CLINICAL TRIAL

Long-term management of breast cancer-related lymphedema after intensive decongestive physiotherapy

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Abstract

Background Treatment of lymphedema is based on intensive decongestive physiotherapy followed by a long-term maintenance treatment. We analyzed the factors influencing lymphedema volume during maintenance treatment.

Method Prospective cohort of 537 patients with secondary arm lymphedema were recruited in a single lymphology unit and followed for 12 months. Lymphedema volume was recorded prior to and at the end of intensive treatment, and at month 6 and month 12 follow-up visits. Multivariate models were fitted to analyze the respective role of the three components of complete decongestive therapy, i.e. manual lymph drainage, low stretch bandage, and elastic sleeve, on lymphedema volume during the 1-year maintenance phase therapy.

Results Mean volume of lymphedema was $1,054 \pm 633$ ml prior and 647 ± 351 ml after intensive decongestive physiotherapy. During the 1-year maintenance phase therapy, the mean lymphedema volume slightly increased (84 ml—95% confidence interval [CI]: 56–113). Fifty-two percent of patients had their

lymphedema volume increased above 10% from their value at the end of the intensive decongestive physiotherapy treatment phase. Non-compliance to low stretch bandage and elastic sleeve were risk factors for an increased lymphedema after 1-year of maintenance treatment (RR: 1.55 [95% CI: 1.3–1.76]; P < 0.0001 and RR: 1.61 (95% CI: 1.25–1.82); P = 0.002, respectively). Non-compliance to MLD was not a risk factor (RR: 0.99 [95% CI: 0.77–1.2]; P = 0.91).

Conclusion During maintenance phase after intensive decongestive physiotherapy, compliance to the use of elastic sleeve and low stretch bandage should be required to stabilize lymphedema volume.

Keywords Breast cancer · Lymphedema · Physiotherapy · Compliance · Elastic garment · Low stretch bandage

Lymphedema remains an important problem in women treated for breast cancer, occurring between 12% and 28% of the cases even with modern therapies [1–3]. Lymphedema is a chronic disorder that can result in significant physical and psychological morbidity. Swelling causes a disproportion in the size of a part of the body and can also interfere with mobility and affect patients' perception of themselves [4]. Reduction of volume is a major goal of lymphedema treatment and may participate to the improvement of quality of life.

Current management of secondary upper limb lymphedema after breast cancer treatment is based on the complete (or complex) decongestive physiotherapy defined by M. Földi in 1989. The different components of decongestive physiotherapy include low-stretch bandaging, manual lymph drainages, exercises and skin

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care [5]. Complete decongestive physiotherapy is currently divided into two successive phases. The first phase consists of intensive treatment and may be implemented in hospital to allow substantive reduction of lymphedema volume. The second phase consists of a maintenance treatment at home [5, 6]. Modalities of maintenance therapy are not well codified. The aim of our study was to describe the effect of the maintenance therapy on lymphedema volume reduction and to analyze the impact of the different components of treatment, in women with upper limb lymphedema after breast cancer treatment.

Methods

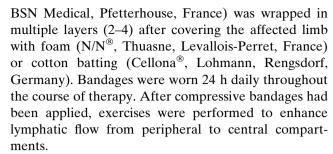
Patients and overview of treatment phases

Eligible patients were women referred for treatment of an upper limb lymphedema after breast cancer treatment to one single center dedicated to lymphedema management. Patients with a past history of lymphedema reduction attempt, by any method, were not eligible. All consecutive eligible women referred between January 2001 and December 2004 were included in this prospective cohort study. Lymphedema treatment was managed as follows: first, an 11-day-hospitalization period for implementing the intensive phase; second, at discharge, the maintenance phase was carried out by the patient and family at home. During hospitalization, education for implementing self-management was an important goal. The patient, and occasionally family members, was taught the self-bandage technique throughout the intensive phase. At least three bandages per week were recommended for maintenance treatment. During this second long-term maintenance phase, follow-up visits were scheduled at 6 (M6) and 12 months (M12). The first day of hospital stay for intensive therapy was the day of inclusion in the cohort.

Complete decongestive physiotherapy

All patients were treated with complete decongestive physiotherapy consisted in combination of manual lymph drainages according to Földi's techniques, bandages, manual lymphatic drainage, exercise, skin care, as recommended by the International Society of Lymphology consensus and Canadian guidelines [7, 8]. Lymphedema treatment was provided by physiotherapist trained in manual physiotherapic techniques, 5 times a week.

