THE EFFECT OF DIFFERENT COMPRESSION PRESSURE IN THERAPY OF SECONDARY UPPER EXTREMITY LYMPHEDEMA IN WOMEN AFTER BREAST CANCER SURGERY

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ABSTRACT

This study evaluated how different levels of pressure under inelastic multi-layer bandages affect the reduction of secondary arm lymphedema and patient comfort throughout therapy. Ninety-six women with lymphedema after breast cancer treatment were randomized into three groups of 32 patients depending on level of applied pressure in compression therapy: group I (control) at 21-30 mmHg; study groups II A at 31-40 mmHg and group II B at 41-60 mmHg. All patients were treated with complex decongestive therapy (CDT) and intermittent pneumatic compression (IPC) before compression. Fixed points of bilateral arms were measured at the start (first visit), after 24 h, 7 days, and 14 days of therapy. Edema severity was measured by summary calculation. Results were presented as a relative metric coefficient of arm lymphedema (RMCAL) which is the difference between sums of circumferences of the edematous arm and the contralateral side expressed in percents. In order to evaluate the patient comfort after finishing a two-week therapy all patients assessed the level of accompanying pain using the numeric pain rating scale (NRS). At the start of therapy median arm circumference difference (RMCAL) was 18.60%, 18.51%, and 19.05% in groups I-II B, respectively. After 24 h the median RMCAL was reduced to 14.49%, 12.13%, and 12.64%. This was further reduced to 10.77%, 6.98%, and 8.48% at one week and 10.28%, 5.75%, and 7.20% in each group, respectively. There was no statistically significant difference between RMCAL values in group II A and II B throughout the therapy. In group II A (NRS = 2), applied bandages were better tolerated than in both II B (NRS = 5) and control groups (NRS = 8). These results demonstrate that inelastic multi-layer bandages applied in groups II A and II B (41-60 mmHg) led to the same reduction of swollen arm circumference with group II being better tolerated. The lowest compression (control at 21-30 mmHg) produced the smallest reduction. In addition, since the greatest reduction was seen in the first week of therapy while the second week served to maintain the reduction, compression garments may be able to be ordered after one week of therapy for more efficient patient care.

Keywords: breast cancer, lymphedema, compression therapy, manual lymphatic drainage

Comprehensive treatment of breast cancer (particularly surgery) can cause

physical and psychological consequences which change patient quality of life (1). The highly variable incidence of acute and late side effects of cancer therapy observed in about 5.5-80% of the patients might be explained by the different tumor stage at the time of detection and initiation of treatment (2). For example, in comparison to patients following sentinel node biopsy, those with lymphadenectomy demonstrate a 4-fold increase in the incidence of lymphedema. Statistics show that each year there are 1.38 million women in the world who develop breast cancer with approximately 21% of these developing secondary arm lymphedema (3,4). Lymphedema occurs within two years after breast cancer treatment in 75% and within three years in 90% of these cases (5). Upper extremity lymphedema develops gradually as a result of damage to the lymphatic vessels. First this leads to accumulation of residual tissue fluid in the lymphatic vessels of the skin and then to subcutaneous tissue followed by muscle fascia and muscle (6). As time progresses an accumulation of macrophages, fibroblasts, and various substances such as extracellular polysaccharides, hyaluronic acid or collagen is observed. As a result, hypertrophy of connective tissue and fatty tissue occurs in some cases. Developing fibrosis correlates with the severity of lymphedema (7). As complications of secondary lymphedema, inflammation of the connective tissue (cellulitis), superficial lymphatic vessels (lymphangitis), skin and subcutaneous tissue (erysipelas), as well as malignant lymphatic transformations (lymphangiosarcoma) were observed (8). Very often, in the area affected by lymphedema, inflammation and disruption of skin integrity are observed which creates favorable conditions for the proliferation of pathogenic microorganisms (9,10). Skin infections are most common in patients with chronic lymphatic edema (11). Numerous studies have shown that in patients suffering from secondary lymphedema susceptible infection areas are the skin around the nails as well as the nails (12).

