

HOME USE OF A MASSAGE PAD FOR CHRONIC SECONDARY LEG LYMPHOEDEMAS – WHAT THE PATIENT CAN EXPECT.

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ABSTRACT

It would seem that the Thermo Cyclopad® has many actions on the body system most of which are beneficial from a holistic point of view. This study indicates that the Thermo Cyclopad® has a use in the management of patients with lymphoedemas of the legs.

The most important finding of the study is the strong and very significant that the massage pad use had on the patient's subjective symptoms, on their ability to undertake the normal activities of daily life and on their quality of life. Longer-term use of the Thermo Cyclopad® might provide benefits beyond those reported in this short study.

INTRODUCTION

Treatment for lymphoedema can sometimes be problematic. While there is little doubt that manual lymphatic drainage, compression garments, skin care, exercise and often medication have been shown to be an effective means of dealing with lymphoedemas, (1, 4, 6, 13, 17) often a complex regimen of therapy must be adhered to (3) which can be prohibitively expensive in the longer term to those of lesser socioeconomic status. Often also the control and self determination of management is taken out of the hands of the person with the problem when it is actually very crucial that a person have a feeling of control. Also it is important, that between visits to the health professional for the treatment of their condition, the patient has some reasonably available strategies to help in the management of their condition in their home environment. This trial aims to show what a patient with chronic secondary lymphoedema of the legs can do in terms of home based management of their condition using a simple massage pad. There is an increasing body of literature which has indicated the potential benefit of vibrational therapy (as can be delivered by a massage pad) in the treatment of conditions which have a similar underlying basis, sequelae and associated symptoms as lymphoedemas (5, 7, 8, 11, 18). In particular, vibration has been indicated to reduce chronic pain (5), and improve wound healing and the regeneration of the lymphatic and blood vasculature (8).

METHODS

20 normal participants (people without any oedema of the legs) and 27 patients with chronic secondary lymphoedema used a Massage Pad (Cyclopad® Niagara Australia) in their own home for three weeks, and were measured (as outlined below) at weekly intervals. All participants used the massage pad according to a defined regimen which was designed to simulate the sequence

used during a lymphoedema drainage massage such as manual lymphatic drainage (although it is acknowledged that the exact nature cannot be mimicked) (3, 13). The aim was to clear lymph nodes and vessels in the abdomen and low back before working downward and clearing vessels in the thighs and calves. The pad has a variable speed control but for this trial the lowest speed was always used. No heating was used, and the frequency of vibration was always held constant. Patients did not take any other treatment in the two weeks prior to or during this trial.

	Pad position	Patient position
1.	Pad at low back	Lying face up
2.	Pad on abdomen	Lying face down
3.	Pad on top of thighs	Lying face down
4.	Pad under thighs	Lying face up
5.	Pad under calves	Lying face up

MEASUREMENT OF LYMPHOEDEMA

All patients in all groups were measured prior to entry into the study and then at 1 week, 2 weeks, 3 weeks and thereafter one month after cessation of the use of the massage pad.

LIMB CIRCUMFERENCE AND VOLUMES

Patient's total limb volume and circumference was measured using a Perometer® which measures limb circumference at 4mm intervals and calculates limb volume. Details of its validation and operation are described elsewhere. (14,15, 19, 20)

EXTRA-CELLULAR AND INTRA-CELLULAR FLUIDS, FAT AND OTHER COMPOSITION PARAMETERS

Body composition (including intra cellular and extra cellular fluid and segmental fluid distribution in the legs and trunk) was measured using the InBody® bioimpedance system. Details of its use have been reported elsewhere (19, 20). Bio-impedance works by passing a number of different frequencies of electrical current through the body. This system is an 8 electrode one which overcomes some of the problems of the 4 electrode systems and eliminates the need for the use of electrodes attached to the skin. With the multi frequency system, since different frequencies take different paths by mathematical modelling it is possible to determine a range of body parameters such as fluids and fat and muscle masses. (16)

FIBROTIC INDURATION

As lymphoedema progresses, the fluid is gradually replaced by fatty tissues and eventually fibrous tissues as a consequence of the sub clinical inflammatory processes which occur. Any fibre build up can significantly impinge on lymphatic drainage. Build up of fibrous tissue was measured using a tonometer (2, 9, 12, 20), which uses defined weight to measure the resistance of tissues, with greater resistance indicating fibrotic induration. Fibrotic induration was measured at three sites on each limb, the calf and anterior and posterior thigh.

