

Research Article

Clinical use of a Night-Time MOBIDERM Garment as a Treatment Modality for Breast Cancer-Related Lymphedema: A Retrospective Longitudinal Cohort Study

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- Lymphedema
- Compression therapy
- Breast cancer
- Night-sleeve
- Maintenance phase

Abstract

Aim: The aim of this observational study was to investigate the use of a night-time compression sleeve (NTCS) as a routine maintenance therapy for breast cancer-related lymphedema (BCRL).

Methods: We performed a retrospective analysis of 145 breast cancer patients who over a five-year period used the Made-to-Measure Mobiderm® NTCS as adjuvant treatment for BCRL. The total sum of the percent differences between the two arms (%) after 6 months of NTCS use was the principal criterion. The circumferences of each patient's arm at the beginning of the NTCS use (baseline measurement=T0), and data from 6 months before (T-1) and 6 months after (T1) the use of the NTCS were considered.

Results: All patients were previously treated for breast cancer. At baseline (T0) the sum of the percent differences between the two arms in the sample of the study (n=145) was $53.1\% \pm 24.2$. Data showed a significant decrease by 6.6% of the sum of the percent differences between baseline (T0) and 6 months after NTCS use (T1) ($p=0.010$). Among the 145 patients, 99 patients (68.3%) were already treated for lymphedema and 74 of them (51.0%) had received a medical examination 6 months before the NTCS use (defined as treated lymphedema patients), while 46 patients (31.7%) were receiving their first medical examination for lymphedema at baseline (defined as newly diagnosed patients). In the newly diagnosed patients subgroup, a greater significant reduction of the sum of the percent differences of -13.4% at T1 compared to baseline was observed ($p=.013$). Among the 74 treated lymphedema patients, the sum of the percent differences after NTCS use (T1) was well maintained with a slight tend to decrease (-2.6%), while between before the NTCS use (T-1) and base line, this percentage significantly increased by 16.9% ($p<.001$).

Conclusion: The reduction of lymphedema observed in this study during the NTCS use period suggests that MOBIDERM® NTCS seems to be associated to a control of lymphedema volume in BCRL patients during the maintenance phase. This night garment might be an adjuvant effective component of the therapy to achieve the volume maintenance goal but its efficacy should be confirmed with a randomized clinical trial.

INTRODUCTION

Breast cancer-related lymphedema (BCRL) is a progressive and chronic debilitating complication characterized by accumulation of fluid in the tissue spaces of the upper limbs [1]. It is a very common consequence after breast cancer treatments and is associated with physical functional limitations, discomfort, swelling, psychological distress and negative overall impact on the patient's quality of life [2,3].

A meta-analysis conducted on 72 studies concluded that more than 20% of breast cancer survivors will develop arm lymphedema [1], making this disease a major public health issue.

At present, BCRL is not a curative disease. Therefore, the treatments are focused on optimizing the long-term swelling reduction, maximizing the preservation of arm function, and preventing BCRL-related complication such as infections [4,5]. According to the International Society of Lymphology (ISL) classification, lymphedema is divided into 3 stages (i.e. Stage I-II-

III) [6]. Usually, patients at stage II, III or more receive an initial (phase I) intensive treatment program which aims to reduce, as much as possible, the lymphedema volume. The complex decongestive treatment (CDT) is a gold standard treatment in improving the limb function and reducing the lymphedema related-symptoms. This treatment includes limb compression bandages, exercise, and manual Lympho drainage and skin care [7]. In particular, the compression bandaging has been suggested to be the part in which the significant reduction of the swelling occur mostly [8]. Following treatment to reduce the swelling, the goal of long-term maintenance treatment (phase II) is to maintain the achievements of the first phase. During phase II, the compression sleeves are the main part of preservation treatment. Patient self-management is also encouraged in this phase [6].

