

Adding Pneumatic Compression Therapy in Lower Extremity Lymphedema Increases Compliance of Treatment, While Decreasing the Infection Rate

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Abstract

Background: Lymphedema (LE) is a chronic condition that requires lifelong treatment. Although pneumatic compression therapy (PCT) is one treatment option, current algorithms consider it as an adjunct to standard LE. The purpose of this study is to evaluate the importance of adapting PCT for lower extremity LE (LEL) in relation to patient compliance and rate of infection.

Materials and Methods: Patients diagnosed with LEL were followed prospectively. Patient demographics, comorbidities, treatment modality, compliance, infection due to LE, and hospitalization were recorded. LEL patients with no-PCT were also recorded in the same time period to evaluate the treatment compliance and the need for physical therapy visits. The no-PCT group received the standard LE care, whereas the PCT group received the standard LE care plus a new-generation pneumatic compression device.

Results: A total of 69 patients were enrolled in this study. The PCT group had 50 patients and no-PCT group had 19 patients. The PCT group had median 58.5 months of LE symptoms, while non-PCT patients had median 23 months of LE symptoms ($p=0.11$). Infection rates decreased by 32% and hospitalizations due to infection decreased by 14% after PCT treatment had been initiated. Physical therapy needs decreased by 24% after PCT use. At median 18 months, follow-up compliance for PCT was 84%, but compliance for manual lymphatic drainage was almost half (53%) in no-PCT group.

Conclusions: PCT leads to a decrease in infection rate, hospital admissions, and physical therapy (PT) visits in clinically significant LEL. Although there is no cost calculation in this study, it can be correlated to significant cost savings due to a reduction of infection and hospitalization and the need for PT visits. Adoption of PCT offers a superior value proposition to not only patients but also the health care system. Cost analysis should be followed.

Keywords: lymphedema, pneumatic compression therapy, management of lymphedema

Introduction

LYMPHEDEMA (LE), DEFINED as swelling that occurs as a result of protein-rich fluid accumulation in the interstitial space, is a chronic and cumbersome condition. Even though breast cancer-related LE is the most studied LE in the literature, lower extremity LE (LEL) is a very common problem as well. Up to 50% of patients who underwent lymph node dissection for cancer such as prostate, gynecological, and melanoma can have LEL, but other diseases such as chronic venous insufficiency (CVI), venous obstruction, lymphatic obstruction or lymphatic destruction, and surgeries such as

knee and hip can cause LEL as well.¹⁻³ Since LE is a progressive disease and can cause complications such as skin fibrosis, hyperkeratosis, adipose tissue accumulation, disability, and infections, treatment should be initiated as early as possible. Fortunately, there is a great attention nowadays to treat LE with new technologies. The goal of current treatment is aimed at lifelong remission with no progression in an effort to provide a good quality of life. The developments in pneumatic compression therapy (PCT) are a good option for the management of LE even though the role of PCT in the treatment algorithm is still not clear. PCT is considered an adjunct to standard LE care for some authors, but with low

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patient compliance, with the current standard treatment, and limited availability of LE-trained physical therapist, PCT should be offered to patients as early as possible.⁴⁻⁶ Similar to The International Society of Lymphology, our comprehensive LE program adapted early PCT as a nonsurgical treatment option. The purpose of this study is to evaluate the necessity of PCT for LEL to increase patient compliance with treatment, to help decrease infection rate and physical therapy (PT) visits.

