Impact of Aggressive Decongestion on the Maintenance Phase in Combined Physical Therapy for Lower Extremity Lymphedema

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Objectives: To evaluate the impact of initial aggressive decongestion (Phase 1) on the maintenance phase of complex physical therapy (CPT).

Materials and Methods: We reviewed 27 patients with unilateral and 3 patients with bilateral lower extremity lymphedema who started CPT between April, 2009 and October, 2010. Twelve patients elected to undergo in-hospital Phase 1 (Group I), while the other 18 started CPT on an outpatient-basis without having Phase 1 (Group O). The extremity volume was assessed at the beginning of CPT, and then 3 and 6 months later.

Results: A significant reduction in extremity volume was achieved in each group after 6 months of CPT: from 9049 ± 1912 mL at the beginning to 7771 ± 1486 mL (p = 0.0033) in group I; and from 7370 ± 1392 mL to 7036 ± 1241 mL (p = 0.0200) in group O. However, after 6 months, extremity volume reduction (−845 ± 1283 mL in group I vs. −404 ± 370 mL in group O; p = 0.7672) and volume reduction rates (−23.6 ± 22.7% in group I vs. −46.4 ± 52.2% in group O; p = 0.2564) did not differ significantly between the groups.

Conclusion: Phase 1 did not have a significant impact on the maintenance phase in terms of control of the extremity volume for at least 6 months after the induction of CPT.

Keywords: leg, lymphedema, combined physical therapy

INTRODUCTION

Combined physical therapy (CPT) is the main-stay of treatment for extremity lymphedema and generally consists of two phases. Phase 1 is an aggressive decongestion phase which includes skin care; manual lymph drainage (MLD); and a range of motion exercises and compression, typically applied with multi-layered bandages (MLB), all aimed at maximal decongestion. Phase 2, which is initiated promptly after Phase 1, aims to conserve and optimize the results obtained in Phase 1. It generally consists of compression with a low-stretch elastic stocking, skin care, continued remedial exercise, and repeated self-based MLD as needed.1 This two-phase treatment has not achieved popularity in Japan; therefore, CPT is induced in various ways. Although patients undergo CPT only on a biweekly- or monthly-basis, they are often well controlled, mainly because successful CPT is dependent on the patients’ diligence.2,3 Thus, we wondered whether Phase 1 treatment is necessary and if so, what is the benefit of Phase 1 treatment? We conducted this study to clarify these points.
**Patients and Methods**

The subjects of this study were 27 patients with unilateral lymphedema and 3 patients with bilateral lymphedema with minimal symptoms in either leg who commenced CPT at our clinic between April, 2009 and October, 2010. The diagnosis of lymphedema was made by physical examination, and skin ultrasound findings indicating inflammatory changes in the skin and the subcutis, and was finally confirmed by lymphangiocintigraphy in all patients. Each patient was given an intradermal injection of 111MBq of $^{99m}$Tc suspended in 0.1 ml human serum albumin ($^{99m}$Tc-HSA) into the first interdigital web. When the inguinal nodes and lymphatic trunks in the leg were not visualized within 1 hour from the injection, and/or this was accompanied by congestion of the $^{99m}$Tc-HSA in the dermis (dermal back flow sign), it was interpreted as reduced lymphatic function. The choice of inpatient/outpatient, with/without phase 1 was totally dependent on patients’ preference. Twelve patients then elected to start Phase 1 treatment on an in-hospital basis (Group I), whereas 18 patients preferred to start CPT on outpatient-basis without undergoing initial aggressive decongestion (Group O). Seven patients in group I and 7 in group O were aged over 70 years old. No patient wished to undergo Phase 1 treatment on an outpatient-basis. The patients in group I were admitted and given daily treatment, including MLD, MLB with low-stretch materials, and exercise by licensed lymphedema therapists and physiotherapists, as described by Földi et al.4, 5 Toward the end of Phase 1, we instructed patients to care for themselves at home, which included care of the skin and methods of drainage and bandaging. When the extremity volume stabilized, and the patients’ self-management of their legs was regarded to be sufficient, they were discharged to continue Phase 2 treatments. When complications of CPT developed, the treatment was discontinued immediately, and the patient was referred to specialists. After the complication had resolved, CPT was re-started from the beginning. Patients in group O were instructed in the same self-management methods as group I, at 1–4 week intervals depending on their ability. Although MLD and MLB were provided at each visit, this aimed mainly at demonstrating techniques.

One patient from group I and two patients from group O were excluded from the final analysis. The patient from group I suffered increased seepage from a lymphocele in the scrotum when the leg was wrapped, so his compression therapy was modified to mild below-knee wrapping, leaving significant amount of edema in the leg intentionally. One patient from group O was not able to continue treatments because of worsening lumbago, and another patient from group O withdrew from the study because of cancer recurrence needing admission. Thus, we assessed 27 patients, 11 patients in group I and 16 patients in group O.

