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ORIGINAL ARTICLE

Prospective multicentre observational study of lymphedema therapy: POLIT study

Observation prospective et multicentrique du traitement du lymphœdème : étude POLIT

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Summary
Objective. — Lymphedema treatment is based on Decongestive Lymphedema Therapy (DLT) with an intensive phase followed by a long-term maintenance phase. This study aimed to observe volume variation over the intensive phase and 6 months later.
Methods. — Prospective multicentre observational study of patients with unilateral lymphedema. The primary objective was to assess lymphedema volume variation between baseline, the end of intensive phase and 6 months later. Secondary objectives were to assess the frequency of heaviness limiting limb function and treatments safety predictors for volume reduction.
Results. — Three hundred and six patients (89.9% women; 59.9 ± 14.3 years old) with upper/lower (n = 184/122) limb lymphedema were included. At the end of the intensive phase, median excess lymphedema volume reduction was 31.0% (41.7—19.9) followed by a 16.5% (5.9—42.3) median increase over the 6-month maintenance period phase. Previous intensive

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treatment was the only significant predictor of this response. As compared to baseline, heaviness limiting limb use was much less frequently reported at the end of the reductive phase (75.5% versus 42.3% respectively), and was more frequent at the end of the maintenance phase (62.6%). The most frequent adverse events reported were skin redness and compression marks (18.4 and 15.7% of patients, respectively). Blisters requiring treatment stoppage were rare (1.4%).
Conclusions. — Intensive phase decreases lymphedema volume and heaviness limiting limb function. The benefit is partially abolished after the first 6 months of maintenance. There is a need to consider how to provide optimal patient care for the long-term control of lymphedema.

MOTS CLÉS
Lymphœdème ;
Cancer ;
Traitement décongestif ;
Bandage ;
Compression

Résumé
Objectif. — Le traitement du lymphœdème repose sur la thérapie décongestive qui associe une phase initiale de traitement décongestif intensif (TDI) suivie d'un traitement d'entretien. L'objectif de l'étude POLIT était de décrire l'efficacité et la tolérance des traitements pendant la phase initiale et six mois après la phase de TDI.
Méthodes. — Étude d'observation prospective multicentrique de patients présentant un lymphœdème unilatéral de membre.
Objectif principal. — Évaluer la variation de volume du lymphœdème entre l'inclusion, la fin du TDI et après six mois de traitement d'entretien.
Objectifs secondaires. — Évaluer la fréquence des lourdeurs handicapantes de membre et la tolérance des traitements ; déterminer des facteurs prédictifs de la variation de volume.
Résultats. — Trois cent six patients présentant un lymphœdème du membre supérieur/inférieur (n = 184/122) ont été inclus. Pendant le TDI, la réduction médiane du volume du lymphœdème était de 31,0 % (41,7—19,9) suivie d'une réaugmentation de volume médian de 16,5 % (5,9—42,3) après six mois de traitement d'entretien. Un TDI antérieur était le seul facteur prédictif de cette réponse. Parmi les patients, 75,5 % rapportaient des lourdeurs de membre à l'inclusion contre 42,3 % à la fin du TDI et 62,6 % à la fin du suivi. Pendant le TDI, rougeurs de peau et marques de compression étaient fréquentes (10,5 et 8,2 % des patients), les lésions de frottement nécessitant l'arrêt du traitement étaient rares (1,4 %).
Conclusions. — Le TDI diminue le volume du lymphœdème et les lourdeurs handicapantes de membre. Ce bénéfice s'atténue lors des six premiers mois du traitement d'entretien. L'amélioration du traitement d'entretien est indispensable à la persistance à long terme du bénéfice du TDI.

Introduction

Lymphedema is a chronic and progressive swelling condition resulting from either a constitutional abnormality of lymphatic vessels (primary lymphedema) or from damage to the lymphatic system responsible for insufficient lymphatic fluid clearance from tissues. It is a frequent and chronic lifelong complication of breast cancer and other cancer-related therapies. As survival after cancer is improved, lymphedema incidence increases over time [1] and dramatically influences patient's quality of life [2]. There is no curative therapy for lymphedema. Treatment efforts are focused on optimizing the long-term swelling reduction, restoring functionality of the affected limb, and preventing potential complications associated with lymphedema. It is now a major public health concern [3].

