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EFFICACY OF DECONGESTIVE THERAPY AND INTERMITTENT PNEUMATIC COMPRESSION IN PATIENTS WITH LYMPHEDEMA OF THE ARM AFTER BREAST CANCER TREATMENT

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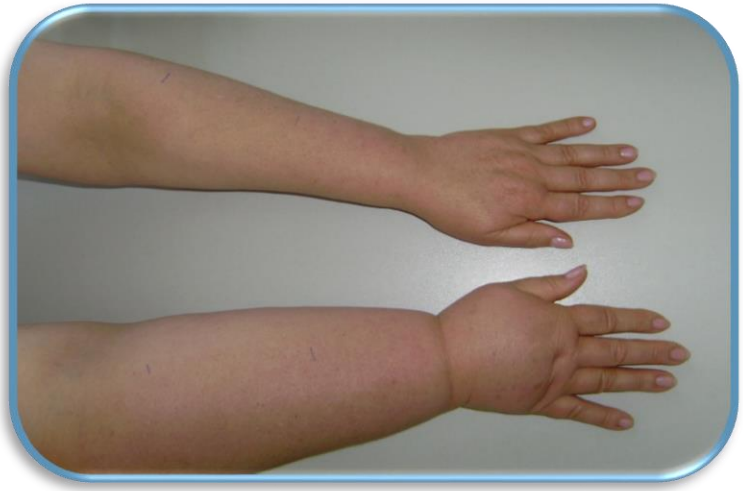
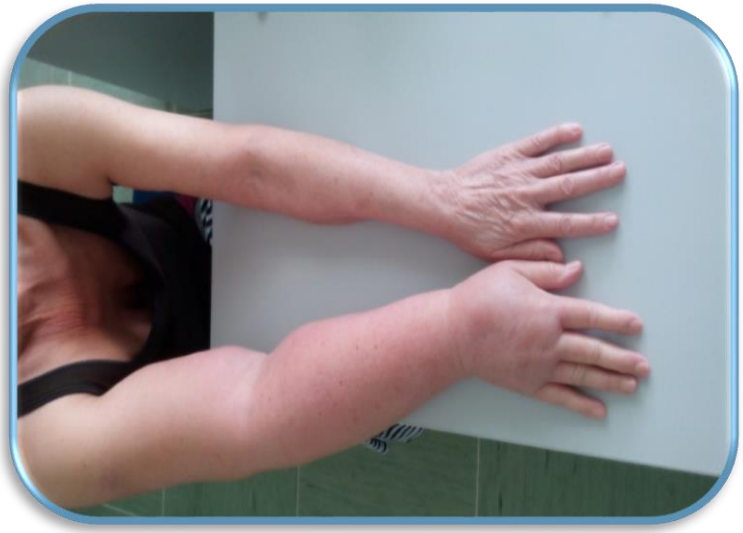
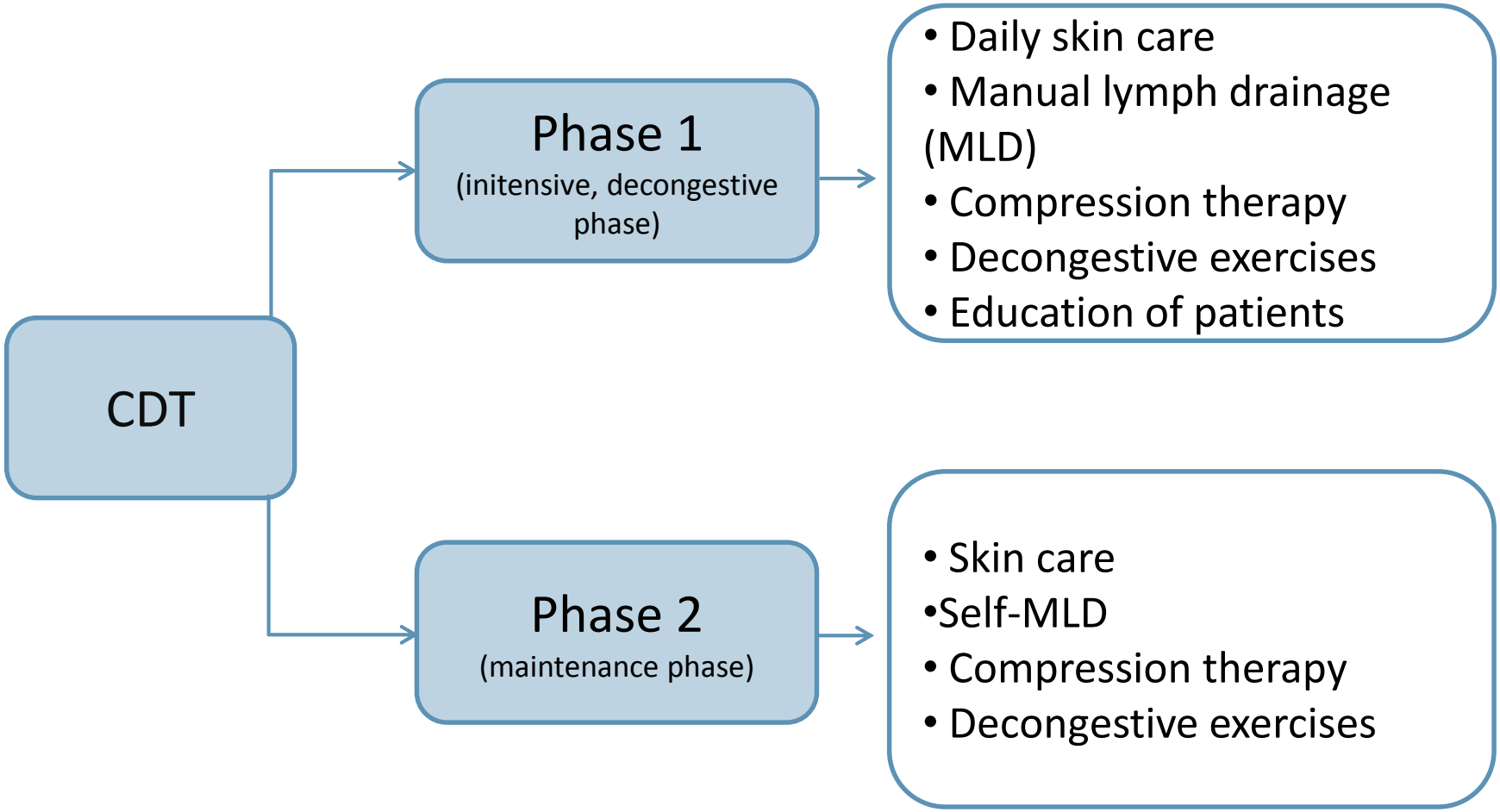
Secondary arm lymphedema (SALE) after breast cancer treatment