Complex decongestive therapy (CDT) is considered an optimal method for reducing lymphedema, although there are no comprehensive studies indicating which individual component of therapy has the greatest impact on its effectiveness. Non-homogeneous conditions described in scientific studies such as limited number of patients, different clinical stages of lymphedema, different techniques of MLD used, and lack of pressure measurements in compression therapy make the results difficult to interpret. However, studies demonstrate that CDT can lead to 70% reduction change in arm volume in reported studies (13). It was also found that it improves quality of life of patients with lymphedema after breast cancer (13). CDT according to the International Society of Lymphology (ISL) consists of the following elements: manual lymphatic drainage (MLD), therapeutic exercises, compression therapy, accurate nail and skin care (14-17). Most often, in the phase of edema reduction, inelastic multi-layer bandages are effectively used. The elasticity of short stretch bandages is between 10-100% (18). The pressure exerted on the limb during the multi-layer compression bandaging is determined by the number of layers, the strength of the pressure, and shape of the legs (19). It has been shown that an upper limit of the applied pressure exerted by short stretch bandages is about 30-40 mm Hg in the case of mixed edema on the lower limbs (20). A randomized study showed that in 36 patients after mastectomy with upper extremity lymphedema, compression therapy using short stretch bandages at lower pressure (20-30 mmHg) was better tolerated while the same level of swelling reduction was observed as for higher pressure (44-58 mmHg) after 24 hours. (18). It should be noted that the pressure exerted by bandages is optimal if it continues the reduction of swelling without lowering patient quality of life. Excessive pressure causes discomfort, while insufficient pressure promotes repeated fluid retention. A recent report shows that

low pressure under bandages was as effective as high pressure in terms of volume reduction in a small group of 36 patients (21). Therefore, we undertook testing to determine whether this relationship would be confirmed in a large group of 96 patients and for longer duration of therapy (21).

MATERIALS AND METHODS

The study consisted of 96 female patients in the age range 35-74 who underwent unilateral modified radical mastectomy at Patey (Polyclinic evi-MED, Gdynia, Poland). The study was approved by the Bioethical Committee of the Gdansk Medical University under the number KB - 3/14. 25 patients required adjunctive therapy with chemotherapy and radiation, 5 patients required only radiation, 34 only chemotherapy, while the remaining 32 patients did not receive additional treatment. All patients were followed at the Polyclinic for at least 14 months post-oncology treatment. Patients were enrolled into the study if they exhibited stage II (ISL criteria) unilateral breast cancer-related lymphedema. All patients were randomized into groups of 32 by a computerized Polyclinic system ("Interclinic") into group I (control at 21-30 mmHg), group II A at 31-40 mmHg, and group II B at 41-60 mmHg compression. Subjects were measured 4 times at the start (first visit), after 24 h, 7 days, and 14 days of therapy.

Edema severity was measured by summary calculation method. For the healthy and affected arms, the sum of circumferences (expressed in cm) was taken at 8 fixed measuring points: the metacarpophalangeal joints, carpometacarpal joints, 2 cm above the wrist, at the widest point of the forearm, 2 cm below the elbow, 2 cm above the elbow, at the half length of the humerus, and 2 cm below the axilla. Results were presented as a relative metric coefficient of arm lymphedema (RMCAL), which is the difference between these sums expressed in percent at a given stage of treatment. The values of RMCAL reflect the level of lymphedema reduction as a measure of therapy effectiveness.

where:

$$RMCAL\ \% = \frac{C_{AA} - C_{HA}}{C_{HA}} \times 100$$

C_{AA} = sum of circumferences of affected arm taken at the fixed measuring points
C_{HA} = sum of circumferences of healthy arm taken at the fixed measuring points

MLD according to Vodder was started on the first day at the clinic and then every 24 hours until the end of therapy. After MLD, an intermittent pneumatic compression device (5-chamber, Metrum-Med., 2001) was applied to all patients under a standard pressure 40-50 mmHg for 30 minutes a day throughout the therapy after the MLD and preceding multi-layer bandaging. Then, the compression therapy was carried out every 24 hours throughout the therapy. In the phase of edema reduction, we used short stretch bandages Matopress (6 cm x 4 m, 8 cm x 5 m, 10 cm x 5 m, 12 cm x 5 m) and other elements such as: foam bandage Matosoft SYNTHETIC (10 cm x 3 m), tubular bandage Tubula cotton (7 cm x 6 m), Matolast – (6 cm x 4 m, Limfoset-Matopat, Torun, Poland). In all treated groups the pressure was measured with Kikuhime device (HPM-KH-01, TT Meditrade, Soro, Denmark) every 24 hr.