Lymphedema management is based on Decongestive Lymphedema Therapy (DLT) consisting of a two-phase long-term management protocol [4]. Although DLT is recommended as the ''gold standard'' therapy [5—9], its modalities are not well codified, especially in the maintenance phase, with disparities of management protocols among centres. Moreover, a comprehensive assessment is required to determine the most appropriate treatment regimen for each patient. In addition, upper and lower extremity lymphedema may not respond in the same way to treatment.

Very few studies have assessed the overall results of this two-phase long-term program on lymphedema volume, and none of them focused on the efficacy/safety profile of this DLT approach.

The aim of this multicentre prospective observational study was to assess the volume variation between baseline, the end of the intensive DLT and after six months of maintenance therapy. Secondary objectives were to assess:

- volume variation between the end of intensive DLT and the end of follow-up;
- frequency of heaviness limiting limb function;
- predictors for volume reduction at the end of intensive phase;
- to record DLT adverse outcomes.

Methods

Study design and population

This observational, prospective, multicentre, longitudinal cohort study was carried out in public and private lymphology clinics in France between July 2009 and August 2010. The study was approved by the Consultative Committee for the Data Processing in Health Research and the Commission on Information Technology and Liberties. All patients received detailed survey explanations and an information letter.

All consecutive adult patients with a clinical diagnosis of unilateral stage II—III upper or lower limb lymphedema of any etiology and hospitalized for intensive decongestive therapy were eligible. Stage I was excluded as lymphedema intensive decongestive treatment and thus is not indicated in this case [10]. Patients with bilateral lymphedema, lymphedema of both upper and lower limbs, intensive decongestive therapy in the previous 6 months, cancer recurrence, and patients with permanent peripheral arterial disease contraindicating compression therapy were not eligible. Lymphedema was considered primary on the basis of clinical examination and in the absence of any identified medical, surgical or cancer-related etiology.

All included patients underwent DLT provided by physiotherapist and physicians trained in manual physiotherapy techniques and lymphedema intensive treatment. They were managed according to the investigator's usual practice and were followed up for 6 months. Treatment was divided into two successive phases: first, an *intensive phase of treatment* implemented over a 1-to 3- week period (the intensive phase was a priori defined as a daily application of treatments for at least 5 consecutive days, i.e. excluding weekend); second, at discharge, the *maintenance phase* was mainly carried out by the patient and family at home. Treatments provided by professionals were recorded. The first day of treatment of intensive therapy (day 1) was the day of inclusion in the cohort. Follow-up visits were scheduled at the end of the intensive phase, and after six months of the maintenance phase, on day 195.

The following data were recorded: patient sociodemographics, lymphedema characteristics (location, etiology, date of onset, type of edema, trophic disorders, staging, volume). Lymphedema volume was then measured on day 5, day 12, day 19 according to the duration of the intensive phase, and finally on day 195.

The presence or absence of heaviness limiting limb use was assessed at baseline and at each follow-up visit. Skin complications and any other adverse events were recorded throughout the study.

Lymphedema volume was calculated for each 5-cm segment for upper limb and each 10-cm segment for lower limb using the truncated cone formula (Fig. 1) [11,12]. This method demonstrated excellent inter- and intra-observer reproducibility in comparison to water displacement, which is considered the gold standard [13,14]. The excess volume (EV) called volume of lymphedema was defined as the difference between the lymphedematous limb volume (LLV) and the contralateral healthy limb volume (HLV). Relative excess volume was calculated according to the following formula: $(LLV - HLV)/HLV \times 100$. Limb volumes were measured by the same operator on day 1, at the end of the intensive phase, and on day 195.

Study outcomes

Outcome parameters were the following: lymphedema volume, percentage reduction in excess volume of the affected limb compared to the contralateral limb between day 1/end of intensive phase, end of intensive phase/day 195, day 1/day 195, heaviness with function impairment and rates of adverse events with a specific focus on skin complications likely to need a treatment or a DLT discontinuation such as infections, blisters, skin intolerance, wound and cancer evolution [6].

Treatment modalities

In this observational study, investigators were asked to describe the therapeutic protocol they applied during the intensive phase as well as their prescriptions for the maintenance phase: manual lymph drainage (MLD), intermittent pneumatic compression (IPC), complex multilayer bandaging (number of layers, day/night use), skin care, physical exercises either guided or not according to each centre protocol. At the end of the intensive phase, the number of effective treatment days and their distribution over the week were recorded.