- abnormal accumulation of interstitial fluid due to mechanical failure of the lymphatic system of the upper limb, usually because of the breast cancer surgery, radiotherapy, infection or trauma.
- incidence: greater than 20% after ALND and less than 10% after SLNB
- functional and not just an aesthetic problem
- activity limitation
- reducing quality of life (QoL)



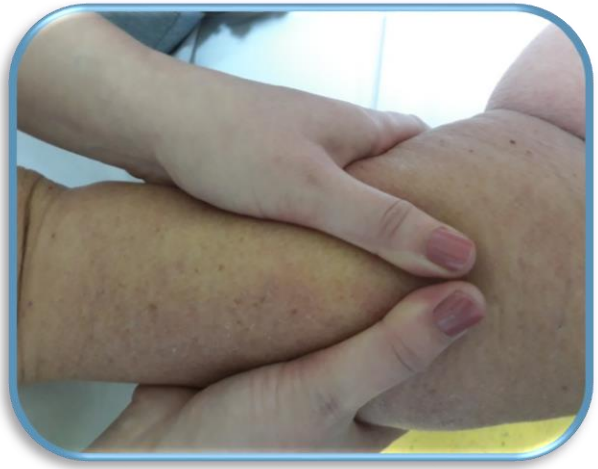


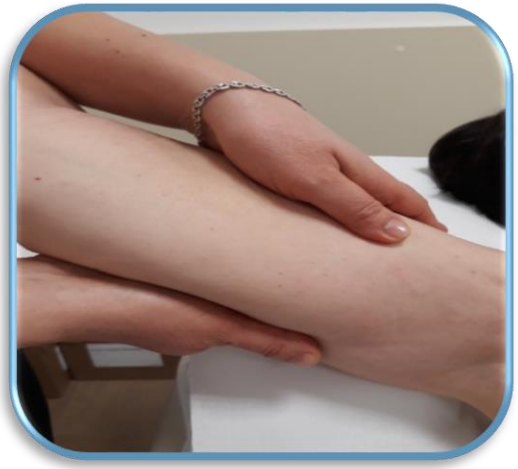
Lymphedema treatment

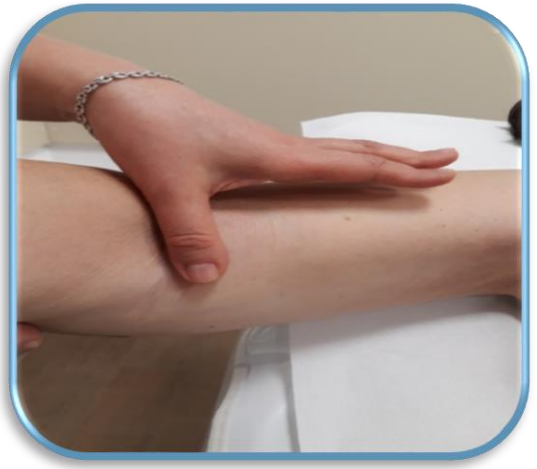


MLD according Vodder technique

- delayed dilatation of the tissue channels
- enhancement of new lymphatic anastomoses formation
- stimulating of lymphangiomotoric activity
- increased resorption of lyquides and proteins
- restitution of the immune system cells







Leal NF at al. Rev Lat Am Enfermagem. 2009.

