



Effectiveness of manual lymphatic drainage and intermittent pneumatic compression in lymphedema maintenance therapy

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Summary: *Background:* To compare the effectiveness of intermittent pneumatic compression (IPC) and/or manual lymphatic drainage (MLD) associated to compression stockings in the maintenance treatment of lymphedema. *Patients and methods:* Patients in the maintenance phase of lymphedema therapy with MLD and compression since more than a year with stable values for weight and circumferences of ankle and calf were asked to participate in a study: Compression had to be worn daily, (1) 4 weeks IPC+MLD, (2) 4 weeks MLD alone, (3) 4 Weeks IPC alone (Order 1 and 3 was randomized). At the beginning and after each 4 weeks, circumference measurements (by hand and by machine: BT600[®], Bauerfeind) were documented, pain and discomfort were assessed, and quality-of-life questionnaires were completed. *Results:* Of 20 participants, 18 (14 female, 4 male), mean age 59.6 years (48–89) could be evaluated. 11 subjects had bilateral, 7 unilateral, 5 primary, 13 secondary lymphedema since 2–20 years (mean 7.7), the subjects had received MLD and compression for 2–14 years (mean 6.4), 1–3 times per week (mean 1.5). The BMI ranged between 21 and 47 (mean 33.7). No differences between any phases were found for: Calf and thigh volume, circumference of calf. Only the ankle circumference was significant less (–0.22 cm) when using “both” (IPC+MLD). Compared to before the study, quality of life was better in all three phases, but with a significantly higher improvement in the phases with IPC than in the phases without. *Conclusions:* There were no differences in objective measurement between MLD alone, IPC alone or both, excepting the minimal significant difference in ankle circumference after IPC+MLD. QOL favored IPC application. Considering the economic consequences of these results, a change of maintenance therapy with MLD weekly over years in favor of permanent care with IPC and few appointments of MLD per year should be considered and further investigated.

Keywords: Lymphedema, manual lymphatic drainage, intermittent pneumatic compression, lymphedema social costs, lymphedema maintenance therapy

Introduction

Lymphedema is a condition caused by a delay in lymphatic drainage: it can be congenital, induced by damage to the lymphatic channels (surgery, trauma, radiation) or occur due to compression of the lymphatic channels (tumors compressing them or obesity-related lymphedema). Typically, the toes and the dorsum of the foot show early changes with so-called “box toes” and transverse folds at the base of the toes. The edema has a rather doughy consistency. It is divided into three stages (stage I, reversible overnight; stage II, protein deposits, not reversible overnight; stage III, fibrosis and skin discoloration up to ulceration) [1]. The therapy of lymphedema in stage II and III consists in a first phase of complex physical decongestive therapy (CPD), combining compression (first bandaging, then stockings), added by manual lymphatic drainage

(MLD) and/or intermittent pneumatic compression (IPC) depending on the findings and patient education with exercise, skin care and nutrition [1, 2].

This phase of initial decongestion is followed by the so-called “maintenance therapy” as long as the lymphedema is present. In this phase, compression alone or a combination with MLD, IPC or both are possible, according to the German guideline [1]. The current treatment reality shows, that compression and MLD are mainly used, IPC seldom and specially in addition when MLD and compression stockings cannot keep the decongestion level in the maintenance therapy.

IPC is preferably performed with a device composed by a compressor unit and two boots with 12 overlapping chambers, inflating and deflating regularly from toes to thigh and back. The patient can perform self-management at home, using the device as often as he wishes. IPC products

in treatment are medical devices; should have certification (medical class 2a, DIN EN 60601-1-11) ensuring safe usage in home care setting. IPC is not only used to reduce edema [3], but also to improve blood circulation in patients with arterial circulatory disorders [4, 5] as well as to reduce edema and prevent thrombosis after orthopedic and accident surgery [6]. For lymphological indications, devices with leg cuffs are used, alternatively also panty garments which include the hips and abdomen.

Lymphoedema has increased significantly in our society due to the diagnosis “obesity-related lymphoedema”. The demand for physiotherapy is therefore rising sharply. In Germany, the treatment of stage II and III lymphoedema with MLD is reimbursed by the public health care system, which benefits many patients. On the other hand, physical therapy practices are short staffed, making it increasingly difficult for patients to get appointments.

