intensive lymphoedema management programme, often referred to as combined decongestive therapy (CDT), aims to reduce limb volume, restore limb shape and improve skin and tissue condition (Ko *et al*. 1998). Daily

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treatment is commonly provided over a 3- to 4-week period using manual lymphatic drainage (MLD), multilayer bandaging, isotonic exercises, skin care and, for some, pneumatic compression pumps. This is followed by a maintenance phase of self-treatment when the person wears elastic hosiery and undertakes regular self-massage, skin care and exercise. Maintenance treatment alone is indicated for those presenting with mild, uncomplicated lymphoedema.

MLD was developed in the 1930s by Emil Vodder (Kasseroller 1998). The therapist uses specific hand movements to provide a gentle pumping action on the skin. Although this is a type of massage, no oils are used. This ensures that the maximum skin stretching effect is gained with the minimum of pressure. As a result, lymph flow improves without increasing capillary filtration (Wittlinger & Wittlinger 1992).

MLD has been shown to have a number of physiological effects. These include an increase in the contraction rate of lymphatics (Hutzschenreuter *et al*. 1989), increased reabsorption of protein into lymphatics (Leduc *et al*. 1988), reduced microlymphatic hypertension (Franzeck *et al*. 1997) and improved collateral lymph drainage between the lymphatic territories of the skin (Ferrandez *et al*. 1996). Improved drainage enables fluid to be redirected away from oedematous areas towards the functioning lymph nodes in unaffected areas, an important principle in lymphoedema management. Wittlinger & Wittlinger (1992) also suggest that MLD influences the sympathetic nervous system, promoting relaxation. A simplified version of MLD, often referred to as simple lymphatic drainage (SLD), is commonly taught in the UK to people with lymphoedema, and to their relatives, as a self-help measure (British Lymphology Society 1999).

To date, the evidence-base for MLD and SLD is limited. Most studies of lymphoedema management have focused on the combined effects of CDT (Mirolo *et al*. 1995; Sitzia & Sobrido 1997; Ko *et al*. 1998). Others have evaluated specific interventions such as multilayer bandaging and hosiery (Badger *et al*. 2000) or manual lymphatic drainage and compression (Zanolla *et al*. 1984; Johansson *et al*. 1998; Johansson *et al*. 1999; Andersen *et al*. 2000).

Zanolla *et al*. (1984) studied women with breast cancer-related lymphoedema, comparing patients receiving MLD with those having treatment with pneumatic compression pumps. Limb circumference and subjective assessment of mood were used to measure change. The findings showed similar results for MLD and compression pumps, although the authors concluded that the research was limited owing to small numbers and lack of standardization of method. Johansson *et al*. (1998) also compared MLD with pneumatic compression pumps and found no significant difference between the two treatments. A further study (Johansson *et al*. 1999) measured the effects of compression bandaging with or without MLD in arm swelling. The group receiving bandaging and MLD had a significant reduction in limb volume ($P = 0.04$) and decreased pain ($P = 0.03$), despite the fact that MLD was only given for 1 week. A recent study (Andersen *et al*. 2000) investigated the effect of eight sessions of MLD over 2 weeks, in addition to the standard programme of compression garments, skin care, exercises and information, in 42 women with breast cancer-related lymphoedema. The findings suggested that MLD did not contribute significantly to oedema reduction (Andersen *et al*. 2000), although the MLD treatment course was relatively short and the study group was limited to those with mild to moderate swelling (limb volume <30%).

STUDY AIMS

The aims of the study reported in this paper were:

1 to measure the effects of MLD and SLD on lymphoedema of the arm and trunk;
2 to measure the effects of MLD and SLD on quality of life and symptoms/altered sensations associated with lymphoedema.

PATIENTS AND METHODS

Research design

The study used a randomized, controlled crossover design with two study groups: patients who received MLD followed by SLD and patients who received SLD followed by MLD. For the purposes of the study, SLD was used as a comparative intervention, as it was not believed possible to provide placebo or 'sham' MLD.

Sample

Participants were drawn from the lymphoedema clinic at a large cancer hospital. Subjects who fulfilled the following criteria were eligible for the study: unilateral breast cancer-related lymphoedema for more than 3 months, two consistent limb volume measurements of >10% excess volume, >1 year post cancer treatment, clinically detectable trunk swelling and the ability to provide written consent. Those with active cancer and those on diuretic therapy or other oedema-influencing drugs were excluded from the study. Approval was obtained from the hospital ethics committee and all participants provided

written informed consent. In total, 31 subjects were recruited to the study, with 15 randomized to group A and 16 randomized to group B for the 12 week study period.