Compression therapy

COMPRESSION BANDAGES

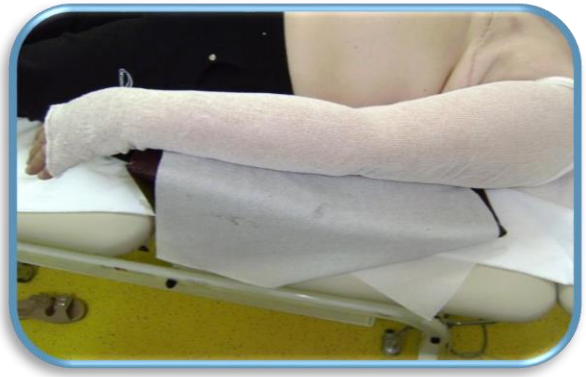
COMPRESSION GARMENTS

- maintains and optimizes the decongestion of the achieved MLD
- prevents the reaccumulation of already evacuated liquid
- supports overstretched inelastic skin
- reduces skin changes and lymphorrhea
- softens subcutaneous tissues

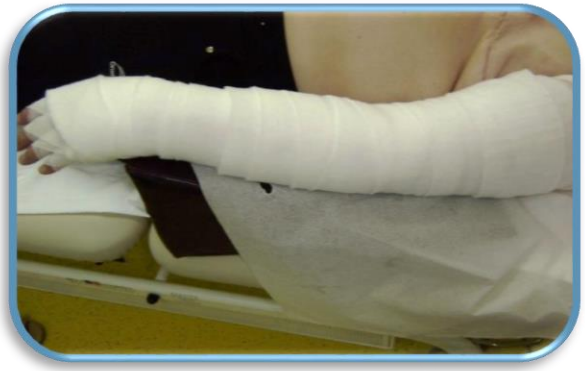
Compression bandages

Sub-bandage pressure

Laplace's Law- P= TxNx4630/CxW

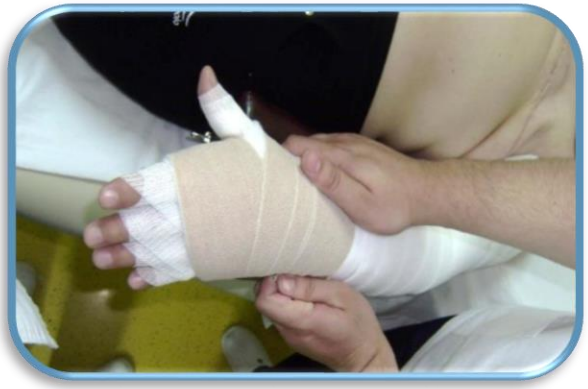


Type of bandage



short stretch multi-layer compression bandages
- low extensibility, high working pressure

Frequency of bandage change



Partsch H at al. Dermatol Surg, 2008.

Exercises with compression applied

1. Exercises of diaphragmatic breathing
2. Remedial exercises
3. Flexibility (stretching) exercises
4. Resistance (weight-lifting) exercises
5. Aerobic exercises

National Lymphedema Network. Available from: http://www.lymphnet.org/pdfDocs/nlnexercise.pdf
Kwan ML at al. J Cancer Surviv, 2011.
Do JH at al. Lymphology, 2015.

Intermittent pneumatic compression (IPC)

- There is no consenssus on standard pressure during application of IPC- in the range of 30-60mmHg (evidence level I-III)
- Application frequency and the duration of IPC are uncomformed (15minutes-1h/2x day, from 2 -3 days to 4 weeks)

Chang CJ at al. Semin Oncol Nurs, 2013.

Feldman JL at al. Lymphology, 2012.

THE AIM OF STUDY

- to compare the efficacy of complex decongestive therapy (CDT) against complex decongestive therapy combined with IPC on size of edema, pain, functional status and quality of life in patients with secondary arm lymphedema after breast cancer treatment.

