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EFFECT OF COMPLEX DECONGESTIVE THERAPY ON EDEMA AND THE QUALITY OF LIFE IN BREAST CANCER PATIENTS WITH UNILATERAL LYMPHEDEMA

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ABSTRACT

There is increasing interest in the health-related quality of life (QOL) of patients with chronic lymphedema. The aim of this study was to ascertain whether complex decongestive therapy (CDT) for upper limb lymphedema results in long-term changes in lymphedema and QOL, and to determine whether the treatment-induced change in the percentage excess volume (PCEV) is correlated with any changes in QOL. Fifty-three patients who had lymphedema were treated with CDT. PCEV and QOL were recorded before and 1 month after CDT, and at a 6-month follow-up visit. PCEV was significantly ($p<0.05$) decreased at 1 month, but significantly ($p<0.05$) increased at 6 months compared to 1 month [but still significantly reduced ($p<0.05$) from baseline]. The QOL scores at 1 and 6 months were significantly higher than the score at baseline, indicating an improvement in the QOL. Significant changes were evident in the single domains of physical functioning, role-physical, mental health, and general health. The change in PCEV was associated with a change in physical functioning, vitality, bodily pain, and general health at 1 and 6 months ($p<0.05$). This study suggests that QOL significantly improved with upper limb lymphedema during the maintenance phase, which was necessarily correlated with the reduction in limb volume.

Keywords: quality of life, lymphedema, complex decongestive therapy, SF-36, breast cancer

The incidence of breast cancer continues to rise in South Korea (1). However, improvements in disease management have led to a well-publicized recent decline in breast cancer deaths (2) and a concomitant greater emphasis on the side effects of treatment (3). Breast cancer-related lymphedema due to impaired lymphatic drainage from the arm secondary to axillary surgery and/or radiotherapy is one of the common side effects, occurring in 12-28% of cases (4,5). Lymphedema is a chronic condition because it is not possible to reverse the damage responsible for the swelling. Affected patients can have an unsightly, uncomfortable arm that is prone to repeated episodes of infections, with the rare – but potentially fatal – complications of secondary lymphangiosarcoma (6). Several physical and emotional factors are related to lymphedema (7,8), including increased weight of the edematous limb with restricted motion aggravated by fibrosis and joint contracture, and altered sensitivity and embarrassment during social interactions (9,10).

The main aim of treatment is not to cure, but to reduce the limb size, usually via manual lymphatic drainage (MLD), skin care, remedial exercise, compression garments,

pneumatic pump, mercury compression, elevation, and microwave and laser therapies (11-13). Treatment involving combined therapies was developed in Europe in the 1930s and was introduced to South Korea in the 1990s (14). One such treatment, complex decongestive therapy (CDT), is now recognized as an effective non-surgical technique for managing lymphedema and is recommended by the International Society of Lymphology (15). Most studies of arm lymphedema have focused on the physical aspects using volumetric measurements of the limb as the primary tool (16). Since patients with lymphedema experience a wide range of psychological and physical difficulties, including depression, embarrassment, resentment, poor body image, impaired limb movement, impaired physical mobility, and pain (17), they would probably benefit from treatment being assessed using a broader clinical approach based on the quality of life (QOL) (18). Evaluating the QOL is becoming an increasingly important issue in breast cancer patients with lymphedema, and the emotional, social, psychological, and sexual effects of breast cancer treatment have been studied (19-21).

The SF-36 (Medical Outcome Study 36–Short Form) is a potentially useful instrument used for evaluating the QOL in cancer patients with lymphedema (18,22-24). The SF-36 has been used as a primary measure of the QOL and its reliability and validity are well established (25). This measure contains eight subscales relevant to the health of the individual: physical functioning (PF), role-physical (RP), role-emotional (RE), mental health (MH), bodily pain (BP), general health (GH), vitality (VT), and social functioning (SF). All scores are range standardized to between 0 (worst possible score) and 100 (i.e., the optimal level of health in that domain) (25). Although a great deal of research is aimed at understanding the QOL of breast cancer patients with lymphedema, such studies into interventions with CDT have generally been undertaken in small numbers of patients (17,18,26,27), typically fewer than 50, using non-validated QOL tools (24), or have used a combination of patients with arm and leg edema (17,18,27). Only a few papers have reported follow-up assessments of arm lymphedema and QOL after CDT.