SUBJECTIVE MEASURES

Prior to and at each assessment week, participants were asked to rate their experience of 20 aspects of quality of life and activities of daily living, using a 10 point Likert rating scale. Their experience of pain was measured using the short form McGill Pain Questionnaire (MPQ). They also rated 10 symptoms commonly associated with chronic swelling such as tightness, heaviness, cramps, skin dryness burning feelings etc using a 10 point Likert scale. (1 = no problem or issue to 10 = worst imaginable problem or issue). Perception of performance of, and satisfaction with, valued occupations was measured using the Canadian Occupational Performance Measure (COPM).

RESULTS

NORMAL GROUP

After three weeks left leg volumes decreased by 126.5 mls (2 %, $p = 0.002$). This result however was not matched in the right leg. The majority of participants had a decrease in right leg volume, however this was not statistically or clinically significant. It is not clear why the left leg, the non-dominant leg in 19 out of 20 normal participants, should show a significant decrease following cycloid vibration therapy.

There were no significant changes in any of the other parameters measured although there were strong trends in terms of a reduction in heart rate after three weeks massage pad use of 4 beats per minute (5.6 %, $p = 0.129$). There were some reductions in weight loss (0.32 kg's, $p < 0.132$) at the end of three weeks of treatment, and while this reduction was not statistically significant it probably has some clinical importance.

Members of the normal group also experienced a non statistically significant (but possibly clinically significant) reduction of 0.28kgs ($p < 0.221$) in body fat mass at the end of three weeks of treatment. This fat mass lost probably contributed to some of the overall weight loss experienced by the group. This group also experienced a slight reduction in basal metabolic rate (10 Kcal, $p < 0.458$) after three weeks of treatment.

SECONDARY LYMPHOEDEMA GROUP

Leg volume showed good clinical change after three weeks massage pad use. Affected leg size continued to decrease when measured at the four-week follow up.

LYMPHOEDEMA GROUP: AFFECTED LEG VOLUME (MEASURED BY PEROMETRY)						
		Initial	Week 1	Week 2	Week 3	Follow up
Number		27	27	26	25	22
Median		7215.0000	7194.0000	7311.0000	6983.0000	6661.0000
Std Deviation		2230.8670	2335.8002	2269.5067	2147.4825	2277.6983
Percentiles	25 th	5906.0000	5657.0000	6001.0000	5931.5000	5322.0000
	75 th	8875.0000	9213.0000	9244.5000	8793.2500	7984.0000

Statistically significant results were obtained for affected leg fluid after the first week of massage pad use ($p=.032$). Results for weeks 1 and 3 for affected leg fluid were clinically significant, while at the four week follow up 55.5 % this group had less fluid than at the third week measurement, with 11 % of the participants having a decrease of ≥ 480 ml.

LYMPHOEDEMA GROUP: MEDIAN AFFECTED LEG SIZE – CLINICAL CHANGES			
Affected leg size – time frame	Sample size (n)	Percent with less swelling	Percent more than 150ml reduction
3 weeks	25	71.4	21.4
4 week follow up	22	55.5	22.2

LYMPHOEDEMA GROUP: AFFECTED LEG FLUID (MEASURED BY BIO-IMPEDANCE)						
		Initial	Week 1	Week 2	Week 3	Follow up
Number		27	27	26	26	22
Median		6.2050	6.0300	6.1100	6.1250	6.0500
Std Deviation		1.5788	1.5132	1.5965	1.4987	1.3959
Percentiles	25 th	4.7550	4.7625	4.8400	4.6200	4.6500
	75 th	7.2175	7.1475	7.0500	7.0975	6.9500