There are few studies on the maintenance phase, little information on the necessary frequency of MLD or on alternatives – similarly, for IPC there are few studies on the sense of single- or multi-stage compression systems, and if so, only over shorter periods of time [2, 9].

Regarding the different possibilities of measures in the maintenance phase, the German guideline Lymphoedema [1] specifies the compulsory wearing of compression, supplemented by education on lifestyle, nutritional counselling, main skin care as well as exercise therapy and, depending on the clinical situation, the addition of MLD and/or IPC. A study on the effectiveness of both methods in the maintenance phase, in comparison or in addition, is not yet available.

Therefore, the aim of the present project is to study patients who are managed in our practice in the “classical” maintenance phase for lymphoedema (round or flat stockings, MLD on a regular basis) and who have had relatively constant leg circumference (and BMI) over the last 12 months. These subjects will maintain compression therapy and be treated with IPC+MLD and IPC alone for 4 weeks each, to compare the circumference and volume measurements as primary endpoint and the quality of life, as well as acceptance as the secondary endpoint.

Patients and methods

This is a researcher-initiated, prospective, randomized, cross-over designed study. The patient database of the vein practice was examined for the following keywords: MLD, lymphoedema, at least 3 examinations in the last 12 months with Bodytronic 600® and measured by hand. These patient files were then checked for inclusion criteria: Stage II or III lymphoedema in the maintenance phase, less than 10% variation at measure points of volume, circumferences or BMI within 12 months, age between 18 and 85, ASA 0-1 (not severe illnesses), body weight <150 kg (restriction on volume-measuring). An information letter and consent form were sent to the potential candidates by post or explained and handed over during the check-up in the practice.

After an initial interview, the following patients were excluded: Not willing to participate or performing another study, not having space at home for the device, not available in the next 3 months (vacations, planned surgery), not able to attend to controls every 4 weeks in the afternoon (2:00–6:00 pm) or not able to complete the questionnaires.

At the first appointment, subjects had to wear their compression stockings (as for every control). General information was recorded (age, weight, height, previous illnesses, side, stage and cause of the lymphoedema, type of previous therapy with compression, frequency and duration of MLD, medication), and subjects completed the Lymph-ICF questionnaire [8], which consists of 28 questions on 5 domains of life, each of which can be rated on a scale of 0–10.

Afterwards they were randomized into one of the two groups (IPC alone first or IPC+MLD first) and the compression stockings were removed. The subjects assumed a standing position and pronounced their current complaints (pain, tension or feeling of congestion) using a numerical rating scale (NRS) from 0 to 10, separately for their right and left leg. The examiner recorded whether the edema was hard or soft (pitting). The subjects’ legs were measured manually at the ankle, below the knee and below the crotch with the tape measure by the same trained practice staff and subsequently with the Bodytronic 600® from Bauerfeind. This device is a digital measuring system that records the volume of the feet, calves, knees, thighs and lower torso of standing test persons.

The study consisted of three blocks of four weeks of treatment each, with compression always worn as basic treatment: The second block was always MLD alone (as before the study), and the order of IPC alone or IPC+MLD for the first or third block was randomized (Figure 1).

MLD was performed as usual, by the patient’s therapist of choice, and the same compression stockings were worn. To ensure the correct use of the IPC, Mr. Frank Müller from

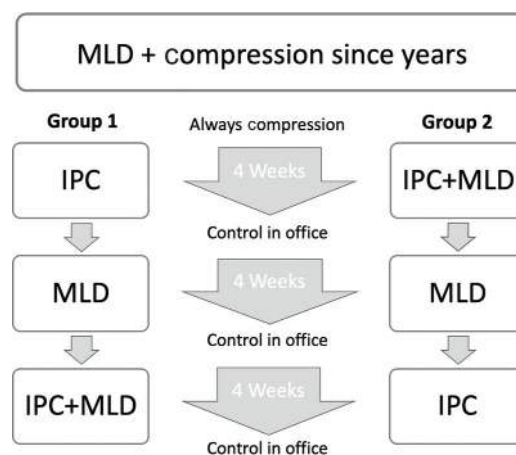


Figure 1. Study diagram: Patients on MLD (manual lymphatic drainage) and compression hosiery since years and in control in the office were randomized in two groups with controls after each 4 weeks. IPC=intermittent pneumatic compression. All patients were on compression hosiery daily throughout the study.

