Support Care Cancer (2012) 20:1031–1036
DOI 10.1007/s00520-011-1178-9

ORIGINAL ARTICLE

Compression garments versus compression bandaging in decongestive lymphatic therapy for breast cancer-related lymphedema: a randomized controlled trial

Myrna King · Audrey Deveaux · Heather White · Daniel Rayson

Received: 6 December 2010 / Accepted: 25 April 2011 / Published online: 8 May 2011

Abstract
Background Lymphedema as a result of curative surgery for breast cancer can lead to long-term morbidity. Decongestive lymphatic therapy (DLT) is recognized as an optimal management strategy for patients with moderate symptomatologies, but there is little data in regard to the most effective means of providing compression therapy within a DLT protocol. We conducted a randomized trial of two forms of compression therapy within the initial treatment phase of a DLT protocol for breast cancer-related lymphedema.
Methods Subjects were required to have mild–moderate lymphedema (10–40% volume difference) acquired as a result of curative breast cancer surgery and were randomized to compression bandaging or garments within the initial treatment phase of a DLT protocol. Primary endpoint was change in affected limb volume assessed via volumetry, and secondary endpoints were symptom control and upper extremity function assessed via visual analogue scales and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, respectively. Endpoints were assessed at day 10 of treatment and at 3 months and compared to baseline.
Results Twenty-one subjects were available for analysis. The group receiving bandaging experienced greater median volume reductions at 10 days (70 vs. 5 mL; $p=0.387$) and at 3 months (97.5 vs. 50 mL; $p=0.182$). The bandaging group also experienced a greater increase in median DASH scores at 10 days (+20.9 vs. +5; $p=0.143$) and at 3 months (+18.4 vs. +3.3; $p=0.065$).
Conclusion Within the initial treatment phase of a DLT protocol for acquired, breast cancer-related lymphedema, compression bandaging may lead to greater volume reduction but worse upper extremity functional status (higher DASH scores) as compared to compression garments.

Keywords Compression garments · Compression bandaging · Decongestive lymphatic therapy · Breast cancer · Lymphedema

M. King
Occupational Therapy, Capital District Health Authority,
Room 326, NS Rehabilitation Center, 1341 Summer Street,
Halifax, NS B3H 4KY, Canada
e-mail: myrna.king@cdha.nshealth.ca

A. Deveaux
Physiotherapy, Capital District Health Authority,
4th Floor Dickson Bldg, 5820 University Ave,
Halifax, NS B3H 4A7, Canada
e-mail: audrey.deveaux@cdha.nshealth.ca

H. White
Senior's Health, Supportive Care and Rehabilitation,
Capital District Health Authority,
Room 2635, 5955 Veterans Memorial Lane,
Halifax, NS B3H 2E1, Canada
e-mail: heather.white@cdha.nshealth.ca

D. Rayson (✉)
Medical Oncology, QE II Health Sciences Center,
Atlantic Clinical Cancer Research Unit,
Room 460 Bethune Building, 1276 South Park Street,
Halifax, NS B3H 2Y9, Canada
e-mail: daniel.rayson@cdha.nshealth.ca

Introduction

Secondary lymphedema refers to the acquired accumulation of interstitial lymph fluid within a limb as a result of impaired lymphatic function [1]. Estimates of breast cancer-related lymphedema (BCRL) prevalence vary widely but it can be observed in 20–30% of patients as a result of local–regional therapies that include an axillary lymph node dissection [2, 3]. The highest incidence is noted in those women who

undergo an axillary node dissection followed by axillary radiotherapy [4]. The advent of sentinel lymph node procedures has been observed to lead to a reduction in incidence following breast cancer surgery but is still associated with a 2–5% absolute risk [5, 6]. Patients undergoing an initial sentinel lymph node biopsy who then subsequently undergo a delayed axillary lymph node dissection have rates of lymphedema that are equal to those patients undergoing an immediate, one-stage axillary procedure [7].

Secondary lymphedema results in swelling of the arm, hand, and trunk which can lead to limb pain, heaviness, and altered sensation. These symptoms can result in functional limitations of the affected limb and psychosocial distress can arise secondary to both symptoms and poor limb cosmesis. Lymphedema also increases risk of cutaneous infection in the affected limb [1, 2].

At present, there is no curative therapy available and treatment is focused on symptom management, preservation of function, and avoidance of infectious complications. Evidence-based comprehensive lymphedema care has been limited by the lack of randomized data defining optimal treatment modalities and sequences [8–10].

