Pneumatic Compression Improves Quality of Life in Patients with Lower-Extremity Lymphedema

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Background: Lymphedema is an incurable and disfiguring disease secondary to excessive fluid and protein in the interstitium as a result of lymphatic obstruction. Pneumatic compression (PC) offers a novel modality for treatment of lymphatic obstruction through targeting lymphatic beds and mimicking a functional drainage system. The objective of this study is to demonstrate improved quality of life in patients with lower-extremity lymphedema.

Methods: Consecutive patients presenting to a single institution for treatment of lymphedema were all treated with PC for at least 3 months. All patients underwent a pre- and post-PC assessment of episodes of cellulitis, number of ulcers, and venous insufficiency. Post-PC symptom questionnaires were administered. Symptom improvement was the primary outcome for analysis.

Results: A total of 100 patients met inclusion criteria. At presentation, 70% were female with a mean age of 57.5 years. Secondary lymphedema was present in 78%. Mean length of PC use was 12.7 months with a mean of 5.3 treatments per week. Ankle and calf limb girth decreased after PC use, (28.3 vs. 27.5 cm, $P = 0.01$) and (44.7 vs. 43.8 cm, $P = 0.018$), respectively. The number of episodes of cellulitis and ulcers pre- and post-PC decreased from mean of 0.26−0.05 episodes ($P = 0.002$) and 0.12−0.02 ulcers ($P = 0.007$), respectively. Fourteen percent had concomitant superficial venous insufficiency, all of whom underwent venous ablation. Overall 100% of patients reported symptomatic improvement post-PC with 54% greatly improved. 90% would recommend the treatment to others.

Conclusions: PC improves symptom relief and reduces episodes of cellulitis and ulceration in lower-extremity lymphedema. It is well tolerated by patients and should be recommended as an adjunct to standard lymphedema therapy. Screening for venous insufficiency is recommended.

INTRODUCTION

Lymphedema is a chronic debilitating disease secondary to excessive fluid and protein accumulation in the interstitium as a result of lymphatic system stasis or obstruction that affects.[1,2] This leads to limb edema in early stages with progression to thickening skin and fibrosis leaving the affected extremity susceptible to skin breakdown and repeated infections. Lower-extremity lymphedema is broadly classified into primary and secondary lymphedema. Primary lymphedema is a rare etiology affecting approximately 1 in every 6,000 live US births.[3] Secondary lymphedema is the most common etiology of lymphedema in the US and abroad with over 90 million affected as a result of parasitic infection, lymphatic trauma, surgery, obesity, radiation therapy, and chronic venous insufficiency.[4]

There is no cure for lymphedema, and hence, the mainstays of treatment have focused on comprehensive symptom control including limb elevation,

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pressure avoidance, skin hygiene and manual lymphatic drainage, and trauma avoidance. Surgical approaches to treatment of lymphatic system that include excision, autologous lymphatic grafting, and lymphovenous anastomoses, have been reported in patients with lower-extremity lymphedema with mixed results showing short-term reduction in limb girth and without reproducible long-term success.[5–8]

PC offers a novel modality for the treatment of lymphedema, wherein intermittent compression targeting all major lymphatic beds and venous drainage system simultaneously mimicks a functional drainage system.[9] Recent studies have demonstrated improvement in control of edema; however, improvement in quality of life (QOL) of patients with lower-extremity lymphedema has yet to be fully demonstrated.[10–12] The primary objective of this study is to demonstrate improved QOL in patients with lower-extremity lymphedema with PC treatment. Secondary objective is two-fold, first to demonstrate reduced infectious complications of lymphedema with PC treatment, and second, to determine the incidence of concomitant venous insufficiency in patients with lymphedema.

METHODS

A prospective observational study of consecutive patients presenting for treatment of lower-extremity lymphedema was conducted from March 2011 to September 2014. Institutional review board approval was obtained before patient enrollment. Lymphedema was diagnosed clinically via a thorough history and physical examination at the initial visit. Inclusion criteria were as follows: age 18 or greater and the presence of lymphedema in the lower-extremity for at least 14 days. Patients were excluded if they were pregnant, had previously used any PC device, or had class IV congestive heart failure. Only 1 limb per patient was included in the analysis, and in cases of bilateral lower-extremity lymphedema, the more symptomatic extremity was selected for analysis. Venous duplex was performed on all subjects at the initial presentation. All patients received standard lymphedema care including local skin care, treatment of infection, and compression. PC was provided with a single device, Flexitouch® (Tactile Systems Technology, Minneapolis, MN), a 32-curved chamber device that inflates and deflates sequentially, mimicking a functional drainage system. It targets both major lymphatic beds and the venous drainage system simultaneously. Each treatment was approximately 45 min. All patients were required to use the device for a minimum of 3 months, 3 treatments per week. In-home training on usage was provided and frequent nursing follow-up with weekly calls to enhance compliance.

Pre- and post-PC data were collected on the number of episodes of cellulitis, the presence of venous insufficiency, the number of ulcers, and limb girth. A self-reported QOL questionnaire was developed to assess symptom severity and improvement on a 5-point Likert scale: greatly worsened, mildly worsened, no change, mild improvement, and great improvement. Given the lack of validated QOL questionnaires for lower-extremity lymphedema, we referenced the lymphedema QOL against the chronic venous insufficiency questionnaire (CIVIQ)-2 QOL questionnaire that examines lower-extremity symptoms in patients with chronic edema in one-third of the subjects.

Statistical Analysis

Descriptive and comparative analyses were performed using chi-squared test for categorical variables and paired *t*-test for continuous variables. All reported P values are 2 sided and $P < 0.05$ was considered statistically significant. Analyses were performed in SPSS version 19.0 (IBM SPSS Statistics, 2010).

RESULTS

A total of 100 consecutive patients with lower-extremity lymphedema met inclusion criteria. The mean age was 57.5 years old, with a female predominance (Table I). Overall, 78% presented with secondary cause of lymphedema. The mean body mass index (BMI) was 33.6 with over 59% meeting National Institute of Health criterion for obesity (BMI >30) and 30% with morbid obesity (BMI >35). Bilateral disease was present in 48%. PC was used by all patients with an average total use of 12.7 months and 5.3 (±2.60) weekly treatments. QOL questionnaires with regard to lower-extremity symptoms were completed by all patients pre- and post-PC. All patients reported overall improvement in lower extremity—related symptoms with 54% greatly improved, 35% moderately improved, and 11% mildly improved (Table II). Furthermore, 90% of respondents reported that they would recommend PC to other patients.

Skin Ulceration and Cellulitis

In the year before PC, 15% of the patients reported 26 episodes of cellulitis, which decreased to 5