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An assesement of the quality of life in patients with chronic lymphoedema treated by complex decongestive therapy/CDT

Abstract

Background. Lymphoedema is an accumulation of protein-rich fluid in the interstitial space. Long-lasting lymphoedema leads to chronic inflammation, fibrosis and tissue damage. Lymphoedema seriously affects a patient's body image, daily activities and mobility. At present, there is no curative treatment: the aim of lymphoedema management is long-term symptom control and an improvement in the health-related quality of life (HRQoL).

Aim. The aim of this study was to assess the following: — the effect of complex decongestive therapy (CDT) on the quality of life of lymphoedema patients; — the effect of CDT on clinical symptom relief; — changes in HRQoL domains as defined in the SF-12 questionnaire.

Methods. 30 patients were enrolled into a treatment group in a Lymphoedema Clinic. We assessed physical symptoms such as pain, heaviness, mobility, the fitting of clothes and body presentation at the beginning of the study, again after two weeks of intensive treatment and then after 4 months of maintenance therapy. Patients completed the SF-12 questionnaire at the beginning and at the end of the study.

Results. The research revealed that complex intensive therapy significantly improves both physical and mental aspects of HRQoL. No correlation between HRQoL improvement and limb volume reduction has been found. CDT and the intensive phase of treatment in particular improved the fit of clothes and limb presentation, relieved pain and heaviness, and also improved limb mobility.

Key words: lymphoedema, complex decongestive therapy, quality of life

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Introduction

Lymphoedema

Chronic lymphoedema is the accumulation of excess protein-rich fluid in the interstitial tissue. Its long-lasting presence leads to the occurrence of the inflammation process, resulting in damage to the tissue affected by lymphoedema [1]. The range of

people suffering from the disease is diverse, including patients with primary oedema, caused by developmental anomalies of the lymphatic system, as well as a wide group of patients with secondary oedema, usually associated with therapy and/or progression of neoplastic disease, inflammation changes in the course of systemic diseases, bacterial infections and injuries.

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Due to the lack of a satisfactory method of causal therapy, the treatment which combines lymphatic drainage, the use of compression garments, exercise and proper skin care, i.e. complex decongestive therapy (CDT), is considered to be the most effective treatment.

Lymphoedema, as a chronic and progressive disease which can only be treated symptomatically, has a strong influence on a patient's quality of life. Patients complain of pain, altered body image and the difficulties in social contact resulting from this.

Quality of life

In the last twenty years, interest in the problem of health-related quality of life (HRQoL) has increased significantly. The reason for this is the taking into consideration of the patient's subjective evaluation of his/her own health as a sign of the holistic approach to the therapy process. The notion of quality of life is very broad and comprises all those realms of the human condition which are significant for that person. HRQoL is a narrower notion and can be defined as the patient's subjective evaluation of the condition of his or her own health. The measurement of the general HRQoL consists of the assessment of the patient's capacity for everyday physical, psychological and social activity [2]. The tools for the measurement of HRQoL should be characterized by the following psychometric criteria:

- reliability: the tool should be free from measurement errors;
- accuracy of the range the tool is required to measure;
- sensitivity: the capacity for registering changes occurring over time [3].

There are two types of tool for HRQoL evaluation: general and specific for a given disease. General tools focus on the main components of the quality of life and can be used in examining patients with various health conditions and suffering from different diseases. Specific tools, in turn, are designed for examining specific groups of patients. At present, it is thought that the assessment of the quality of life should become a routine component of all examination procedures.

In clinical research carried out on various groups of patients, the negative effect of chronic lymphoedema on their quality of life has been proved unquestionably.

While assessing various realms of the quality of life with the use of tools meeting psychometric criteria, the most significant deterioration has been found in the fields of the perception of the patient's

own body, concerns for the future, and the effect of the physical condition on the performance of everyday tasks [4]. Patients with chronic lymphoedema declare pain problems much more often and their psychological condition has a negative effect on their everyday performance [5]. Other research has shown a deterioration in physical efficiency and social activity [6]. Patients suffering from lymphoedema following a mastectomy have more difficulties in adapting to their new health situation and describe a more significant deterioration of the function of a limb than patients after a mastectomy but without lymphoedema [7].