Bösl-Medizintechnik was always present at the first appointment and instructed the patient in the use of the Lymphamat 300, a compression pant from toes to waist, with 12 chambers per leg (total 24 chambers). The devices were collected after the end of the 1st phase so that no IPC could be applied during the “MLD only” phase. The Bösl company was always available to the patients by phone and in person for any questions.

Patients were given home documents with a questionnaire to check off MLD appointments in the next 4 weeks and a sheet to record the frequency of IPC and intensity of cessation. The same examinations and questionnaires were repeated at each control appointment. At last, the subjects were additionally invited to give an assessment of the effectiveness and practicability of the three options in the form of an additional questionnaire.

The study was advised by the Ethics Committee of the Hanover Medical Association and deemed harmless (BO/23/2020); it complies with the requirements of the Helsinki Convention.

Statistics

The number of subjects needed could not be determined at the beginning, as no empirical values were available. Based on the evaluating of decongestion in one afternoon [9], 20 participants seemed to be sufficient for a result in the research question. A maximum of 100 participants should be included, but an interim evaluation should be performed after every 20 participants and, if necessary, the study should be terminated if the significance is sufficient.

The variables collected were partly related to the person (e.g. quality of life) and partly to the individual leg (circumference, volume, discomfort) – for the latter, the mean values were calculated if both legs were affected, otherwise only the value for the affected leg was used. For the Lymph-ICF questionnaire, the mean value of the answered individual items was calculated for the 5 dimensions and the total value (0–10 in each case).

The results are presented by mean, and standard deviation as well as median, minimum and maximum. In order to compare the different treatments, t-tests for paired samples were calculated. In addition to the significance calculation, Cohen's *d* was calculated as a measure of the effect size of the differences. According to Cohen, *d*=0.2 mean “small”, 0.5 “medium” and ≥ 0.8 large effect sizes. [10].

Results

The first evaluation after 20 subjects showed no differences between the different treatment options related to the primary endpoint (circumferences and volume), so further recruitment was stopped. There were 10 subjects randomized to the “IPC first” group and 10 randomized

to the “IPC+MLD first” group, 15 women and 5 men. From the second group, 2 subjects dropped out of the study prematurely and were excluded: One subject with osteoarthritis had severe knee pain and did not tolerate the pressure of IPC; One subject felt uncomfortable under IPC and did not want to continue using it. Therefore, the evaluation was carried out with 18 subjects, 14 female, 4 men, mean age 59.6 years (48–79), mean BMI at start 33.7 (20.9–47.2), 5 primary and 13 secondary lymphedemas (further information in electronic supplementary material [ESM] 1).

The IPC-sessions lasted 45–60 minutes and their frequency varied during the 4 weeks of treatment between 12 and 42 applications (mean 21.8 ± 8.3) in the phase “IPK alone” and between 11 and 39 applications (mean 20.8 ± 8.2) in the phase “IPK+MLD”. The mean pressure varied from 31 mmHg to 104 mmHg (mean 63.5 ± 5.2). The frequency of MLD during the phases “MLD alone” and “MLD+IPC” hardly changed compared to “before the study”:

Objective results

Circumferences and leg volumes

All measurements were taken between 2 and 6 p.m., the variances between the measurement times for the individual persons were very small.

Figures 2A–2D show the manually measured circumferences of ankle and calf and the machine-measured volumes of calf and thigh at each measurement point for each participant, Figure 3A–3D the changes of mean values as box-blots. Table I shows the mean values at every measurement point and their differences in relation to each other. There were significant differences only for the ankle circumference: it decreases significantly in the phase “IPC+MLD” (-0.22 cm) compared to the baseline value (Cohen's *d* 0.08) and is also significantly smaller compared to “IPC alone” (Cohen's *d* 0.07). Calf circumference tends to decrease in all treatment variants, but these changes are not statistically significant (Cohen's *d* 0.01–0.08). There are no significant differences in calf and thigh volume (Cohen's *d* 0.00–0.04).