Statistical analysis

Data are presented as count (percent) or median, range, except otherwise stated. Means and associated 95% confidence intervals (CI) were calculated for excess volume and its variations. The following predictive factors for volume reduction at the end of intensive phase defined as a reduction in excess. Volume of at least 20% were tested in univariate analyses: sex, age, activity status (''working/retirement/work stoppage/homemaker''), lymphedema characteristics (primary/secondary, upper/lower limb, date of onset, relative excess volume as a qualitative variable with a cut off at 40%), previous intensive decongestive therapy (in the last 6 months, previous maintenance therapy). Any variable achieving a *P*-value of 0.15 or less were entered in a multivariate logistic regression model. A result was considered as statistically significant if its *P*-value was ≤ 0.05 in the multivariate model. As this study is an observatory of clinical practices with different management strategies at each phase, we did not calculate any *P*-values for other endpoints (i.e. because of the absence of adjustment). Data were processed and analyzed by SAS-WINDOWS™ software (version 9.2).

Sample size calculation

Considering that 60% of patients should have an excess volume of less than 15% at the end of the intensive phase, a sample size of 300 patients was necessary to ensure a result precision of $\pm$10% (95% CI).

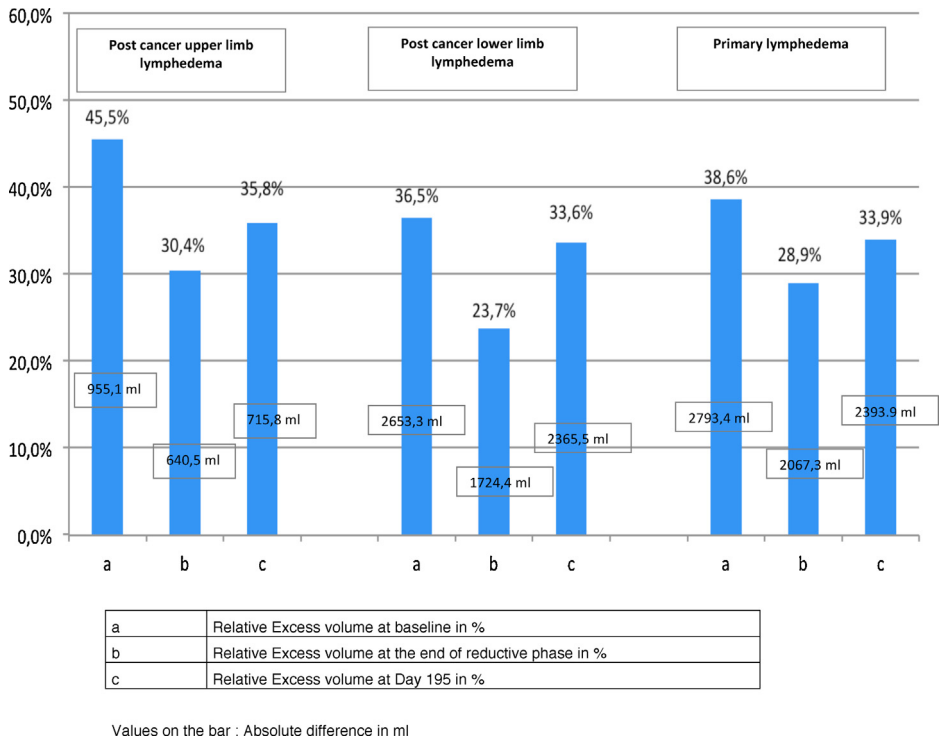

Figure 1 Relative excess volume over the study period according to origin and location of lymphedema.
Excès de volume relatif pendant l'étude en fonction de l'étiologie et de la localisation du lymphœdème.

Results

Population

Patient demographic data and lymphedema characteristics are given in Table 1. At baseline, 306 patients (89.9% female) suffering from upper ($n = 184$) or lower limb ($n = 122$) lymphedema were included in 12 centres. Mean age was 59.9 ($\pm$14.3) years. Most upper limb lymphedema ($n = 178$) were breast cancer-related lymphedema, whereas lower limb lymphedema were secondary in 47.5% of cases and primary in 52.5% of cases (genitalia involvement in 6 cases). Patients with primary lymphedema were younger (47.6 [$\pm$15.3] years versus 63.3 [$\pm$12.0] years= and more frequently men (24.2% versus 6.3%) than those with secondary lymphedema. Five patients were excluded because of protocol violation at the end of the intensive phase. Forty patients representing 13.1% of the study population did not perform the final clinical assessment at the end of the maintenance phase and were considered lost to follow-up. Among patients interviewed, 9.5% refused to come back due to geographical remoteness from the clinic and because there was no new planned treatment; 3.6% were totally lost to follow-up without even any phone contact; no one died.