METHODS

prospective, randomized, parallel, non-blind study

The inclusion criteria for the study :

- unilateral axillary dissection
- clinically verified lymphedema (difference in circumference between affected and unaffected arm greater than 2 cm at minimum 1 measurement level)
- more than 3 months from the breast cancer surgery and radiotherapy
- patient-signed informed consent form

METHODS

The exclusion criteria:

- metastatic breast disease
- clinically verified acute cellulitis or lymphangitis of upper limb
- untreated and poorly-controlled hypertension
- New York Heart Association (NYHA) class II, III and IV heart failure
- deep venous thrombosis and anticoagulant therapy
- shoulder and upper limb damage caused by neurological, orthopedic or rheumatic diseases diagnosed prior to breast cancer surgery
- diagnosed and medically treated psychiatric disorders
- liver cirrhosis
- nephrotic syndrome

Intervention

CDT group (control)

- skin care
- MLD according to Vodder technique
- short stretch multi-layer compression bandages
- decongestive exercises

CDT+IPC group (experimental)

- skin care
- MLD according Vodder technique
- **IPC – for 30 min/day, at a pressure of 40 mmHg**
- short stretch multi-layer compression bandage
- decongestive exercises

once a day, 5 days a week, for 3 weeks

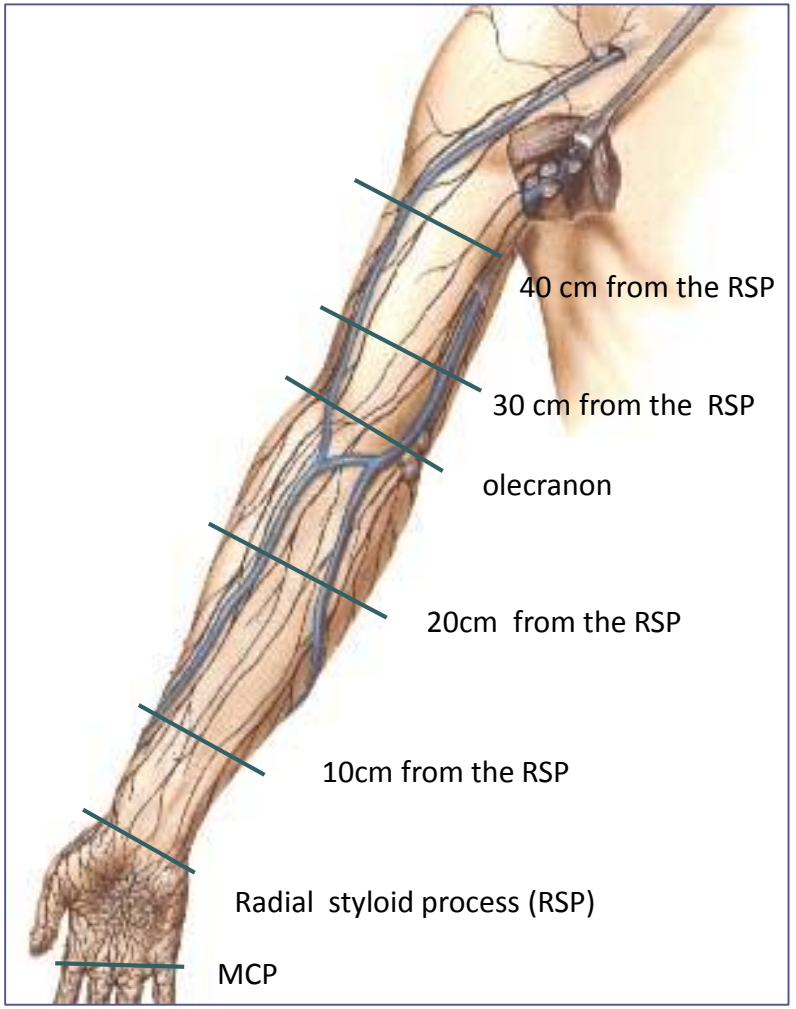
The subjects were instructed to continue administering the skin care, compression sleeve and exercises on their own for 3 months after the end of treatment (T2)

Outcome measures

- SALE - arm circumference measured at 7 symmetrical levels

Lymphedema size :

$$\frac{\text{total circumference of the affected arm} - \text{total circumference of the unaffected arm}}{\text{total circumference of the unaffected arm}} \times 100$$

