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Utilizing Complete Decongestive Therapy to Treat Lymphedema: Evidence from Contemporary Literature

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Introduction

A "Systematic Review of the Evidence for Complete Decongestive Therapy in the Treatment of Lymphedema from 2004 to 2011" was commissioned as part of the American Lymphedema Framework Project's (ALFP) review of literature concerning 13 various aspects of lymphedema management.

Publications from the 11 major medical indices and from the authors own reference articles were reviewed with the goal of critically analyzing current literature regarding the management of lymphedema (LE) with all the components of Complete Decongestive Therapy (CDT) both singularly and in combination. The Best Practice for the Management of Lymphoedema from the International Lymphedema Framework Project (ILFP) was used as the guide for search terms related to articles to be reviewed. Inclusion and exclusion criteria were established for the 99 articles reviewed. Of these, 26 met the inclusion criteria. In addition, 14 review articles and two consensus articles were reviewed. One case study, which did not meet the inclusion criteria, was included as it was a unique case study on genital edema.

Once the articles to be reviewed were determined, the authors categorized the study evidence using the Oncology Nursing Society Putting Evidence into Practice (PEP) guidelines. A consensus of the authors was used to determine not only inclusion/exclusion but also where each article fell within the PEP guideline ratings.

There were several challenges faced by the authors, such as a lack of a uniform definition of what constitutes LE. Many studies did not have control groups or randomization, well-controlled interventions, agreement on the correct dosage of CDT, and the blinding of assessors. Most studies were small in size, and the few having follow-up assessments had a high dropout rate.

Additionally, it was difficult to determine which of the separate aspects of CDT (Manual lymph drainage [MLD], compression bandaging/compression garment [CB/CG], exercise, skin care) were responsible for the success of the therapy.

Some of the studies also incorporated intermittent pneumatic pumps as part of their CDT treatment plans or did not include the exercise component.

These limitations explain why there was only moderately strong evidence for the use of CDT in the treatment of LE.

While CDT has been used successfully in Europe and the United States and Canada for more than 30 years, the "evidence-based medicine" standards have been lacking. It was the purpose of this systematic review to determine the strengths and weaknesses concerning the levels of evidence on CDT as a treatment modality for lymphedema and to guide future research efforts to support the continued use of CDT as a best practice in lymphedema management.

Results

A report on the 26 articles meeting inclusion criteria plus the one unique case study (for a total of 27 studies) follows.

Fifteen articles were rated as "likely to be effective." They included seven randomized controlled trials (RCTs), four retrospective studies, three prospective studies, and one unique case-controlled study.

Breast-cancer related lymphedema (BCRL) was the most common among the studies, with twelve studies focusing on this aspect of utilizing CDT for patients with LE. Three studies included both upper and lower extremities.

Differing types of measurements were utilized to determine the volume of the lymphedematous limb. Circumference measurement with a tape measure was most common, with nine studies using this method, while two used perometry, five volumetry or a combination of volumetry and circumference. One study used ultrasound and calipers to measure tissue thickness, and one measured the pressure under the compression bandaging.

Studies reviewed had a range of subjects from 29 to 537 participants. Of these studies, nine reported no follow-up, two had a 24-hour follow-up, one had a 6-month follow-up and three had 12-month follow-up.

In 14 of the 15 studies, assessors were not blinded to the intervention. Only two studies measured how lymphedema impacted their quality of life (QOL).

Two studies were judged to be "benefits balanced with harm." Volume change was the focus of one study with BCRL. It included 31 subjects who had their volume change with exercise alone or in combination of exercise and wearing compression garments. Unfortunately, this study only had a 24-hour follow-up. The other was a prospective study with 57 participants with lower extremity LE. These subjects received between two and four weeks of MLD combined with CB and exercise. There was a one-month follow-up. Measurements were taken circumferentially. Neither study blinded the assessors, but both studies assessed the impact of intervention on the QOL.

"Effectiveness not established" was scored for the remaining ten articles with seven being prospective, two retrospective, and one the single unique case study. Once again, BCRL was the primary focus in six studies while three included lower extremity LE. The one unique case study was included as it reported on genital lymphedema.

Of these ten studies, eight measured volume reduction by circumference, one by volumetry, and one by lymphoscintigraphy. Three studies assessed QOL. Subject size ranged from 1 to 82 participants. Follow-up was reported: four studies, none; one for three months; one for 6 months and one for 12 months. Only one study blinded the assessors.

CDT

Perhaps the 2009 review by Devoogdt et al.[1] best summed up what those in the field treating LE know: "CDT is an effective therapy of lymphedema but the role of each component is unclear. . ." Leal et al.[2] wrote in their review of treatment modalities that "within the therapeutic modalities used for LE treatment, CDT undoubtedly has the strongest scientific support."

