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Effect of Complex Decongestive Therapy Program on Volume and Functioning in Breast Cancer-Related Lymphedema: Global Effect and Predicting Factors

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Abstract

Background: The aim of this prospective study was to investigate the effect of a first and repeated complex decongestive therapy (CDT) program on volume and functioning in patients with unilateral breast cancer-related lymphedema (BCRL) and to identify whether the volume before treatment and/or the number of previous treatment influence outcomes.

Methods and Results: In total, 100 and 42 patients with BCRL treated by 499 CDT (6 hours a day during 5 consecutive days) between April 2018 and December 2021 were included. Patients were assessed using volume including percentage of excess volume and percentage reduction in excess volume and lymph-International Classification of Functioning-UL questionnaire. After CDT, a significant reduction in BCRL volume (50%) and improvement in functioning (30%) were observed. The volume reduction was greater when the BCRL volume before treatment was low (10%–20%) and when CDT was performed for the first time. The functioning improvement was identical whatever the volume is before treatment and the number of previous CDT.

Conclusion: A greater volume reduction after CDT was obtained in BCRL with low volume before treatment and after the first CDT. Such findings support the need for early intensive BCRL treatment to control volume and improve functioning.

Keywords: breast cancer-related lymphedema, complex decongestive therapy, volume, functioning, quality of life

Introduction

Breast cancer (BC) is the most commonly diagnosed cancer among women in the vast majority (140/184) of countries worldwide, representing a quarter of all cancers diagnosed in women. It is also the leading cause of cancer-related deaths among women.[1] BC-related lymphedema (BCRL) also known as "arm swelling" appears in 21.4% when axillary lymph node dissection is necessary and in 5.7% when a sentinel lymph node biospy is performed.[2] The risk factors to develop a BCRL are mastectomy, axillay lymph node dissection, the number of lymph nodes removed (>10), and overweight.[2] BCRL usually appears within 2–5 years after surgery, but the risk remains for a lifetime with 15% of cases appearing at 5 years or later. BCRL occurrence and severity are also correlated to obesity which is a modifiable factor.[3] The BCRL clinical signs are skin tightness, swelling, and decreased arm mobility. It induces pain, numbness, the uncomfortable feeling of heaviness in the limb, and an increased risk of infection.[2,4] The BCRL induces activity limitations and participation restrictions affecting their social and professional environments, body image, emotional well-being, and quality of life (QoL).[5] Therefore, an appropriate assessment of BCRL response to treatment in the three domains (body function and structure, activities, and participation) of the International Classification of Functioning (ICF) of the World Health Organization (WHO) is crucial.[6]

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Manual lymph drainage (MLD) is the treatment historically developed for lymphedema. Despite lacking robust scientific evidence, MLD, along with pressotherapy, continues to be commonly prescribed by doctors, performed by physiotherapists, and requested by patients. Moreover, recent studies demonstrated the lack of effect of MLD in preventing or reducing BCRL.[7,8] Consensus documents now recognize complex decongestive therapy (CDT) as the treatment of choice.[4,9,10] CDT consists of using compression (multilayer bandages with limited elasticity and/or contention stocking), physical exercises, skin care, therapeutic patient education, MLD, and pneumatic intermittent compression.[4,9,10] CDT has two distinct phases: phase 1, known as the intensive phase, aims to alleviate the congestion while phase 2, known as the maintenance phase, aims to optimize and sustain the achieved outcomes.

The first aim of this prospective study was to evaluate the effect of the CDT on the volume and functioning in women with unilateral BCRL. The second aim was to assess if the percentage in excess volume (PEV) before treatment influence the CDT effect. The last aim was to assess if the effect of CDT varies whether the CDT was performed for the first time (intensive phase) or in a long term (maintenance phase).