LYMPHOEDEMA GROUP: AFFECTED LEG FLUID – CLINICAL CHANGES			
Leg fluid – time frame	Sample size (n)	Percent with less fluid	Percent with less fluid ≥ 200 ml
1 week	27	63.6	27.2
3 weeks	26	50	26.6

Trunk fluid decreased over three weeks of massage pad use after initially increasing. Results for the second and third weeks of massage pad use were clinically significant, as outlined in table. At the four week follow up measurement trunk fluid had increased to be more than at the initial measurement. The reasons for this are uncertain but it possibly indicates the need for additional clearance here.

LYMPHOEDEMA GROUP: TRUNK FLUID (MEASURED BY BIO-IMPEDANCE)						
		Initial	Week 1	Week 2	Week 3	Follow up
Number		27	27	26	25	22
Median		15.6000	15.7000	15.4000	15.4500	15.8000
Std Deviation		3.9437	3.9845	4.0975	3.7098	3.7873
Percentiles	25 th	13.4000	13.2500	13.6000	13.4000	13.4000
	75 th	18.8000	18.8000	20.0000	18.8500	18.6000

LYMPHOEDEMA GROUP: MEDIAN TRUNK FLUID – CLINICAL CHANGES			
Trunk fluid – time frame	Sample size (n)	Percent with less fluid	Percent with less fluid ≥ 200 ml
2 weeks	31	40	22.5
3 weeks	30	23.3	20

Extra-cellular fluid also showed some clinical change after two and three weeks of massage pad use, however these changes were not maintained at the follow up. This data suggests the need for ongoing use of the massage pad.

LYMPHOEDEMA GROUP: TOTAL EXTRA CELLULAR FLUID (MEASURED BY BIO-IMPEDANCE)						
		Initial	Week 1	Week 2	Week 3	Follow up
Number		27	27	26	25	22
Median		12.2000	12.0000	11.9000	12.0000	12.100
Std Deviation		2.8876	2.9384	3.1168	2.6595	2.598
Percentiles	25 th	10.5500	10.5000	10.5000	10.5250	10.500
	75 th	14.0000	13.7000	14.6000	13.7000	13.600

LYMPHOEDEMA GROUP: MEDIAN EXTRA-CELLULAR FLUID – CLINICAL CHANGES			
ECF – time frame	Sample size (n)	Percent with fluid change	Percent with fluid change ≥ 200 ml
2 weeks	27	48.3 less	35.4 less
3 weeks	26	56.6 less	40 less
4 week follow up	22	55.5 more	37 more

FIBROTIC INDURATION

Softness in participant's calves increased throughout three weeks of using the massage pad, indicating that fibrotic induration decreased during this time. Minimal changes were recorded for softness at anterior and posterior thigh over the three weeks. At the four week follow up measurement calf softness had decreased slightly, but the amount was not significant. There were no significant changes to softness at the other locations at the follow up.

LYMPHATIC FUNCTION

Two persons with lymphoedema agreed to undergo lymphoscintigraphy before and after massage pad treatment. There was no significant change in clearance rates indicating that the massage pad does work significantly by improving lymph drainage, however the sample size is very small which represents a significant limitation.

SUBJECTIVE RESULTS

CANADIAN OCCUPATIONAL PERFORMANCE MEASURE (COPM)

All participants reported that their performance of valued daily activities improved ($p=.000$) and that their satisfaction with performance of daily activities also improved ($p=.000$) after three weeks use of the massage pad.

QUALITY OF LIFE AND ACTIVITIES OF DAILY LIVING QUESTIONNAIRE

Participants reported improvements on 14 of the 20 areas measured by the questionnaire after three weeks of using the massage pad. These results are summarised in the table below. A clinically significant change is one of three or more than three units (points on the Likert scale) or 30 %.