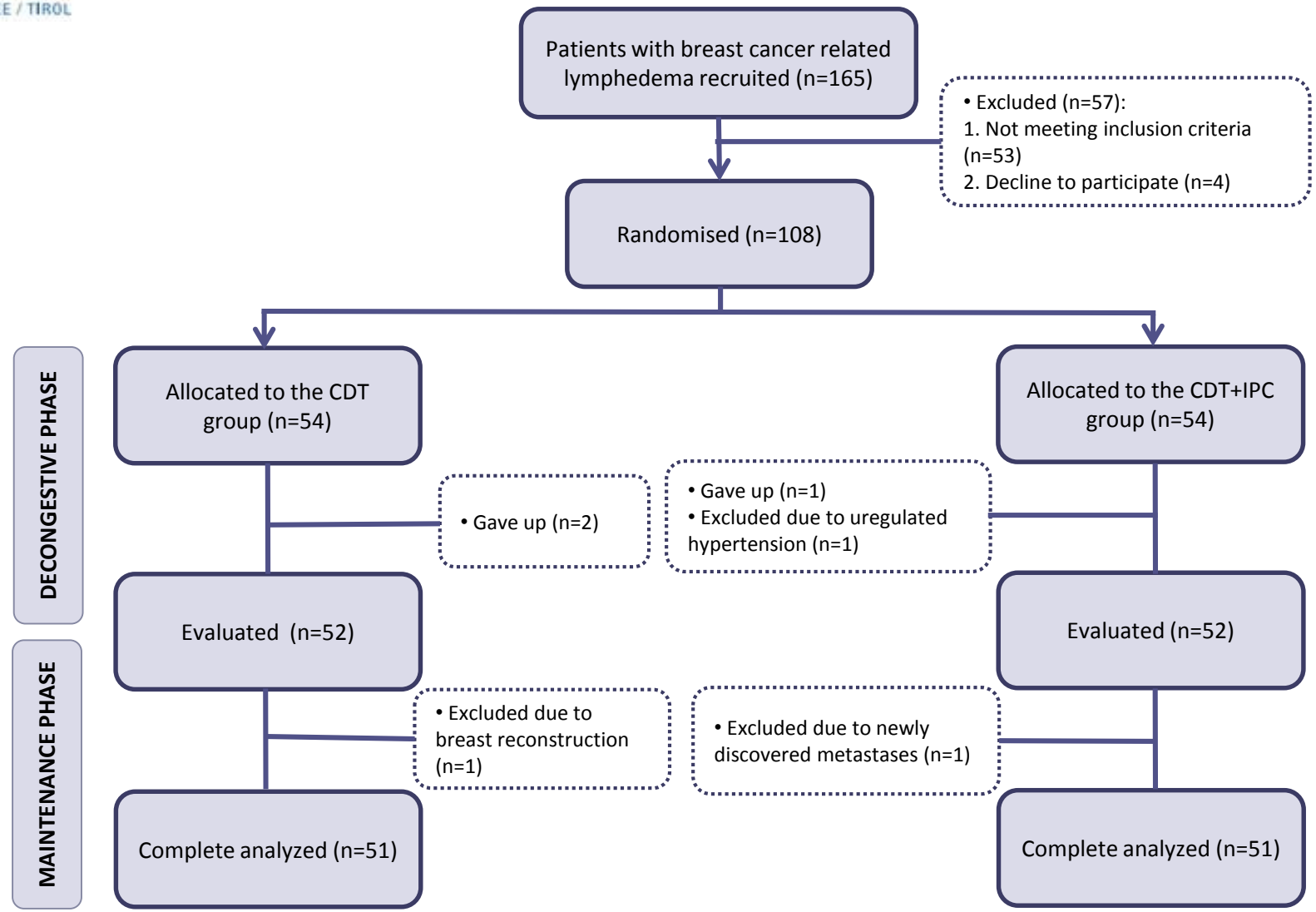


- Visual Analog Scale (VAS) for pain
- shoulder range of motion (ROM)
- Disability of the Arm, Shoulder and Hand questionnaire (DASH)
- Functional Analysis of Cancer Treatment-Breast 4+ (FACT B4+)

Statistical analyses

- descriptive methods
- analysis of variance for repeated measures (rANOVA)
- analysis of covariance (ANCOVA)
- Mann-Whitney U- test
- chi-square test
- Fisher's exact test
- p-value <0.05