Other research, carried out with non-standardized tools, has shown that patients with chronic lymphoedema are more often affected by feelings of fear, depression, difficulties in contacts with partners, workmates and in social encounters [8], abandon their hobbies much more often and seek psychological help [9, 10].

The aim of the study

The aim of the study was the assessment of the following:

- complex decongestive therapy (CDT) and its effect on the quality of life for patients with chronic lymphoedema, measured by the SF-12 test;
- the effect of CDT on the clinical symptoms felt by patients;
- the most significant changes in patients' realms of life as defined in the SF-12 test.

The research project has been approved by the Bioethical Commission of The Poznań University of Medical Sciences. A licence for the use of the SF-12 questionnaire in clinical research has been obtained.

Material

Thirty women with chronic lymphoedema of various etiologies, aged 32–71 (average age of the subjects was 56.8 ± 8.99 years) qualified for the research. The subjects were patients of the Lymphoedema Therapy Outpatient Clinic. Each of them had been informed of the purpose and character of the research and had given written permission for it to be conducted. The patients had been informed that the data contained in the SF-12 questionnaire would be used only as part of the cognitive study and would remain anonymous.

The people who qualified for the research had sufficient circulation, properly functioning kidneys and liver, and had no features of active neoplastic disease or deep vein thrombosis. Four subjects had

been diagnosed with diabetes, treated with oral medication; 13 subjects were taking hypotensive medication and had appropriate blood pressure; in 2 subjects' medical history, hypothyreosis had been diagnosed and was treated with hormone substitution during the research.

The diagnosis of lymphoedema was made on the basis of the interview, physical examination, basic laboratory examination and lymphoscantiscanning.

Twenty-two of the patients (73.33%) had upper limb oedema (of which only one was bilateral), while 8 (26.66%) had symptoms of lymphoedema in the lower limbs (4 of them bilateral).

In 22 patients (73.33%), secondary lymphoedema was diagnosed: in 9 it had been caused by a mastectomy, in 11 by a mastectomy with consecutive radiotherapy, in 1 it was the effect of past erysipelas, while 1 patient had undergone irradiation of the superclavicular lymph nodes due to lymphogranulomatosis maligna. The group of patients with primary oedema consisted of 8 people (26.66%). In all of them, the first symptoms of the disease occurred in adolescence but only 3 had positive family history.

According to the classification of the British Lymphology Society (www.lymphoedema.org/bls) (Table 1) the patients who qualified for the research suffered from mild, uncomplicated (6 people, 20%) or severe, complicated (24 people, 80%) forms of lymphoedema.

The characteristics of the researched group are presented in Table 2.

The average duration of the disease was 111 months (± 143.81 months). The majority of the research group (25 people, 83.3%) had never received therapy before, 4 people had temporarily had massages with the use of pneumatic pumps, which had not produced sufficient effects, while one person had undergone a debulking operation (whose type has not been established, as the patient has lost the documents concerning the hospitalization).

The starting volume of the oedematous limb was 2976.20 ml (± 104.43). In the group of patients with unilateral alterations the average volume of

the oedema was 878.92ml (± 383.31), which amounted to 41.92% (± 18.83).

The symptoms which prompted the patients to pay a visit to the clinic were, first of all, worrying alterations in the appearance of their limbs (23 people); the feeling of heaviness of the limb(s) (22 people); difficulties with garments fitting (16); pain (11); and mobility limitation (8). The diversity of the symptoms declared by the patients in subgroups of clinical and etiological classification is presented respectively in Tables 4 and 5. In the medical history, complications in the form of acute inflammatory episodes of subcutaneous tissue were found in 19 patients, out of which 6 had experienced it more than 5 times.

Methods

General outline

The patients who agreed to take part in the research were obliged to remain under the control of the Lymphoedema Therapy Outpatient Clinic of the Chair and Department of Palliative Medicine in the Poznań University of Medical Sciences for the period of 4 months from the beginning of the therapy.