An oval-shaped polyurethane large sensors (12 x 10.5 cm diameter) were placed on the cotton sleeve and fixed with plaster. Sensors were located on the front of the forearm closer to the elbow and on the lateral side of the distal arm (18). Patients were advised to exercise daily for 20-30 minutes, to facilitate the drainage of lymph from the swollen arm (22-24). After the two-week therapy, patients also assessed the level (0 - 10 points) of accompanying pain filling out a questionnaire with a numeric pain scale (NRS) (*Fig. 1*). The lowest value of the scale indicates a lack of pain while the highest expresses the strongest imaginable pain (25,26).
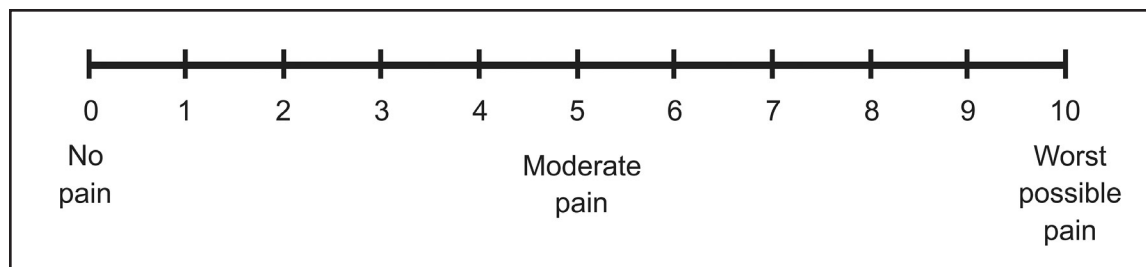
Fig. 1. Numeric pain rating scale

Statistics

Statistical analyses of the data were performed with STATISTICA 10 PL software (Statsoft Inc. USA) and Excel 2010 (Microsoft). The Shapiro-Wilk test was used to evaluate normality and the Kruskal-Wallis test was used to determine whether all samples originate from the same distribution. Significance level (p) was set at 0.05.

RESULTS

Median arm circumference difference expressed as RMCAL value at the start of therapy in the control group and groups II A and II B was 18.60%, 18.51%, and 19.05%, respectively. After 24 h, median of RMCAL value was 14.49% in control group while and 12.13% and 12.64% in groups II A and II B (*Table 1*). After one week of therapy a decrease in difference of circumferences between healthy and lymphedematous arm was observed (*Fig. 2*) with RMCAL value at 10.77% in control group and 6.98% and 8.48% in groups II A and II B. After 14 days of therapy only a slight decrease in RMCAL values was observed in all groups. In comparison with the initial stage, total arm circumference in all groups showed a significant median difference of arm circumference after 24 hours and 7 days. There was no statistically significant difference between RMCAL values in group II A and II B throughout the therapy. There was a statistically significant difference between

RMCAL values between the control group and II A and II B groups. RMCAL value was almost twice as low in group II A as in control group. In group II A (NRS = 2) applied bandages were better tolerated than in both II B (NRS = 5) and control groups (NRS = 8) (*Fig. 3*).

DISCUSSION

Some authors consider the compression therapy as a gold standard in the treatment of lymphedema while other elements of CDT are treated as a supplement to therapy (27). In order to evaluate the effectiveness of therapy using multi-layer bandaging and/or compression garment a clinical trial involving 83 patients suffering from primary or secondary arm or leg lymphedema was carried out. The results showed that a much better result was achieved when both bandages and garments were applied throughout the treatment. This procedure ensured greater and long-lasting reduction of swelling than was observed in the case when only compression garments were used (28). Similar conclusions were reached by another team of scientists who carried out an almost identical study involving 90 women diagnosed with unilateral arm lymphedema with 20% increase in volume compared to the healthy arm. The patients were divided into two groups, in one group the swelling was reduced by bandaging for 18 days and then with 24 weeks compression garment treatment; in the second group only a compression