SIGNIFICANT QUALITY OF LIFE AND ACTIVITIES OF DAILY LIVING RESULTS			
Variable	Sample size (n)	Significance (p)	Percent clinically significant
Range of movement	27	.000	40
Exercise	26	.000	44
Stairs	27	.000	32
Sleeping	27	.000	29
Clothes	27	.000	28
Self consciousness	27	.001	33
Impact on day to day life	27	.009	18
Impact on ability to do job	27	.03	24
Impact on meeting needs of family / household	27	.014	11
Impact on recreation	25	.007	28
Depression re condition	27	.033	18
Happiness – quality of life	27	.022	11
Happiness with treatment	24	.000	42
Amount of control	26	.000	54

The areas which did not show a statistically significant change after using the massage pad were driving, shoes worn, getting dressed, socialising, needing time off from work and needing help with family/household activities.

SYMPTOMS:

Participants reported significantly less symptoms for 8 of the 10 symptoms measured throughout the trial. Significant changes were reported after both the first week and the third of massage pad use for tightness, heaviness, cramps pins and needles, skin dryness and size difference (perceived amount of swelling). All had a statistical significance of ($p < 0.05$). Symptoms which did not change significantly after use of the massage pad were burning feeling and perceived temperature difference.

CONCLUSIONS

The combination of statistical and clinical results achieved from this trial indicate that the Thermo Cyclopad® has a valid place in the range of treatments available for chronic swelling of the legs due to lymphatic problems. Participants with lymphoedema experienced a good clinical decrease in leg volume after three weeks cycloid vibration therapy and also when measured at the follow up. This maintenance of leg volume reduction may indicate a longer-term effect of the therapy. It is not clear however why leg volumes for this group increased in the short term (after one and two weeks of therapy) before decreasing.

Cycloid vibration therapy had a significant short-term effect on the amount of leg fluid of participants with lymphoedema. Good clinical effects were also obtained after three weeks and at follow up, indicating a possible trend. Trunk fluid and extra cellular fluid also reduced by clinically significant amounts after cycloid vibration therapy for this group, however these reductions were not maintained at the follow up. This fact suggests that ongoing use of the equipment is likely to produce a beneficial ongoing positive result.

Resistance to compression (fibrotic induration) at the calf was reduced after three weeks of vibration therapy, however this change was not maintained when measured at the follow up. Induration at the other sites was not affected by cycloid vibration therapy. This fact also suggests that ongoing use of the massage pad is likely to produce a beneficial ongoing positive result.

The lymphoedema participants experienced a clinical decrease in diastolic blood pressure when measured at the follow up, however while using cycloid vibration therapy this and the other cardiovascular parameters had little change. The reason for this is unclear but it would be worthy of further investigation.

Body fat mass decreased by 2.2 kg for the lymphoedema participants after cycloid vibration therapy and this group still had a 1 kg loss in body fat mass when measured at the follow up, which are clinically (but not statistically) significant findings. Changes to body mass index, body fat mass weight and leg volume were associated in this group, indicating that cycloid vibration therapy may have had a systemic effect on these participants.

These reductions are very relevant and exciting and since body mass is one of the major exacerbating factors of lymphoedema and reduction is likely to have significant benefit of the patient's lymphatic system. (Parboo, pers comm., 2003)

The subjective results of the trial are excellent. Participants reported that their performance of and satisfaction with performance of valued daily living activities had increased after using the massage pad. The majority of quality of life and activities of daily living measures were rated better after using the massage pad. Reported improvements to pain, tightness and other symptoms would have contributed to an increased perception of well being and ability. Participants perception of improvement in leg swelling may reflect changes in lymphatic functioning which are too small to be measured accurately by bioimpedance or perometry. They should not however be discounted. As well as contributing to increases in wellbeing, possible increases in levels of activity following cycloid vibration therapy may contribute further to reductions in objective measures of lymphoedema and oedema, as seen in this trial.

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