Manual lymph drainage treatment lasted 30 min. Then, a low stretch compressive bandage (Somos®,



Complete decongestive physiotherapy also integrated meticulous skin care. Sky dryness was systematically treated with moisturizer. Patients were instructed to avoid cutaneous effractions (e.g. cuts, burn, insect bites, cat scratch, cracks in dry skins) and to protect their skin during daily activities (e.g. using gloves for gardening, thimble when sewing). Obese patients were advised to lose weight and were provided with dietary instructions.

Data collected

Data included characteristics of breast cancer stage and treatment (age at cancer diagnosis, mastectomy/tumorectomy, radiotherapy, chemotherapy, antiestrogens drugs), complications (radiation-induced brachial plexopathy, erysipelas), patient characteristics, BMI (calculated as weight/height²), date of onset lymphedema and lymphedema volume at inclusion. Lymphedema volume was calculated for each 5-cm segment by utilizing the formula for a truncated cone: $H \times (C2 + Cc + c2)/12\pi$, H = height, C = circumference of the top of the cone, c = circumference of the base of the cone [9, 10]. This method demonstrated excellent inter- and intra-observer reproducibility in comparison to water displacement, which is considered the gold standard [11, 12].

Lymphedema volume was defined as the difference between the lymphedematous limb (VL) and the healthy limb volume (VH). Upper limb volumes were measured by the same operator at inclusion, at the end of intensive decongestive physiotherapy, at M6 and M12 follow-up visits.

At both follow-up visits, the actual treatment applied by the patient for the past 6 months was recorded, i.e. whether he actually used manual lymph drainage, self bandages (number per week) and elastic sleeve.

Statistical analysis

Data are presented as counts and percent for categorical variables and median with interquartile range (IQR) or mean with standard deviation (SD), unless



otherwise stated. Volumes were compared across groups using *t* tests and adjusted analyses were performed using analysis of covariance (ANCOVA). All tests were two-sided and *P*-values under 0.05 were considered as significant. Analyses were performed using R 2.2.0 statistical software (R Development Core Team, Vienna, Austria, 2005).

Results

Descriptive characteristics

A total of 537 women were included in our study. Two of them were excluded because of missing data. Main clinical characteristics of patients, breast cancer treatment and arm lymphedema management are presented in Table 1. During follow-up, 24 (4%) patients died. Overall, follow-up data were available in 426 (80%) and 356 (67%) patients at M6 and M12 follow-up visits, respectively.

Intensive decongestive physiotherapy

Lymphedema volume was $1,054 \pm 633$ ml prior intensive decongestive physiotherapy and 647 ± 351 ml after intensive decongestive physiotherapy (Fig. 1).

Table 1 Patient characteristics at inclusion (before the intensive decongestive physiotherapy)

	Patients $n = 535$
Age at inclusion, median (range), ys	62 (34–91)
Body Mass Index, median	26.9 (24.4–30.7)
$(IQR*), kg/m^2$,
Breast cancer characteristics	
Age at breast cancer, median	51 (24–81)
(range), ys	` ,
Side (right side), n (%)	274 (51)
Type of surgery	` /
Mammectomy, n (%)	258 (48)
Tumorectomy	267 (50)
None	10 (2)
Radiotherapy, n (%)	517 (97)
Chemotherapy, n (%)	337 (63)
Antiestrogens drugs, n (%)	269 (50)
Patient with evolutive cancer	98 (18)
at inclusion, n (%)	
Radiation-induced brachial	39 (7)
plexopathy, n (%)	
Mammalian reconstruction, n (%)	63 (12)
Lymphedema	
Lymphedema onset delay, median	22 (6–60)
(IQR*), months	
Duration of lymphedema, median	34 (14–91)
(IQR*), months	. ,
Patient with past erysipelas, n (%)	177 (33)

^{*}IQR: interquartile range

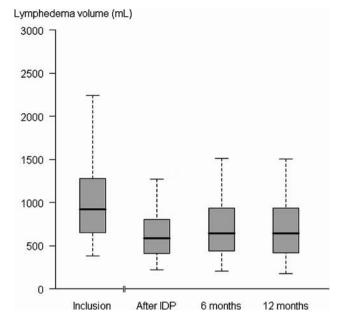


Fig. 1 Distribution of lymphedema volume at study time points. The box and whiskers plots represent the median (middle line), the 25th and 75th percentiles (box limits) and the 5th and 95th percentile (outer whiskers) of the distribution. IDP: intensive decongestive physiotherapy

Volume of lymphedema was thus found to decrease significantly under intensive decongestive physiotherapy (P < 0.0001), with a mean absolute volume reduction of 407 ml (95% confidence interval [CI]: -440 to -374 ml). Foam was used in bandage padding in 372 patients (70%), and cotton in 163 (30%). At discharge, class 3 elastic sleeve (20–36 mm Hg) were fitted in 458 patients (86%) and class 2 (15–19 mm Hg) in 77 patients (14%).