Materials and Methods

The study was approved by the Institutional Review Board (Ethics Committee) of CHU UCL Namur site Godinne and performed within the framework of the National Institute for Health and Disability Insurance reference center lymphedema convention in accordance with the Declaration of Helsinki as revised in 2013. All participants gave their approval and signed a consent document.

Patient recruitment

Clinical data of women newly treated for a BCRL at the Lymphedema Reference Center CHU UCL Namur site Godinne between April 1, 2018, and December 31, 2021, were prospectively collected. All patients benefited during a period of five consecutive days from a CDT program during 6 hours each day (30 hours = 1800 minutes in total) including multilayer bandaging 24 hours/24 hours, physical exercise (strengthening, bicycle, nordic walking, etc.) with multilayer bandaging (3.5 hour/day), education to nutrition, multilayer bandaging and exercise (1.5 hour/day), pneumatic intermittent compression (1 hour/day), skin care, and self-manual drainage. The program was performed by six trained physical therapists from the Lymphedema Reference Center. The inclusion criteria was as follows: women with unilateral BCRL lymphedema stage II or III (according to 2020 ISL staging of lymphedema).[4] The exclusion criteria were as follows: limb abnormalities (agenesis), size of the affected body part increased by <10% in comparison to the nonaffected side, localized lymphedema only at a specific location of the upper limb such as hand or forearm, missing data, and incomplete CDT program.

Clinical and functional outcome assessments

Before treatment, patient's age, weight, and height were collected. Outcome measures (volume and Lymph-ICF-UL questionnaire) were taken before treatment and after intensive and maintenance phase treatments by the trained physical therapists team. The primary outcome was the upper limb volume expressed in milliliters (mL). The volume was calculated on both arms by using the truncated cone formula calculated from the circumferential measurements taken every 4 cm from the wrist to the upper arm by experienced physical therapists.[11] The absolute BCRL excess volume (EV) representing the EV of BCRL in comparison with the healthy arm was calculated as the difference between the BRCL arm volume (V_L) and the healthy arm volume (V_H) as follows:

$$V_L - V_H = EV$$

The relative BCRL EV representing the PEV of BCRL in comparison to the healthy arm was expressed as the PEV was calculated as the difference between the V_L and V_H, divided by the V_H as follows:

$$[(V_L - V_H)/V_H] * 100 = PEV$$

The percentage of BCRL volume reduction after CDT was expressed as the percentage reduction in EV (PREV) and calculated as the difference between the EV before treatment (EV BT) and the EV after treatment (EV AT) divided by EV BT as follows:

$$[(EVBT - EVAT)/EVBT] * 100 = PREV$$

It is considered to be the most effective way to determine the efficacy of CDT.

The secondary outcome was the validated French version of the Lymphedema Functioning Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL) questionnaire (annex 1).[12,13] The Lymph-ICF-UL is a self-reported specific questionnaire that evaluates impairments in function, activity limitations, participation restrictions, and QoL in patients suffering from BCRL according to the International Classification of Functioning (ICF) of the WHO.[6,12,13] According to the WHO taxonomy, impairments in function, activity limitations, and participation restrictions can be quantified using the following scale: a score between 0 and 4 means no problem; 5 and 24 a small problem, 25 and 49 a moderate problem; 50 and 95 a severe problem; and 96 and 100 a very severe problem[6,13]) The Lymph-ICF-UL score (between and 100) was calculated accordingly as follows:

$$\text{Sum of scores}/(29 - \text{the number of unanswered questions}) * 10 = \text{Lymph} - \text{ICF} - \text{UL score}$$

The functioning change after CDT expressed as the percentage reduction in Lymph-ICF-UL score was calculated as the difference between the Lymph-ICF-UL score before treatment (Lymph-ICF-UL score BT) and the Lymph-ICF-UL score after treatment (Lymph-ICF-UL score AT) divided by Lymph-ICF-UL score before treatment (Lymph-ICF-UL score BT) as follows:

$$[(\text{Lymph} - \text{ICF} - \text{UL score BT} - \text{Lymph} - \text{ICF} - \text{UL score AT})/\text{Lymph} - \text{ICF} - \text{UL score BT}] * 100 = \text{relative reduction in Lymph} - \text{ICF} - \text{UL score}$$