4 patients with secondary lymphedema after oncologic surgery finished the survey, equally distributed (2 in each group), aged between 55 and 79, 1 male, 3 females. Their results do not differ from the general group and all 4 patients prefer the combination of MLD and IPC as best treatment.

Changes in complaints and quality of life

The mean value of the complaints according to the numerical analogue scale on the day of admission was 2.5 ± 2.8 . Figures 2E and 2F show the development of complaints and QoL on the day of examination.

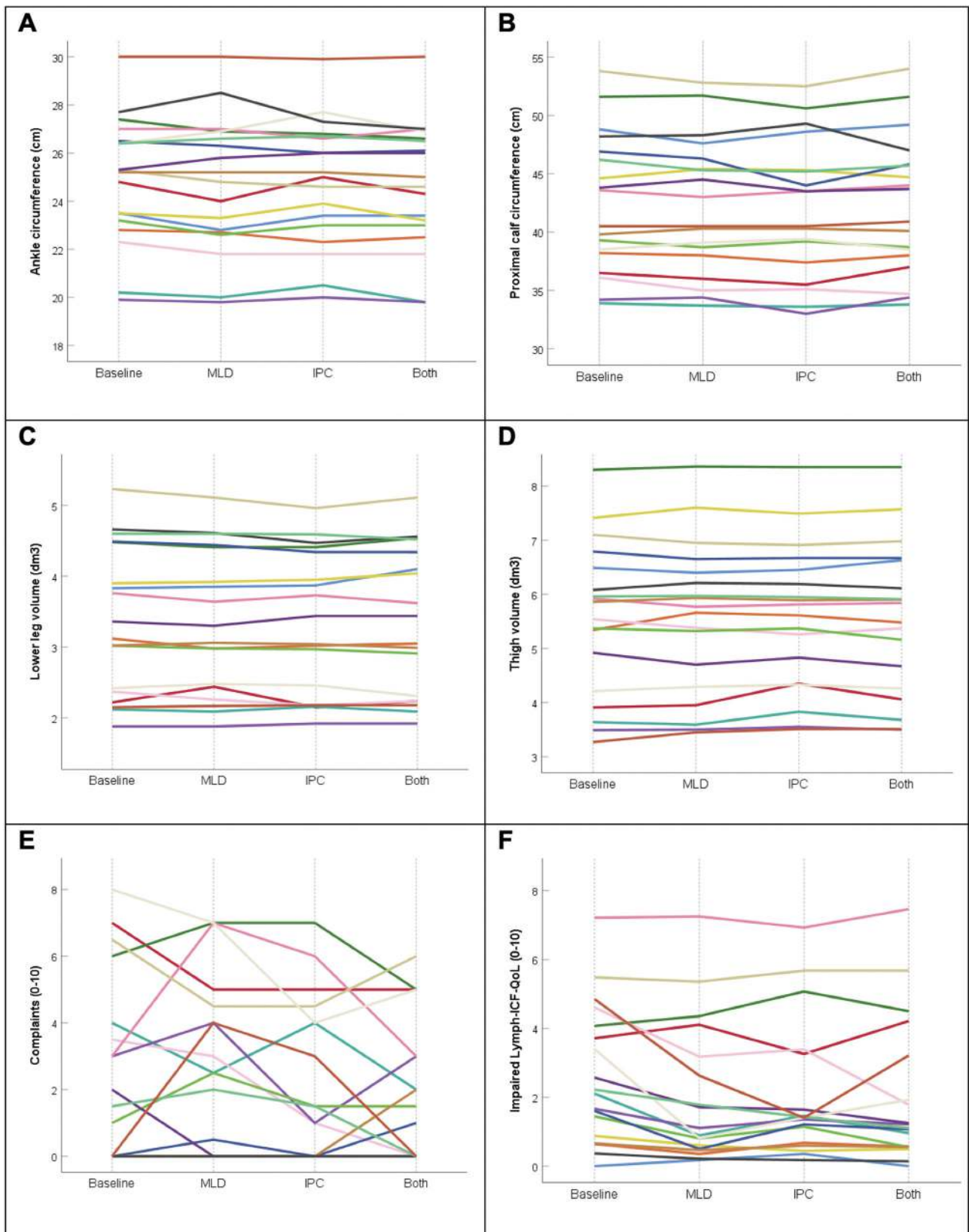


Figure 2. Development of the manual circumference measurement in cm at the ankle (A) and the proximal calf (B) in a standing position as well as the volume measurements of the lower leg (C) and the thigh (D) performed with BT 600® (measurements in standing position) and of complaints (scale 0–10, E) and impaired QoL (scale 0–10, F) per test person over the course of the study. Each line represents one subject: on the Y axis the starting value (after years of MLD and daily compression hosiery), the first vertical dashed line represents the measurement result after IPC alone plus daily compression hosiery, the second dashed line represents the measurement result after MLD alone with daily compression hosiery and the third dashed line represents the result after MLD plus IPC and daily compression hosiery. MLD: Manual lymphatic drainage, IPC: Intermittent pneumatic compression, Both: MLD and IPC application in the same week.