The first visit involved the initial qualification on the basis of the interview and physical examination. During the visit, the following examinations were also carried out:

- the taking of blood for routine laboratory tests: morphology, creatinine, glucose, electrolytes, AspAt, AlAt, bilirubin, electrophoresis;
- the measurement of limb volume;
- an assessment of blood flow in the lymphoedematous limb in order to exclude the possibility of the coexistence of fresh deep vein thrombosis;
- lymphoscantiscanning in order to confirm the diagnosis and define the stage of disease advancement.

During the first visit the patient also completed the questionnaire for life quality assessment (SF-12). After receiving the results of the image tests the patient began the complex decongestive therapy. The period of intensive therapy lasted for 2 weeks. The patients came to the clinic every day between 9.00 am and 12.00 noon and were subjected to lymphatic drainage and multilayer bandaging according to generally accepted rules. The following materials were used for the bandaging: on skin, a non-stretch cotton sleeve; on fingers or toes, gauze bandages of high elasticity (Matolast), then a synthetic undercoat of padding (Matoban) externally and short-stretch elastic bandages (Matopres). At home, the patients were asked to perform the rec-

Table 1. Clinical classification of chronic lymphoedema according to The British Lymphology Society

Mild	Severe
Normal shape	Distorted limb shape
Intact healthy skin	Abnormal skin
Subcutaneous tissue soft and pitted	Subcutaneous tissue non-pitted
Excess limb volume < 20%	Excess limb volume > 20%

Table 2. Characteristics of the research group

Patient	Age	Limb	Type of lymphoedema	Clinical classification	Time
EA	67	Upper	Secondary	Severe	4 years
MT	45	Lower (both)	Primary	Mild	18 years
JZ	51	Upper	Secondary	Severe	10 years
HM	55	Upper	Secondary	Severe	1 year
EK	50	Upper	Secondary	Severe	4 months
BK	45	Lower (both)	Primary	Severe	30 years
HC	67	Lower	Primary	Severe	10 years
WB	54	Upper	Secondary	Severe	2 years
ME	52	Lower	Primary	Severe	20 years
UM	64	Upper	Secondary	Severe	14 years
HR	62	Upper	Secondary	Severe	7 years
IR	68	Upper	Secondary	Severe	6 years
KM	70	Upper	Secondary	Severe	14 years
DP	50	Upper	Secondary	Severe	6 years
BW	63	Upper	Secondary	Mild	1.5 months
BS	65	Upper	Secondary	Severe	6 months
MM	62	Upper	Secondary	Mild	4 months
IM	52	Upper	Secondary	Severe	6 years
HB	57	Upper	Secondary	Severe	2 years
BG	71	Upper	Secondary	Severe	6 years
IP	67	Upper	Secondary	Severe	6 months
BB	58	Upper	Secondary	Severe	3 months
IM	63	Upper	Secondary	Mild	6 months
DS	53	Upper	Secondary	Severe	12 years
PW	55	Lower (both)	Primary	Severe	8 years
DN	54	Upper (both)	Primary	Severe	45 years
GK	54	Lower (both)	Primary	Severe	45 years
KK	54	Upper	Secondary	Severe	1 year
MW	44	Lower	Secondary	Mild	5 months
RS	32	Lower	Primary	Mild	3 years

ommended exercises and wear the bandages until the following morning, taking them off no earlier than 2 hours before the next planned visit. At week-ends, the subjects of the research were left without compression bandages.

During the intensive therapy the patients were instructed on proper skin care of the oedematous limb(s) and taught to carry out simple lymphatic drainage at home. The second visit took place after the end of the intensive therapy and consisted of the following:

- an evaluation of the clinical symptoms in a 4-step range, where 0 meant lack of improvement, 1 — slight improvement, 2 — significant improvement, 4 — condition having been like that before the disease;
- a physical examination;
- the measurement of limb volume;
- the fitting of compression garments.

The third visit took place two weeks after the end of the intensive therapy and consisted of:

- a physical examination;
- the measurement of limb volume.

Successive visits took place at one-month intervals. Generally, each patient made 6 visits to the clinic during the period of the research. During the visit which ended the 4-month observation period, the patient was again asked to complete the quality of life questionnaire SF-12 and perform a self-evaluation of clinical symptoms.