According to the 2020 ISL staging of lymphedema, CDT data were divided into four groups (A–D) whether the PEV before treatment was between 10%–20% (group A), 20%–

40% (group B), 40%–60% (group C), and 60%–120% (group D).[4]

CDT data were also divided into group 1 including CDT performed for the first time (intensive phase) into group 2 including CDT performed for the second to the fourth time and group 3 including CDT performed for the fifth time or more (maintenance phase).

Statistical analysis

All data collected during the study were entered into an Excel file. The results' relative evolution was obtained by a log transformation of the measures in the statistical model. The model's coefficients were transformed by an exponential. Thus, the means shown in the results are geometric means for the relative evolution. Fixed coefficients (arithmetic or geometric means), 95% confidence intervals (CIs), and p-values are shown for all the patients and each group. CI was used to compare between groups' evolution. All the analyses were performed in R 4.2.0 with lmerTest package.

Results

The participants and study flowchart are detailed in Figure 1.

Patients (n = 142) mean age was 71 years (interquartile range [IQR] median: 62.5–79.0, min 42, max 95), whereas median BMI was 28.67 kg/m^2 (IQR median: 25.20–33.40, min 17.21, max 53.23) before treatment.

The number of CDT according to the PEV before treatment was 58 in group A, 238 in group B, 117 in group C, and 86 in group D.

The number of CDT according to the number of CDT previously performed was 65 in group 1 (first CDT), 94 in group 2 (second to fourth CDT), and 340 in group 3 (fifth or more CDT).

The median delay between CDT was 189 days (CI: 77; 812) for group 2 and 175 days (CI: 63; 826) for group 3 without difference between groups.

Global CDT effect on volume and functioning

After CDT, a significant reduction in absolute (EV) and relative (PEV) EV was observed leading to a mean PREV of 51.4%.

A significant reduction in Lymph-ICF-UL score was also observed leading to a mean percentage reduction in Lymph-ICF-UL score of 31.2% (Table 1).

Influence of the PEV before treatment on volume and functioning

After CDT a significant reduction in absolute (EV) and relative (PEV) EV was observed in groups A to D leading to