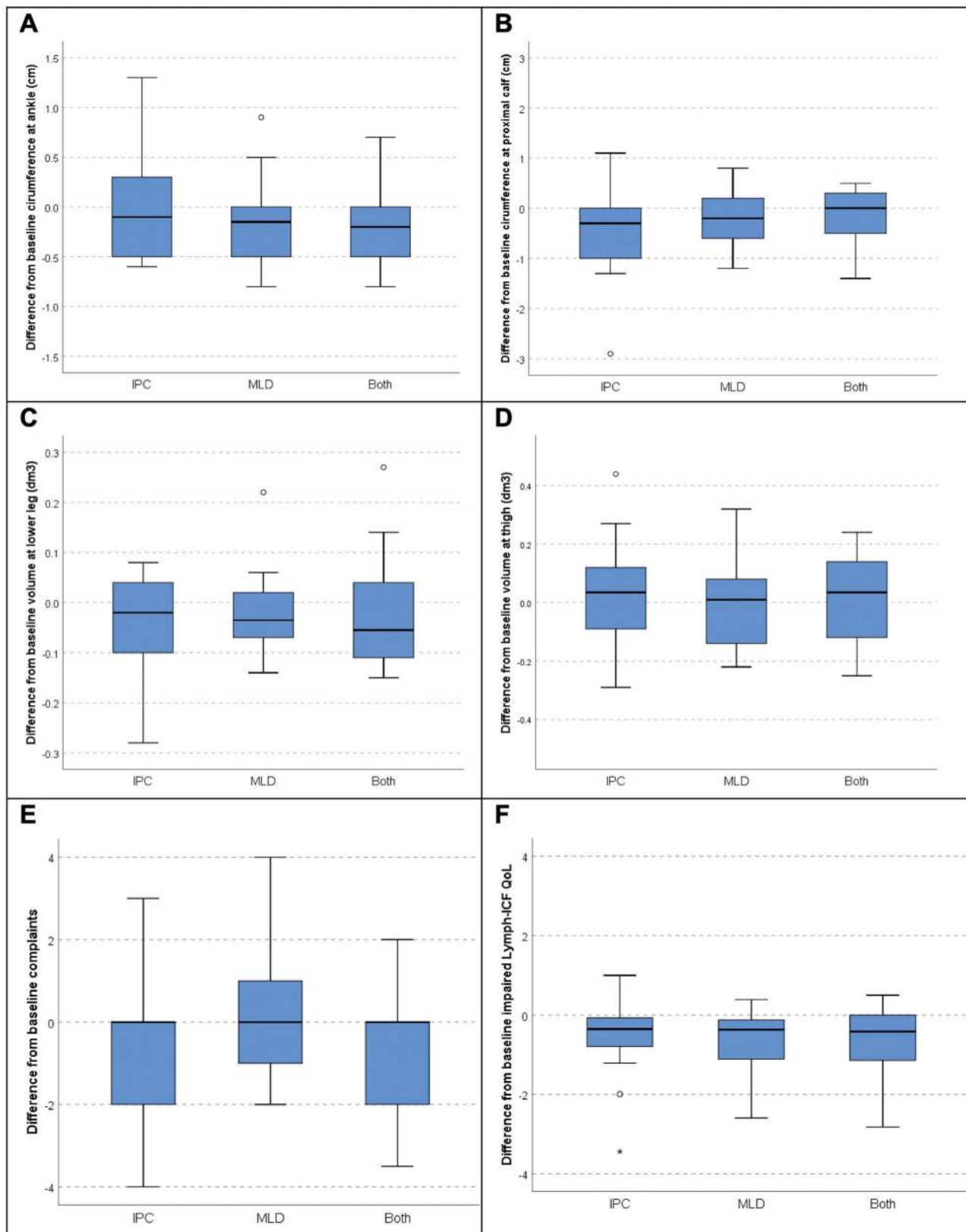


Figure 3. Boxplot of differences compared to baseline of manual circumference measurement for ankle (A) and calf (B), of volume measurements with BT 600® for lower leg (C) and thigh (D), and of complaints (scale 0–10, E) and impaired QoL (scale 0–10, F). Legend: MLD: Manual lymphatic drainage, IPC: Intermittent pneumatic compression, Both: MLD and IPC application in the same week.

Table II shows the results of the Lymph-ICF-QoL questionnaire before treatment sorted by the mean value of the result. Interestingly, respondents also reported 10 points for multiple items, even though they had already

been treated with compression and MLD at this moment. Symptoms were most severe when kneeling (5.3 mean) and standing (4.6 mean). The feeling of heaviness received 4.4 points (mean).

Table II. Restriction of QoL (Items of Lymph-ICF-QoL questionnaire) at baseline, sorted by the strength of the restriction

Problem	Function	Mean	Std. dev.	Median	Minimum	Maximum
Kneeling	Mobility	5.3	3.4	5.5	0	10
Prolonged standing	Mobility	4.6	2.9	5.0	0	10
Feelings of heaviness	Physical	4.4	3.4	5.0	0	9
Sadness	Mental	3.7	3.7	2.5	0	10
Wear clothing or shoes of choice	Social	3.7	3.2	3.5	0	10
Feeling unattractive	Mental	3.7	3.8	2.5	0	10
