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Original Article

Addition of vibration to simple lymphatic drainage in the management of breast cancer-related lymphedema: A randomised controlled cross over pilot study

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Key words

upper limb lymphedema, self-management, vibrator, excess limb volume

Abstract

Purpose: Breast cancer-related lymphedema (BCRL) is a chronic disease. Simple lymphatic drainage (SLD) is considered standard care for lymphedema in combination with complete decongestive physiotherapy (CDP). However, two problems are seen with SLD for BCRL: difficulty massaging the back and shoulder region due to functional disorder; and difficulty performing the same technique each time, because massage is performed by hand. We attempted to develop a new methodology focusing on the use of vibration to improve tissue microcirculation. This study investigated whether SLD with vibration in standard CDP treatment for BCRL could improve outcomes compared to SLD alone.

Methods: Group A performed 4 weeks of SLD with daily vibration, followed by a 1-week non-vibration period. This was then followed by 4 weeks of daily SLD alone. Group B performed 4 weeks of SLD alone, followed by a 1-week non-vibration period and then 4 weeks of vibration with SLD. The washout period was decided based on a previous experiment. The vibrator and SLD were used twice a day, with the vibrator used immediately after SLD. We then examined the effects of SLD with vibration and SLD alone on excess limb volume.

Results: Twenty women were initially recruited, 10 excluded (8 excluded from enrolment and 2 excluded from analysis due to lack of data) and 10 completed the study. SLD with vibration achieved reduc-

tions in excess limb volume for all patients. On the other hand, 3 patients showed increased excess limb volume using SLD alone.

Conclusions: Vibration by combining vibration with SLD offers potential benefits compared to SLD alone as supportive care in the management of BCRL.

Introduction

Breast cancer-related lymphedema (BCRL) remains an important complication, occurring in 12-28% of cases, even with the use of modern therapies [1) 2)]. Swelling commonly affects the arm, although edema of the adjacent trunk and breast is also often present, as these areas drain via similar lymphatic pathways. Problems associated with lymphedema include altered sensations such as discomfort and heaviness [3)], psychological distress [4)], difficulties with physical mobility [5)] and increased risk of recurrent infection [6)]. Intensive lymphedema management programs, often associated with combined decongestive physical therapy (CDP), aim to reduce limb volume, restore limb shape and improve skin and tissue condition [7)].

Patients have to continue simple lymphatic drainage (SLD) by themselves for the long term. However, two problems with SLD have been identified. The first problem is the difficulty patients experience in adequately massaging the back and shoulder region. This is because women with lymphedema more frequently report pain, demonstrate bilateral impairments in shoulder range of motion (ROM) and upper extremity strength compared to women without lymphedema, and present with greater restrictions in upper limb activities [8)]. The second problem is the difficulty in stably performing the same technique each time. This is because SLD is typically performed alone and by hand, so the effects will not be the same for each condition every time. Supportive devices for SLD thus appear likely to prove helpful.

The present study focused on the use of vibration as a safe and easy application of supportive devices in self-management. To date, several studies have examined evidence for the use of slight vibration. Our previous studies have described the development of a new methodology and have confirmed the safety of this approach [9)]. The new technique can be used safely and easily by patients with pressure ulcer undergoing artificial dialysis. Two other studies have examined the effects of vibration on lymph drainage. In an animal study, Ohhashi et al.[10)] showed that slight vibration induced increases in lymph flow rate, lymph protein concentration and number of cells in lymph. In a clinical setting, Ohkuma found that vibration can reduce the circumference of the affected limb in combination with hyperthermia and magnetism[11)]. However, that study used vibration in combination with two other factors, so the specific effects of vibration for lymphedema patients receiving standard care have not yet to be clarified. In addition, the vibration device used by Ohkuma was not portable, limiting the applicability to lymphedema patients performing self-management every day at home. We therefore expect that our new device could prove effective for lymphedema patients in supporting SLD.

The purpose of this pilot study was to investigate whether vibration with SLD in standard CDP treatment could improve outcomes compared to SLD alone among women with stage II or late II lymphedema after treatment for breast cancer.

Patients and methods

1. Research Design

This study used a randomized, controlled cross-over design with two study groups: patients receiving vibration with SLD followed by SLD alone; and patients receiving SLD alone followed by vibration with SLD.