The purpose of this study was to ascertain the long-term physical and psychological impacts of CDT-based treatment for arm lymphedema and to determine whether limb volume changes resulting from CDT treatment are associated with changes in the QOL.

METHODS

Subjects

The study was performed with the approval of the Health Research Ethics Board of the University of Youngdong. Data were collected from breast cancer patients who had experienced lymphedema and who had been referred by a physician for lymphedema treatment to three outpatient physical therapy clinics in South Korea between March 1, 2003, and October 30, 2005. The inclusion criteria for the study were as follows: (1) female, (2) at least 19 years old, (3) no known neurological disorder that would interfere with completion of the measures, (4) ability to complete a questionnaire, (5) no history of treatment for other types of cancer, (6) no known untreated or unstable medical conditions, (7) no edema in lower limbs, (8) completion of adjuvant chemotherapy, radiation, and surgical treatments for breast cancer at least 3 months and at most 5 years previously, (9) agreement to fully receive decongestive treatment five times per week, and (10) unilateral upper limb lymphedema. Seventy-eight patients met all of these eligibility criteria, of whom seven refused to participate and three were excluded since they had active disease and/or were receiving treatment for recurrent cancer. Five patients did not visit the clinic during the follow-up period, one patient died, nine patients refused

to complete the SF-36 and volume measurements in follow-up assessments (five patients became too ill or physically or mentally fatigued to respond, and four patients declined to participate for personal reasons). Complete data were obtained from the remaining 53 eligible patients (67.9%).

Settings

Informed consent was obtained after performing a clinical examination and documenting general characteristics. Each patient received treatment from a physical therapist, which consisted of a "decongestive phase" that lasted 2-4 weeks depending on the condition of lymphedema and patient's economic status, during which the patients received treatment daily. The patients then followed a "maintenance phase" of self-care. The decongestive-phase programs consisted of MLD, compression bandaging, remedial exercise, and skin care, with each MLD session lasting 45-60 minutes. Treatments were performed by physical therapists certified in Vodder's technique of MLD who had at least 5 years of experience of treating lymphedema. A low-pH skin lotion (Eucerin, Beiersdorf, Norwalk, CT) was applied prior to bandaging the limb using padding (Artiflex, Beiersdorf) and low-stretch bandages (Rosidal K, Lohmann, Neuwied, Germany). The protocol also included teaching the patients to perform self edema-control activities (e.g., self-administered MLD, exercise, self-applied bandages, and skin care) that were to be continued at home in the maintenance phase. Patients were issued with compression garments as a final component of the treatment. The protocol in the maintenance phase consisted of wearing compression bandages or hosiery at all times, a daily session of self-administered MLD, skin care, and an exercise program. The use of daytime bandages on at least three days per week was recommended during the maintenance phase. During the maintenance phase, follow-up visits were scheduled at 1 and 6 months.

Data Collection Procedure

A trained physical therapist measured the arm circumference at six locations (hand, wrist, forearm, elbow, and two locations on the upper limb) using a tape measure along the lateral aspect in each upper limb (28) before treatment (baseline) and at 1 and 6 months after treatment. Lymphedema volume was calculated for each segment by utilizing the formula for a truncated cone: volume=$H(C^2+Cc+c^2)/12\pi$, where H=height, C=circumference of the top of the cone, and c=circumference of the base of the cone (27,29,30). This method has demonstrated excellent inter- and intraobserver reproducibility in comparison to water displacement, which is considered the gold standard (31,32).

Each segment was measured three times, and the average reduction in arm circumference was calculated by the following formula with the unaffected limb used as a normal control for the affected limb (percentage excess volume; PCEV): PCEV = [(affected volume – unaffected volume)/unaffected volume] x 100.

Patients also completed the SF-36 questionnaire (Korean version, QualityMetric Incorporated, Lincoln, RI) at the initial visit and 1 month after completion of the decongestive phase, and then at 6 months in the clinic.