Feeling frustrated	Mental	3.6	3.2	2.0	0	10
Stiffness in legs	Physical	3.3	3.2	3.0	0	9
Tension of the skin	Physical	3.2	2.6	2.5	0	8
Lack of self-confidence	Mental	3.2	3.6	2.0	0	10
Prolonged sitting	Mobility	3.1	2.5	3.0	0	7
Take stairs	Mobility	2.9	3.1	3.0	0	10
Walk more than 2 km	Mobility	2.7	3.5	1.5	0	10
Pain in the legs	Physical	2.7	2.8	1.0	0	8
Practice sports	Social	2.6	2.5	2.0	0	8
Tingling in the legs	Physical	2.3	2.8	1.0	0	8
Do social activities	Social	2.2	2.9	0.5	0	8
Feeling uncertain about the future	Mental	1.9	2.7	1.0	0	8
Disappointment in health care	Mental	1.9	2.5	1.0	0	8
Drive a car	Mobility	1.9	2.5	0.0	0	8
Do a job	Social	1.8	2.1	1.0	0	7
Household chores	General tasks/household	1.7	2.7	0.0	0	9
Going on vacation	Social	1.7	2.2	0.0	0	6
Ride a bike	Mobility	1.5	1.9	0.0	0	5
Perform hobbies	Social	1.5	2.5	0.0	0	8
Dependent on others	General tasks/household	1.4	2.4	0.0	0	7
Organizational problems	General tasks/household	1.2	2.0	0.0	0	7
Infections of the skin	Physical	0.0	0.0	0.0	0	0

Notes. The maximum score is 10; the minimum score is 0. The questionnaire is divided into 5 dimensions: Mobility, Body, Domesticity, Psyche and Social.

helpful and 61% found decongestion with IPC alone helpful. However, 13(72%) missed the direct contact with the therapist (further information ESM 2).