Treatment interventions

Group A received 3 weeks of daily MLD followed by a 6-week non-treatment period. This was followed by 3 weeks of daily SLD. Group B received 3 weeks of SLD, followed by a 6-week non-treatment period and then 3 weeks of MLD (Fig. 1).

Three therapists fully qualified in the Vodder method of MLD provided the MLD treatments, which were standardized, with each therapist following the same protocol for treatment to the neck, anterior and posterior trunk and swollen arm, always moving fluid towards the unaffected side. The details of each treatment session were recorded daily on a diary sheet. Treatment consisted of a 45-min MLD session, performed Monday to Friday, over a 3-week period (a total of 15 treatments).

The SLD was taught by the researcher and therapists and performed by subjects for 20 min each day during the SLD period. Subjects were given a leaflet describing the SLD sequence, which comprised treatment to the neck, unaffected axilla and anterior chest wall, followed by abdominal breathing exercises. Specific movements were taught for the neck and axilla and subjects were instructed to use a relaxed hand to gently stretch the skin on the chest wall in the direction away from the swollen area, repeating the movements five times in various positions. Their technique was monitored weekly during the study and each participant kept a diary recording the areas covered and time taken each day for SLD.

All subjects were given advice on skin care and information on lymphoedema and were fitted with new elastic sleeves at the beginning of the MLD and SLD treatment periods.

Assessments and outcome measures

Baseline and demographic data were recorded for each subject and included age, limb volume, time since breast cancer treatment, duration of lymphoedema, side of swelling and details of breast cancer treatment. The principal researcher (A.F.W.) undertook all the measurements and did not provide any of the MLD treatments. The following measurements were recorded before and after MLD and SLD at weeks 0, 3, 9 and 12.

Excess limb volume

Limb volume was determined by using the formula for calculating the volume of a cylinder ($v = c^2/\Pi$) (Kuhnke 1976). Circumferential measurements were taken with a tape measure at 4-cm intervals along the arm, allowing calculation of the total volume of affected and unaffected arm. Excess limb volume represented the difference between both limbs, expressed in millilitres.

Caliper creep on the affected and unaffected sides as measured by modified Harpenden skinfold calipers and the line method

Individuals with arm lymphoedema secondary to breast cancer treatment commonly have trunk swelling in the area behind the axilla. Modified skinfold calipers have been shown to be an indicator of trunk oedema, as measured by the change in skinfold size (caliper creep), provided the method is standardized (Roberts *et al*. 1995). In lymphoedema, the displacement of interstitial fluid as a result of the caliper pressure is influenced by the degree of oedema. The creep value is therefore greater when the level of trunk oedema is high, as more fluid is displaced.

The skinfold calipers are applied to each end of a horizontal 4-cm line drawn on a predetermined, anatomical point on the trunk at the posterior axillary area, and held

Number of weeks

Grp	0	1	2	3	4	5	6	7	8	9	10	11	12
A	-	MLD	MLD	MLD	N	N	N	N	N	N	SLD	SLD	SLD
B	-	SLD	SLD	SLD	N	N	N	N	N	N	MLD	MLD	MLD

MLD=manual lymphatic drainage
SLD=simple lymphatic drainage
N= non-treatment period

Figure 1. Outline of interventions.

in place for 60 s. The skinfold sizes at 10 s and 60 s are recorded and caliper creep is calculated as the difference between these two readings.

Dermal thickness on the affected side using high-resolution, high-frequency skin ultrasound

Lymphoedema affects the skin and underlying tissues, and previous research has suggested that ultrasound may provide information on the amount of oedema present in these areas (Gniadecka 1996). The thickness of the dermis is likely to be influenced by the level of oedema present, although the validity and reliability of skin ultrasound in the identification and measurement of dermal thickness has not been fully ascertained. Easy accessibility to the method prompted its use in this study, particularly as a step towards developing new outcomes measures in a currently limited field.