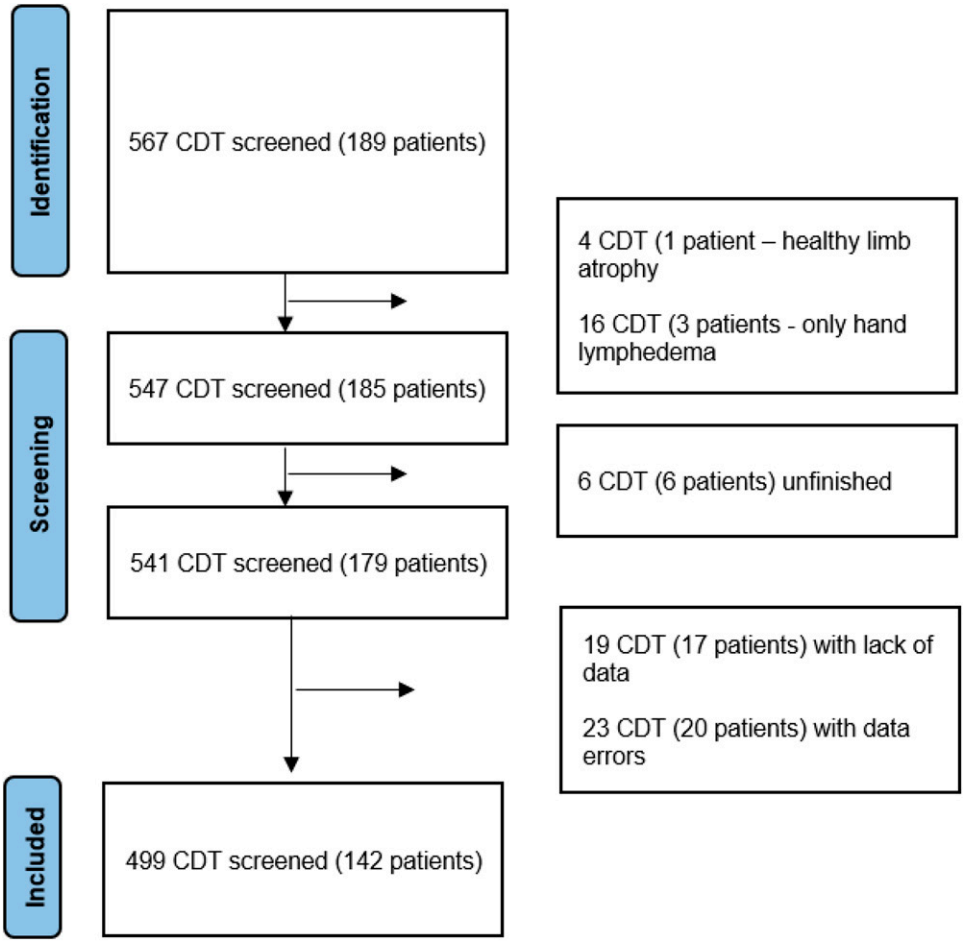

FIG. 1. Flowchart of the study subjects.

Table 1. Global CDT Effect on Volume and Functioning

	Before treatment	*After treatment*	*Difference*	p *value*
EV (ml)	949 (870; 1029)	511 (431; 590)	−438 (−409; −467)	<0.0001
PEV (%)	40.4 (37.5; 43.4)	22.4 (19.4; 25.3)	−18.1 (−16.9; −19.2)	<0.0001
PREV (%)	/	/	51.4 (48.6; 53.9)	<0.0001
Lymph-ICF-UL scores	39.2 (36.7; 41.7)	28.2 (25.7; 30.7)	−11.0 (−9.7; −12.3)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−31.2 (−28.0; −34.1)	<0.0001

EV and PEV values are arithmetic means (CI), PREV value is geometric mean (CI).
Lymph-ICF-UL scores are arithmetic means (CI), relative reduction in Lymph-ICF-UL score is geometric mean (CI).
CDT, complex decongestive therapy; CI, confidence interval; EV, excess volume; PEV, percentage of excess volume; PREV, percentage reduction in excess volume.

a mean PREV ranging from 40% to 72% (Table 2). The PREV was significantly higher in group A than in groups B, C, and D (respectively, 95% CI: 67.8; 76.1 vs 49.0; 56.0, 32.9; 45.6 and 35.3; 49.3) and was significantly higher in group B than in group C (respectively, 95% CI: 49.0; 56.0 vs 32.9; 45.6), whereas there was no difference between groups C and D (respectively, 95% CI: 32.9; 45.6 vs 35.3; 49.3).

After CDT, a significant reduction in Lymph-ICF-UL score was observed in groups A to D leading to a mean relative reduction in Lymph-ICF-UL score in all groups ranging from 29% to 35% (Table 2). No difference between groups was found (respectively, 95% CI: −20.9; −38.9 vs −26.4; −35.2 vs −22.1; −35.0 vs −27.8; −41.5).

Influence of the number of previous CDT on volume and functioning

After CDT, a significant reduction in absolute (EV) and relative (PEV) EV was observed in groups 1 to 3 leading to a mean percentage reduction of EV (PREV) ranging from 49% to 60% (Table 3). The PREV was significantly higher in group 1 than in group 3 (respectively, 95% CI: 53.9; 65.9 vs 45.7; 52.3), but not in comparison to group 2 (respectively, 95% CI: 53.9; 65.9 vs 45.8; 57.7). The PREV was similar in group 2 and group 3 (respectively, 95% CI: 45.8; 57.7 vs 45.7; 52.3).