Compression therapy using fitted garments is a pivotal aspect of treatment with most studies observing volume reductions compared to pre-treatment values although reported mean volume reductions vary considerably [11, 12]. One of the major treatment strategies utilized in the management of BCRL is decongestive lymphatic therapy (DLT), sometimes referred to as complex decongestive physiotherapy (CDP) [13–15]. The initial treatment phase of DLT comprises four treatment elements: manual lymph drainage massage (MLD), compression bandaging, exercises with the bandaging in place, and education regarding skin care.

There remains controversy regarding the most effective means of providing compression therapy within the DLT protocol. Compression bandaging and compression garments, although both demonstrating efficacy, have rarely been directly compared in a randomized trial within the initial treatment phase of a DLT protocol. The goal of this study was to directly compare the effects of compression garments versus compression bandaging within the initial treatment phase of a DLT protocol on limb volume, lymphedema-related symptoms (pain, heaviness, and tension), and functional impairment for BCRL.

Patient population

Participants were recruited from the Lymphedema Care Program at the Capital District Health Authority in Halifax, Nova Scotia, Canada. All participants had been referred to the Lymphedema Program by an attending medical, radiation, or surgical oncologist at any stage of their treatment or follow-up following a breast cancer diagnosis.

Participants with demonstrable BCRL who met the following inclusion criteria were eligible to participate: (1) percentage volume difference between the lymphedematous and the contralateral (control) limb of 10–40% (mild–moderate lymphedema); (2) presence of one or more of pain, heaviness, tension, and/or functional impairment; and (3) greater than 3 months post-surgery and radiation therapy for breast cancer treated with curative intent. Reasons for exclusion were (1) prior treatment for lymphedema, (2) clinical or radiologic evidence of local cancer recurrence, (3) surgery or radiotherapy for bilateral breast cancer, (4) active cutaneous infection, and/or (5) clinical or radiographic suspicion or evidence of upper extremity deep venous thrombosis.

Treatment interventions

All participants attended daily treatment sessions, Monday to Friday, over a 2-week period for a total of ten treatment sessions. Participants received manual lymph drainage massage by two therapists trained in DLT, followed by skin care, compression glove/sleeve, and exercises. During the initial treatment phase, patients were randomized to wear a compression glove and sleeve (group 1) or compression bandages (group 2), day and night, as tolerated. At the end of the 2-week treatment, all participants were provided with a new sleeve and glove which was worn during day time only (Mediven 95 class 1, maximum 12 h). Participants were instructed in skin care and kept a journal to record daily wearing schedule and daily exercises for a 3-month period.

Materials and methods

Valco Mediven 95 (20–30 mmHg) ready-made, circular knit compression garments were used for group 1. Compression bandaging used for group 2 consisted of layering of the following products: BSN Medical Easifix finger bandages, tubular cotton stockinette, BSN Medical Artiflex padding wrap with foam inserts, and BSN Medical Comprilan bandages (6 cm, 2×8 cm, 10 cm). LaPlace's law was used to make the limb into a cylinder shape so that pressure was not increased at the smallest diameter (wrist). Overlap for the application of bandaging was ~50–60%. The end product was one of "feel for tolerance" by both the therapist and patient with daily re-wrapping of bandages and weekly re-wrapping of finger bandages. Each subject was re-measured on day 5, day 10, and at 3 months at approximately the same time of day as their day 1 measurement. Randomization was achieved with a random number table employed following signed, informed consent.

Study objectives and endpoints

The study had two objectives as follows: (1) to compare the volumetric effect of compression bandaging versus compression garments within the DLT protocol and (2) to compare the effect of compression bandaging versus compression garments on self-reported clinical symptoms of pain, heaviness, and tension as well as functional impairment.

The primary endpoint was the change in affected limb volume, from baseline, assessed via volumetric measurements on the 10th treatment day and 3 months post-treatment completion. Secondary endpoints included changes in (1) clinical symptom assessment (pain, heaviness, and tension) via the use of visual analogue scales and (2) assessment of upper extremity function via the use of the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire [16]. Both secondary endpoints were evaluated on the 10th treatment day as well as 3 months following completion of therapy and compared to baseline.

Ethics approval

Approval was obtained from the Capital District Regional Health Authority Research Ethics Committee, Halifax, Nova Scotia, Canada, with all participants providing written informed consent.