Materials and Methods

Between June 2013 and December 2017, patients diagnosed with LEL were included in the study. All patients who underwent treatment for LE in the comprehensive LE program were followed prospectively. Patient demographics, comorbidities, treatment modality, patient compliance with LE treatment, and LE-related infection and hospitalization were recorded. Patients received their standard LE education and care. This includes compression stockings, comprehensive decongestive treatment, manual lymphatic drainage (MLD), exercise, and infection prevention precautions. Based on our comprehensive LE program guidelines, patients are evaluated by an LE physician in the first visit and then all patients are educated by a trained LE nurse. After LE educational materials are provided to the patients, they are encouraged to see an LE-trained physical therapist for complete decongestive treatment. Based on the patient's condition and insurance reimbursement policy, patients who were prescribed and had insurance coverage for PCT received a Bio Compression Systems Model SC-3008-DL (Bio Compression Systems, Inc., NJ). There were some patients who could not get PCT. These patients were followed to compare their treatment compliance of MLD, infection rate, and hospitalization. Patient demographics, treatment compliance, hospital admission, cellulitis rates, and disease progression were collected from the patient's electronic medical records.

This study was approved by University of Pittsburgh, IRB no.: MOD12090476-02/PRO12090476.

Statistical analysis

Distribution of categorical and continuous variables between the two groups was compared using chi-square and *t*-tests, respectively. Statistical analyses were conducted with R program version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Sixty-nine patients were enrolled in this study; 50 patients had PCT and 19 patients had no-PCT, but received complete decongestive therapy (CDT). There was no significant difference between the groups regarding age, body mass index (BMI), gender, and the LE etiology (Table 1). The mean age was 55.8 ± 18.7 years in the PCT group and it was 63.8 ± 18.7 years in the no-PCT group ($p=0.12$). The majority of patients were female (77%). BMI was 35.7 ± 11.8 kg/m² in the PCT group and it was 37.1 ± 12.8 kg/m² in the no-PCT group ($p=0.69$). The majority of the patients had CVI in the PCT group ($n=27$; 54%); in contrast, only five patients (26%) had CVI in no-PCT group ($p=0.04$). Ten percent ($n=5$) patients had >2-year history of DVT (deep venous thrombosis) in the PCT group, but it was 42% ($n=8$), were in the no-PCT group with a history of DVT (in 2-year) ($p=0.002$). Leg/hip surgery was similar between the groups and it was around 40% ($p=0.87$). Abdominal, groin/inguinal surgery rates were also similar ($p>0.05$).

The median duration of LE-related symptoms was 58.8 months in the PCT group and 23 months in the no-PCT group ($p=0.11$). The median PCT was 18 (4–72) months. Cellulitis without hospital admission was 40% ($n=20$) before initiating PCT; however, cellulitis rate decreased by 32% (40%–8%) at median 18-month follow-up after initiating PCT. Hospital admission due to infection was 26% ($n=13$) before PCT, but decreased to 12% ($n=6$) at median 18-month follow-up. The compliance for PCT at the median 18-month follow-up was 84%, and the need for PT visit for MLD decreased by 24% during the follow-up in the PCT group. On the other hand, in the no-PCT group, almost half of the patients (47%) quit MLD during the follow-up (Table 1). Patients reported leg MLD is time-consuming and difficult to do at least 5 days per week.

Discussion

Although, the most common reason of LEL is cancer surgery involving lymphatics, radiation therapy, infection, and CVI, noncancer surgeries are also risk factors for LEL.^{2,7,8} LE is a distressing situation in terms of diagnosis and treatment, and its treatment is lifelong. Most of the patients in the no-PCT group quit or reduced their daily treatment due to the time-consuming and difficult nature of doing MLD daily.

TABLE 1. COMPARISON GROUPS WITH AND WITHOUT COMPRESSION PUMP IN PATIENTS WITH LOWER EXTREMITY LYMPHEDEMA

	Compression pump group N=50 (72%)	No compression pump group N=19 (28%)	p
Age, mean \pm SD (years)	55.8 \pm 18.7	63.8 \pm 18.7	0.12
Gender (female)	37 (74)	16 (84)	0.37
BMI (kg/m ²), mean \pm SD	35.7 \pm 11.8	37.1 \pm 12.8	0.69
Symptom duration-months, median (25%, 75%)	58.5 (10, 133.5)	23 (13.5, 54)	0.11
Chronic venous insufficiency	27 (54)	5 (26)	0.04
Deep venous thrombosis	5 (10)	8 (42)	0.002
Leg/hip surgery	20 (40)	8 (42)	0.87
Groin/inguinal surgery	5 (10)	3 (16)	0.80
Abdomen surgery	20 (40)	12 (63)	0.09

BMI, body mass index; SD, standard deviation.