Most authors agreed the methodology for teasing out the effectiveness of the various aspects of CDT resulted in less than stellar studies. Part of the difficulty in determining the effectiveness of each component is the synergistic effect of combining MLD with CB. MLD was never intended to be the sole treatment modality of LE. It was designed to be used in conjunction with CB since once the edematous fluid has been moved out of the tissues, fluid would quickly return without the external support of bandages replacing the tissue pressure.

One study in 2005 by Karadibak et al.[3] attempted to isolate the effects of MLD within the CDT treatment in a RCT of BCRL in 53 cancer survivors. One group of 27 received the standard CDT, which included MLD while the control group of 26 received CDT without MLD. The group who did not receive MLD as part of their protocol, received a reduction in their lymphedema by 36% while the group who received MLD achieved a 56% reduction. This greater reduction with MLD does show the contribution of MLD within the context of CDT.

A cross-over RCT study was done by Williams et al.[4] in 2002. In this study, 16 participants with more severe, chronic lymphedema received MLD daily compared to a group of 15 who did self-MLD. After six weeks, the groups switched interventions. In this study, MLD compared to self-MLD led to greater reductions in swelling in both the arm and in the trunk.

In another RCT cross-over study of 42 women with mild or early onset BCRL, Andersen et al.[5] found that compared to compression alone, MLD was not a significant factor in reducing volume. However, McNeely et al.[6] conducted an RCT study with 50 BCRL participants and found MLD with compression bandaging was more beneficial than the use of compression bandages alone.

A difference in study protocols may be the primary reason for contradictory findings in some of the studies, which points to the need for more research. As an example, MLD was done for 30 minutes, 45 minutes, or 60 minutes a session. Treatments were once a week, 2-3 times a week or 5 times a week, (one study did it twice a day 5 days a week). The course of treatment lasted anywhere from 2 weeks to 6 or more weeks; some were a set length while others went until patient's volume loss plateaued. During treatment, some protocols used compression bandaging, while others used compression garments. The exercises used were not described and a few protocols did not include exercises in the treatment.

Acute and long-term management of lymphedema with CDT

Most of the articles available for review dealt with the use of CDT or some of its elements or abridged protocols of CDT for the intensive phase of treatment. Only a few articles looked at long-term management of lymphedema.

In spite of the differences in methodology and protocol, the clear outcome in most studies was an immediate improvement in limb volume whether using CDT or a variant.

The limb reductions achieved in the different studies covered a range: Jeffs[7] reported 70% reduction. Yamamoto et al.[8] reported 59% for patients with arm LE and 73.5% for patients with leg LE. McNeely et al.[9] reported 44-46% reduction; Kim et al.[10] reported 43.6% reduction; Vignes et al.[11] reported 36-38% reduction; Pinell et al.[12] reported 22% reduction (this included patients with active tumors).

The long-term results of CDT were harder to determine. Only a few studies included follow-up.

Johnstone et al.[13] had a median follow-up of 7.5 months, but a very small sample size (11 patients returned for follow-up out of an initial 82 patients). Of these, the 7 who reported adherence to their home program had continued to reduce and the 4 who didn't had begun to increase in limb volume again. Kim et al.[14] had a 6 month follow-up and found that 42% of the subjects had regressed to just being 15% below where they had started. Mondry et al.,[15] with a 12 month follow-up, also noted limb size increasing during follow-up. Vignes et al.[16] had the largest number of patients (426) of whom 356 were available for 12 month follow-up. These patients had a home program of wearing compression garments daily and bandaging 3 nights a week (and having MLD 1-3 times a week). There were continued reductions of more than 10% in 28% of these patients.

These studies were consistent with previous follow-up studies (Boris et al.[17] and Ko et al.[18]) which also found that adherence to a home program of compression is important to maintaining results and following active self-care, such as decongestive exercises/self-MLD can lead to continued reductions.

Quality of life (QOL)

Quality of life and improved function are two important results of treatment, but they

were examined in only a few of the studies. The general outcome was that after lymphedema treatment, quality of life improved, even if the results of treatment (i.e., limb reduction) were not fully maintained.

Williams et al.[19] found treatment that included MLD improved emotional function and decreased sleep disturbance, while using self-MLD instead did not have this effect. Kim et al.[20] found that for people with either leg or arm lymphedema, the increased size of their limb led to a decreased QOL and the decreased limb volume from treatment led to an increase in QOL, measured at 6 month follow-up. Mondry et al.[21] found that QOL gradually increased during treatment and at 3 month, 6 month and 12 month follow-up, even if limb size began to increase again.

Compression bandaging

Badger et al.[22] conducted a RCT using compression bandaging, followed by compression garments after reduction compared to using only compression garments as the tool for reduction. This study showed using compression bandaging first was twice as effective in reducing lymphedema as using only compression garments.