Outcome assessments

All assessments were performed at baseline prior to initiation of protocol therapy, at day 5, day 10, and 3 months following day 1 of treatment. An independent examiner, blinded to the type of compressive therapy utilized, completed all outcome assessments.

Limb volume was assessed using volumetric and circumferential measurements.

Circumferential measures were taken at 4-cm intervals, wrist to axilla, of both affected and unaffected limbs (formula—volume = sum of c^2/π) [17]. Excess limb volume was expressed in milliliters difference between affected and unaffected limbs.

Volumetric measurements were obtained using an arm volumeter filled with lukewarm water. Participants were seated on a chair and immersed their arm in the volumeter until the webspace between the long and ring fingers rested on a bar. The placement of the bar inside the volumeter was predetermined in a dry test with each participant. The bar placement was recorded for each participant and the setup was reproduced for each measurement session. Amount of water displaced was measured using a graduated cylinder.

Clinical symptoms of pain, heaviness, and tension were assessed using visual analogue scales. These measures were completed on day 1 prior to the first treatment session, day 5, day 10, and at 3 months for each participant. Upper extremity function was assessed using the DASH questionnaire [16]. The DASH is a 30-item questionnaire designed to measure physical function and symptoms related to the upper extremity. It was completed on day 1, prior to the first treatment session, on day 10, and at 3 months following completion of treatment.

Statistical analysis

Descriptive statistics were used to describe the differences in volumetric assessments and DASH scores for each group at the previously described time points. Volumetric measures, DASH scores, and clinical symptom scores at day 10 and 3 months were compared to day 1 assessments. Median values for outcomes at day 10 and at 3 months, each as compared to day 1 baseline values, were compared using the Wilcoxon rank sum test.

Results

A total of 132 patients were screened for the study. Twenty-three met inclusion criteria and provided written informed consent with two withdrawing consent, resulting in 21 participants available for analysis. The two patients that withdrew consent did not attend scheduled appointments nor did they return phone calls. Ten were randomized to group 1 and 11 randomized to group 2. One participant in group 2 was unable to complete the 3-month evaluation secondary to cancer recurrence.

Clinical characteristics of the entire patient cohort are presented in Table 1. The treatment arms were reasonably well balanced with the exception of more patients in group 1 (garments) having received a sentinel lymph node biopsy (100% vs. 64%) as well as an axillary node dissection (100% vs. 73%).

Median changes in volume and DASH scores, with interquartile ranges, are presented in Table 2. There were no statistically significant differences observed between the groups for either volumetric assessments or DASH scores at the two time points (day 10 and 3 months), each compared to day 1 values. Numerically, compared to baseline, the group receiving bandaging experienced greater median volume reductions (−70 vs. −5 mL^3 at day 10, −97.5 vs. −50 mL at 3 months) but median DASH scores were also higher (suggesting worse functional status) for the bandaged group (+20.9 vs. +5 at day 10, 18.4 vs. 3.3 at 3 months), with the results at 3 months almost reaching statistical significance. There were no significant differences observed between the two compression methods in subjective symptomatologies as measured by the visual analogue scales with a trend toward lower pain scores favoring the bandaging group at 3 months (p=0.16).

Table 1 Clinical characteristics

	Group 1: garments (n=10)	Group 2: bandaging (n=11)
Age, range (mean, years)	57 (44–69)	64.5 (52–76)
Affected limb (right/left)	4/6	4/7
Surgical procedure		
MRM	5	5
BCS	5	6
SLNB	10	7
ALND	10	8
Axillary radiation	5	6
Positive lymph nodes	3	5
Time from surgery to day 1 of protocol therapy (median months, range)	25.5 (4–103)	27 (7–156)

Discussion

The goals of lymphedema care include primary prevention, minimization of fluid accumulation and morbidity as well as maximization of functional capacity of the affected limb. The endpoints of lymphedema care can be evaluated from both subjective (self-reported symptoms) and objective (limb volumetric changes) perspectives with a comprehensive assessment requiring both types of evaluations. Due to the intensive nature of the compression component within DLT, it is important to evaluate this aspect of care from both symptomatic and functional perspectives.

The relative importance of each of the components of DLT remains to be elucidated although compression therapy is a cornerstone of all DLT programs [18].

The results from our randomized study did not demonstrate significant volumetric differences between compression garment application and compression bandaging within the DLT protocol employed. Median volumes were lower at both day-10 and 3-month time points in both groups with relatively wide inter-patient ranges. Numerically, compression bandaging resulted in greater median volume reductions at both time points.