Despite maintenance therapy, within a few months after intensive therapy, a loss of clinical benefit is usually observed and reported in terms of volume variation [9]. Described as a 'rebound effect', this quick increase of lymphedema volume justifies the need to improve maintenance phase treatment modalities. Vignes et al. [10], studied the risk of treatment failure during the maintenance phase at 1, 2 and 4 years and reported failure rates of 38.1%, 53.1% and 64.8%, respectively. The benefit provided by compressive bandages during the night in association with day compression sleeve supports a conclusion that 24-hour-a-day compression treatment is the most effective therapy in the maintenance of lymphedema volume after the first phase of intensive treatments [10]. While the long-term use of compression therapy to manage lymphedema is well documented and recommended by the International Lymphoedema Framework (ILF) [11], the effect of night compression garment on top of daily compression is still insufficiently described. It has been argued that auto-bandaging has some limitations, such as patient compliance, time burden, and the need of a highly skilled caregiver to help the patient applying the bandages. Moreover, it is well recognized that the key factors for treatment success in chronic disease is compliance to treatment [12]. In this sense, a night-time compression sleeve (NTCS) has been suggested to be an easy-to-use alternative to auto-bandaging to improve self-management and compliance to long-term treatment. Recently, Mestre et al. [13], have investigated the efficiency of an auto-adjustable night garment in the management of lymphedema that indicated this device, used in conjunction with a day-time compression sleeve, restricted early rebound effect and helped stabilized lymphedema volume during the first three months after a successful decongestive lymphedema treatment. To our knowledge, no data are available regarding the effectiveness of more long term use of a night compressive garment in patients affected by BCRL, justifying this retrospective longitudinal study.

The Oncological Rehabilitation Centre (Ce.Ri.On.) in Florence, have been treating BCRL since 2005. In 2009, they began to prescribe the MOBIDERM® NTCS in addition to daily standard treatments. The aim of this retrospective study was to expose our experience with the MOBIDERM® NTCS to evaluate its usefulness in the control of lymphedema in breast cancer patients.

MATERIALS AND METHODS

This longitudinal retrospective study included patients (1) affected by BCRL who at some time between 2009 and 2014 used

the Mobiderm® NTCS as an adjuvant treatment for lymphedema, and (2) who had a baseline measure of lymphedema (T0, the beginning of the NTCS use) and a follow-up measure 6 months after the NTCS use (n=145). Excluded from the study, were the patients who did not have follow-up after 6 months of NTCS use (n=49) and patients who did not use the NTCS prescribed by physicians (n=23). The main reason cited by patients who did not use the device was the difficulty in wearing the NTCS. Among the 145 patients, 99 patients (68.3%) were already treated for lymphedema and 74 of these patients (51%) had received a medical examination 6 months before the NTCS use (treated lymphedema patients group). Before the NTCS use, these patients received one of the following standard treatments: Manual Lymph drainage (n=15), pressotherapy (n=12), bandaging (n=22) and made to measure stretch elastic on a flat weft day-time compression sleeve (class II) (n=52).

Conversely, 46 patients of the sample (31.7%) were attending their first medical examination for lymphedema (newly diagnosed lymphedema patients subgroup). This subgroup of patients had not previously received any lymphedema treatment and began using NTCS after this first medical examination.

After prescription of the NTCS, the patients have continued to be treated with one of the following standard treatments: Manual Lymph drainage (n=17), pressotherapy (n=12), bandaging (n=38) and day-time compression sleeve (n=84).

Women wore the NTCS before sleeping and removed it when they woke up in the morning. All patients could put on the compression garment without the help of others. Guidelines on the compression garment handling and care were provided by a physician during the medical examination. The NTCS was made to measurements and was always customized to the patient's arm measurements, re-calibrated during the follow-up visits, or changed according to arm evolution.

DATA EXTRACTION

We extracted, from Ce.Ri.On. database, data on patients' characteristics, treatments, medical history and lymphedema management. The measurements of the circumferences of each patient's arm were observed during 3 medical examinations: at the beginning of the NTCS use (the baseline measurement =T0), 6 months before (T-1) and 6 months after (T1) baseline.

Lymphedema measurement

Since this is a retrospective study, our analysis was based on data of lymphedema measurement collected for clinical reasons from 2009 to 2014. This study used the sum of the percent differences between circumferential measurements at four precise points on the arm as a measure of lymphedema [14]. The measurements of the arms were taken each time by the same person (i.e. M.) following the same procedure with a standard retractable tape measure. We analyzed data regarding the circumference of the arms of patients in 4 places (halfway down the upper arm, elbow, halfway down the forearm, and the wrist). In each of these areas, a percent difference was calculated standardizing the absolute differences between 2 circumferences by the largest circumference (i.e. if the circumference of the left arm measures 350 mm and the corresponding circumference

of the right arm measures 300 mm, the percent difference was calculated as follows: $|350-300|/350 \times 100 = 14\%$. The total sum of the percent differences between the two arms was used as a measure of lymphedema. This method was already used in previously published work [14].