Maintenance therapy, M6

After 6 months of maintenance therapy, lymphedema volume slightly increased. Mean increase of lymphedema volume was 78 ml compared to volume at discharge. Compared to measurement at the end of the intensive phase, 217 patients (51%) had their lymphedema volume increased of more than 10% whereas it remained stable (between $\pm 10\%$) in 85 patients (20%) and decreased in 124 patients (29%).

Maintenance therapy, M12

At 12 months, mean variation of lymphedema volume of the 356 evaluated patients was 22 ml (95% CI: –3 to 46 ml) as compared to 6 months value and 84 ml (95% CI: 56–113 ml) as compared to discharge value at discharge. Compared to measurement at the end of the intensive phase, 186 patients (52%) had their

lymphedema volume increased of more than 10%, whereas it remained stable ($\pm 10\%$ variation) in 71 patients (20%) and decreased 99 patients (28%).

Factors influencing the results of maintenance therapy

At M12 follow-up visit, 235 patients (66%) were receiving manual lymphatic drainage (1–3 per week), 249 (70%) were doing regular self bandages (median: 4, interquartile range: 2–6) and 317 (89%) were wearing elastic sleeve.

The risk of increase of lymphedema volume (more than 10% increase) during the maintenance phase therapy was more than 50% higher for people not using low stretch bandage and elastic sleeve compared to people using these methods (adjusted relative risks: 1.55 [95% CI: 1.3-1.76]; P < 0.0001 and 1.61 [95% CI: 1.25-1.82]; P = 0.002) for low stretch bandage and elastic sleeve, respectively). By contrast, the risk of increase of lymphedema volume during the maintenance phase therapy was the same for people using or not manual lymphatic drainage (Table 2).

When considered in a multivariable covariance analysis model, the use of low stretch self-bandages allowed a 99 ml (SE: 33) additional volume reduction during maintenance therapy, compared to no use of bandages (Table 3). Use of elastic sleeve allowed a 118 ml (SE: 49) additional volume reduction during maintenance therapy, compared to no use of elastic sleeve. Effects of self bandages and elastic sleeve were independent from each other (P = 0.49 for interaction). These effects did not depend upon the magnitude of

Table 2 Risk of increase of lymphedema volume during maintenance phase therapy

	n (% of total)	n (%) of patients with volume increase (>10%)	RR (95% CI)	P
MLD				
Yes	246 (69)	129 (52)	1*	
No	110 (31)	57 (52)	0.99 (0.77 to 1.20)	0.91
Low s	stretch banda	nge		
Yes	263 (74)	120 (46)	1*	
No	93 (26)	66 (71)	1.55 (1.30 to 1.76)	< 0.0001
Elasti	c sleeve			
Yes	322 (90)	159 (51)	1*	
No	34 (10)	27 (79)	1.61 (1.25 to 1.82)	0.002

^{*}Reference category; MLD: manual lymph drainage; All risks are adjusted for the three variables presented in the table



Table 3 Compliance factors related to maintenance therapy results

1		
	Parameter estimate (SE)	P
Lymphedema volume at discharge, after intensive decongestive physiotherapy	0.03 (0.044)	0.5
Low stretch bandages Elastic sleeve	-99 (33) -118 (49)	0.003 0.017

No interaction was found between bandages and elastic sleeve (P = 0.49)

lymphedema volume after intensive decongestive physiotherapy.

Discussion

This is the first study analyzing role of the different components of complete decongestive physiotherapy after intensive treatment on upper limb lymphedema. During the maintenance phase, we noted a low increase of lymphedema volume after reduction during intensive decongestive physiotherapy. At M12 follow up visit, lymphedema volume was stable in 20% of patients and increased in 52% of patients. But in 28% of patients, lymphedema volume kept decreasing of more than 10% as compared with lymphedema volume at the end of intensive decongestive physiotherapy. Among the different components of the maintenance therapy, low stretch bandages and elastic sleeve appeared to have an independent additional effect on lymphedema volume at M12 follow up visit whereas manual lymph drainage did not.