The method of assessing quality of life with the use of the SF-12 questionnaire

The SF-12 questionnaire is an original test, created for the purpose of assessing health-related quality of life. The SF-12 meets all the psychometric criteria (of reliability, accuracy and sensitivity) and can be used for the assessment of HRQoL both

in large populations and in the small groups included in clinical research [11]. The test assesses eight HRQoL components: general health condition, physical efficiency, effect of the psychological and physical condition on everyday activities, mood, energy, pain and social performance. The patient does not need much time to complete the questionnaire and can do this during the visit to the clinic. The brevity of the form is undoubtedly an advantage of the SF-12, especially as the patient has to answer the questions several times during the examination.

The patients were given the test for independent completion during their first and last visits to the clinic. The answers were evaluated according to the key in the number and the percentage scales. The higher the score, the better the HRQoL assessment.

Statistical analysis

The data obtained were subjected to statistical analysis, the purpose of which was to examine the significance of the differences and the relationships between the features. The research used a Student's t-test and the ANOVA one-factor variance analysis for features whose spread agreed with the normal distribution, or the Mann-Whitney and Kruskal-Wallis tests for those which lacked such agreement.

The examination of volume changes over time was tested with the use of ANOVA variance analysis in the system with repeated measurements.

The relationship between features was analyzed with the use of the Pearson correlation coefficient

for features in agreement with the normal distribution, or the Spearman correlation coefficient for those without such agreement.

Results

Limb volume

During the 4-month observation period an average limb volume reduction (Vmed) of 329 ml (± 226.50 ml) was achieved. The limb volume change obtained during the intensive therapy (i.e. between measurements 1 and 2 and successive ones) was statistically significant ($p < 0.0001^{***}$), while further volume reduction obtained during the maintenance therapy (i.e. between measurements 2 and 3 and successive ones) was not ($p > 0.05$). The alterations in Vmed over time are shown in Table 3.

In the group of patients with unilateral alterations, the calculated average oedema volume (ΔV_{med}) was 878.92ml (± 383.31), which amounts to 41.92% (± 18.83) ($\Delta V_{med}\%$). After the 4-month therapy period, those values amounted to 503.36ml (± 331.54) and 23.67% (± 15.00).

The dynamics of alterations over time of the ΔV_{med} and $\Delta V_{med}\%$ parameters are shown respectively in Tables 4 and 5.

The quality of life assessment with the use of the SF-12 questionnaire

During the CDT period an improvement in the patients' quality of life was achieved ($p < 0.0001^{***}$).

Table 3. Changes in the Vmed value in consecutive measurements

Measurements	Vmed [ml]	SD	-95.00%	+ 95.00%
1.	2967.2	04.43	2763.4	3188.9
2.	2713.7	99.86	2510.3	2917.1
3.	2697.9	109.44	2475.0	2920.9
4.	2681.0	108.49	2460.0	2902.0
5.	2655.4	122.40	2406.1	2904.7
6.	2638.7	10,4,83	2425.2	2852.2

Table 4. ΔV_{med} in consecutive measurements

Measurement	Measured limbs	ΔV_{med} [ml]	Mean	Minimum	Maximum	SD
1.	25	878.92	770.00	402.00	1672.00	383.31
2.	25	599.84	605.00	130.00	1334.00	320.12
3.	25	546.96	525.00	70.00	1244.00	335.78
4.	25	543.20	533.00	16.00	1319.00	372.13
5.	25	545.48	449.00	37.00	1609.00	407.02
6.	25	503.36	432.00	25.00	1152.00	331.54

Table 5. ΔV_{med} [%] in consecutive measurements

Measurement	Measured limbs	ΔV_{med} [ml]	Mean	Minimum	Maximum	SD
1.	25	41.92	37.00	20.00	76.00	18.83
2.	25	28.26	26.00	5.00	57.00	14.74
3.	25	24.94	25.00	3.00	60.00	14.25
4.	25	25.38	24.00	0.50	65.00	17.41
5.	25	24.56	22.00	1.00	57.00	15.59
6.	25	23.67	23.00	1.00	57.00	15.00

Table 6. The p coefficient values for specific HRQoL components

HRQoL Domains	p
Physical role	0.000012
Physical functioning	0.000050
Bodily pain	0.000463
Social functioning	0.001944
Mental health	0.003286
General health	0.007686
Vitality	0.010788
Emotional role	0.017818
HRQoL (in general)	0.000003

HRQoL — health-related quality of life

The change was observed both in the general HRQoL and in its components covered by the SF-12 questionnaire. The differences between the starting assessment and that made at the end of the 4-month observation period were statistically significant for all HRQoL components. The changes in the value of general life quality and its specific aspects in the grade and the percentage scales are shown in Tables 6 and 7, while the p coefficient values for specific HRQoL realms are shown in Table 8.