Data Analysis

Descriptive data are expressed here as mean and SD values. Testing of all variables using the one-sample Kolmogorov-Smirnov test revealed that they were normally distributed. One-way analysis of variance (ANOVA) with repeated measures was used to detect significant effects of CDT on the edema and QOL before CDT, and at both 1 month and 6 months after CDT. In the event of significant values of *F* in the ANOVA, the Bonferroni correction test of critical differences was used to detect significant differences between means. Pearson's

TABLE 1
Baseline, 1-month, and 6-month Quality of Life (QOL) Values (Mean±SD) Assessing Functional Status and Well-being Attributes of Patients with Unilateral Arm Lymphedema]

	Baseline	1 month	6 months	p
Functional status				
Physical functioning	61.25±16.10	64.68±15.87	67.30±13.51	0.004
Social functioning	64.30±21.83	63.54±18.26	69.59±16.98	0.098
Role-physical	52.34±16.97	54.76±17.18	55.55±14.73	0.001
Role-emotional	52.53±24.90	55.10±16.41	57.81±17.76	0.184
Well-being				
Mental health	54.11±16.84	59.47±20.09	58.79±14.79	0.004
Vitality	57.83±18.31	59.53±20.02	59.86±17.70	0.250
Bodily pain	61.28±22.00	63.13±23.53	66.20±22.63	0.782
General health	64.36±16.76	66.85±16.52	71.91±19.29	0.020

product-moment correlation coefficients were calculated to examine the relationships between the PCEV and QOL. The collected data were analyzed using standard statistics software (SPSS ver. 12.0), and a probability of $p<0.05$ was considered statistically significant.

RESULTS

Descriptive Characteristics

The fifty-three patients were aged 51.0 ± 6.7 years, and their body mass index was 19.0-30.7 (23.9 ± 3.3) kg/m2. Forty-six patients (86.7%) were educated to at least high school level, 32 patients (60.4%) had a religion, and 28 patients (52.8%) were not currently working. The majority (92.4%) of patients reported a high or moderate economic status, and 44 patients (83.0%) were married. Thirty-four patients (64.2%) had received both surgery and radiotherapy for cancer, with the length of time since surgery/ radiotherapy being 0.3–4.7 (2.5 ± 1.5) years.

PCEV

The PCEV differences between the abnormal and normal arms at baseline, 1 month, and 6 months were 49.28 ± 21.98%, 28.66 ± 11.29%, and 41.64 ± 17.31%, respectively. The PCEV was significantly ($p<0.05$) higher at baseline than at 1 and 6 months reflecting significant effect of treatment during the decongestive and maintenance phases. The PCEV was also significantly ($p<0.05$) higher at 6 months compared to than at 1 month.

Measurement of QOL

Table 1 presents the mean scores for all domains of the SF-36 for the patients. The scores for the PF and GH domains differed significantly among baseline, 1 month, and 6 months. *Figs. 1 and 2* illustrate the differences between the mean scores. The scores in the PF, RP, and GH domains were significantly higher at 6 months than at baseline, indicating an improved QOL in these domains

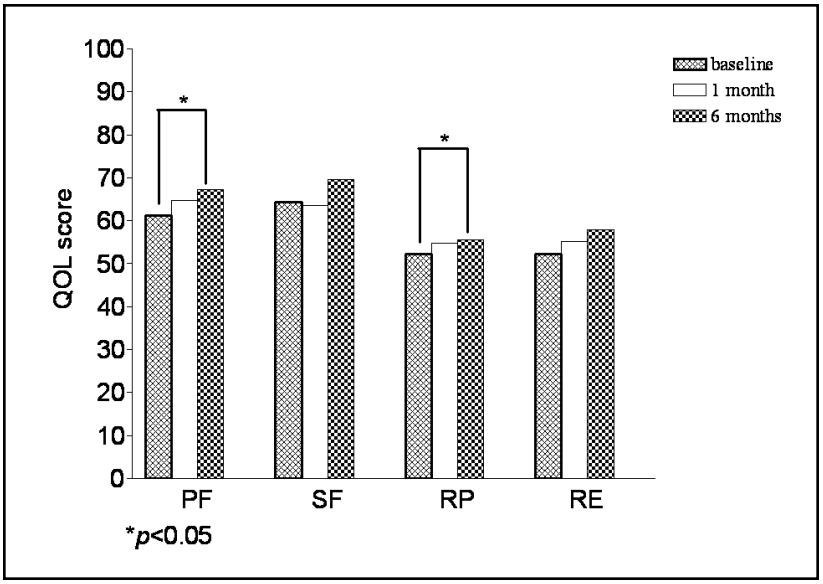

Fig. 1. Mean quality of life (QOL) scores at baseline, 1 month, and 6 months in the physical functioning (PF), social functioning (SF), role-physical (RP), and role-emotional (RE) domains.