Description of DLT components

The different components are presented in Table 2. The intensive phase was mainly composed of manual lymphatic drainage for 99.3% ($n = 299$) of patients and daily multilayer bandages for 99.7% ($n = 300$) of patients. The daily multilayer bandages were composed of at least one protection layer for 96.7% of patients (cotton or jersey); at least one layer of padding material for 86.3% of patients (Mobiderm® for 55.6% of them; Mousse N/N® for 20.1%; unidentified cotton wool or foam for 24.3%); at least one layer with short stretch material for 86.6% of patients (Somos® for 47.2% of them; Biflexideal® for 30.3%; Rosidal K® for 17.3%; others for 5.2%). Median duration of intensive phase differed between centres and habits of treatment. It was observed that it lasted 5 days (Q1—Q3: 5—9) for patients treated with a daily multilayer bandage including Mobiderm® padding and 10 days (Q1—Q3: 5—11) for patients treated with a daily multilayer bandage with other types of padding material. The maintenance phase was mainly based on daytime compression for 95.8% of the patients and nighttime compression for 78.9% of the patients (using bandages or hosiery during night treatment). During the maintenance phase, less than one-third of patients (30.5%) did physical exercises (unsupervised in 85.7% of cases), with a median weekly duration of 20 minutes and 3 weekly sessions in 61.9% of cases.

Evolution of lymphedema volume

Lymphedema volume and its variations in the whole population are summarized in Table 3. The lymphedema volume variations between baseline and the end of intensive TDI phase and between the end of the intensive phase and end of the follow-up were respectively of —32.1%, +16.5%. So that for the whole LDT, between baseline and end of

Table 1 Demographic and clinical characteristics at inclusion.
Caractéristiques démographiques et cliniques à l'inclusion.

	All patients[a] ($n = 306$)
Age, years	61 (51; 71)
Female	275/306 (89.9)
BMI, kg/m²	26.5 (23.2; 30.9)
BMI >30 kg/m²	81/270 (30.0)
Patients with secondary lymphedema	240/306 (78.4)
Patients with cancer (lower or upper limb)	219/240 (91.3)
Patients with primary lymphedema	66/306 (21.6)
Duration of lymphedema, years	
Primary lymphedema	11.5 (5; 21)
Secondary lymphedema	5.0 (2; 12)
ISL stage	
II/early III	251/306 (82.0)
III (elephantiasis)	55/306 (18.0)
Previous treatments within the last 12 months	
Intensive decongestive therapy	144/306 (47.1)
Maintenance therapy	286/305 (93.8)
Activity status	
Working	94/304 (30.9)
Homemaker	16/304 (5.3)
Retired	169/304 (55.6)
Work stoppage	25/304 (8.2)

[a] Data for continuous variables are shown as median (Q1; Q3), and data for categorical variables are shown as number (%).

follow-up, the lymphedema volume reduction was −18.3%. As shown in Fig. 1, similar results were observed in the sub-population of secondary upper limb lymphedema. For lower limbs, secondary and primary lymphedema showed similar variations. Similar results were also observed whatever the type of padding used to compose multilayer bandages. The median volume reduction achieved after the first 5 days of treatment in the sub-population of patients treated with daily multilayers bandaging including Mobiderm® padding was −27.4% (Q1, Q3: −36.8, −16.1) and −22.2% (Q1, Q3: −34.1, −15.1) with other types of padding.

Clinical symptoms

A marked decrease in the percentage of patients complaining of heaviness limiting limb use was observed at the end of the intensive phase (from 75.5% at baseline to 42.3%). At the end of the follow-up, complaints of heaviness were more prevalent (62.6%) than at the end of the intensive phase.

Adverse events

Safety was documented for 269 patients throughout the whole study period. The most frequent adverse events were skin redness and compression marks reported in 18.4 and 15.7% of patients, respectively. Skin complications likely to need a therapy or DLT discontinuation such as infection, blisters or skin intolerance were observed in 6.3, 4.0 and 3.6% of the patients, respectively. Frequency of adverse events during each treatment phase is detailed in Table 4.