After CDT, a significant reduction in Lymph-ICF-UL score was observed in groups 1 to 3 leading to a mean relative reduction in Lymph-ICF-UL score in all groups ranging

Table 2. Change in Volume and Functioning According to the PEV Before Treatment (Groups A to D)

Groups PEV (%)	*Before treatment*	*After treatment*	*Difference*	p *value*
Group A				
10–20				
EV (mL)	533 (453; 614)	280 (200; 361)	−252 (−183; −322)	<0.0001
PEV (%)	20.0 (17.6; 22.3)	10.0 (7.6; 12.4)	−10.0 (−7.5; −12.5)	<0.0001
PREV (%)	/	/	72.2 (67.8; 76.1)	<0.0001
Lymph-ICF-UL score	35,7 (31,7; 39,8)	26,1 (22,0; 30,1)	−9,7 (−6,0; −13,4)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−30,5 (−20,9; −38,9)	<0.0001
Group B				
20–40				
EV (mL)	759 (702; 818)	426 (368; 484)	−333 (−299; −368)	<0.0001
PEV (%)	30.9 (29.5; 32.3)	16.8 (15.5; 18.3)	−14.0 (−12.8; −15.3)	<0.0001
PREV (%)	/	/	52.6 (49.0; 56.0)	<0.0001
Lymph-ICF-UL score	38,2 (35,4; 41,0)	27,8 (25,0; 30,6)	−10,4 (−8,6; −12,3)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−30,9 (−26,4; −35,2)	<0.0001
Group C				
40–60				
EV (mL)	1052 (985; 1118)	632 (565; 698)	−420 (−371; −468)	<0.0001
PEV (%)	46.0 (44.1; 47.7)	28.3 (26.4; 30.0)	−17.7 (−16.0; −19.4)	<0.0001
PREV (%)	/	/	39.6 (32.9; 45.6)	<0.0001
Lymph-ICF-UL score	40,0 (36,7; 43,3)	29,2 (25,9; 32,5)	−10,8 (−8,2; −13,4)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−28,9 (−22,1; −35,0)	<0.0001
Group D				
60–120				
EV (mL)	1705 (1615; 1794)	825 (735; 914)	−879 (−823; −936)	<0.0001
PEV (%)	78.8 (76.2; 81.4)	43.7 (41.1; 46.3)	−35.1 (−33.1; −37.1)	<0.0001
PREV (%)	/	/	42.8 (35.3; 49.3)	<0.0001
Lymph-ICF-UL score	43,9 (39,6; 48,3)	30,1 (25,8; 34,5)	−13,8 (−10,8; −16,9)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−35,0 (−27,8; −41,5)	<0.0001

EV and PEV values are arithmetic means (CI), PREV values are geometric means (CI).
Lymph-ICF-UL scores are arithmetic means (CI), relative reduction in Lymph-ICF-UL scores are geometric means (CI).

Table 3. Change in Volume and Functioning According to the Number of Previous CDT (Groups 1 to 3)