Discussion

Discussion of the number of cases and duration of intervention

There are already studies confirming the short-term effectiveness of MLD+IPC in the maintenance phase of lymphoedema [1], but no comparative study between the two procedures in the longer term. Of course, one month is not a “long time”, but it is certainly sufficient to allow an increase of edema in case of a possible undersupply. According to the ethics vote, an evaluation should take place after every 20 subjects included to determine whether another 20 would have to be recruited or not. Already after the first recruitment phase, the results of IPC alone tended non-significantly to be better than MLD alone. Due to the high effort both for the study participants (especially in the phase “IPK plus MLD”) and for the

conduct of the study, it seemed appropriate to conclude the study.

Discussion of the nature of the study population

The patients in the study are a very homogeneous group concerning the lymphedema. They had been on maintenance therapy for years, had remained constant in terms of weight and calf circumference measurements for over 1 year, and had high compliance and adherence to therapy as measured by the fact that they came for check-ups every 3 months, their measurements were constant over the entire time, and there was hardly any pitting edema, as is to be expected under good therapy with MLD and compression.

The subjects were always examined on the same day of the week as the initial examination and at the same time, always between 2 pm and 6 pm. The patients were not supposed to have any holidays during the study phase – if these were planned, the start of the study was postponed. Thus, it is not only a group with constant values in their previous history, but also constant measurement circumstances

Table III. Comparison of costs of MLD vs. IPC

Time MLD	Cost per session	times / week	Cost MLD per year	4 Dr. visits/year	Total Cost 1 Year	10-year Costs MLD	10 years IPC plus MLD*	Money Saving option
30	29.23 €	1	1,519.96 €	80 €	1,599.96 €	15,999.60 €	7,207.60 €	55.0%
	29.23 €	2	3,039.92 €	80 €	3,119.92 €	31,199.20 €		76.9%
45	43.83 €	1	2,279.16 €	80 €	2,359.16 €	23,591.60 €	8,959.60 €	62.0%
	43.83 €	2	4,558.32 €	80 €	4,638.32 €	46,383.20 €		80.7%
60	58.45 €	1	3,039.40 €	80 €	3,119.40 €	31,194.00 €	10,714.00 €	65.7%
	58.45 €	2	6,078.80 €	80 €	6,158.80 €	61,588.00 €		82.6%

Notes. Calculation of the costs for the maintenance therapy per year and in 10 years based on German prices 2022 considering MLD/IPC and the visit to the specialist every 3 months to prescribe MLD treatment (which is 20 Euro per visit at the specialist in Germany, this was not a calculating mistake!). Compression garments are not included, as they should be offered anyway and are not subject of change. The price per IPC Device lies between 3,000–3,500 Euro depending on the cuffs needed, including 10 years guaranty – we took “worst-case-price” of 3,500 Euro once for the calculation for 10 years. *Including IPC device, one visit to the doctor per year, 12 MLD per year.

during the study: same day of the week and thus also the same routines, working hours, etc., no holiday periods with variations in load or MLD frequency in all study phases.

Discussion of the results

We sampled objective (circumference and volume of the legs) as well as subjective parameters (pain and QOL) after each treatment month with the three modalities MLD+IPK, IPK alone, MLD alone and compared to baseline, where patients had been treated for at least one year with MLD alone (always with compression, before and during the study).

Considering the objective measurements, the deviations from baseline were minimal. The only – very small – significant differences were found at the ankle circumference (circumferential change 0.8%; Cohen’s $d < 0.1$). This discrete difference did not influence the calf volume, where no significantly different values were assessed.

The subjective results are based on two aspects: The pain and discomfort reported in the standing position after taking off the compression (VAS 0–10), and on the QoL measured by the Lymph-ICF questionnaire [8].

The pain and discomfort values do not differ significantly from each other; at most, a tendency towards a slightly better value under treatment with both procedures can be noted in the graph. The graph itself, compared to all the other “line per patient” graphs in this publication, shows a high variability of curves. There are three patient lines drawing “a house-roof” – starting low (left point), having two higher pain-values at MLD alone and IPC alone and then again, a lower one at IPC plus MLD (pink and brown line very large outliers, dark green less; Figure 2E). The two large outliers, who have significantly more complaints with IPC or MLD alone, but not with MLD+IPC, could perhaps be interpreted as a nocebo effect in the expectation of treatment with IPC+MLD. Both patients were randomized to the IPC group first and received MLD+IPC only at month 3.