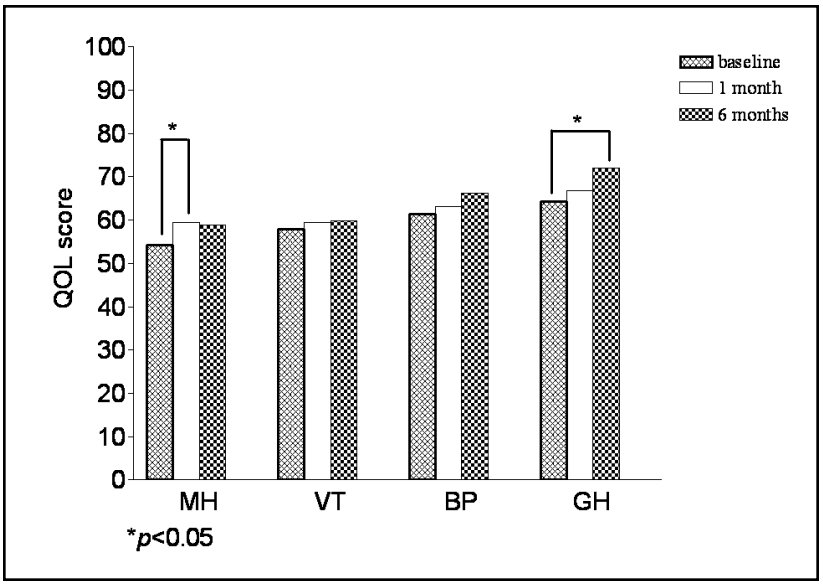

Fig. 2. Mean QOL scores at baseline, 1 month, and 6 months in the mental health (MH), vitality (VT), bodily pain (BP), and general health (GH) domains.

at 6 months. The score in the MH domain was significantly higher at 1 month compared to baseline.

Relationship Between PCEV and QOL

The PCEV of edema was negatively correlated with SF-36 subscales *(Table 2)*, including physical functioning at baseline, 1 month, and 6 months, VT, BP, and GH at 1 month.

TABLE 2
Spearman Correlations Between the Percentage Excess Volume (PCEV) and QOL]

	Baseline	1 month	6 months
Functional status			
Physical functioning	–0.55**	–0.46**	–0.50**
Social functioning	–0.18	–0.25	–0.18
Role-physical	–0.19	–0.10	–0.16
Role-emotional	–0.26	–0.15	–0.11
Well-being			
Mental health	–0.22	–0.23	–0.50
Vitality	–0.15	–0.27*	–0.42*
Bodily pain	–0.19	–0.28*	–0.51**
General health	–0.19	–0.30*	–0.55**

*p<0.05; **p<0.01.

DISCUSSION

Lymphedema can be viewed as a QOL issue due to the difficulties affecting functioning at work or at home, altered body image, low self-esteem, difficulty dressing, and a loss of interest in social activities (17,33,34). This study was undertaken to examine whether the QOL at long-term follow-up was improved in breast cancer patients with lymphedema following CDT, and whether limb volume changes were associated with any detected changes in the QOL. During the decongestive phase, we noted that the PCEV decreased from 49.29 ± 21.98% at baseline to 28.66 ± 11.29% at 1 month. The percentage reduction in the lymphedema volume has varied from 20% to 80% in previously published series, but these have employed diverse calculation formulas (e.g., in terms of the circumferential measures used and different intervals between the two measures) (29,35-37). There was a small increase in the lymphedema volume during the maintenance phase. Boris et al (30) reported that persistence of reduced lymphedema volume was associated with compliance. Földi et al (37) found in a 3-year follow-up that more than 50% of the patients maintained the initial reduction in lymphedema obtained after the decongestive phase.