2. Setting

Participants were drawn from the lymphedema clinic at a cardiovascular hospital in Ishikawa Prefecture, Japan. Several professions were involved in the treatment of lymphedema at this

clinic, including a doctor and nurses and physiotherapists, with about 50 patient visits per year. They qualified as a therapist of lymph drainage in the medical lymph drainage association of Japan. Most patients underwent surgery for breast cancer at other hospitals and then came to this clinic for treatment of lymphedema. The intervention period was from April until December 2009.

3. Subjects

Subjects who fulfilled the following criteria were eligible for the study: unilateral upper limb lymphedema after treatment for breast cancer; two consistent limb volume measurements showing >10% excess limb volume; >12 months since surgery or adjuvant treatment, in order to provide a reliable follow-up period to detect any possible metastases; lymphedema stage II or late II according to the criteria of the International Society of Lymphedema[12] ; and continued CDP including SLD. Exclusion criteria included subjects with active cancer and those on diuretic therapy or other edema-influencing drugs.

All protocols were approved by the ethics committee at Kanazawa University and all participants provided written informed consent prior to enrollment by researcher. The randomization sequence was generated by random sampling numbers. Sequentially numbered opaque envelopes containing study group assignments were provided to the recruitment clinics. Clinic staffs were unaware of study group assignments. All patients received open-label treatment for 9 weeks.

4. Intervention

Group A performed 4 weeks of SLD with daily vibration, followed by a week non-vibration period. This was then followed by 4 weeks of daily SLD alone. Group B performed 4 weeks of SLD alone, followed by a week non-vibration period and then 4 weeks of vibration with SLD. The washout period was decided based on a previous experiment[10] (fig.1). SLD was included in each period and during the washout period due to its clear place in gold-standard care.

The vibrator and SLD were used twice a day by the patient, with the vibrator used immediately after SLD.

The present vibrator (RelaWave; Matsuda Micronics, Chiba, Japan) was developed in collaboration with Matsuda Micronics and the universities affiliated with the authors. The size of the vibrator was 616×182×114 mm (length×width ×height) (fig.2). The intensity amplitude modulation cycle and vibration time could be adjusted using the attached controller. Operation of the controls was quite easy. Frequency and horizontal vibration acceleration of the vibrator were 47 Hz and 1.78 m/s^2, respectively, according to the results of our previous studies[9]. Vibration was applied for 15 min twice a day. The vibrator was placed under the affected limb with a cushion between the vibrator and the affected limb to avoid direct contact with the skin. This cushion was composed of urethane and 20 cm long, 15 cm wide and 10 cm thick. The frequency and

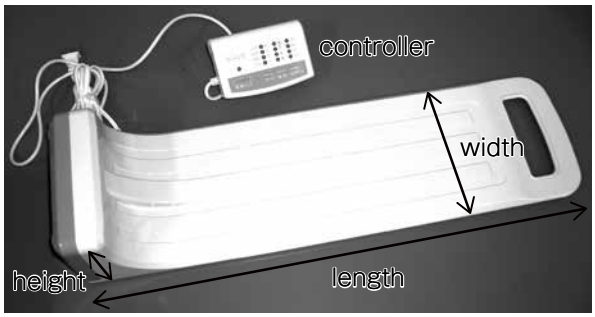

Fig. 2 Vibrator

The size of the vibrator is
616×182×114 mm (length×width×height)

Number of weeks	1	2	3	4	5	6	7	8	9
Group A	Vibration with SLD				Wash out period	SLD			
Group B	SLD					Vibration with SLD			

Fig. 1 Outline of intervention

SLD ; simple lymphatic drainage
Washout period ; patients carried out SLD as usual.

horizontal vibration acceleration of the vibrator were equal in each position when subject put their upper limb on the center of the cushion.

The principal researcher undertook all measurements using a tape measure at 7 points: elbow; 10 cm, 15 cm, and 20 cm above the elbow; and 10 cm, 15 cm, and 20 cm below the elbow. Measurements were recorded at weeks 0, 4, 5 and 9, as several studies have shown the need for an investigating period over 4 weeks[3) 11) 12)] and completed each day from 1:00 PM to 4:00 PM.

Participants recorded the time of SLD and whether they performed SLD using the vibrator each day. A researcher performed weekly monitoring of continued SLD use and application of the vibrator during the study period.