**Data collection**

Limb measurements were done by the same operator at inclusion, being at the end of Phase 1 in group I, and then 3 and 6 months after the initiation of CPT. The points of measurements are shown in **Fig. 1**. Starting at the upper edge of the patella, At the upper edge of the patella, circumferences were measured at 10 cm intervals, upward to the level of the pubis, and downward to the ankle. The distances of $a$ and $b$ were measured separately for calculation. The distances between $a$ and $b$ were measured separately for calculation.
ankle. The distances of a and b were measured separately for calculation. The volume of the limb was calculated by the following formula for a truncated cone, as described by Casley-Smith:

\[
V = \frac{h(C^2 + Cc + c^2)}{12\pi}
\]

where \(V\) is the volume of an extremity segment, \(C\) and \(c\) are the circumferences at each end, and \(h\) is the distance between the ends. Thus, the extremity volume is the sum of all segment volumes except for the foot.

The actual volume reduction was calculated as;

\[
\text{Actual volume reduction} = (\text{Extremity volume after treatment}) - (\text{Extremity volume before treatment}).
\]

The volume reduction rate was calculated as;

\[
\text{Volume reduction rate} = \frac{(\text{Extremity volume after treatment}) - (\text{Extremity volume before treatment})}{(\text{Contra-lateral extremity volume})}.
\]

Statistical analysis

Results are expressed as means ± standard deviation or count (percentage), unless otherwise indicated. The Wilcoxon signed rank sum test was used to determine the significances of the changes in extremity volumes, the actual volume reductions, and the volume reduction rates in each group. The Mann-Whitney U-test was used to compare the above parameters between the groups. Statistical analyses were performed using StatView J-5.0 (SAS Institute, Cary, NC, USA). A \(p\)-value of less than 0.05 was considered significant.

RESULTS

Table 1 summarizes the patient characteristics of both groups. Patients in group I were older (group I: 74 ± 6 years vs. group O: 64 ± 13 years, \(p = 0.0431\)) and had larger differences in extremity volume between the legs (group I: 2816 ± 1545 ml vs. group O: 1221 ± 674 ml).

<table>
<thead>
<tr>
<th>ISL stage</th>
<th>Group I (n = 11)</th>
<th>Group O (n = 16)</th>
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ISL: the International Society of Lymphology; s/p: status post-; N.S.: not significant
Aggressive Decongestion in CPT

The hospital stay for group I was 10–15 (mean 12) days. One patient suffered an increase in systolic blood pressure to >200 mmHg on the first night of Phase 1, but this was settled with adjustment of the bandage pressure. Thereafter, she completed Phase 1 without further problems. Another patient complained of chest discomfort on the first day of Phase 1. Her CPT was discontinued immediately and she was referred to a cardiologist. Although the findings of screening electrocardiogram were within the normal range, she was found to have significant coronary artery stenosis causing angina. After successful coronary intervention, Phase 1 treatment was re-started and completed without problems. There were no reported complications in group O. All of these patients were instructed in the self-management methods over 6–12 (mean 8) weeks.

The changes in extremity volume, actual volume reduction, and volume reduction rates for both groups are shown in Figs. 2–4, respectively. Throughout the study period, affected extremity volume was larger in group I than in group O: at 9049 ± 1912 ml vs. 7370 ± 1392 ml (p = 0.0089) at inclusion, 8413 ± 1170 ml vs. 7059 ± 1321 ml (p = 0.0089) at 3 months, and 8204 ± 1182 ml vs. 7036 ± 1241 ml (p = 0.0179) at 6 months, respectively. In group I, the extremity volume decreased from 9049 ± 1912 to 7771 ± 1486 ml (p = 0.0033) at the end of phase 1, accounting for a −1278 ± 873 ml, −49.5 ± 26.0% reduction. However, toward the end of 6 months, it increased again to 8204 ± 1182 ml. This was still a significant reduction (p = 0.0044) from the initial volume. In group O, the extremity volume decreased gradually from 7370 ± 1392 ml to 7036 ± 1241 ml (p = 0.0200) over 6 months. The actual volume reduction in group I vs. group O was −595 ± 1178 ml vs. −382 ± 383 ml (p = 0.7298) at 3 months and −845 ± 1283 ml vs. −404 ± 370 ml (p = 0.7672) at 6 months, respectively. The volume reduction rate in group I vs. group O was −13.8 ± 20.4% vs. −42.5 ± 42.8% (p = 0.1671) at 3 months and −23.6 ± 22.7% vs. −46.4 ± 52.2% (p = 0.2564) at 6 months, respectively. There were no significant differences between the groups. When looking at the individual actual volume reduction, the changes in extremity volume were relatively mild and uniform in group O, whereas they were varied much in group I.

**Discussion**

The results of this study show that Phase 1 treatment, involving initial aggressive decongestion, does not impact significantly on the maintenance phase, in terms of control of the extremity volume, for at least 6 months after the induction of CPT.