We found that the self-reported PF, RP, MH, and GH scores were significantly changed by our intervention. Sitzia and Sobrido (17) reported similar improvements in the QOL of patients following MLD or simple massage and compression bandaging. Based on the Nottingham Health Profile Part 1 (NHP-1), they reported that patients had the greatest improvement in physical mobility. They also concluded that the NHP-1 was useful in assessing physical aspects of the QOL, but less helpful with regard to psychological and emotional attributes. In contrast, we found that using the SF-36 resulted in the detection of significant changes in physical,

functional, and psychosocial post-treatment measures. Weiss and Spray (27) also reported that CDT improved the QOL of patients with peripheral lymphedema due to various causes. The trend toward increases in PF scores in the study participants supports the theory that CDT is beneficial for women with secondary lymphedema after breast cancer treatment. Subjects expressed greater confidence in using their affected arm for activities of daily living, and some mentioned that they were again able to lift objects with the affected arm after the decongestive phase. This may explain the trend toward increased RP, MH, and GH scores, inasmuch as the subjects were less aware of their disease, were confident that CDT prevents the edema from increasing, and therefore felt healthier overall. Although the lymphedema volume was increased at 6 months compared to 1 month, the data showed trends toward increases in almost all domains of the SF-36. A recent similar study (38) investigated the long-term effects of CDT in 20 patients with breast cancer-related lymphedema, and found similar results for QOL: there were no significant change in QOL immediately after treatment, but QOL scores had consistently increased by 6 months. These observations suggest that CDT programs improve the QOL.

The study reported here differs from previous evaluations (18,27) of changes in the QOL in lymphedema patients following CDT in that it included only breast cancer patients with lymphedema and reported follow-up assessments of QOL after CDT. In contrast, the studies of Godoy et al (18) and Weiss and Spray (27) involved patients with multiple diseases (and only a small number of breast cancer patients with lymphedema) and reported only short-term results.

Despite CDT inducing significant edema volume reductions, the results from this study did not support an association between limb volume reduction and scores in any of the domains of the SF-36 except for the PF score at baseline, a finding that is supported by Mondry (38), Sitzia et al (16), and Weiss and Spray (27). The significant correlations at 1 and 6 months (i.e., in the maintenance phase) support an association with PF, VT, BP, and GH. The lack of association suggests that a reduction in the edema volume is only partly responsible for an improvement in the QOL. It is therefore reasonable to postulate that education programs for edema control influence the association between limb volume reduction and the QOL. These data highlight the importance of broadening care to treat these patients beyond the physical ramifications of lymphedema, and they also suggest that more effective treatment of the physical condition increases the likelihood of the emotional and social status also improving. Nonetheless, a multidisciplinary approach is desirable for optimizing the QOL of a patient with lymphedema.

The main strength of our study was to deal only with patients with lymphedema after breast cancer. The treatment was homogeneous and provided by a physiotherapist who specialized in lymphology. The intensive treatment program allowed education, giving advice about avoiding infection such as cellulitis, and learning self-bandaging and self-administered MLD. However, the limitations of this study mean that its results must be interpreted cautiously. These limitations include the absence of a non-treatment control group, which meant that the effects of CDT on the QOL could not be distinguished from the effects of simply participating in a clinical research study. Moreover, the extent to which improvements in edema volume and the QOL are attributable to poor internal validity factors such as measurement errors, testing effects, and statistical regression could not be determined. Twenty-five (32.0%) of the original sample of 78 patients were lost to follow-up, of whom 9 withdrew due to recurrent cancer, death, illness, or fatigue, and the others did not complete the study due to poor motivation. We consider this to be an acceptable attrition rate for a sample of mostly older women who had received treatment for breast cancer.

In such populations, the persuasive power of the researchers may be very important to ensuring active participation by patients. Although the loss to follow-up might have introduced bias, our findings suggest that the CDT program induced lymphedema management that had a substantial impact on the QOL.

The findings reported here emphasize the need to evaluate the long-term QOL in patients with lymphedema and not merely to measure the limb volume. Further studies are needed to compare the effects of different modalities of treatment on the QOL of patients with various characteristics and clinical symptoms.

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