Predictive factors of response to DLT

Univariate analysis revealed three potential predictive factors of response to intensive therapy: activity status, previous intensive decongestive therapy, and initial excess of volume of the affected limb (≥40% versus <40%). Multivariate analysis showed that a previous intensive treatment was the only significant predictor of response to the reductive phase, with an increased risk of treatment failure in patients previously treated (OR = 2.4 [1.4–4.1], $P = 0.002$). In regards to predictors of response to maintenance therapy, univariate analysis found no initial factor associated with therapeutic response at the end of the maintenance phase.

Discussion

Although DLT is backed by a longstanding experience and is worldwide recognized as an ''effective therapy'' for all limb lymphedemas [15,16], the nature and components of the outcome ''effective therapy'' have been very poorly addressed in clinical studies. Limb volume variation

Table 2 Components of the two phases of DLT.
Traitements réalisés pendant les deux phases de traitement décongestif du lymphœdème.

Intensive phase of DLT ($n = 301$)[a]		6-month maintenance phase ($n = 261$)[b]	
Manual lymphatic drainage (MLD)	299 (99.3)	Manual lymphatic drainage (MLD)	199 (76.8)
Daily multilayer bandaging (MB)	300 (99.7)	Regular multilayer bandaging use	32 (12.3)
Intermittent pneumatic compression (IPC)	140 (46.5)	Intermittent pneumatic compression use (IPC)	33 (12.7)
Daily combination MLD/IPC	138 (45.8)	Nighttime compression therapy	206 (78.9)
		Daytime hosiery	249 (95.8)
		Physical exercises	79 (30.5)

Results are expressed in number (%).
[a] 301 patients with at least one component of DLT documented.
[b] 261 patients with at least one component of DLT documented.

Table 3 Lymphedema volume and its variation over the whole DLT period.
Volume du lymphœdème et des variations pendant toute la durée du traitement décongestif du lymphœdème.

	Intensive phase		Maintenance phase
	Day 1 ($n = 288$)[a]	End of intensive phase ($n = 288$)	Day 195 ($n = 242$)
Relative excess volume, %	38.7 (23.6; 56.0)	25.2 (14.5; 40.0)	32.1 (16.9; 46.5)
Excess volume variation, %			
From day 1 to end of reductive phase		−31.0 (−41.7; −19.9)	
From end of reductive phase to Day 195			+16.5 (−5.9; +42.3)
From day 1 to day 195			−18.3 (−36.3; +1.5)

Data are shown as median (Q1; Q3) or number ratio. Data are given without extreme values.
[a] Volume of contralateral limb is not documented for 3 subjects.

Table 4 Adverse events recorded over the whole DLT period.
Événements indésirables collectés pendant toute la durée du traitement décongestif du lymphœdème.

	Intensive phase	Maintenance phase
Adverse events, n (%)		
Skin redness	31/296 (10.5)	21/255 (8.2)
Compression marks	24/293 (8.2)	18/254 (7.1)
Itching	15/293 (5.1)	10/253 (4.0)
Adverse events likely to need treatment discontinuation, n (%)		
Infection	1/294 (0.3)	16/255 (6.3)
Blister	4/293 (1.4)	7/252 (2.8)
Skin intolerance	0	8/253 (3.2)
Wound	0	2/253 (0.8)
Cancer evolution	0	4/252 (1.6)

was the most evaluated objective efficacy outcome and has been mainly assessed in breast cancer-related upper limb lymphedema [17—22]. Moreover, studies were often monocentre studies carried out by highly qualified experts [17—20,23]. The safety of DLT has never been prospectively evaluated. As a common rule, any method of treatment has to be efficient, safe and widely applicable before being recommended. As there is no general agreement on outcomes, excess volume variation as the primary one and symptom with function impairment (heaviness limiting limb use) as a secondary one were tested. Overall, both parameters varied in parallel. Excess volume decreased by 31 and 33.2% of patients did not relate heaviness anymore at the end of intensive phase. Both improvements were substantially lost at six months with only 18.3% excess volume reduction and 12.0% of patients still relating heaviness improvement. This result was consistent whatever the etiology and clinical presentation of lymphedema. These results could suggest that heaviness with function impairment is at least in part linked to volume excess.