Statistical analysis

The usual univariate descriptive statistics were performed. Paired Student's *t*-test was used to compare baseline with T-1 (i.e. data referred to 6 months before baseline) and baseline with T1 (i.e. data referred to 6 months after baseline), reporting both the *p* value and the confidence interval of 95%.

Analyses were conducted using the statistical software package Stata Statistical Software: Release 12. College Station, TX: Stata Corp LP.

Details of the product

The made-to-measure Mobiderm® night-time compression sleeve (Thuasne, Saint-Etienne, FRANCE) consists of an active low-stretch garment which uses the patented MOBIDERM technology composed of foam blocks in soft adherent webbing, and designed to apply a pressure between 10 and 15 mmHg. It creates on the skin (and under the skin) zones of differentiated pressure between the foam blocks and their perimeter allowing a local drainage to facilitate oedema fluid evacuation. Having a shear effect on subcutaneous tissues, MOBIDERM is also known to soften the skin, especially the indurated areas frequently occurring in chronic lymphedema (Figure 1).

RESULTS

We extracted data on 145 breast cancer patients affected by secondary arm lymphedema. Socio-demographic and clinical characteristics of this sample are reported in Table 1. All patients had surgery, most of which quadrantectomy (60.0%), and received at least one of the following treatments: chemotherapy, radiotherapy or hormone-therapy. The patients were included

Characteristics	n = 145	%
Age (mean/SD)	66.6 ± (12.5)	
Stage		
I	31	21.4
IIA	44	30.3
IIB	19	13.3
IIIA	17	11.7
IIIB	5	3.4
IIIC	12	8.3
IV	3	2.1
Missing	14	9.7
Treatments received ^a		
Chemotherapy	86	59.3
Radiotherapy	108	74.5
Hormone therapy	108	74.5
Body Mass Index (mean/SD)	27.5 ± (5.7)	
Obesity (BMI ≥ 30)	23	15.9
Type of surgery		
Halsted Mastectomy	7	4.8
Quadrantectomy	87	60.0
Modified Mastectomy	25	17.2
Modified Mastectomy and Quadrantectomy	2	1.4
Mastectomy and prosthesis	20	13.8
Parietal recurrence	4	2.8
Years from diagnosis (mean/SD)	13.5 ± (10.4)	
Baseline of the percent differences between the two arms (%) (mean/SD)	53.1 ± (24.2)	

^aPatients may have received more than one treatment

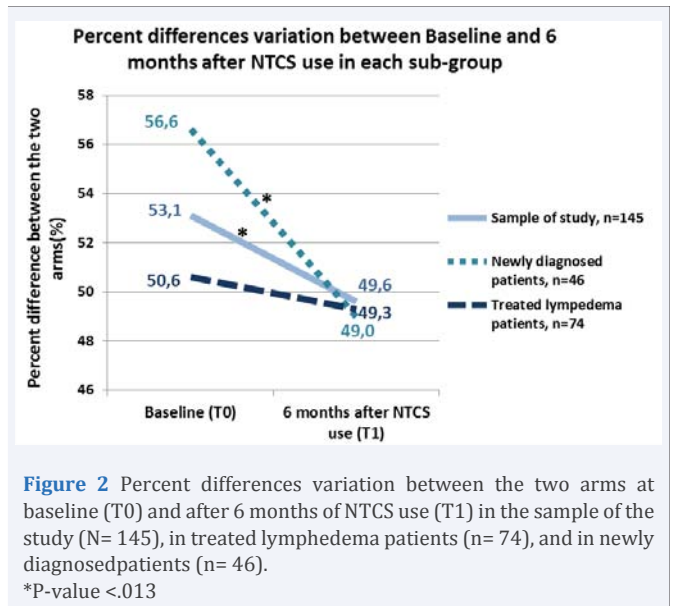


Figure 2 Percent differences variation between the two arms at baseline (T0) and after 6 months of NTCS use (T1) in the sample of the study (N= 145), in treated lymphedema patients (n= 74), and in newly diagnosed patients (n= 46).