					TABLE 1

TABLE 1
Statistical Characteristic of the RMCAL (%) and the NRS Values in All Tested Groups

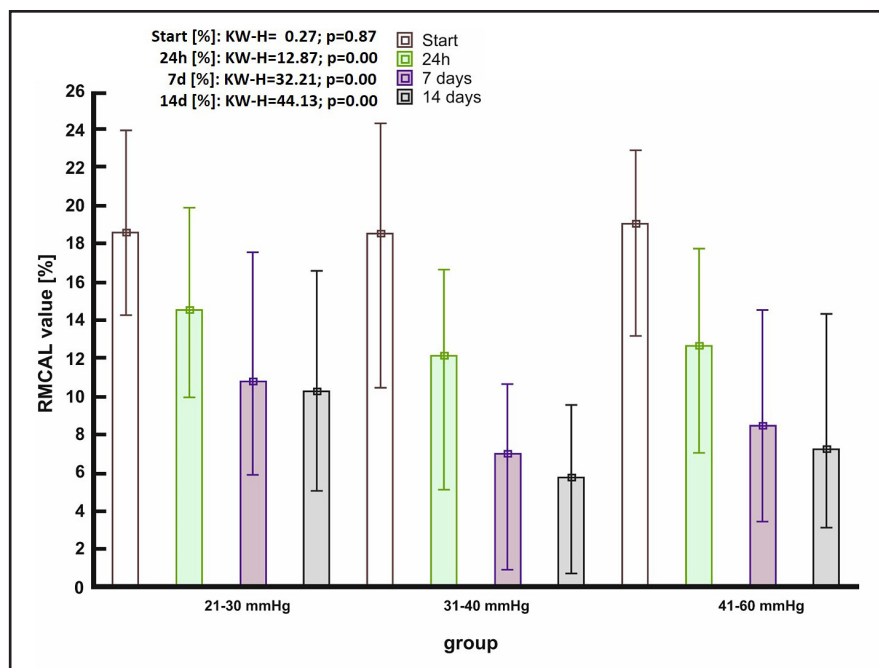| Group	Phase of therapy	Median	Minimum value	Maximum value	Standard deviation SD
Control group 21 – 30 mmHg	Start	18.60	14.24	23.94	2.53
	24 h	14.49	9.93	19.88	2.47
	7 d	10.77	5.87	17.52	3.24
	14 d	10.28	5.03	16.61	3.08
	NRS	5.00	1.00	9.00	2.00
Group II A 31 - 40 mmHg	Start	18.51	10.47	24.32	3.37
	24 h	12.13	5.12	16.65	2.86
	7 d	6.98	0.93	10.62	2.36
	14 d	5.75	0.72	9.56	1.90
	NRS	2.00	0.00	6.00	1.68
Group II B 41 - 60 mmHg	Start	19.05	13.14	22.89	2.54
	24 h	12.64	7.01	17.72	2.41
	7 d	8.48	3.43	14.55	2.29
	14 d	7.20	3.11	14.31	2.38
	NRS	8.00	3.00	10.00	1.86