A 20-MHz ultrasound scanner (Hadsund, Dermascan-C, Cortex Technology APS, Denmark) was used to obtain cross-sectional images of the skin at four sites on the swollen arm: (a) 8 cm down from the elbow crease on the inner forearm (forearm); (b) 12 cm down from the supraclavicular joint over the deltoid muscle (deltoid); (c) 4 cm out from the posterior axillary crease on the back (posterior axilla); (d) 12 cm down from the axillary crease on the side above the waist (flank). Sites were always located to anatomical reference points to ensure the same site was used for subsequent readings. A ring of hydrocolloid dressing (Granuflex®) was cut to the size of the scanner head and placed on the skin over each measurement site. This ensured that the image size and distance from the skin was always the same and allowed a standard amount of ultrasound gel to be used within the Granuflex® ring. Dermal thickness was calculated in millimetres by measuring the distance on each image between the surface entry/echo line and the border between the lower dermis and subcutaneous layer using specifically designed programmes on Matlab® software.

EORTC QLQ C30 quality of life questionnaire

At the time of the study, there were no condition-specific quality of life tools available for lymphoedema. This patient-completed instrument consists of 30 functional, symptom and individual items designed to address a range of quality of life issues relevant to a broad spectrum of cancer patients (Aaronson *et al*. 1993). Permission to use the instrument was obtained.

Symptoms/altered sensations scales

Researchers such as Woods (1993) and Casley-Smith *et al*. (1993) have highlighted the effect of lymphoedema treatment on various symptoms and sensations associated with lymphoedema, although there are no instruments currently validated to measure these changes. For the purposes of this study, six women with arm swelling were questioned regarding the altered sensations experienced by people with breast cancer-related lymphoedema. A 12-item patient self-report questionnaire was developed and was tested for content validity, prior to the study, through discussions with another four patients and two lymphoedema specialists. The final questionnaire consisted of 11 sensations of pain, discomfort, heaviness, fullness, bursting, hardness, heat, cold, numbness, weakness and tingling to which rating scales of 0–5 were applied (0 = none and 5 = worst possible), and one overall distress scale. Subjects recorded the scores for before and after treatment on the same questionnaire in different colours to enable them to make a subjective comparison.

Statistical analysis

The mean difference between pre- and post-treatment values was recorded for both MLD and SLD treatment periods in all outcome measures, except for the symptoms/altered sensations scales. Comparison was made using paired *t*-tests. Results were expressed as mean differences, with 95% confidence intervals (CIs) produced for the differences. Significant interaction was assumed to have occurred should the difference between statistical groups achieve $P < 0.05$. In the symptoms/altered sensations measures, analysis was based on the proportion in whom the symptom improved over the treatment period, analysed by matched pairs for the different treatments.

RESULTS

There were no statistically significant differences in baseline clinical and demographic data between groups A and B (Table 1). Two subjects withdrew because of ill-health (one developed herpes zoster infection and the other developed a chest infection). Both were randomized to group B and had completed the SLD period of the study. A total of 29 subjects completed both the MLD and SLD treatment periods.

Table 1. Comparison of details of patients in groups A (MLD first) and B (SLD first)

	Group A Mean (SEM)	Group B Mean (SEM)	*P*-value
Number	15	16	
Age	59.7 (2.1)	59.3 (2.4)	0.897
Limb volume (% excess)	30.1 (4.9)	39.5 (4.4)	0.167
Time since cancer diagnosed (months)	125.9 (21.8)	145.1 (22.1)	0.543
Duration of lymphoedema (months)	82.5 (14.7)	118.4 (22.0)	0.191
Side of swelling			
Right	5 (33%)	7 (44%)	0.552
Left	10 (67%)	9 (56%)	
Breast cancer treatment			
Local excision	9 (60%)	8 (50%)	0.576
Mastectomy	6 (40%)	8 (50%)	
Axillary sampling	8 (53%)	12 (75%)	0.338
Axillary clearance	6 (40%)	4 (25%)	
No surgery	1 (7%)	0 (–)	
Breast radiotherapy			
Yes	12 (80%)	14 (88%)	0.57
No	3 (20%)	2 (12%)	
Axillary radiotherapy			
Yes	10 (67%)	11 (69%)	0.901
No	5 (33%)	5 (31%)	
Tamoxifen			
Yes	7 (47%)	3 (19%)	0.097
No	8 (53%)	13 (81%)	

Table 2. Mean change in excess volume (ml) before and after MLD and SLD

	Number of patients	Mean excess volume before treatment	Mean excess volume after treatment	Mean change	95% CI	*t*	*P*-value
MLD	29	746	674	71	(16–126)	2.66	0.013
SLD	31	753	724	30	(–4 to 63)	1.81	0.08

Table 3. Comparison of mean difference in excess limb volume (ml)after MLD and SLD

Number of patients	Mean excess volume after MLD	Mean excess volume after SLD	Mean difference	95% CI	*t*	*P*-value
29	674	713	39	(–1 to 78)	2.02	0.053

Excess limb volume

MLD produced a statistically significant reduction in excess limb volume (mean difference, d = 71 ml, 95% CI = 16–126, P = 0.013) (Table 2). Following SLD, there was a non-significant mean reduction in excess limb volume of 30 ml (d = 30 ml, 95% CI = –4 to 63, P = 0.08). The difference between excess limb volume post-MLD and post-SLD just failed to achieve statistical significance (d = 39 ml, 95% CI = –1 to 78, P = 0.053) (Table 3).