In literature, excess volume reduction obtained after intensive phase of DLT varies from 20 to 73% [6—8,11—13]. Our results with a 30.9% of reduction in breast cancer are quite close to the 39% mean reduction obtained by Vignes et al. at the end of reductive phase in a cohort of 537 breast cancer patients [19] or Szuba et al. in 79 patients with either cancer or primary lymphedema [17], but are less marked than results from Forner-Cordero's et al. who obtained in 171 patients a 70% reduction of volume excess [22], or Ko et al. who obtained a 59.1% reduction after breast cancer and 67.7% in lower limb lymphedema [15]. Patients from Forner-Cordero et al. study had a more recent lymphedema (4 years) than ours (8.2 years), which is known to be associated with tissue structural modification and less mobilisable lymph fraction [23]. Differences in care organization and patient selection could also explain this discrepancy. Patients in Ko's et al. study [15] did not have any previous intensive treatment whereas nearly half in ours already have had intensive treatment in the past. The only independent variable predictive of volume reduction after intensive therapy was the presence of previous intensive DLT. Patients who already experienced DLT in the past year had a significant 58% reduction of probability to achieve at least 20% of volume reduction. Excess volume reduction after the intensive phase of DLT was identical in patients with secondary and primary lymphedema in line with the results of the two previous monocentre studies which included these patients [15,17]. Sex differences do not seem to have an effect on volume reduction.

The substantial loss of clinical benefit at six months observed in our study has previously been reported in terms of volume variation. There is a great deal of debate as to which components of physical treatment programs are the most crucial [24]. In a prospective cohort of 537 patients with secondary upper limb lymphedema, Vignes

et al. showed that among the different components of a 1-year maintenance therapy, low stretch bandaging and elastic sleeve appeared to have an independent additional effect on lymphedema volume whereas manual lymph drainage did not [19]. In a further study on 682 patients, the same team concluded that wearing an elastic sleeve and overnight bandage are the most efficient components of maintenance therapy for lymphedema after intensive decongestive physiotherapy [20]. A Cochrane review was made on randomized controlled trials that tested physical therapies with a follow-up period of at least six months [24]. One study on 42 patients randomized to two weeks MLD + hosiery or to hosiery alone showed that improvements seen in both groups were attributable to the use of compression sleeves and that MLD provided no extra benefit at any point during the trial [25]. In our study, maintenance therapy was applied in most patients by means of daytime hosiery (95.8%) and/or bandages (12.3%) and night compression therapy using bandaging (45.2%) or hosiery (46.0%). As regards pneumatic compression therapy (PCT), used both as a way of reducing and controlling edema, is an approach to which there is a divided opinion. It was used in 46.5% of our patients in the reductive phase and 12.7% of patients in the maintenance phase. Lastly, 76.8% benefited of long-term MLD applied by a professional. Despite all these treatments, medium excess limb volume increased by 16.5%. All these data and our own study show that there is a clear need for well-designed, large-scale randomized trials to determine which component or combination of components in DLT works most effectively.

Our study has its weaknesses and strengths. These results have been obtained from a survey without any randomization of treatments so that they cannot be formally attributed to the treatment. This study was not designed to evaluate the specific efficiency of each component of treatment. So, since almost all patients received MLD in addition to bandages during the intensive phase, it is not possible to identify each one's contribution to the global treatment efficiency.

Among the strengths of our study, it should be underlined that it is a large and prospective multicentre study. This large participation has allowed the inclusion of a substantial number of patients in this cohort, with a limited population selection bias. Follow-up was made by trained physiotherapists and practitioners. The protocol was standardized and training was made in order to limit measurement variations between centres. Tape perimeter measurements taken at defined intervals were chosen from other validated or more sophisticated options as it is the method used in daily clinical practice. Moreover, as patients suffered from unilateral lymphedema, the normal limb acted as the patient's own control and any significant reduction/increase has been reported as the percentage reduction/increase in the excess limb volume.

The results obtained in this observational cohort study cannot be compared with those from clinical randomized studies to assess their relevance in real life. However, we have prospectively recorded detailed skin and general adverse events during treatments. The rates of those susceptible to interrupt treatments are much higher than the less than 1% previously reported [26]. Moreover, our results indicate possible efficacy of the treatments which may need to be confirmed in randomized trials.

Conclusion

We observed a 31% lymphedema volume reduction after the intensive phase. However, part of the benefit was lost 6 months later. This study confirms that the maintenance phase presents challenges to patients and clinicians. Thus, there is a need to consider how to provide optimal patient care during the maintenance phase. Results from the present study may help to define the profile of patients, the sample size and the outcomes in future well designed randomized clinical trials that are needed to evaluate new strategies for the long-term control of lymphedema.

Disclosure of interest

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