No correlation was observed between the extent of V_{med} and ΔV_{med} wzgl [%] (relative average) and the extent of HRQoL improvement ($p > 0.05$). For specific HRQoL components, in turn, the degree of limb volume reduction correlated only with the improvement within the realm of the influence of the psychological condition on everyday performance ($p < 0.05$).

While analyzing the extent of HRQoL improvement in patients with similar levels in the reduction of clinical symptoms, no statistically significant differences were observed for any of the assessed symptoms ($p > 0.05$).

The scale of the relief of clinical symptoms

Within the 4-month therapy period, the relief of clinical symptoms was observed. While evaluating the influence of the entire therapy on the relief of clinical

Table 7. The assessment of the relief of clinical symptoms

Clinical symptoms	p
Body perception	
After the intensive phase	< 0,01**
After the maintenance phase	> 0.05 (NS)
After 4 months	< 0.001***
Heaviness	
After the intensive phase	< 0.001***
After the maintenance phase	> 0.05 (NS)
After 4 months	< 0.001***
The fit of clothes	
After the intensive phase	< 0.01**
After the maintenance phase	> 0.05 (NS)
After 4 months	< 0.001***
Pain	
After the intensive phase	< 0.05*
After the maintenance phase	> 0.05 (NS)
After 4 months	< 0.001***
Mobility	
After the intensive phase	> 0.05 (NS)
After the maintenance phase	> 0.05 (NS)
After 4 months	< 0.01**

NS — non significant

symptoms, significant improvement was observed for all the symptoms evaluated. At specific stages of the therapy, the following results were obtained:

- after the period of intensive therapy, there was a significant improvement in the patients' evaluation of all symptoms except mobility;
- further therapy did not bring statistically important changes to the evaluation of the clinical symptoms.

The differences in the evaluation of clinical symptoms during specific stages of the therapy and after 4 months of observation are shown in Table 7.

Discussion

Quality of life

The answers to the SF-12 questionnaire, completed by the patients before and after the 4 months

of therapy, showed a statistically significant improvement in the evaluation of HRQoL (0.0001***) and all its components. The analysis of the changes in the evaluation of the HRQoL domains showed that the biggest change took place in that of the effect of physical condition on everyday performance. The most significant improvement was observed in the physical aspects.

No link was observed between the degree of limb volume reduction and the change in HRQoL, which indicates that the improvement in HRQoL felt by the patients is independent of oedema volume reduction. Similarly, no link was observed between HRQoL improvement and the degree of the relief of all assessed clinical symptoms.

So far, there have not been many references in the literature concerning the problem of life quality for patients treated for chronic lymphoedema. The few existing reports, however, show a positive influence of complex decongestive therapy on patients' quality of life and its specific realms.

Stizia and Sorbido [12] assessed the effect of CDT on the quality of life for patients suffering from lymphoedema in the course of various malignancies. The research group consisted of 34 patients and the research tool was the Nottingham Health Profile (NHP) questionnaire. In addition, the authors used a 9-grade scale of skin condition evaluation, known as the Skin Index. The research showed an improvement in the general quality of life, most significantly in the field of general fitness. No correlation, however, was observed between limb volume reduction and a change in any NHP domain except pain. It was also observed that an improvement in HRQoL correlates with an improvement in skin condition, assessed by means of the Skin Index.

Mirola et al [13] assessed the change of life quality during CDT using the "Functional Living Index — Cancer". During the intensive treatment and consecutive maintenance therapy, a slight but statistically significant improvement in the quality of life was observed. No correlation, however, was observed between the quality of life improvement and lymphoedema reduction.