The main strengths of our study were to be monocentric and to deal only with patients with lymphedema after breast cancer. All patients were recruited in a single department of lymphology and were hospitalized for the first time for intensive decongestive physiotherapy. The treatment was homogeneous and provided by physiotherapists specialized in lymphology. Hospitalization for treating patients with upper limb lymphedema after breast cancer allows to educate, to give advice for avoiding infectious complications, to learn for self-bandaging and to fit compressive garments. Follow up visits and lymphedema volume measurement were ensured by trained practitioners.

This study, however, has some limitations. First, because the treatments were not randomly allocated, we cannot exclude that treatment effects were actually due to unidentified confounding factors. Second, although all included patients had been contacted by phone to remind them of the follow-up visits, the

proportion of patients lost to follow-up at 12 months was relatively high. However, the rate of patients still followed at 6 months was higher and results not substantively different at 6 and 12 months. Last, assessment of compliance to the different components of maintenance therapy was crude. For clarity, we did not recorded partial compliance to recommendations.

The different components of lymphedema treatment, called complete decongestive physiotherapy, include low stretch bandages, manual lymph drainage, exercises and skin care [7, 8, 13]. Percentage of reduction of lymphedema volume varied 20-80% in the previous the published series but calculation formulas were diverse (perimetric measures, different interval between two measures) [5, 6, 14–17]. Low stretch bandage is the cornerstone of lymphedema management. Indeed, MacNeely et al. have compared in a recent randomized study two groups of women with secondary arm lymphedema. The first group (26 patients) received manual lymph drainage and low stretch bandage, the second (27 patients) only low stretch bandage for 21 consecutive days. No difference was showed in the two groups, except for the mild lymphedema (difference between the two arms below 150 ml) [18]. Johansson et al. in a not randomized study, found that the combination of manual lymph drainages with low stretch bandages was slightly better than low stretch bandages alone [19]. Andersen et al. published a randomized study showing that manual lymph drainage did not contribute to reduce significantly lymphedema volume in women receiving standard therapy (elastic sleeve, exercises, advices about lymphedema, skin care) [20]. Compression sleeve alone cannot produce a significant reduction in upper limb volume when fitted to a previously untreated lymphedema but has a great utility in the maintenance phase of therapy to maintain lymphedema volume [19, 21].

Maintenance therapy may prevent, in part, the skin thickening and fibrosis of the subcutaneous tissues and fat deposition forming a solid component to the swelling [22, 23]. A long-term effective reduction of lymphedema volume also promotes the maintenance of limb function and may reduce the incidence of recurrent infection [24]. Moreover, other psychological and social sequelae were reported in women with secondary lymphedema after breast cancer treatment: frustration, distress, depression, anxiety, disability, difficulty in domestic, social and sexual domains [25, 26]. The different sequelae and complications of cancer breast treatment trend to a diminution of the quality of life in women with secondary lymphedema [27]. Maintenance therapy may be helpful in improving quality of life with decrease lymphedema volume. Few

authors have suggested the importance of compliance in the stabilization of a reduced lymphedema volume after intensive decongestive physiotherapy. Boris et al. have proposed a maintenance therapy based on 24-h compression garment wear and a patient-specific physical therapy exercise program to be performed twice daily at home for 15-20 min. In this study, compliance was evaluated by the percentage of time of patients wore a compression garment and adherence to exercises. Persistence of reduced lymphedema volume was associated with compliance [28]. In Földi's study, in a 3-year follow-up program, more than 50% of the patients maintained the initial reduction in lymphedema obtained after intensive decongestive physiotherapy. A complete re-increase of lymphedema volume was due to the patient' failure to comply, abandoning low stretch bandages [5].

We concluded that bandages and elastic sleeve are the cornerstone of maintenance therapy after intensive decongestive physiotherapy. Patients should be persuaded to wear elastic sleeve every day. Self bandages are applied in the evening, kept the whole night and removed after awakening. Low stretch bandages are well tolerated for a long period whereas elastic garment are not, especially at night. A frequency of three bandages per week is recommended. Quality of life, perceived comfort, heaviness, mobility in the lymphedematous limb improved after lymphedema treatment [27]. Further studies are needed to compare different modalities of treatment during the maintenance phase and to assess the efficacy of measures enhancing compliance and patient's commitment.

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