Median DASH scores also did not differ significantly, at either time point, between the two groups. Interestingly, the numeric scores were higher for the group receiving compression bandaging with a trend towards being significantly higher at the 3-month time point (p=0.065). Of note, higher DASH scores reflect worse or poorer functional status, resulting in a possible paradox of divergent outcomes between these two methods of compressive therapy and possible trade-offs of greater volume reduction yet worse functional outcome. It is possible that the greater "vigor" involved with the regular application of compression bandaging, as compared to garments, may have negatively impacted overall symptomatologies and/or function, despite a greater volume-reducing impact. Our finding of an impact on 3-month DASH scores from 10 days of initial compression bandaging suggests the possibility of longer term functional impact related to vigorous compression during the initial treatment phase. Although this observation needs to be confirmed by further work, it raises the possibility of tissue and or functional sensitivity to vigorous compression therapy during the early phase of the DLT protocol.

Badger et al. [17] had previously demonstrated a significantly greater reduction in limb volume with multi-

Table 2 Volumetric and DASH results (median values and interquartile ranges; IQR)

	Group 1: garments (n=10)	Group 2: bandaging (n=11)[a]	p value
Median volume (IQR) day 1 (mL)	2,335 (260)	2,450 (700)	
Δ median volume (IQR) at day 10 (mL)	−5 (190)	−70 (290)	0.387[b]
Δ median volume (IQR) at 3 months (mL)[a]	−50 (217.5)	−97.5 (120)	0.182[b]
Median DASH score (IQR), day 1	18.8 (30)	29.2 (24.1)	
Δ median DASH score (IQR) at day 10	+5 (14.1)	+20.9 (21.7)	0.143[b]
Δ median DASH score (IQR) at 3 months[a]	+3.3 (21.7)	+18.4 (31.7)	0.065[b]

[a] One patient in group 2 was unable to complete the 3-month evaluation due to cancer recurrence

[b] All p values reported are in comparison to values on day 1

layered bandaging compared to hosiery alone but did not assess functional status nor was accrual limited to breast cancer-related lymphedema. Those with BCRL had to have been at least 12 months post-treatment (as opposed to 3 months in our study) and they assessed a longer treatment interval (24 vs. 12 weeks) than we did.

The major limitation of our study was slower than expected accrual and small sample size. Over the study timeframe, a total of 132 subjects with mild to moderate lymphedema were screened with only 21 eventually meeting study eligibility requirements and providing informed consent. Interestingly, Dayes et al. [18] observed a similar phenomenon when screening for a randomized trial comparing therapies for established breast cancer-related lymphedema. Of 437 patients screened for their study, only 49 met inclusion criteria with only 24 subjects (5.5%) consenting to protocol therapy.

We specified inclusion and exclusion criteria similar to those suggested by Dayes et al. in order to target those patients most likely to derive benefit from treatment. The majority of our referrals came from radiation, surgical, and medical oncologists and involved patients who were at varying stages of their surgical, radiation, and/or systemic therapies. Accrual, therefore, may have been limited due to the time from completion of surgery and radiation therapy specified by our inclusion criteria (3 months) and/or competing therapeutic decision-making and/or interventions.

Study strengths included consistency of therapist personnel, with the manual lymph drainage component of treatment administered by one of two therapists for the entire study cohort and duration. As well, all volumetric and patient-reported evaluations were administered or overseen by an independent examiner who, at all time points, was blinded to the type of compressive therapy employed.

The results of our study remain hypothesis generating and require confirmation but suggest that, within the initial treatment phase of a DLT program, compressive bandaging may result in a greater volumetric effect but compression garment application may result in fewer symptoms and better functional status. Although we did not measure interface pressures during compression, it is likely that differences in pressures generated by the two different methods of compression during the initial treatment phase of the DLT protocol may have accounted for the observed differences in both volume reduction and DASH scores. We observed worsening edema and/or DASH scores during therapy in a small number of cases. This may be explained by the fact that our patient population was accrued from active oncology practices and most of those accrued, although >3 months post-surgery/radiation as specified in the eligibility criteria, were still relatively early in follow-up and were mostly referred due to new-onset lymphedema which may have been in evolution during the treatment phase.

Given that the goals of lymphedema care are non-curative and aimed at improving quality of life and functional status, further work exploring this dichotomy and establishing best patient-centered endpoints should continue.