5. Characteristics

These data included age, limb volume at the baseline, time since cancer diagnosis, duration of lymphedema, and details of breast cancer treatment. Characteristics of subjects were described in each patient.

6. Analysis

Limb Volume was determined using the following formula to calculate the volume of a truncated cone[13)] :

$$V=\frac{\pi h}{3}\sum_{n=1}^{m}([\forall r_n{}^2]+r_n\times r_{n+1}+r_{n+1}{}^2)$$

Excess limb volume (%) = (affected limb volume - unaffected limb volume) / unaffected limb volume × 100.

Difference in excess limb volume (%) = pre-treatment excess limb volume (%) - post-treatment excess limb volume (%).

Difference in excess limb volume was determined by subtracting values for the last time vibration was used from values at baseline. The median in each group was calculated and compared to vibration with SLD and SLD alone.

Results

1. Recruitment, Participant Flow and Characteristics

Patients were recruited from April until December 2009. A total of 20 patients were recruited. Five patients did not meet the inclusion criteria, and 3 patients did not provide consent. As a result, 12 patients were recruited, with 7 patients in Group A and 5 patients in Group B. Two patients in Group A were excluded from analysis due to a lack of the 3rd data because of their private schedule (fig.3). These patient's data

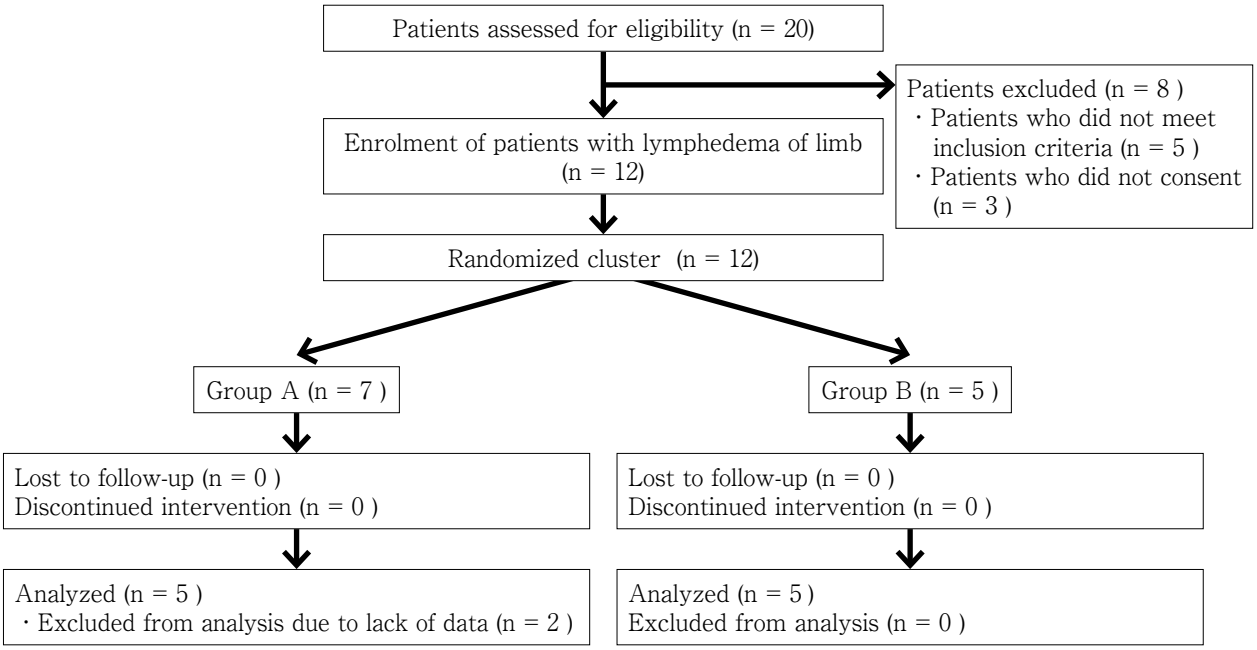

Fig. 3 Participant flow

Group A performed 4 weeks of SLD with daily vibration, followed by a 1-week non-vibration period
Group B performed 4 weeks of SLD alone, followed by a 1-week non-vibration period and then 4 weeks of vibration with SLD.

were not specific change and not difference between include and exclude from characteristics of each patient. One noteworthy finding was that no adverse effects occurred due to physical discomfort from the vibration with the SLD. Table 1 shows the characteristics of each patient. The data was collected at the first time on the 1st week. Nobody changed the treatment and self-management for lymphedema.