Caliper creep

Caliper readings were available from 21 subjects and showed that MLD reduced caliper creep on the affected side (d = 0.23 mm, 95% CI = –0.01 to 0.47, P = 0.06) (Table 4), indicating an almost significant reduction in trunk oedema. Following SLD there was non-significant increase in caliper creep on the affected side. Comparison of post-MLD and post-SLD creep values did not achieve statistical significance (Table 5).

Table 4. Mean difference in caliper creep (mm) before and after MLD and SLD on affected and unaffected side

	Number of patients	Mean creep before treatment	Mean creep after treatment	Mean difference	95% CI	*t*	*P*-value
MLD							
Affected side	21	1.18	0.95	0.23	(–0.01 to 0.47)	1.99	0.06
Unaffected side	21	0.78	1.06	–0.28	(–0.56 to 0.00)	2.06	0.053
SLD							
Affected side	23	0.97	1.04	–0.07	(–0.22 to 0.09)	0.90	0.38
Unaffected side	23	1.03	0.96	0.07	(–0.18 to 0.32)	0.58	0.57

Table 5. Mean difference in caliper creep (mm) on affected side after MLD and SLD

Number of patients	post MLD mean creep	post SLD mean creep	Mean difference	95% CI	*t*	*P*-value
210	95	1.00	–0.06	(–0.33 to 0.22)	0.43	0.669

Table 6. Mean difference in dermal depth (mm) before and after MLD and SLD on affected side at four sites

	Number of patients	Mean depth before treatment	Mean depth after treatment	Mean difference	95% CI	*t*	*P*-value
Forearm							
MLD	28	2.37	2.36	0.01	(–0.10 to 0.12)	0.19	0.85
SLD	31	2.37	2.34	0.03	(–0.09 to 0.15)	0.48	0.63
Deltoid							
MLD	26	2.48	2.32	0.15	(0.12 to 0.29)	2.30	0.03
SLD	29	2.46	2.38	0.08	(–0.05 to 0.20)	1.30	0.21
Posterior axilla							
MLD	28	2.20	2.08	0.12	(–0.03 to 0.26)	1.66	0.11
SLD	31	2.18	2.22	0.04	(–0.17 to 0.10)	0.56	0.58
Flank							
MLD	28	2.02	1.99	0.03	(–0.14 to 0.20)	0.37	0.71
SLD	29	2.10	2.02	0.08	(–0.02 to 0.18)	1.62	0.12

Dermal thickness

MLD significantly reduced dermal thickness at the deltoid site on the upper arm (d = 0.15, 95% CI = 0.12–0.29, P = 0.03) while SLD did not (Table 6). Neither MLD nor SLD demonstrated significant changes at the forearm, posterior axilla or flank sites.

Quality of life

Results from the EORTC QLQ C30 self-report questionnaire showed that MLD improved emotional function in terms of reducing worry, irritability, tension and feelings of depression (d = 7.2, 95% CI = 2.3 to 12.1, P = 0.006). It also improved dyspnoea (d = –4.6, 95% CI = –9.1 to –0.15, P = 0.04) and reduced sleep disturbance (d = –9.2, 95% CI = –17.4 to –1.0, P = 0.03). The other subscales did not achieve statistical significance with MLD. SLD did not result in significant changes to any of the quality of life parameters.

Symptoms/altered sensations

This self-report questionnaire showed that MLD was significantly more likely than SLD to improve pain [odds ratios (OR) = 9.0, 95% CI = 1.2–394.5, P = 0.01), discomfort (OR = 12.0, 95% CI = 1.8–513.0, P = 0.002), heaviness (OR = 11.0, 95% CI 1.6–473.5, P = 0.003), fullness (P < 0.001), bursting (P = 0.008) and hardness (OR = 18.0, 95% CI = 2.8 to 750.0, P < 0.001).