Fig. 2. RMCAL values in both control and tested groups throughout the therapy
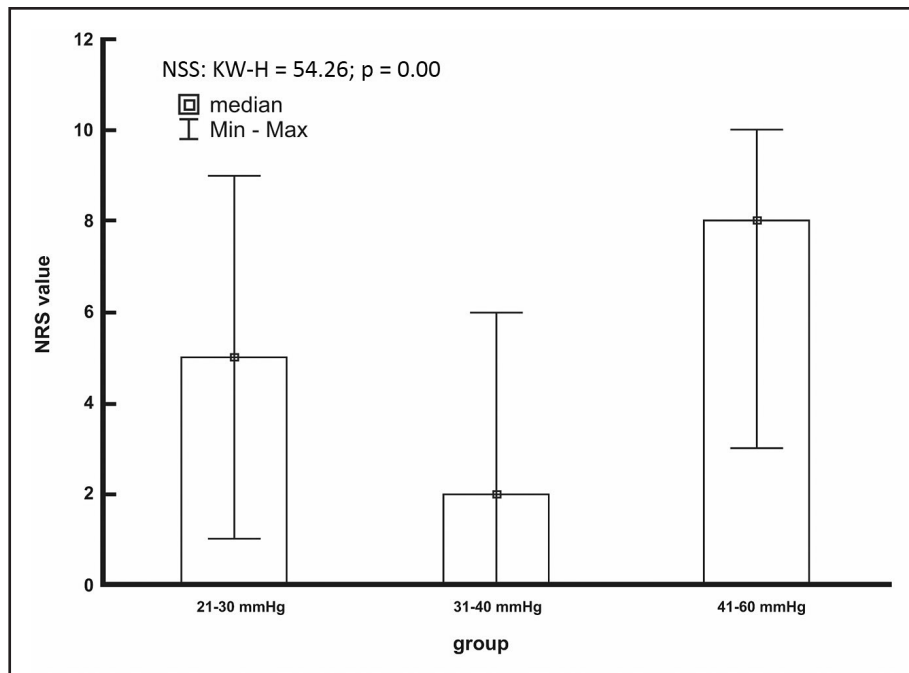
Fig. 3. Statistical characteristic of the pain level estimated using the numeric pain rating scale (NRS) after two weeks of therapy in both control and tested groups

garment was used for the same period of time. The treatment effects were measured on the first day, after 19 days, and after 7, 12, and 24 weeks, respectively. These data showed that in the first group the average reduction of swelling volume was 31%, while in the second group 15.8% (29). In compression therapy, the pressure depends on the extensibility/elasticity of the material, which is ensured by the manufacturer and by the the exerted force of the therapist during therapy. The short stretch bandages are made of cotton without the addition of elastomers (30). It has been shown that this type of bandage extends to less than 70% of its original length, producing during physical activity (muscle contraction) a high working pressure in comparison at rest (31). Many studies confirm that the practitioners applying bandages to patients suffering from leg ulcers rarely perform pressure measurements because they are convinced that they always exert the recommended pressure range (32).

Achieving the desired level of pressure under bandage becomes possible only after multiple repetition of the application because it has been proven that the tension varies significantly depending on the person who applies it (33). An interface pressure under short stretch multi-layer bandages applied on the leg by an experienced bandager should be more than 60 mmHg and 30-40 mmHg on the arm (34). Damstra et al in their study concerning pressure changes under short-stretch bandages applied on legs over time demonstrated a 48% pressure drop as compared to an initial value at 24 hours (35). Moreover, on the upper limb the pressure drop during two hours reached 41-48% increase at 24 hours to 55-63% depending on the applied initial pressure (36). Both material fatigue and edema volume reduction contribute to the pressure drop under applied bandages. It is observed more with inelastic than with elastic bandages and compression garment, which suggests that inelastic

material has to be re-applied more frequently (37). For this reason, in our study inelastic multi-layer bandages were re-applied every 24 hours.

It is necessary to remember that the measurement can be performed only in vivo due to friction between layers of bandages and pressure difference in supine and standing position to determine static stiffness index (SSI). In order to achieve an optimal and effective pressure it is necessary to develop a standard therapeutic protocol to try to control pressure levels under compression bandages or garment (34,35). In compression therapy, the pressure measurement should be obtained using proven equipment. Here, the Kikuhime device was used since it has been confirmed in scientific studies. It was noted that this device used on limbs was characterized by a coefficient of pressure variation equal to 4.17% (36). Keller et al showed that among 63 nurses having from 0 to more than 10 years of experience in leg bandaging, only 9.5% were able to apply it with the proper pressure. Due to the training from Kikuhime device service in the same group of nurses, the situation has considerably improved since 31.7% of them were able to apply bandages under the correct pressure (38). It is necessary to have an extensive experience which allows proper selection of elements such as material type, pressure level, and product type (39). In a case of unilateral limb swelling, the difference between volume of affected and unaffected limb is measured and usually expressed as percentage or in milliliters (ml). There are many different techniques available including water displacement method, inverse water volumetry (IVW), or bioimpedance but most often volume is calculated from circumferential measurements using calculator or computer program. In patients under palliative care, this method is not used to calculate volume but to track circumference changes at fixed points of measurement (40). In our study, we used the same technique but in a simplified version. Instead of measuring arm volume, we calculated the difference between sums of circumferences taken at measuring points of both arms. This method is hygienic, easily accessible, and reproducible but perhaps not directly correlated to volume.