LE is an inflammatory process, which increases fluid and adipose tissue accumulation and skin fibrosis, which can result in complications such as severe swelling, cellulitis, and disability in the affected extremity if left untreated or if treatment is delayed. This process is rapid and irreversible,^{4,9–11} making it important to treat LE as early as it is diagnosed. CDT is the main treatment of LE that consists of multilayered compression bandaging, exercise, skin care, education, MLD, and compression garments, but PCT and surgical procedures are in the treatment algorithms as well.^{4,9} The effectiveness of MLD alone as a singular treatment modality is controversial. Prospectively completed studies and meta-analyses have shown that MLD is safe, but not adequate for the long-term management of LE.^{5,12} Furthermore, MLD requires management by an expert physical therapist, which is logistically limited and leads to high resource utilization and overall cost of care.⁴ On the other hand, our study shows that almost half of the patients quit MLD in 1-year follow-up.

PCT improves LE symptoms such as less clinical swelling, skin fibrosis, and pain in 90% of patients, which improves quality of life.^{10,13–15} PCT is offered as an adjunct, or in some cases an alternative treatment option for LE. As in-home therapy, it offers increased convenience and availability with minimal long-term resource utilization. Their concomitant garments are easier to wear and remove. Most importantly, in elderly patients and patients who have comorbidities such as arthritis, PCT is more convenient than MLD. However, using PCT in management of LE, the compliance of PCT, and the effect of PCT on infection are debated in the literature.^{16–20} Since use of PCT was more comfortable, patients' compliance was higher in our study. The compliance for PCT was 84% at the median 18-month follow-up, while compliance for MLD was only 53% in no-PCT group. In our study, all the patients were using PCT ≥ 5 days per week. Even though patients in the no-PCT group were trained and encouraged to do MLD every day, 47% of them did not do MLD at least 5 days a week. In the median 18-month follow-up, the need for PT visits decreased by 24% in the PCT group.

Cellulitis is another crucial part of LE complications and one of the most detrimental complications for patients who have LEL. Once it happens, it often recurs several times and severely restricts patients' daily activities. In epidemiological studies, the prevalence of cellulitis is around 12.6%–28% in LE patients.^{21,22} Almost a quarter of LE patients will have at least one cellulitis or skin infection in the affected limb. Cellulitis not only threatens patient's lives but also increases the cost of LE treatment. Initiating appropriate LE treatment as early as possible may reduce the risk of worsening LE and recurrent cellulitis.^{23,24} In our study, in the PCT group, cellulitis in the affected leg occurred in 40% ($n = 20$) of patients and hospitalization due to cellulitis was 26% ($n = 13$). This high rate of cellulitis patients had median 58.5 months of LE-related symptoms and was not diagnosed with LE, nor had they started LE treatment before they were seen in our comprehensive LE clinic. After PCT was initiated, infection rate decreased by 32% and hospital admission rate decreased by 14% in the PCT group. These reductions are not only important in the success of the PCT but also reduced the overall cost of care. It is obvious that reducing LE-related complications provides patients a better quality of life as well.

In this prospectively followed and retrospective analyzed clinical study, we have some weaknesses; first, it is a single-center observational study, second, the number of patients is low, and third, it is difficult to compare complications as the no-PCT group had a shorter duration of LE symptoms than the PCT group.

Conclusion

Early diagnosis of LE and intervention with PCT is the key to decrease infection rate, hospital admission, and PT needs in LEL; these reductions may be converted to significant cost savings. The use of PCT reduces the need for self-MLD in patients, which can be difficult to do to a person's own legs at least 5 days per week, especially in elderly or inactive patients. Adoption of PCT may offer a superior value to not only patients but also to the health care system.

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