RESULTS



Flow chart of the study

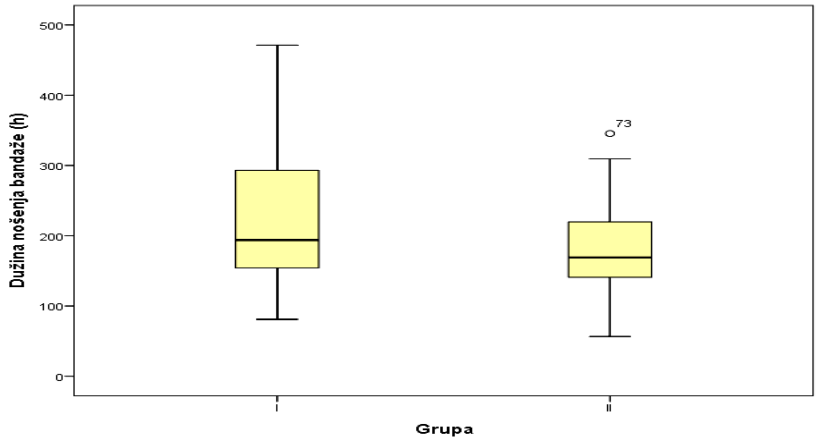
clinical characteristics of the patients before treatment	CDT group		CDT+IPC group		t-test
	X̄ (SD)	min-max	X̄ (SD)	min-max	p
Age (Yrs)	58.1±8.0	41-77	55.4±8.8	37-73	**0.112**
Body Mass Index (BMI)	28.4±4.3	17.9-37.9	28.8±4.9	20.8-43.6	**0.636**
Number of lymph nodes removed	14.2±6.6	3-42	14.2±5.9	5-35	**0,975**
Number of lymph nodes involved	2.8±6.1	0-32	3.0±5.6	0-34	**0.853**
Duration of lymphedema (months)	36.5±43.9	0.5-170	43.3±38.2	3-185	**0.406**
Time from surgery (months)	53.4±50.0	3-185	61.3±42.1	10-192	**0.389**
Time until lymphedema onset (months)	17.0±22.9	0-124	19.6±28.2	0-147	**0.607**
Size of lymphedema (%)	6.99±5.36	1.99-25.0	6.53±3.83	2.13-16.3	**0.616**

Clinical characteristics of the patients

clinical characteristics of the patients before treatment	CDT group	CDT+IPC group	p ($\chi 2$)
TYPE OF BREAST SURGERY	N (%)	N (%)	**0.539**
Radical mastectomy Breast conserving surgery	30 (58.8) 21 (41.2)	34 (66.7) 17 (33.3)	
AFFECTED ARM			**0.154**
Dominant Non-dominant	28 (54.9) 23 (45.11)	35 (68.6) 16 (31.4)	
REPORTING PAIN AND OTHER SYMPTOMS IN THE ARM			**0.318**
Yes No	44 (86.3) 7 (13.7)	48 (84.1) 3 (5.9)	

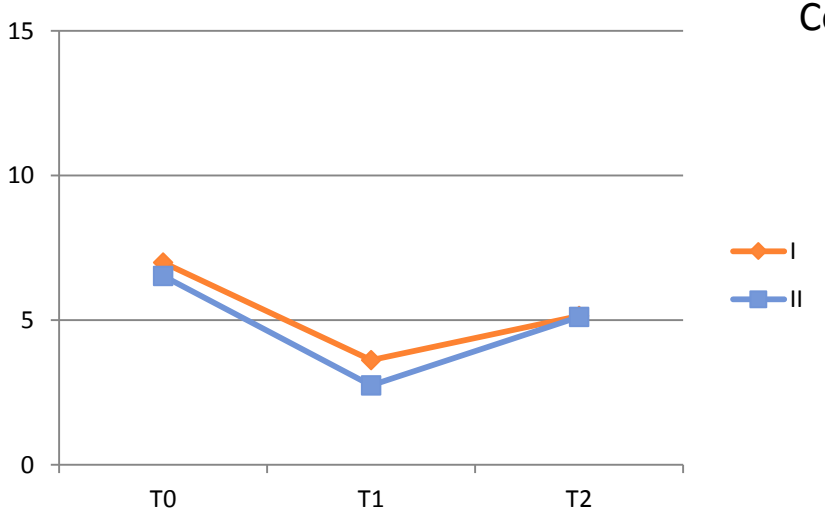
Clinical characteristics of the patients

Patients characteristics	CDT group		CDT+ IPC group		t-test
	X̄(SD)	min-max	X̄(SD)	min-max	P
VAS	4.07±3.19	0-10.0	3.57±2.46	0-9	**0.377**
DASH	38.2±18.9	7.5-85.0	31.4±16.4	10.2-92.5	**0.056**
Duration of wearing of the bandages (hours)	217,5±97,8	81-471	181,7±57,8	57-346	**0,026**



Distribution of patients in relation to the duration of wearing of the bandages

Comparative efficacy of two therapeutic protocols (CDT nad CDT+IPC) on lymphedema size