CPT consists of meticulous skin care, MLD, compression therapy, and decongestive exercise therapy. It usually
starts with the decongestion phase (Phase 1), in which MLB and MLD are applied by trained therapists on daily-basis. It aims to drain the pool of protein-hyaluronic acid fluid and maximally restore the extremity volume. This is followed by Phase 2, in which patients maintain the results of Phase 1 actively, by using elastic compression hosiery and, if necessary, self-based MLD, MLB, and skin care.5)
The effectiveness of Phase 1 in relieving lower extremity lymphedema has been described, particularly in relation to reducing the extremity volume beyond 6 months from Phase 1. Budger et al. verified the effectiveness of using MLB first, before the wearing of compression hosiery. They found that edema reduction at 24 weeks was better for patients who had used MLB for 18 days, and then wore compression hosiery, than for those who wore only compression hosiery. After an average follow-up of 9 months, Ko et al. also reported that reduced extremity volume was maintained in 82% of patients with lower extremity lymphedema, who were compliant with their treatment. In the current, retrospective study, since the choice of inpatient/outpatient were totally dependent on patients’ preference, the enrollment of the patient was significantly biased. This may be interpreted that older and more diseased patients tended to prefer in-hospital treatments. Taking this biased enrollment into account, we assessed changes in the extremity volume using 3 different parameters, namely the extremity volume, actual volume reduction, and volume reduction rate, and there was no statistical differences between changes in each of the values.

However, this aggressive decongestion phase seems to have distinct advantages. Both the patient and physicians and therapists can recognize and share the best shape of the current extremity at the end of Phase 1, which is a tentative goal of the next step and a strong incentive for the patient. It is thought that 24-hour MLB and daily MLD, including a tissue softening technique, offer the better results. Moreover, patients are often moved deeply by the therapists’ diligence during Phase 1, which again inspires the patient to pursue life-long treatment. Phase 1 complications are discovered more easily than those of Phase 2 because Phase 1 is carried out in the hospital, and Phase 2, in the home of the patient. As we reported, aggressive decongestion can cause serious complications, especially at the beginning when a large amount of interstitial fluid shifts into the circulation in a short period. None of the group O patients reported complications, although it is highly likely that we simply were unaware of any. Földi et al. describes the compelling reasons for starting Phase 1 on an in-patient basis as follows: malignant lymphedema, lymphedema of the head and the genitalia, poor general condition with or without serious complications and/or infection, infants, advanced disease such as lymphorrhea, and transportation problems. All of these criteria are proposed to ensure patients’ safety and strictness of treatment, promoting successful CPT.

Two-phase CPT may be ideal, but some patients are too busy to attend to daily treatments or to be admitted, and the others cannot afford the expense. For these patients, we provide advice on self-management techniques, designed according to what they can achieve. Since Phase 1 treatment is performed in few institutes in Japan, the opportunities are limited. We know, however, that many patients are doing well and keeping their extremities in very good shape despite the difficulties. Indeed, the success of CPT depends on patients’ diligence. Conversely, non-compliance is associated with a poorer response to CPT. If the patient does not consistently wear their compression hosiery, relapse is imminent and the affected extremities will return to the pre-treatment state within 1 week.

A few of our patients could maintain the minimum extremity volume achieved in the course of Phase 1. This stands to reason since the treatments provided by trained specialists would be surely more effective than self-based management. Unfortunately, there are too few therapists to provide constant support for these patients, and family support is often difficult, which isolates the patient further, and may eventually result in failure of the CPT.

The goal of CPT varies according to each patient’s life style and perspectives. Patients with leg lymphedema for decades are often so accustomed to the edema that they are happy with any reduction in swelling; however, they might become noncompliant if the treatment is too much trouble for them. In the present study, 7 of the 12 patients in group I and 7 of the 18 patients in group O were over 70 years. Weak, elderly patients may find it difficult to put on compression tights or bandages on their legs and may feel that the hosiery is burdensome. Moreover, the lower extremity pathophysiology is complicated and multifactorial, often complicated with functional venous insufficiency, and thus hard to manage.

Phase 1 treatment seems indicated for patients who accept it and its goals are higher, particularly in terms of extremity volume; however, the absence of Phase 1 is not a failure of CPT, and should be accepted. CPT aims not only to control extremity volume, but it also helps to prevent malignancies, such as angiosarcoma, and reduce cellulitis. The patient’s ability to incorporate CPT comfortably in their life is the key to them making a life-long commitment. From our perspective, an efficient insurance system for patients and medical staffs, more lymphologists and trained therapists, and adequate information and support are necessary to achieve successful CPT results in Japan.
Since this is a retrospective study of a small number of patients, we cannot make a definite conclusion. However, we do believe that the tendency is similar in every institute, thus justifying the need for a randomized, prospective study. The frequency of cellulitis and malignant formation as well as quality of life should also be assessed in a larger number of patients over a longer period.

**Conclusion**

We conclude that Phase 1 treatment is effective for reducing the extremity volume, but is not truly necessary to maintain the extremity volume reduced for at least 6 months in the current Japanese situation. For successful CPT, we should endeavor to incorporate it properly for each patient. The overall medical system supporting patients with lymphedema needs to be improved.

**References**