Williams [14] in his quoted work also evaluated patients' quality of life, using the EORTC QLQ-30 questionnaire. The research showed that only after the lymphatic drainage period was there a statistically significant improvement in the quality of life, especially in its emotional aspects. The research did not define the coefficient of correlation between limb volume reduction and the change in quality of life and its specific domains.

Pain et al [15] examined the effect of oedema size and limb mobility, assessed by objective tools, on HRQoL for 48 patients with lymphoedema following a mastectomy. The quality of life was evaluated by means of the SF-36 questionnaire. The researchers observed a decidedly worse assessment in the domains describing mobility and pain in the research group in comparison with respective values in the general population. The degree of limb efficiency in objective measurements correlated with the mobility evaluation in SF-36. For oedema volume in turn, no such relationship was observed. It may, therefore, be indirectly concluded that limb mobility means more for the improvement of life quality for patients with lymphoedema than limb volume.

From the above quoted sources we can conclude that patients who are treated with CDT experience an improvement in the quality of life.

It is very difficult to carry out a comparative analysis of the research conducted so far. While limb volume was measured in the same way in all of the research, the scheme for conducting the therapy, its duration, as well as the groups of patients participating, were all very different. In addition, a different tool for assessing the quality of life was used in each piece of research, which also restricts the possibilities of comparative interpretation. In spite of this, it seems significant that in all the studies, regardless of the differences between them, life quality assessment improved as a result of the treatment.

Another analyzed problem is the identification of factors affecting the extent of HRQoL improvement. The factors listed most often in the references are the degree of limb volume reduction, the level of experienced pain, limb efficiency assessment and skin condition.

In the research covered by this study, no connection was observed between HRQoL improvement and volume reduction or the degree of relief of clinical symptoms. In the works quoted by the author, a relationship between HRQoL and the level of experienced pain, limb efficiency and skin condition was observed. No such relationship was observed for limb volume reduction. It is, therefore, possible that limb volume measurement, HRQoL value and the scale of evaluating clinical symptoms are independent indices of treatment efficiency.

The extent of the relief of clinical symptoms

Along with the alteration in limb volume, clinical symptoms subsided during the treatment. After the 4-month therapy, patients reported the signifi-

cant relief of such ailments as negative changes in appearance, difficulties with clothes fitting, the feeling of limb heaviness, pain and limited mobility. However, the most important for the relief of symptoms of the illness was the intensive therapy, as after that period of treatment a significant positive change was felt by patients in all aspects except limb mobility. In turn, further therapy did not bring statistically significant changes in the evaluation of symptoms.

The perceived pain level, changes in the patient's own body image and the degree of limb mobility deficiency are considered subjective indexes/indices of the effectiveness of lymphoedema treatment [16]. So far, there has been no standardized tool which would assess the level of the symptoms characteristic of a patient with chronic lymphoedema. For that reason, some of the authors included, as a complementary tool, the evaluation of clinical symptoms made by the patient on the basis of a method developed for specific research.

While assessing the effect of the therapy on the symptoms reported by the patients, Woods [4] observed an improvement in the perception of a patient's own body (46% of the subjects), the fit of clothes (65%), and limb mobility (43%). The research group consisted of 37 women who had had a mastectomy and who had been treated for lymphoedema for at least 6 months. The therapeutic schemes used were not uniform for the whole group of patients.

Hardy and Taylor [17] examined a group of 219 patients suffering from lymphoedema of various etiologies: 144 patients qualified for intensive therapy, while the others, with smaller alterations, began the therapy at the maintenance stage. The researchers observed that after treatment patients reported less pain, had fewer difficulties with clothes fitting, improved limb mobility, and a lower level of frustration and fear. The study does not contain the assessment of clinical symptoms at specific stages of the treatment.

Williams [14] compared the efficiency of lymphatic drainage and self-massage in a group of 37 women with lymphoedema following a mastectomy. He concluded that the drainage, which is an integral part of the intensive treatment stage, has a decidedly bigger influence than self-massage on the relief of clinical symptoms, such as pain, discomfort, the feeling of heaviness, fullness, burst-

ing and stinging. However, the research value of the works assessing specific CDT elements is controversial [18].

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