Changes in the lymphedema size during the observed period

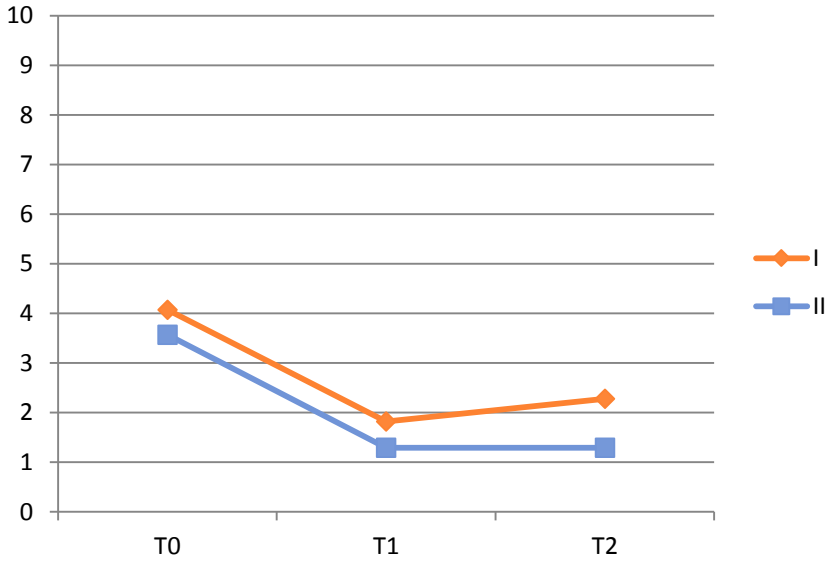
Comparison of lymphedema size in repeated measures

Lymphedema size	F*	p	Partial Eta Squared
before the treatment (T0)- 3 weeks after the treatment (T1)	479,07	0,00	0,83
3 weeks after the treatment (T1)-3 months after the treatment (T2)	70,83	0,00	0,42

Time: F=158,73; df=1,79; **p=0,00**

Time x Group interaction: F=2,20; df=1,79; **p=0,12**

Comparative efficacy of two therapeutic protocols on the level of pain



Changes in VAS during the observed period

Comparison of VAS in repeated measures

VAS	F*	p	Partial Eta Squared
before the treatment (T0)- 3 weeks after the treatment (T1)	125,71	0,00	0,56
3 weeks after the treatment (T1)-3 months after the treatment (T2)	2,20	0,14	0,02

Time : F=73,67; df= 2,0; **p=0,00**

Time x Group interaction : F=0,58; df=2,0; **p=0,56**

Comparative efficacy of two therapeutic protocols on shoulder range of motion

Baseline, post-treatment and after 3-month follow up ROM in the both groups and repeated measures ANOVA for ROM

Sholuder ROM	T0		T1		T2		*p value	
	CDT	CDT+IPC	CDT	CDT+IPC	CDT	CDT+IPC	T0-T1	T1-T2
Flexion	143±24	153±24	156±19	164±17	158±21	168±15	**<0.001**	**<0.001**
Abduction	134±37	143±36	146±30	162±25	152±32	171±20	**<0.001**	**<0.001**
Internal rotation	62±28	68±23	73±22	80±16	80±20	85±12	**<0.001**	**<0.001**
External rotation	74±23	83±16	86±10	88±6.5	86±13	89±3	**<0.001**	**0.37**
Extension	48±6	48±5	49±3	50±2	49±4	50±0	**<0.001**	**1.00**

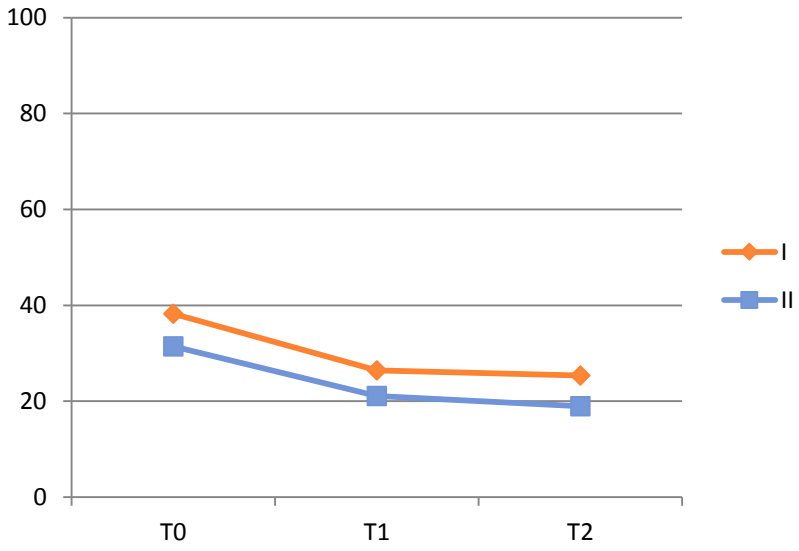
*Repeated-measures ANOVA

Comparative efficacy of two therapeutic protocols on shoulder range of motion

Sholuder ROM	Time × Group interaction		
	F	df	p
Flexion	0.37	1.67	**0.65**
Abduction	2.99	1.56	**0.07**
Internal rotation	0.11	1.63	**0.85**
External rotation	2.01	1.33	**0.15**
Extension	0.41	1.78	**0.64**