Acknowledgments The authors would like to thank the following who served as independent, blinded examiners over the course of the study: Rosemary Mooney OT regNS, Lisa Rand OT regNS, Alexia Mizuik PTA, Rosina Wilmott OTA, Terry Green PTA, and Bonita Spears PTA. The authors would also like to thank Kellie Hayes, Health Solutions, who supplied the compression garments.

Funding sources Breast Cancer Foundation Atlantic Chapter

Conlicts of Interest None.

References

1. Lawenda BD, Mondry TE, Johnstone PAS (2009) Lymphedema: a primer on the identification and management of a chronic condition in oncologic treatment. CA Cancer J Clin 59:8–24
2. McLaughlin SA, Cohen S, Van Zee KJ (2010) Lymphedema. In: Harris JR, Lippman ME, Morrow M, Osborne CK (eds) Diseases of the breast, 4th edn. Lippincott Williams and Wilkins, Baltimore, pp 586–597
3. Lacomba MT, Sanchex MJY, Goni AZ et al (2010) Effectiveness of early physiotherapy to prevent lymphoedema after surgery for breast cancer: randomised, single blinded, clinical trial. BMJ 340: b5396. doi:10.1136/bmj.b5396
4. Deutsch M, Land S, Begovic M et al (2008) The incidence of arm edema in women with breast cancer randomized on the National Surgical Adjuvant Breast and Bowel Project study B-04 to radical mastectomy versus total mastectomy and radiotherapy versus total mastectomy alone. Int J Radiat Oncol Biol Phys 70(4):1020–1024
5. Mansel RE, Fallowfield L, Kissin M et al (2006) Randomized multicenter trial of sentinel node biopsy versus standard axillary treatment in operable breast cancer: the ALMANAC trial. J Natl Cancer Inst 98:599–609
6. Lucci A, McCall LM, Beitsch PD et al (2007) Surgical complications associated with sentinel lymph node dissection (SLND) plus axillary lymph node dissection compared with SLND alone in the American College of Surgeons Oncology Group trial Z0011. J Clin Oncol 25:3657–3663
7. Goyal A, Newcombe RG, Chhabra A et al (2008) Morbidity in breast cancer patients with sentinel node metastases undergoing delayed axillary lymph node dissection (ALND) compared with immediate ALND. Ann Surg Oncol 15(1):262–267
8. Badger C, Preston N, Seers K et al (2004) Physical therapies for reducing and controlling lymphoedema of the limbs. Cochrane Database Syst Rev 4:CD003141
9. Kligman L, Wong RK, Johnston M et al (2004) The treatment of lymphedema related to breast cancer: a systematic review and evidence summary. Support Care Cancer 12(6):421–431
10. Karki A, Anttila H, Tasmuth T et al (2009) Lymphoedema therapy in breast cancer patients—a systematic review on effectiveness and a survey of current practices and costs in Finland. Acta Oncol 48:850–859
11. Damstra RJ, Partsch H (2009) Compression therapy in breast cancer-related lymphedema: a randomized controlled comparative

study of relation between volume and interface pressure changes. J Vasc Surg 49(5):1256–1263
12. Didem K, Ufuk YS, Serdar S et al (2005) The comparison of two different physiotherapy methods in treatment of lymphedema after breast surgery. Breast Cancer Res Treat 93(1):49–54
13. Koul R, Dufan T, Russell C et al (2007) Efficacy of complete decongestive therapy and manual lymphatic drainage on treatment-related lymphedema in breast cancer. Int J Radiat Oncol Biol Phys 67:841–846
14. Karki A, Anttilla H, Tasmuth T et al (2009) Lymphoedema therapy in breast cancer patients—a systematic review on effectiveness and a survey of current practices and costs in Finland. Acta Oncol 49:850–859
15. McNeely ML, Magee DJ, Lees AW et al (2004) The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. Breast Cancer Res Treat 86:95–106
16. Hudak PL, Amadio PC, Bombardier C (1996) Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) (corrected). The Upper Extremity Collaborative Group (UECG). Am J Ind Med 29(6):602–608, Erratum in: Am J Ind Med 1996;30(3):372
17. Badger CMA, Peacock JL, Mortimer PS (2000) A randomized, controlled, parallel-group clinical trial comparing multilayer bandaging followed by hosiery versus hosiery alone in the treatment of patients with lymphedema of the limb. Cancer 88:2832–2837
18. Dayes IS, Levine MN, Julian JA et al (2008) Lymphedema in women with breast cancer: characteristics of patients screened for a randomized trial. Breast Cancer Res Treat 110:337–342