2. Outcomes

SLD with vibration achieved reductions in excess limb volume for all patients (Table 2). The most effectiveness was ID 5 and showed that difference in excess limb volume was over −10%.

It's severity of unilateral limb was moderate[14] and she operated SLD 10 minutes every day, stocking and bandaging. The other side, the least was ID 1 and showed that difference in excess limb volume was less −1.0%. It's severity of unilateral limb was mild and she operated SLD 15 minutes every day, stocking and intermittent pneumatic compression device (IPC).

Discussion

Patients with BCRL have to continue SLD by themselves for the long term. We strongly believe that supportive devices for SLD are a necessity to prevent increasing severity of lymphedema and to minimize the daily burden of SLD. An IPC has been developed as a supportive device for SLD, enabling reductions in limb volume for lymphedema patients[15]. However, the device carries a risk of damage to the lymphatic system due to the intensity of compressions[16]. Conversely, our vibrator is safe because no compressions are applied. However, exposure to vibrations over 2.5m/s^2 per day has been associ-

Table 1 : Patient characteristics

ID Group	Age (years)	Body mass index	Duration of lymphedema (years)	Treatment for cancer	Time after cancer treatment (years)	SLD 1)	MLD 2)	Stockings 3)	Bandaging 3)	IPC 4)	House work 3)	Working 3)
1 A	43	19.5	2	axillary lymph node dissection, axillary radiotherapy, tamoxifen	2	105	0	3	0	270	4	3
2 A	63	25.0	20	extended radical mastectomy	27	140	120	1	0	80	2	8
3 A	58	28.2	2	axillary lymph node dissection, axillary radiotherapy, tamoxifen	2	70	0	8	0	0	3	3
4 A	65	19.1	20	extended radical mastectomy	38	560	80	8	8	0	6	2
5 A	62	29.9	3	axillary lymph node dissection, tamoxifen	4	70	0	4	6	0	5	0
6 B	41	22.1	2	axillary lymph node dissection, tamoxifen	2	70	60	11	0	20	0	0
7 B	60	25.7	8	extended radical mastectomy, tamoxifen	11	105	0	8	8	0	3	4
8 B	52	24.1	2	axillary lymph node dissection, axillary radiotherapy, tamoxifen	3	70	0	8	8	420	3	8
9 B	55	23.2	3	axillary lymph node dissection, axillary radiotherapy	3	70	20	0	0	0	4	0
10 B	55	24.5	1	axillary lymph node dissection, axillary radiotherapy, tamoxifen	1.5	140	80	8	0	0	4	4

The data of the first time.
1) total minutes per week 2) total minutes per month 3) total hours per day 4) total minutes per month

Table 2 : Difference in excess limb volume

ID-group	Vibration with SLD			SLD		
	Excess limb volume (%)		Difference in excess limb volume (%)	Excess limb volume (%)		Difference in excess limb volume (%)
	First time	After 4 weeks		First time	After 4 weeks	
1-A	11.3	10.5	−0.8	7	5.6	−1.4
2-A	13.7	6.2	−7.5	6.4	9.8	3.4
3-A	54.6	45.2	−9.4	40.4	38.2	−2.2
4-A	31.7	24.4	−7.3	25.8	24.8	−1.0
5-A	31.7	19.8	−11.9	13.4	17.1	3.7
Median	31.7	19.8	−7.5	13.4	17.1	−1.0
6-B	3.2	-6	−9.2	14.4	8.4	−6.0
7-B	30.9	25.8	−5.1	28.3	20	−8.3
8-B	26.7	25	−1.7	26.9	24.9	−2.0
9-B	21.5	15.1	−6.4	24.4	20.7	−3.7
10-B	11.2	7.2	−4.0	8.4	11.1	2.7
Median	21.5	15.1	−5.1	24.4	20	−3.7

ated with hand-arm vibration syndrome and the Ministry of Health has called attention to this issue[17−19]. The several reports indicated that the large frequency was risk of acute reductions in finger blood flow[18, 19]. However, low frequency effected of increasing blood flow[20, 21], prompting healing pressure ulcer[9] and safety method[20]. In our study, vibrations were limited to 0.4m/s^2 each day[17], representing a safe condition. Vibration with a frequency of 47Hz and a horizontal acceleration of 1.78m/s^2 was applied for 15 min, twice a day. A previous study has shown that the device and application conditions are safe[9], but no evaluations of effectiveness and safety for lymphedema patients have been reported.