Comparative efficacy of two therapeutic protocols on DASH

Comparison of DASH score in repeated measures



DASH	F*	p	Partial Eta Squared
before the treatment (T0)- 3 weeks after the treatment (T1	162,09	0,00	0,62
3 weeks after the treatment (T1)-3 months after the treatment (T2)	4,36	0,00	0,04

Changes in DASH score during the observed period

Time : F= 113,15; df= 1,73; **p=0,00**

Time x group interaction: F=0,36; df=1,73; **p=0,67**

Repeated measures ANOVA for subscales of FACTB4+

subscales of FACTB4+	T0		T1		T2		*p value	
	CDT	CDT+IPC	CDT	CDT+IPC	CDT	CDT+IPC	T0-T1	T1-T2
PWB	18.9±5.1	20.5±4.9	21.1±4.1	23.0±3.6	20.9±5.0	23.9±3.5	**<0.001**	**0.25**
SWB	22.1±5.1	22.9±4.8	23.2±4.7	23.8±4.7	23.6±4.0	23.9±4.2	**<0.001**	**0.25**
EWB	17.3±4.7	19.0±4.5	18.7±4.1	20.3±4.0	18.2±4.3	20.6±3.0	**<0.001**	**0.62**
FWB	18.2±4.6	20.0±4.4	19.5±4.7	21.4±3.8	19.6±4.5	21.5±4.0	**<0.001**	**0.61**
BCS	18.3±5.5	20.3±5.8	20.8±5.2	22.4±5.5	21.1±5.6	22.9±4.9	**<0.001**	**0.44**
ARM	12.2±4.8	12.7±3.8	14.4±4.1	15.2±2.9	14.5±4.6	15.6±2.9	**<0.001**	**0.37**

Repeated measures ANOVA for total scores of FACTB4+

total scores of FACTB4+	T0		T1		T2		*p value	
	CDT	CDT+IPC	CDT	CDT+IPC	CDT	CDT+IPC	T0-T1	T1-T2
FACTB-TOI	55.3±13.1	60.4±12.7	61.5±11.8	66.8±11.0	61.5±13.7	68.2±10.2	**<0.001**	**0.33**
FACT G	76.4±15.2	82.3±15.6	82.5±13.9	88.6±13.1	82.4±14.5	89.8±11.4	**<0.001**	**0.45**
FACT B	94.7±19.0	102.6±19.5	103.5±17.4	110.9±17.0	103.3±19.1	112.7±15.6	**<0.001**	**0.42**
FACT B4	106.9±22.2	115.3±21.9	118.0±20.1	126.1±18.4	117.8±22.2	128.4±16.8	**<0.001**	**0.42**

Comparative efficacy of two therapeutic protocols on quality of life

FACTB4+	Time × Group interaction		
	F	df	p
PWB	2.71	1.67	**0.08**
SWB	0.43	1.50	**0.60**
EWB	1.45	1.73	**0.24**
FWB	0.01	1.57	**0.99**
BCS	0.11	1.57	**0.85**
ARM	0.45	1.43	**0.57**
FACTB-TOI	0.73	1.61	**0.46**
FACT G	0.58	1.39	**0.50**
FACT B	0.64	1.49	**0.48**
FACT B4+	0.68	1.46	**0.47**

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Strenght of the study

- institution specialized in the treatment of lymphedema
- patients with breast cancer related lymphedema
- cleary defined inclusion and exclusion criteria
- relatively large patient sample
- prospective and randomized study
- clearly defined and consistent therapy protocol in both study groups
- MLD was performed by two trained physiotherapists and under the supervision of the researcher
- the measurements were carried out by physiotherapists and the researcher, taking care to ensure that same person perform all three measurements in one subject
- significant time spent by therapists with each subject during the study

Limitations of the study

- estimation of patient adherence with the various components of CDT during the maintenance phase were based on the patient's reporting and were not clearly defined
- the role of IPC during the maintenance phase of treatment could not be adequately assessed
- relativly short the follow-up time

CONCLUSIONS

- IPC as a supplement to standard CDT does not contribute to a greater reduction of breast cancer related arm lymphedema compared to CDT alone

CONCLUSIONS

- CDT combined with IPC is no more efficient than CDT alone on the level of pain, functional status and quality of life in patients with secondary arm lymphedema after breast cancer treatment.

CONCLUSIONS

- Estimation of IPC efficacy is hampered by the lack of unique protocols regarding the duration and frequency of individual sessions and the size of the pressure, as well as the existence of various types of compressive pumps, which differ in the length of the compression cycle, the number of chambers and the design of the sleeves.

Greetings from Banja Luka!