Groups number of previous CDT	*Before treatment*	*After treatment*	*Difference*	p *value*
Group 1				
0				
EV (mL)	1033 (932; 1133)	523 (422; 623)	−510 (−430; −590)	<0.0001
PEV (%)	44,5 (40,7; 48,2)	23,2 (19,4; 26,9)	−21,3 (−18,3; −24,3)	<0.0001
PREV (%)	/	/	60,0 (53,9; 65,9)	<0.0001
Lymph-ICF-UL score	43,9 (40,3; 47,6)	31,1 (27,5; 34,8)	−12,8 (−9,3; −16,2)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−34,9 (−26,5; −42,3)	<0.0001
Group 2				
1–3				
EV (mL)	857 (763; 950)	487 (394; 581)	−369 (−302; −435)	<0.0001
PEV (%)	36,0 (32,5; 39,5)	20,7 (17,3; 24,2)	−15,3 (−12,7; −17,8)	<0.0001
PREV (%)	/	/	52,1 (45,8; 57,7)	<0.0001
Lymph-ICF-UL score	41,3 (38,0; 44,6)	29,7 (26,3; 33,0)	−11,7 (−8,8; −14,6)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−31,1 (−23,8; −37,8)	<0.0001
Group 3				
>3				
EV (mL)	949 (863; 1035)	505 (419; 591)	−444 (−409; −479)	<0.0001
PEV (%)	40,4 (37,2; 43,6)	22,2 (19,0; 25,4)	−18,2 (−16,9; −19,5)	<0.0001
PREV (%)	/	/	49,1 (45,7; 52,3)	<0.0001
Lymph-ICF-UL score	36,1 (33,1; 38,9)	25,6 (22,6; 28,4)	−10,5 (−9,0; −12,0)	<0.0001
Relative reduction in Lymph-ICF-UL score (%)	/	/	−30,4 (−26,6; −34,0)	<0.0001

EV and PEV values are arithmetic means (CI), PREV values are geometric means (CI).
Lymph-ICF-UL scores are arithmetic means (CI), relative reduction in Lymph-ICF-UL scores are geometric means (CI).

from 30% to 35% (Table 3). No difference between groups was found. A significant difference in Lymph-ICF-UL scores before treatment was observed between group 1 and group 3 (respectively, 95% CI: 40.3; 47.6 vs 33.1; 38.9).

Discussion

Our study confirms the efficacy of a 5 days intensive CDT program (±1800 minutes of treatment) to decrease the absolute and relative EV leading to suppress half of the BCRL. Such findings are in agreement with previous studies assessing the percentage of volume reduction after treatment. In a retrospective study with 107 patients, Liao et al. found a similar volume reduction of 50.5% after 10–26 CDT sessions of 90 minutes (±900 to 2340 minutes), whereas we obtain such results after only 5 consecutive days of 360 minutes (±1800 minutes).[14] In a prospective study with 171 patients, Forner-Cordero et al. found a volume reduction of 72% after 10–20 CDT sessions of 90 minutes (±900–1800 minutes) similar to the one obtained in our group of patients with a PEV between 10% and 20% before treatment.[15] In a prospective study with 79 patients, Szuba et al. found a volume reduction of 44% after a mean treatment duration of 8 days.[16]

However, assessing volume reduction alone is not sufficient to estimate the global benefit of CDT program in patients with BCRL. An appropriate assessment in the three domains of the World's Health Organization's International Classification of Function, Disability and Health -ICF- model is mandatory.[6] The ICF classification assess problems in functioning including QoL. Indeed, in a large prospective study including 244 patients, Jorgensen et al. found a correlation between lymphedema and impaired QoL evaluated with the Lymph-ICF, the DASH, and SF-36 questionnaires. However, they did not assess the effect of CDT on QoL.[17] We used the French version of the Lymph-ICF-UL questionnaire which has a good reliability and is appropriate for use in clinical practice and research.[12] Such a self-reported questionnaire gives information on physical and mental function, household and mobility activities, as well as life and social activities assessing problems in functioning including QoL in patients with BCRL.[6,12] As it includes all aspects of QoL, the lymph-ICF-UL is a lymphedema-specific QoL questionnaire. Furthermore, its use is recommended in two systematic reviews.[18,19] Our study found a significant improvement in functioning with a one-third reduction of the lymph-ICF-UL score after CDT. In a prospective study with 95 patients, De Vrieze et al found a Lymph-ICF-UL change after CDT.[12] In a prospective study with 37 patients, Sezgin et al. found after an intensive phase CDT program an improvement in upper limb function and QoL assessed by the DASH and SF-36 questionnaires.[20] Other studies also reported QoL improvement assessed by FACT-B + 4, EORTC QLQ C30, and EORTC QLQ-BR23 questionnaires.[21,22] In contrast, in a prospective study, Mondry et al. did not find any improvement in QoL, whereas pain assessed by Visual Analog Scale (VAS) scores was reduced after 2–4 weeks of CDT.[23]

The second aim of our study was to assess whether the PEV before treatment and the number of previous CDT programs may influence the effectiveness of the CDT program.