The novel finding from this investigation was suggested that excess limb volume was reduced by SLD with vibration in compared to SLD alone. The difference from ID5 and ID1 was the severity of unilateral limb and time to spend for self management. We thought that the edema of ID5 has been left in spite of SLD and ID1 have been enough for SLD.

Given the cross-over design, 1-week wash-out period and researcher confirmation of participants continuing SLD and adequately using the vibrator every week, we could be confident in the veracity of this result. Reduction of edema using the vibrator appears effective by addressing two problems associated with SLD. First, the vibrator provided slight vibrations to the skin in the affected limb and back, which are difficult areas for the patient to massage. We checked that this area could be stimulated uniformly while supine in a preliminary test prior to the main study. Second, participants could repeatedly achieve suitable intensity and frequency of stimulation using the vibrator. SLD alone can be limited in achieving such stability because of the manual strength and endurance required to repeatedly perform the technique. Furthermore, the timer on the vibrator prevented overexposure to vibrations.

In addition, subjects could safety and easily use this simple, portable device in their home. No patients in this study reported dropped out or any side effects; nausea, psychroesthesia, rubor at skin. This was probably because of this condition of vibrator was low and used the cushion. If the condition will be changed, we cannot secure this result. Patients need to be able to perform SLD every day, and this vibrator was able to be adapted to daily life in each patient for 9 weeks, facilitating SLD with usual self-management.

Although vibration was effective for patients with lymphedema, this research has several limitations. First, only use as a supportive device for

SLD was examined and we cannot make any comment on results without SLD. Vibration in this study represented a slight stimulation, similar to the soft massage of SLD moving skin. We guessed that vibration played a role in supporting this technique. However, this device cannot support massage for areas around the axillary lymph nodes and transport of lymph to the thoracic duct in SLD. In addition, specialists have to check about technique when using this device as same as a periodic teaching technique of SLD for outpatients. Furthermore, this study included only a small subject population, a short study period and difficulties in blinding the group assignment for outcome assessments. These limitations must be kept in mind when considering the results of this study. Further studies are required to be investigated more thoroughly in trials with larger sample size, longer follow-up periods.

Conclusion

We evaluated reductions in excess limb volume by combining vibration with SLD compared to SLD alone in women with stage II or late II lymphedema after treatment for breast cancer. This result suggests that vibration can be applied as a new supportive modality for SLD.

Acknowledgement

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Conflict of Interest

None

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乳癌術後のリンパ浮腫患者に対する簡易的リンパドレナージに追加した振動の効果：ランダム化クロスオーバーパイロット研究

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キーワード
上肢リンパ浮腫，自己管理，加振器，患肢容積過剰率

要　旨

目的：乳癌術後患者のリンパ浮腫に対し、リンパ浮腫の標準的治療として複合的理学療法が行われており、その一環として簡易的リンパドレナージ（SLD）がある。しかし、SLDは患者自身で行う手技であり、機能障害のために背中や肩へのマッサージが困難であること、毎回一定の技術での実施が困難であることが問題である。我々は、加振器を用いたマッサージ効果に着目し、乳癌術後のリンパ浮腫患者に対し、SLDに振動を追加した場合、SLD単独よりも効果があるかを検証した。
方法：対照期はSLD単独実施、介入期はSLDに振動器を追加して実施し、対象者は対照期または介入期のいずれかを先に実施するグループに分けた。SLDは１日２回実施し、振動器はSLD直後に使用した。アウトカムは、対照期と介入期の容積過剰率で評価した。
結果：20名がリクルートされ、除外８名とデータ欠損２名を除き、全過程を終了したのは10名であった。SLDに振動を追加した介入期では、10名全員が容積過剰率減少を示した。
結論：乳癌術後のリンパ浮腫患者の管理において、SLDへの加振は、補助的療法として有効であることが期待できる。