DISCUSSION

A physical treatment programme combining MLD, support and compression with multilayer bandaging and/or hosiery, skin care and exercise is recognized as best practice in lymphoedema management (Ko *et al.* 1998). Petrek *et al.* (1998) recently highlighted the need to provide evidence for the efficacy of each specific therapy within this programme. The randomised-controlled trial reported here aimed to measure objectively the extent to

which MLD influenced a number of treatment outcomes. This was a quasi-experimental design in which efforts were made to control and record treatment variables and reduce researcher bias. SLD was used as the comparative intervention as it was not believed possible to provide 'sham' MLD.

The results showed that MLD provided a statistically significant reduction in limb volume and improvement in several quality of life parameters and symptoms associated with lymphoedema. These findings support the use of MLD in the management of breast cancer-related lymphoedema, although the study does have a number of limitations.

Although the researcher did not provide the MLD treatments or take part in the randomization process, she was aware, at each measurement point, of what treatments had been provided and, thus, may have unintentionally biased the data. Subjects were also aware of which treatment intervention they were receiving at each point during the trial. The placebo effect of daily contact with therapists is difficult to predict, but clearly the experience of having massage and the relationship between therapist and subject could influence individual subjects' perception of the MLD treatment.

The study used a variety of outcome measures. The method of measuring and calculating limb volume in this study has been shown to be reliable, particularly when used in a consistent manner by the same operator (Stanton *et al*. 2000). However, as already noted, many patients also present with oedema of the trunk, particularly in the area posterior to the axilla. To date, there has been little exploration of methods for assessing trunk swelling and, consequently, it was felt useful to incorporate the use of the modified Harpenden skinfold calipers and ultrasound scanner within this study.

The modified skin calipers provide a reproducible and portable method for assessing trunk oedema (Roberts *et al*. 1995), although data were obtainable in only 21 patients. Four subjects were obese, which created difficulties in holding the calipers in place. In two subjects there were difficulties in lifting the skinfold because of radiation damage. Another had scarring from reconstructive surgery and a further subject was unable to tolerate the caliper pressure because of skin sensitivity due to multiple infective episodes.

The mean caliper data from the affected, swollen side almost reached significance and the results may have been influenced by the small data set. However, the non-significant ($P = 0.09$) but marked increase in caliper creep on the unswollen side after MLD appears to indicate movement of lymph into this unaffected area, as would be expected (Table 4). This suggests that the calipers are sensitive to changes in trunk oedema and further validatory work is required.

Lymphoedema is known to affect the dermal and subcutaneous layers of the skin. High-frequency ultrasonography provides a non-invasive approach to skin assessment and has been shown to give information on intradermal oedema (Gniadecka 1996; Hu *et al*. 1998). In the present study, it was assumed that an increase in water content (oedema) would directly influence dermal thickness. Certainly, the baseline dermal thickness measurements at all four sites used in this study were greater on the oedematous side. It is likely, however, that the use of ultrasound images in the assessment and measurement of skin and tissue condition in lymphoedema is complex. Lower frequency ultrasound would provide more information on subcutaneous thickness, and further studies are required to validate the use of ultrasound in the assessment of lymphoedema and measurement of treatment response.

Simple lymphatic drainage was used in this study as the comparative intervention. It did not achieve a significant effect with the outcome measures, although there was a trend to reduction in limb volume. Clinical experience shows that SLD is useful over the long term and provides an effective self-treatment which is particularly indicated when MLD is not available or in the months following CDT or MLD (British Lymphology Society 1999). Subjects in the study appeared to learn SLD more readily once they had experienced MLD, although some did find SLD difficult to use, and consideration must be given to how the technique is taught and monitored over time. The quality of SLD and length of treatment times may have influenced results within this study, and future exploration of SLD should be undertaken within a longitudinal design.

Manual lymphatic drainage provides a means of redirecting fluid from lymphoedematous areas towards functioning lymphatics. It is also the treatment of choice for trunk, breast, head and neck and genital oedema in patients in whom the application of support and compression is often impractical. This study has provided insight into the effects of MLD, without the influence of multilayer bandaging, and results indicate that manual lymphatic drainage has a useful role in the management of breast cancer-related lymphoedema.

The use of a randomized crossover design and a variety of outcome measures have provided a range of quantitative and qualitative data on the effects of MLD. The limitations of the study are acknowledged. Further studies are required to explore the effects of MLD and SLD over the longer term and in different types of lymphoedema,

in order to establish the cost-effectiveness of these approaches within the lymphoedema treatment programme. Work should also be undertaken to further develop and validate outcome measures in this field.

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