*P-value < 0.013

regardless of lymphedema stages. Obesity (BMI ≥ 30) was present in 15.9% of the sample. The sum of the percent differences between the two arms at the beginning of the NTCS use (baseline = T0) in the sample of the study was 53.1% (± 24.2%). The variations of the sum of the percent differences observed between baseline and after 6 months of NTCS use are illustrated in Figure 2. Data showed a significant collective average decrease of 6.6% of the percent differences among all samples (n=145) between baseline

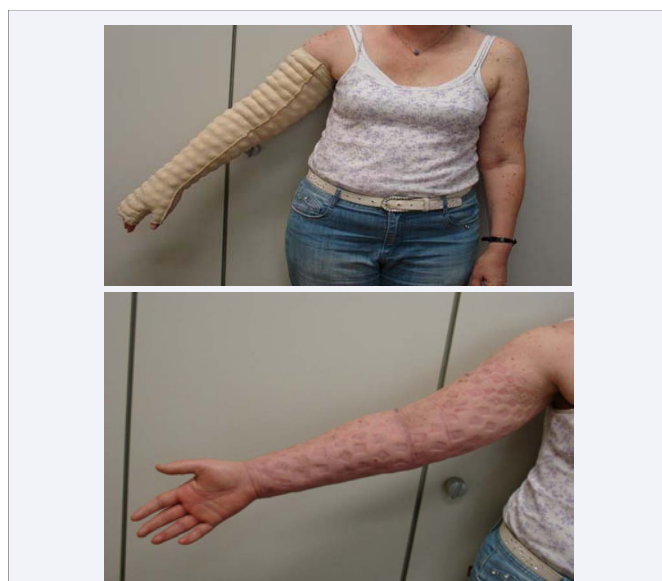
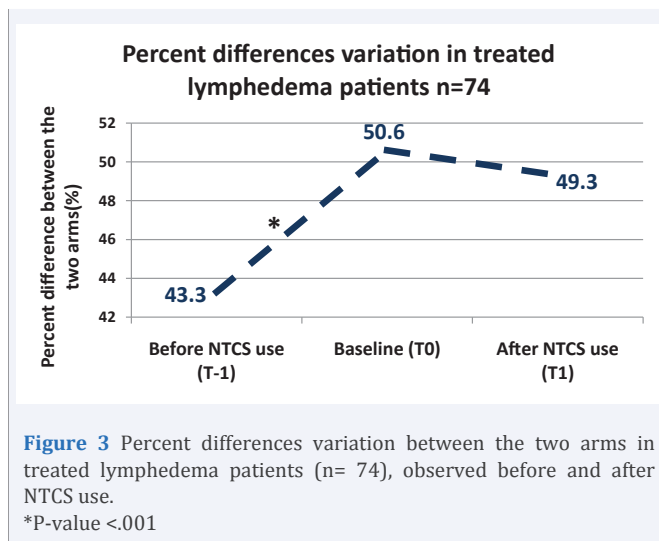


Figure 1 The night-time compression sleeve (NTCS).



(T0) and T1 ($p=.010$). Among the newly diagnosed patients, there was a greater significant reduction of 13.4% after 6 months of NTCS use (T1) compared to baseline ($p=.013$). Among the 74 treated lymphedema patients, the percent differences after NTCS use was stabilized, while in the period before the NTCS use (T-1) and baseline, this percent differences significantly increased by 16.9% ($p<.001$) Figure 3.

DISCUSSION

The present retrospective study suggests a correlation between the use of the Mobiderm® Night garment and a reduction and stabilization of the lymphedema evolution over time in breast cancer patients.

During the maintenance phase of lymphedema treatment, the main goal is the stabilization of lymphedema volume. The main component of the treatment, largely recommended in this phase, is compression therapy 24 hours a day. Hence, the use of a daytime compression sleeve should be associated with a compression overnight therapy [10]. In this way, identifying the most effective and easy-to-use night treatment to optimize the effect of the daytime sleeve, is one of the most important success factors in the treatment of BCRL.