Damstra et al.[23] compared the effectiveness of low pressure (20-30 mm Hg) and high pressure (44-58 mm Hg) bandages on people with BCRL. They found no significant difference in outcome and the lower pressure bandages were better tolerated. In another study, Damstra et al.[24] found that the sub-bandage pressures dropped significantly after a few hours and by 24 hours were 55-63% less. This makes it important to reapply compression bandages daily when possible.

Lympho-venous disorders

There were two articles related to this topic: one a 2008 consensus document by an international panel of experts on this issue (Partsch et al.[25] which reviewed the literature on compression treatment for venous and lymphatic disorders and the other by Shrubb et al.[26] reviewing the literature on general management of DVTs (blood clots) to apply it specifically to people with lymphedema who develop DVTs. The recommendations from these articles were the following:

- To prevent edema and blood clots: low level compression garments of 10-30 mmHg
- To heal ulcers, to prevent post-thrombotic syndrome (swelling that develops later in people who have had blood clots), or to manage lymphedema: high level compression garments of 30-40 mm Hg
- For situations where compression greater than 40 mm Hg is needed: use inelastic Velcro® compression items or short stretch bandages rather than compression garments
- For patients with lymphedema who develop a DVT (once patient is ambulatory): continue compression in order to prevent swelling from worsening
- For patients who are bedbound: compression may be contraindicated if it impairs blood flow

Differential Impact of CDT

A number of studies tried to determine what factors affected the effectiveness of CDT. Among the factors examined were the presence of active cancer; age; weight/BMI; the original amount of swelling; the length of time swelling had been present; and the length of treatment/number of sessions.

Pinell et al.[27] found even in patients with active tumors, CDT worked to reduce swelling, but the results took longer to achieve.

Yamamoto et al.[28] found while amount of swelling was correlated with age, the effectiveness of treatment was not; Liao et al.[29] also found age did not correlate with effectiveness of treatment.

Vignes et al.[30] found the weight of the patient did not affect the effectiveness of treatment.

Liao et al.[31] found the amount of swelling did not correlate with the percent of reduction, although an earlier study by Ramos et al.[32] had found a correlation.

Yamamoto et al.,[33] Liao et al.,[34] and Vignes et al.[35] all found although the duration of the lymphedema correlated with more swelling, it did not affect the amount of reduction in treatment.

Liao et al.[36] and Yamamoto et al.[37] also both found the length of treatment/number of sessions was not correlated with amount of reduction. Yamamoto et al.[38] also found the maximum reduction (about a 50% decrease in swelling) was generally achieved in the first few days, after which the rate of reduction began to taper off.

Discussion

There was a clear and definite trend indicating CDT, even watered down, led to improvements in the patients' otherwise progressive condition. There was evidence the results were possible to maintain if patients adhered to their home program.

It was still not clear how much of a role each component of CDT plays in the outcome and how the interaction among the components affects the outcome.

Among the areas needing more research are the following:

1. What is the most effective home program for patients to maintain/improve their results and what are ways to optimize patients' ability to adhere to this?
2. What are the effects of BMI, co-morbidities, onset/duration, and other factors on the effectiveness of treatment?
3. What are the effects of CDT on improved function and QOL and how can these been further enhanced?
4. What are effective ways to assess and treat genital, facial, truncal and breast lymphedema? (There was a real dearth of material on this!)
5. What is the evidence for the current risk reduction strategies in helping people keep their lymphedema under control?
6. What are effective ways to address issues such as radiation fibrosis?
7. Is there an optimum CDT protocol?

Conclusion

Based on clinical observations CDT is considered the gold standard in treatment and management of lymphedema, but more research with more uniform standards of measurements need to be conducted. This includes RCTs with control groups, blinded assessors, objective measurements of volume, function and/or mobility, larger group sizes with longer follow-up periods, more consistent protocols, with more standard dosing of CDT components. The authors felt a more universal definition of lymphedema also needs to be established.

The authors recognized with the various etiologies of lymphedema (primary and secondary) and with the varying protocols of treatment, it is difficult to state with absolute certainty the effectiveness of each component of CDT. What is recognized, universally

among therapists, is CDT, the most effective tool available to clinicians for the treatment and management of lymphedema. The authors also acknowledge better and more comprehensive research is required to understand the varying aspects confounding the successful treatment of lymphedema. These include the effects of BMI, patient adherence during treatment and afterwards to maintain reduction achieved during therapy, co-morbidities, as well as a greater understanding of the lymphatic system and how alteration of it – whether due to birth abnormalities or trauma or surgical intervention -- can influence the transport capacity leading to lymphedema. While limb lymphedema can be successfully managed with CDT, special areas of concern for treatment including breast, truncal, genital, and facial edema which need to be addressed.

Until further research is conducted and analyzed, CDT remains the best option not only for the physical needs, but also for quality of life issues for patients with lymphedema.

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