The correlation between treatment effectiveness and pressure in compression therapy exerted on the upper limb was taken up by Damstra and Partsch. The authors evaluated the effect of pressure in compression therapy on the reduction of secondary arm lymphedema in women after breast cancer. In this study, 36 tested patients were divided into two groups (18 patients each group) with the first group using an applied pressure of 20-30 mmHg and the second group at 44-58 mmHg. The pressure was measured by a Kikuhime device at the start, after two hours, and after 24 hours while the reduction of edema volume was determined volumetrically. The results demonstrated lack of statistical significance between these two groups. However, in the group of patients who were treated with lower pressure, a much higher tolerance for bandages was observed (18). In our study, we planned to use the sensors of identical size (large) and position on the forearm as it was in the study of Damstra and Partsch. The authors described the preclinical studies, which showed that spontaneous decline pressure below them is lower in comparison with small sensors. Furthermore, the use of large sensors reduces the influence of the circumstances difference at two points of pressure measurement (18). Based on these results, the authors suggested that 20-30 mmHg is the optimal pressure and the best tolerated by patients. These conclusions allowed us to select this pressure as the control pressure and therefore apply it to the control group. The intermediate pressure 31-40 mmHg used in our study in tested group II A has not been considered by Damstra and Partsch. Furthermore, in our second tested group II B the pressure 41-60 mmHg applied to patients was similar to that used by the authors. They showed that in the case of arm lymphedema, compression does not reduce swelling in a dose-dependent

manner as in the lower extremities due to much lower venous pressure in the arm than in the leg (18). We strove to ensure an appropriate patient comfort during both rest and physical activity and to maintain bandages in the correct position. The smallest decline in the RMCAL values was observed in the control group (21-30 mmHg). This was likely due to bandages falling down when applied at the lower pressure, which can result in accumulation of fluid under the bandages. Furthermore, in the control group we observed skin irritation resulting from the loose bandages, which also resulted in a decrease in patient comfort. Hansdorfer-Korzon and Burakowska suggested attention to skin care in patients after breast cancer therapy who are particularly susceptible to injuries (mostly mechanical) (41). Group II A was characterized by the same efficacy of the therapy as group II B but in group II A applied pressure was not an obstacle to recommended kinesiotherapy. In this group, bandage movement and discomfort were not observed as in the control group. Shah et al showed that CDT leads up to 70% reduction of lymphedema, which was confirmed by our group II A results (68.94%) (13) compared to a reduction of 44.73% in the control group. These data clearly confirm that such a high degree of lymphedema reduction previously reported is possible only under strict control of compression bandages. Between 7 to 14 days in both control and tested groups, a slight decrease in the RMCAL values was observed as compared to a decrease marked between 24 hours and 7 days of treatment. Leduc and Colls confirmed the fact that the most effective therapy was in the first week while in the second week of therapy they observed stabilization of lymphedema (42). Damstra and Partsch did not show that higher bandage pressure of 44-58 mmHg was more effective than lower pressure 20-30 mmHg. We found the same in our study and also that patients complained of pain at pressures greater than 41-60 mmHg patients.

CONCLUSIONS

Inelastic multi-layer bandages applied in groups II A (31-40 mmHg) and II B (41-60 mmHg) led to the same reduction of swollen arm circumference and patients tolerated the lower pressure better suggesting the use of the lower pressure in the future. In addition, it was confirmed that the greatest decrease in swollen arm circumference was obtained in the first week of therapy with the following week only maintaining the effects of compression therapy. Therefore, it should be possible to measure the arm after one week of therapy for determining an appropriate compression garment for long-term use.

CONFLICT OF INTEREST AND DISCLOSURE

All authors declare that no competing financial interests exist.

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