The data analysis from 145 operated breast cancer patients has been conducted to observe the effect of MOBIDERM® made-to-measure NTCS. The results obtained in the entire sample showed that during the 6 months of NTCS use, the sum of the percent differences between the two arms decreases significantly. Interestingly, in the newly diagnosed patient's subgroup the decrease observed is more pronounced than those observed in the entire sample. We also observed in treated lymphedema patients subgroup, a stabilization of arm while previously they had a significant increase in the percent differences between the two arms during the previous 6 months when they were not using the NTCS. The night compressive sleeve is an add-on treatment during maintenance phase which goal is to extend the results obtained by an intensive phase. Among the patients of this study, this device was prescribed also to patients already on daily treatment and showing an increase in their lymphedema percent differences between the two arms during the 6 months follow-up

previous to the introduction of the night garment. Stabilization of their lymphedema is an interesting goal "Per Se" for this patients already treated for lymphedema and severe patient which might extend the maintenance phase duration and delay the next intensive phase treatment. This observation suggests that the clinical response level of patients to a same treatment may differ. This strategy to optimize the treatment with a good compliance of these patients already treated and mostly severe patients appears to be effective.

Despite compression therapy, follow-up examination or other therapy instructions, some authors point out the difficulty to retain the long-term reduction of lymphedema that is achieved during the intensive phase. In a cohort study (POLIT), it was described that the excess volume median reduction was 31% at the end of the intensive phase with partially reverse results 6 months later during the maintenance phase with a 16.5% median increase [9]. The interest of a night compression sleeve was recently studied by Mestre et al. [13], in a randomized controlled trial which assessed the efficiency of an auto-adjustable night garment to better maintain the clinical benefit of the intensive phase. While the lymphedema volume increased (+3.20% at 1 month) in the control group, in the night user group, the increase was two times less (+1.80%).

The results of the present study point out the potential benefit of a night-time compression sleeve to optimize the clinical outcome of patients affected by lymphedema, and suggest this could also represent a valuable alternative to night-time self-bandaging. Even if the use of garments or bandages during the night are encouraged and recommended by ILF and HAS [11,15], only few study investigates the role of night garment in maintenance phase. Compression sleeve with high pressure level were daily used but night compression is often provided by bandages. There is many existing compressive garments used daily but not for 24/24 hours because of the level of pressure provided and the low rate of tolerance during night. No previous specific study on the effect of the only garment exists and having described the combination of effect day + night. A comparative trial between garments and bandage was published by King et al. [16], but concerns the intensive phase of the lymphedema treatment and not the maintenance phase which is the most challenging period for out-patient. The MOBIDERM® made-to-measure NTCS assess in this study applied a low compression level (10-15mmHg) to improve night compliance. On top of the compression component of this garment, the MOBIDERM® technology used promotes mobilization of lymphatic fluid. This product is an add-on treatment to their daily compressive approach (sleeve, bandage, combination of sleeve and bandage...) during maintenance phase and as part of the whole strategy. This study provide some interesting data and suggests that adding this night garment might provide patient lymphedema stability and even a trends to volume reduction which are the main goals for the maintenance phase.

This study has some limitations. The retrospective nature of this study is the main limitation; hence no causation can be inferred from the results. Moreover, even if the evaluation of limb variation is the most objective efficacy outcome, symptoms and quality of life should have been an interesting additional

data to collect. However, this study has also some strength. Firstly, it should be noted that it is the first and largest cohort (145 patients) who were assessed to investigate the role of a night garment. Secondly, the long-term follow-up over a 6-month period is also an important feature of this study. Therefore, the results from the present study may help to define the profile of patients, the sample size and the outcomes of future, well-designed, randomized clinical trials that are needed to confirm the contribution of the NTCS for the long-term control of lymphedema. Despite the MOBIDERM® made-to-measure NTCS observed effects; its characteristics should be confirmed in a comparative well-designed phase III study.

In conclusion, the reduction of lymphedema observed in this study during the NTCS use period suggests that MOBIDERM® NTCS seems to be associated to a control of lymphedema volume in BCRL patients during the maintenance phase. This night garment might be an adjuvant effective component of the therapy to achieve the volume maintenance goal but its efficacy should be confirmed with a randomized clinical trial.

Moreover, the MOBIDERM®NTCS seems to be an easy-to-apply alternative solution that enables patients to manage their treatment without assistance from others.

CONFLICT OF INTEREST

Alessandro Toccafondi disclosure grants from Thuasne, during the conduct of the study; that is a contract as medical writer. None of the others contributing authors has any conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript. The sponsor participated in the decision to publish the results.

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