We found that the BCRL volume reduction was significantly greater in patients with a low PEV before treatment. In agreement with previous studies, this means that patients with a low BCRL volume before treatment are the ones who respond the most to CDT. Liao et al. found that a greater volume reduction was correlated with lower EV before treatment, duration of lymphedema, and age.[14] In a prospective study including 137 patients, Haghighat et al. showed a significant correlation between the volume reduction and the

initial lymphedema volume after 10–15 (intensive phase) CDT sessions.[24] In a retrospective study including 57 patients, Keskin et al. noted a negative correlation between the PEV before treatment and the percentage of volume reduction after treatment concluding that the most important predictive factor for the CDT effect was excess of volume before treatment and education level.[25] All these findings support the fact that volume reduction is significantly enhanced if the patients with BCRL are treated early emphasizing the need for early BCRL appropriate treatment. In contrast, we found that the decrease in Lymph-ICF-UL score is similar in both groups meaning that functioning improvement does not depend on the volume before treatment. To the best of our knowledge, this relation has never been studied before.

We also found that the BCRL volume reduction was significantly greater in patients treated for the first time (group 1—intensive phase) than in patients treated in maintenance phase (group 3). We did not identify any studies comparing the volume reduction after CDT in the intensive and maintenance phases. In contrast, the functioning improvement assessed by means of Lymph-ICF-UL score was similar in all groups. In a prospective study with 95 patients, De Vrieze et al found a Lymph-ICF-UL change in the intensive phase but not in the maintenance phase, whereas Kim et al. also revealed that QoL assessed by the SF-36 questionnaire is significantly more increased during the maintenance phase compared with the intensive phase.[12,26] However, in our study, the score before treatment was better in the maintenance phase than in intensive phase which emphasize the positive medium- and long-term impact of the initial CDT sessions on functioning and QoL. A possible explanation can be the beneficial effect of the patient education to self-management received by the patient during the intensive phase CDT including body weight management, physical activity, and compliance with wearing a compressive garment.

This study has several limitations. First, this is a prospective study without control group. This may be partially compensated by the large number of patient and CDT and by the fact that the clinical and functional outcomes assessment is systematically performed in our lymphedema reference center. Second, to assess the effect of CDT effect on volume and functioning according to the volume before treatment and the number of previous CDT, we considered the number of CDT and not the number of patients. This approach could potentially introduce a patient effect type bias. However, our statistical analysis avoids this bias by using generalized linear mixed models. Third, we present the global Lymph-ICF-UL score instead of the five domains scores of the lymph-ICF score (physical function, mental function, household activities, mobility activities, and life and social activities). Future research should study modifications in the fivr domains. Lastly, the study did not consider the time from which the patient was recruited for CDT after the onset of their lymphedema which appears to be an important factor in lymphedema management.[27]

Conclusion

This study confirms the reduction in EV and reveals the improvement in functioning obtained after an intensive CDT program in patients with unilateral BCRL. A better result was obtained in patients treated for the first time and with low volume before treatment supporting the need for an early treatment.

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Authors' Contributions

T.T.V. conceptualization (supporting), data curation, and writing—original draft; P.B. conceptualization (supporting), data curation, and writing—original draft; C.M. investigation and writing—review and editing; J.F. conceptualization (lead), investigation, and writing—review and editing; M.R. software (lead) and writing—review and editing; A.L. methodology (lead) and writing—review and editing; T.D. supervision and writing—review and editing (lead).

Author Disclosure Statement

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