The QoL-results are based on the Lymph-ICF questionnaire [8] show that the patients suffer primarily from limitations in mobility and physical performance, but also from mental aspects (Table II). With a mean value of 2.6 ± 2.0 , these are not very pronounced complaints in the overall

collective, as is to be expected in the maintenance phase of lymphoedema.

Figure 2F shows that all these values are better after the treatment phases than at the beginning of the survey. This is surprising for the “MLD only” phase, as it involves the same therapy as before the study. It could correspond with a so-called Rosenthal-effect during the study, i.e. the sole improvement in satisfaction due to the positive expectation in the additional therapy option. This effect is greater in the two “therapy” phases (“MLD+IPC” and “IPC alone”) than in the “control” phase (MLD alone).

The last day of the study, patients were asked questions about their satisfaction with the three different options (MLD alone, ICP alone or both), from a medical, QoL and organization point of view. These results are very variable. Some patients would like to receive both procedures, others only MLD or only IPC – this also depends on personal circumstances, such as the compatibility between therapy and work. Overall, the treatment with IPC, as well as the combination of both procedures is very well accepted.

Conclusions

Lymphatic therapy is more than just decongestion or compression therapy. However, IPC seems to be a sufficient substitute for manual lymphatic drainage therapy, at least for a certain period of time. It would therefore be optimal to aim for a combination of both, possibly with one or two MLD per month and IPC at home in between. This would have the advantage that the patients could be guided by the therapist to open the lymphatic channels by self-massage on the neck and the lymph therapist, as an important professional in the therapy of lymphoedema, would ensure the regularly necessary contact with the patient. A visit to the doctor would then only be necessary every 12 months in the maintenance phase or on the recommendation of the lymph therapist.

In a system like Germany, where both the visit to the doctor and the visit to the therapist are paid for by the health insurance companies and where IPC is also financed if indicated, this is a simple way of saving resources and relieving

the burden on the solidarity system in order to be able to continue to treat the individual in a secure way. The possibility of sparing money for health care insurances varies between 55 and 85% after 10 years, see Table III. Still we have to consider, that the relief is not only financial for the health care system, but a general saving of resources: The “resource” therapist, who is often not available during the acute decongestion phase, because the continuous therapy with MLD with 1–2 sessions of 45–60 minutes per week ties up mostly all capacities. Also, time-economically it is an advantage for the patient: he or she is not bound to appointments and can combine the decongestion with other things, such as a nap, a telephone call or reading a book.

In other countries, where the patient has to pay for IPC, MLD and possibly even compression and the doctor’s visit for lymphoedema completely themselves, the question is almost even more interesting and important for the individual as a victim of the disease within the limits of their financial possibilities.

Summary

The results of the present study suggest that compression stockings supplemented by IPC alone or in combination with MLD in the maintenance phase shows equivalent results to MLD alone – at least in a period of 4 weeks. The savings for the solidarity system in combining 1 MLD per month with IPC at home would be enormous – this would ensure continuity in contact with an experienced therapist who can recommend an appointment with the doctor if needed. This would then no longer take place quarterly but possibly annually.

Further studies with the aim of making sensible use of resources and possibly implementing IPC in the decongestion phase, as well as accompanying the introduction of the IPC/MLD combinations, would be desirable.

Electronic supplementary material

The electronic supplementary material (ESM) is available with the online version of the article at <https://doi.org/10.1024/0301-1526/a001090>

ESM 1. General characteristics of the included subjects (Table)

ESM 2. Final assessment of the different therapy options (Table)

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Conflict of Interest

EM declares that there are no conflicts of interest existing. FA was reimbursed for his statistical analysis at Bösl Medizintechnik GmbH and Bauerfeind AG.

Open Data

At the XIX World Congress of the International Society of Phlebology (UIP), 12th–16th September 2022 in Istanbul, Turkey. At the 64th meeting of the German Society of Phlebology September 29th–October 1st, Hanover, Germany. At the 49th Veith Symposium, November 15th–19th, New York, USA.

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